Study on the Legal Aspects of Supplementary Protection Certificates in the EU

Final Report

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ABSTRACT

This Study examines the functioning of the system of supplementary protection certificates (SPCs) established in the EU by Regulation 1768/92/EEC on SPCs for medicinal products (now: Reg. 469/2009/EC) and Regulation 1610/96/EC on SPCs for plant protection products (hereinafter: the Regulations). The functioning of the Regulations is considered in the context of adjacent legislation concerning marketing authorisation for medicinal products and plant protection products (Directives 82/2001/EC and 83/2001/EC; Regulation 1107/2009/EC).

Within this context, the Study focuses *inter alia* on:

- the impact of the CJEU case law on the SPC system and the practice of the NPOs;
- the challenges posed by technical developments for the SPC legislation;
- the impact of the UPCA on the scope of the *Bolar* exemption;
- the models for creating an SPC-manufacturing waiver;
- the interaction between SPCs and the Unitary Patent Package;
- the options for creating a unitary SPC.

Based on legal analysis, supplemented by a fact-finding process, the Study identifies critical issues, explores possible solutions and formulates some recommendations.

EXECUTIVE SUMMARY

General remarks

1. This Study examines the functioning of the system of supplementary protection certificates (SPCs) established in the EU by Regulation 1768/92/EEC on SPCs for medicinal products (now: Reg. 469/2009/EC) and Regulation 1610/96/EC on SPCs for plant protection products (henceforth: the Regulations) from a legal perspective. The functioning of the Regulations is considered in the context of adjacent legislation concerning the marketing authorisations for medicinal and plant protection products. Furthermore, the Study examines the impact of the UPCA on the *Bolar* exemption and the option for creating a manufacturing waiver. Finally, the Study investigates legislative and institutional options for creating a unitary SPC complementing the system of European patents with unitary effect in the internal market ("unitary patents").

Background of the SPC legislation

2. The purpose of the SPC legislation was to create patent-like *sui generis* rights compensating patent holders for the time loss experienced in two sensitive technological fields where new products are subject to extensive regulatory procedures prior to commercialisation. By establishing common standards in this regard, the EU legislature sought to prevent the emergence of diverging national legislation, so as to safeguard the integrity of the internal market. Furthermore, the SPC Regulations were aimed at preserving the competitiveness of Europe as an attractive location for pharmaceutical and plant-protection-related research. At the relevant time other jurisdictions, such as the US and Japan, had already enacted legislation providing for an extension of the patent term, *inter alia*, in the pharmaceutical field.

3. Although SPCs conform in many ways to patents and are therefore generally recognised as a form of intellectual property (IP), they are clearly distinct from other IP rights. First, SPCs are of a hybrid nature: their grant is contingent on the existence of a basic patent and of a marketing authorisation (MA) covering the product. Second, SPCs are based on the Regulations, i.e. on Union law with direct effect throughout the EU; however, unlike, for instance, Union trademarks and Community designs, they are not unitary titles of protection. Under the current system SPCs are national, territorially restricted rights granted by national offices. Both features – the hybrid nature of SPCs and their construction as national rights based on an act of Union law – contribute to the fact that SPCs are quite unique, both within the EU and internationally. They also account for a number of peculiarities addressed in this Study.

Methodology

4. The Study primarily employs a legal-analytical approach. It identifies and examines the relevant legal sources, undertakes an analysis of CJEU case law and national jurisprudence, and provides an account of the scholarly literature. In addition, the appraisal of relevant issues is also based on a fact-finding

process. For this purpose, the Study includes, on the one hand, an evaluation of data provided by readily available sources, such as registration statistics. On the other hand, data and information were specifically collected for the Study. A questionnaire was distributed to the National Patent Offices (NPOs) in order to identify and document divergences of law and practice as well as issues considered problematic. Furthermore, the experience and opinions of stakeholders were investigated by way of an online survey (conducted by IfD Allensbach) and through qualitative interviews. The representatives of both NPOs and stakeholders were invited to participate in the presentations and discussions at workshops organised in Munich in March and September 2017. The data collected and contributions received are documented in the Annexes to the Study.

System efficiency and demand for reform

5. Measuring the efficiency of an incumbent legal system is difficult. In this regard the Study primarily relies on the evaluations expressed in the communications by the NPOs and by stakeholders. There is general agreement that the system, by and large, fulfils its purposes. However, regarding the details of protection, some legal uncertainties have arisen that could jeopardise the smooth functioning of the SPC regime. In particular, inconsistencies and unclear notions resulting from the CJEU's interpretation of central provisions in the SPC Regulations make it difficult for the NPOs to adapt their own practice to the criteria elaborated by case law without causing divergences in relation to their own previous practice or that of other offices. While originator companies tend to be basically confident that the system will correct itself in the long run, generic manufacturers contend that an overhaul is needed in order to strike the right balance. That a need for adjusting the balance exists is also specifically emphasised by the latter group in view of the limitations of the rights conferred, which are considered to be too narrowly tailored to respond efficiently to the challenges of enhanced global competition. Apart from that, all parties agree that a demand for reform exists as far as the creation of a unitary SPC system is concerned.

6. The Study aims at a systematic review of the SPC legislation. In the limited context of this executive summary, we will focus on three topics: the prerequisites and the scope of SPC protection as interpreted by the CJEU, the breadth of limitations and exceptions, and the creation of a unitary SPC system.

Conditions for granting SPCs: the impact of CJEU case law

7. For a deeper understanding of the impact of CJEU case law, it is necessary to revisit the legislative objectives reflected in the *travaux préparatoires* and in the preamble to the SPC Regulation on medicinal products as enacted in 1992. From those sources it emerges quite clearly that the original intention was to incentivise research in new active ingredients. Indeed, the SPC was to be granted only on the basis of the first MA in the Member State concerned (Art. 3(d) Reg. 469/2009). Only one SPC was intended to be possible for any active ingredient (Art. 3(c) Reg. 469/2009). The combined effect of these provisions was that a certificate should be granted only for substances that were

authorised for the first time as active constituents of a medicinal product. If the product had already been authorised in the past, and the applicant identified new uses or a new formulation of the product and obtained a more recent MA, an SPC was meant to be excluded due to either Art. 3(d) Reg. 469/2009 or Art. 7 Reg. 469/2009, depending on whether the applicant relied on the first or the second MA obtained.

8. This limitation of the subject matter eligible for a certificate corresponded to a conscious decision of the EU legislature. The *raison d´être* of SPCs was not the mere fact that medicinal products (or plant protection products) are subject to a product approval. Such requirements also exist in other technical fields. The main reason for creating SPCs was the assumption that because of the significant amount of pre-clinical and clinical work needed to develop the data necessary for obtaining a marketing authorisation for a new active ingredient, pharmaceutical research could become unprofitable. Expressed in the terminology of IP theory, the reason for the extended exclusivity was that the standard 20-year term of patent protection was deemed insufficient to prevent a market failure (see Recitals 3-6 Reg. 469/2009). At that time, this risk was perceived only for new active ingredients, but not for excipients, adjuvants, new formulations or new indications of old active ingredients. As a consequence, where a substance was already authorised as an active ingredient of a drug, it could still be possible to obtain patents for inventive uses, formulations, manufacturing processes or variants of the substance. But since the prerequisites for obtaining an MA are considerably less demanding in such cases as compared to MAs for new active ingredients, the need for additional incentives beyond ordinary patent protection was considered minor. The interest of the public in obtaining access to the medicament after the lapse of the regular patent term was therefore given precedence.

9. In practice, the system envisaged by the historical lawmakers underwent changes. By resorting to a teleological approach, the CJEU has developed the legislation. This also occurred where the text itself was not ambiguous or contradictory, and even where the intention of the lawmakers could not have been clearer. The results of this process are ambivalent. The Study attempts to evaluate the implications from both an atomistic and a holistic perspective.

10. The first requirement laid down in Art. 3(a) Reg. 469/2009 – that the product be protected by a basic patent in force – was the subject of several preliminary rulings. Nevertheless, the CJEU has so far failed to deliver a clear test for applying Art. 3(a) Reg. 469/2009. We identify three reasons why this is the case. First, the Court ruled in *Medeva* that, in order for the product to be protected within the meaning of Art. 3(a) Reg. 469/2009, it must be "specified" in the wording of the claims of the basic patent. Whether that requirement is fulfilled must be assessed on the basis of the law applicable to the basic patent (*Eli Lilly*). However, the law applicable to the basic patent does not provide for a distinction between products that are "specified" in the wording of the claims and products that are not "specified" in the wording of the claims. Second, the CJEU has not explained the purpose and the policy behind the *Medeva*-requirement. Finally, in *Actavis I* the CJEU introduced the requirement that the product must embody the core inventive advance of the patent. While in *Actavis I* that requirement was based on Art. 3(c) Reg.

469/2009, *Actavis II* refers to Art. 3(a) Reg. 469/2009 as well. As a result, it is unclear whether the inventive-advance test supplements or replaces the *Medeva*-requirement, or if it should apply only when Art. 3(c) Reg. 469/2009 is also relevant. Against this background, the Study identifies possible options for clarifying Art. 3(a) Reg. 469/2009, all based on the law applicable to the basic patent. The choice among the different options is a matter of policy. In consideration of the possible purposes underlying the case law of the CJEU, the Study recommends adopting the inventive-advance test elaborated by the English courts.

11. The teleological approach has significantly impacted the other requirements laid down in Art. 3 Reg. 469/2009. For instance, the prohibition in Art. 3(c) Reg. 469/2009 was interpreted as precluding the grant of a second certificate only when the same applicant filed the second application. This is exactly the opposite of what the rule provides for; it even goes beyond Art. 3(2) Reg. 1610/1996, which limits the grant of a second certificate to the case in which two applications are co-pending. In *Neurim*, the Court held that the scope of the patent must be considered in assessing whether an MA is the first one issued for an active ingredient, thereby relativising the principle that the issue of an SPC and its duration must be based on the first MA in the Member State and in the EU/EEA. However, nothing in the wording of Art. 3(d) and Art. 13 Reg. 469/2009 suggests that the scope of the patent is of any relevance for determining the first MA for a specific active in a Member State and in the EU/EEA. The consequences of the decision are unclear. Some NPOs understand *Neurim* as being applicable only to the factual scenario referred to in the headnotes of the judgment (a product for which an MA for veterinary use had been obtained subsequently being the subject of an MA for human use). Other NPOs – the clear majority – also apply *Neurim* when the earlier MA was for the same species as the MA submitted in support of the application for a certificate.

12. The impact of CJEU jurisprudence on the scheme originally provided for by the legislation is substantial. By abandoning the principle of one SPC per new active ingredient and admitting SPCs for products already authorised in the past, it risks undermining the balance of interests on which the SPC legislation was based. The Study recommends that the gap between written law and case law be closed. The choice between the different options is policy-oriented. If the arguments inducing the Court of Justice to liberalise the SPC system are considered convincing and better suited to the needs of pharmaceutical innovation, they deserve to be codified. If the arguments in favour of granting only one SPC per active ingredient on the basis of the first MA granted in the Member State are still considered valid, the pertinent case law should be corrected.

Third-party issue

13. Neither the *travaux* nor the preamble to the SPC Regulations convey a clear notion of who is meant to be the beneficiary of the protection granted. On the one hand, this could be the holder of any patent that covers the product for which the certificate is requested. On the other hand, it could be only the patentee that has invested in the development of a marketable product and

has obtained the MA submitted in support of the application for a certificate. The lack of precision in this regard is irrelevant as long as the patent proprietor and MA holder are the same person or act in accordance with each other. However, if they are separate entities and cooperation is denied, the question arises whether the patentee can obtain a certificate even if it has not contributed to the development of the product and the unrelated MA holder (and potential infringer) disagrees. The Study suggests that this is an issue which must be resolved by the legislature and not by the courts. Indeed, it turns upon the fundamental policy question of what the purposes of the legislation are and who its intended beneficiary is. If the aim of the SPC regime is to encourage investments in the development of marketable products after an invention is made, then only the patentee that has contributed directly (MA ownership) or indirectly (licence agreement; joint development agreement) to developing the product covered by the MA should benefit from the supplementary protection.

Rights conferred and limitations

14. Article 5 of the Regulations stipulates that SPCs confer the same rights as the basic patent and that the same limitations and obligations apply, but subject to Art. 4. Under Art. 4 of the Regulations, the certificate confers a purpose-bound protection. Indeed, the latter is limited to uses of the product as a medicinal product or plant protection product that has been authorised before the expiry of the certificate. As a consequence, it is not clear whether the mere manufacturing of the active ingredient protected as such by the basic patent for export or stockpiling purposes would infringe the certificate or not.

15. The introduction of new limitations beyond those stipulated for patents is of interest in particular in the context of so-called manufacturing waivers. Such provisions can take the form of a limitation allowing companies to manufacture SPC-protected products either to export them (export waiver) or to keep them in stock until the SPC has lapsed (stockpiling exception). From a legal perspective, manufacturing waivers in both forms are consistent with the purpose of the SPC Regulations to provide an extended period of time to compensate for the delay in the commercial exploitation of the invention that arises in consequence of the requirement for a marketing authorisation under Directives 2001/82 and 2001/83. That rationale is satisfied if the exclusive rights granted by the SPC only extend to activities that are delayed by such requirement. The production of an active ingredient or of a medicinal product including the active ingredient for export or stockpiling purposes does not require a marketing authorisation. Therefore, allowing these activities after the expiration of the basic patent does not run counter to the legal objectives of the SPC system. However, the question of whether the introduction of such limitations is warranted in order to provide a level playing field for generic companies located in the EU and those having their basis in jurisdictions where no corresponding restrictions apply raises a number of economic and political issues that require further investigation.

16. Both patents and SPCs are subject to the so-called *Bolar* exemption, which allows using protected subject matter in order to conduct studies and trials for regulatory approval. The majority of the EU Member States provide for a *Bolar*

exemption that is broader at least to some extent than the minimum standard laid down in Art. 10(6) Dir. 2001/83 or Art. 13(6) Dir. 2001/82. However, with the UPCA coming into force, the national provisions implementing Art. 13(6) Dir. 2001/82/EC and Art. 10(6) Dir. 2001/83/EC will no longer apply to European patents with unitary effect or to those European patents without unitary effect that are enforced before the UPC. Instead, the exemption laid down in Art. 27(d) UPCA will apply: this includes a dynamic reference to Art. 13(6) Dir. 2001/82/EC and Art. 10(6) Dir. 2001/83/EC, thus requiring a narrow interpretation. By contrast, national patents or European patents not litigated before the UPC may remain subject – in most EU Member States – to more liberal rules. The Study contends that the resulting fragmentation should be avoided in favour of a uniform approach. Taking account of the fact that in the course of the Study a broad approach to the *Bolar* exemption was welcomed, or at least not rejected, by a majority of stakeholders, and considering that the majority of the EU Member States have implemented a *Bolar* exemption that goes beyond the minimum standard, the Study recommends first amending Dir. 2001/82 and Dir. 2001/03 so that activities aimed at generating data for filing an MA for innovative products in the EU/EEA are also allowed. Further, the Study recommends extending the exemption to activities geared towards the acquisition of an MA in a non-EU/EEA country. This must be set forth in a separate act of Union law, since the latter activities are outside the scope of Dir. 2001/82 and Dir. 2001/03. In view of the referral to Union law included in Art. 20 UPCA and of the reference to Dir. 2001/83 and Dir. 2001/82 included in Art. 27(d) UPCA, such amendments will operate directly in proceedings before the UPC. An amendment of the UPCA to bring the wording of Art. 27(d) into line with the reform could further be smoothly adopted under Art. 87(2) UPCA.

17. Another issue of interest for both patents and SPCs in this context concerns the fact that the *Bolar* exemption or the experimental use-exemption do not apply to third parties that supply substances required for conducting a clinical trial or a research study. Several authors in the scholarly literature endorse the view that the legal objectives underpinning the two exemptions are ill-served by a restrictive approach that penalise mostly entities (like SMEs or universities) that rely on third-party suppliers. The Study proposes a bundle of legislative measures to ensure that delivery of substances by third parties is allowed if the activity of the supplied person is covered by the experimental use- or *Bolar* exemption.

Extension of the SPC regime?

18. Plant protection products and medicinal products are not the only products whose marketing is subject to the prior grant of an authorisation. *De lege lata*, the question is whether an authorisation granted under any piece of legislation other than Dir. 2001/82/EC or Dir. 2001/83/EC should be sufficient to trigger the grant of an SPC. This question is in particular relevant for drug/device combinations. *De lege ferenda* this raises the issue of whether an SPC-like compensation regime must also be created for products in other technical fields. The principle of equal treatment under Union law and the prohibition of discrimination under WTO law are equally relevant here. The study addresses both issues with a focus on medical devices.

19. With respect to medical devices as such, the Study does not offer a recommendation, since the question is of an economic nature. By contrast, it identifies the legal criteria that should govern the potential action of the lawmakers in this field. These criteria should ensure respect of international law and primary Union law, provided that the prohibition of discrimination under Art. 27 TRIPS also applies to SPCs. The reason why specific medicinal products can be protected by SPCs is that the regulatory procedures are preceded by clinical trials that require considerable time and investments in the case of new active ingredients, so that the lawmakers assume that ordinary patent protection will not be sufficient to recover such investments. If a similar risk is documented in the field of medical devices, an extension of the SPC protection would be recommended.

20. With respect to drug/device combinations, the Study considers it appropriate to admit SPC protection when all conditions for granting the certificate – except an MA granted under Art. 8 Dir. 2001/83 – are met. However, a situation in which an active ingredient is authorised for the first time for medicinal use only as an ancillary substance to a medical device is absolutely exceptional. The question is, therefore, only of practical relevance because of *Neurim*.

Creating a unitary SPC

21. In accordance with a large majority of NPOs and stakeholders, the Study endorses the view that the unitary patent should be complemented by an SPC of equal dimensions. It is true that *de lege lata* SPCs – as national rights – can already be obtained on the basis of a unitary patent, and that such rights can be enforced extraterritorially in proceedings before the UPC. However, the lack of a single granting procedure for SPCs would constitute a lacuna in the upcoming unitary patent system. After presenting and examining the institutional and legal options for establishing a unitary SPC system, the Study contends that a choice must be made between mandating an EU institution – already existing, newly established, or "virtual" – or entrusting the EPO with this task. In the case of an EU institution being charged with the grant, appeals must be directed to the General Court, whereas appeals against decisions made by a Unitary SPC Division located at the EPO could be filed at the UPC. From the point of view of expertise and consistency of the system, the second option appears preferable. On the other hand, from a legal point of view the first option is more easily implemented. Involving the EPO requires a more complex approach. However, as pointed out in the Study, the legal hurdles are not insurmountable. The majority of the stakeholders consulted in the Study favoured a system in which (i) a team of experts from the NPOs (virtual office or virtual Unitary SPC Division) examines the application and grants the certificate, and (ii) the UPC hears appeals lodged against decisions rejecting the application.

22. Regarding the kind of MA that can support the application for a unitary SPC, there is no technical cogent reason for not allowing also national MAs as a basis for a unitary SPC. The Study considers it feasible, in accordance with proposals advanced by stakeholders, to grant a unitary SPC on the basis of a bundle of national MAs, with its territorial scope being restricted accordingly.

Within this model two options are explored: the option of an SPC with static territorial scope that could be combined with national SPCs; and the option of a unitary SPC with a dynamic territorial scope that could extend to any other Member State where an MA is granted before the expiration date of the patent. In the field of plant protection products for which no Union authorisation is available, the model of a unitary right with dynamic territorial scope is clearly recommended. With respect to medicinal products, the choice is less obvious. In most cases it will be possible for the applicant to make use of the centralised procedure. For the remaining cases it may be acceptable to resort to a bundle of national SPCs.

23. Irrespective of the institutional design of the Unitary SPC Division, the legal framework accompanying its establishment will have to include guidelines and implementing rules structuring and informing procedural practice. The Study emphasises the importance of such rules as an instrument not only for enhancing the transparency and consistency of administration at the Unitary SPC Division, but also for bolstering coordination and harmonisation of practice in a horizontal and a vertical fashion, i.e. among the national offices and at the national and European level.

OVERVIEW

INDEX

LIST OF ABBREVIATIONS

AAPS J	Official journal of The American Association of Pharmaceutical Scientists
AdP database	Database on SPC applications provided by Cabinet Alice de Pastors
AG	Advocate General
Allensbach Survey	Survey on the Legal Aspects of the Supplementary Protection Certificates in the EU, 2017 (Annex III of this Study)
ANDA	Abbreviated New Drug Application
API	Active pharmaceutical ingredient
Art.	Article
BGH	*Bundesgerichtshof*/German Federal Supreme Court
BPatG	*Bundespatentgericht*/German Federal Patent Court
BPatGE	Entscheidungen des Bundespatentgerichts (Magazine)
CHMP	Committee for Medicinal Products for Human Use
CIPA	Chartered Institute of Patent Attorneys
Civ.	Civil Division (UK)
CJEU	Court of Justice of the European Union
Clin Med (Lond).	Clinical Medicine, the journal of the Royal College of Physicians
CP	Centralised procedure
CPC	Community Patent Convention
CTMR	Community Trade Mark Regulation
CVMP	Committee for Medicinal Products for Veterinary Use
DCP	Decentralised procedure
Dir.	Directive
DKPTO	Danish Patent and Trademark Office
DPMA	Deutsches Patent- und Markenamt/German Patent and Trade Mark Office
DPS	Deutsche Patentschrift
EBA	Enlarged Board of Appeal
EC	European Community
ECHR	European Convention on Human Rights

ECJ	European Court of Justice
ECPA	European Crop Protection Association
ECtHR	European Court of Human Rights
Ed(s)	Editor(s)
EDMA	European Diagnostic Manufacturers Association
edn	Edition
EEA	European Economic Area
EEC	European Economic Community
EFPIA	European Federation of Pharmaceutical Industries and Associations
EFTA Court	European Free Trade Association Court
EIPR	European Intellectual Property Review (Journal)
EJRR	European Journal of Risk Regulation, published by Cambridge University Press
EMA	European Medicines Agency
EMJ Innov	The European Medical Journal
EPA	Economic Partnership Agreement
EPC	European Patent Convention
EPO	European Patent Office
ESCMID	European Society of Clinical Microbiology and Infectious Diseases
et seq./et seqq.	et sequens/et sequentes
ETP	European Technology Platform
EU	European Union
EUIPO	European Union Intellectual Property Office
EUTM	European Union Trade Mark
EuZW	Europäische Zeitschrift für Wirtschaftsrecht (Journal)
EWCH	England and Wales High Court
Fr. CPI	French Intellectual Property Code (consolidated version of January 1, 2014)
FTA	Free Trade Agreement
GCEU	General Court of the European Union
GebrMG	Gebrauchsmustergesetz/German Utility Model Act
GRUR Int.	Gewerblicher Rechtsschutz und Urheberrecht – Internationaler Teil (Journal)

GRUR	Gewerblicher Rechtsschutz und Urheberrecht (Journal)
GRUR-Prax	Gewerblicher Rechtsschutz und Urheberrecht. Praxis im Immaterialgüter- und Wettbewerbsrecht (Journal)
GRUR-RR	Gewerblicher Rechtsschutz und Urheberrecht Rechtsprechungs-Report (Journal)
I.P.Q.	Intellectual Property Quarterly (Journal), Published by Sweet & Maxwell
IFAH	International Federation for Animal Health
IIC	International Review of Intellectual Property and Competition Law (Journal)
INN	International non-proprietary name
INPADOC	EPO worldwide legal status database
INPI	French industrial property institute, Institut national de la propriété industrielle
Int J Nanomed	International Journal of Nanomedicine
IntPatÜbkG	German Law from 27 November 1963 on the Implementation of International Patent Treaties
IPC	International Patent Classification
IPE	International Preliminary Examination
IPEA	International Preliminary Examination Authority
IPO	Intellectual Property Office
It. CPI	Industrial Property Code of Italy (Legislative Decree No. 30 of February 10, 2005)
IUPAC	International Union of Pure and Applied Chemistry
J	Journal
J. Marshall Rev. Intell. Prop. L.	John Marshall Review of Intellectual Property Law
JIPLP	Journal of Intellectual Property Law & Practice
JIPR	Journal of Intellectual Property Rights
MA	Marketing authorisation
mAB	Monoclonal antibody
mABs	Multi-discplinary journal, Taylor & Francis
Medicinal Products Code	Dir. 2001/83/EC
Medicinal Products Regulation	Reg. 469/2009 (or Reg. 1768/92)
Mitt.	Mitteilungen der Deutschen Patentanwälte (Journal)

MPI	Max Planck Institute for Innovation and Competition
MRP	Mutual recognition procedure
NCE	New Chemical Entity
NGO	Non-governmental organisation
No	Number
NPO	National patent office
OJ	Official Journal
OLG	Oberlandesgericht/German Court of Appeal
p.	Page
p.m.a.	Post mortem auctoris, after the death of the author
PA	Patent Act
para.	Paragraph
PAT	Patents Appeal Tribunal
PatG	Patentgesetz/German Patent Act
PATSTAT	Patent statistics database of the EPO
PC	Paris Convention for the Protection of Industrial Property
PCT	Patent Cooperation Treaty
PEB	Patent Examination Board
PharmR	Zeitschrift für Pharmarecht (Journal)
Plant Protection Products Regulation	Reg. 1610/96
PLT	Patent Law Treaty
PPP	Plant Protection Products
PPPAMS	Plant Protection Product Authorisation Management System
PTA	patent term adjustment
PTE	patent term extension
Q	Question
R.P.C.	Reports of Patent and Trade Mark Cases (Journal)
Reg.	Regulation
Sec.	Section
Sing. L. Rev.	Singapore Law Review (Journal)
SmPC	Summary of product characteristics
SPC Regulations	Reg. 1610/96 and Reg. 469/2009

SPC	Supplementary protection certificate
TBA	Technical Board of Appeal
TEU	Treaty on European Union
TFEU	Treaty on the Functioning of the European Union
UK IPO	UK Intellectual Property Office
UN	United Nations
Unitary Patent Package	A Regulation creating a European patent with unitary effect; a Regulation establishing a language regime applicable to the unitary patent; an Agreement between EU countries to set up a single and specialised patent jurisdiction
UPC	Unified Patent Court
USPTO	United States Patent and Trademark Office
v	Versus
WHO	World Health Organisation
WIPO	World Intellectual Property Organisation
WTO	World Trade Organisation
ZPO	Zivilprozessordnung/German Code of Civil Procedure

TABLE OF LEGISLATION

International law

CARIFORUM EPA	Economic Partnership Agreement between the CARIFORUM States, of the one part, and the European Community and its Member States, of the other part [2008] L 289/I/3 (pending ratification)
CETA	Canada-European Union Comprehensive Economic and Trade Agreement, signed on 30 October 2016, approved by the European Parliament on 15 February 2017, by Canadian Parliament on 11 May 2017; provisionally applied by the EU and Canada since 21 September 2017
ECHR	Council of Europe, European Convention for the Protection of Human Rights and Fundamental Freedoms, as amended by Protocols, 4 November 1950, ETS 5
EPC	Convention on the Grant of European Patents of 5 October 1973 [1974] 13 International Legal Matters 268
FTA EU – Colombia, Peru	Trade Agreement between the European Union and its Member States, of the one part, and Colombia and Peru, of the other part [2012] OJ L 354
FTA EU – Georgia	Association Agreement between the European Union and the European Atomic Energy Community and their Member States, of the one part, and Georgia, of the other part [2014] L 261/4
FTA EU - Japan	Agreement between Japan and the European Union for an Economic Partnership, consolidated version of 7 December 2017 (not yet in force)
FTA EU - Korea	Free trade Agreement between the European Union and its Member States, of the one part, and the Republic of Korea, of the other part [2011] OJ L 127
FTA EU – Moldova	Association Agreement between the European Union and the European Atomic Energy Community and their Member States, of the one part, and the Republic of Moldova, of the other part [2014] L 260/4
FTA EU – Singapore	Free Trade Agreement between the European Union and the Republic of Singapore (pending EU ratification)
FTA EU – Vietnam	EU – Vietnam Free Trade Agreement: Agreed text as of January 2016 (not yet in force)
GATT	General Agreement on Trade and Tariffs 1994, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, 1867 U.N.T.S. 187, 33 I.L.M. 1153 (1994)

Marrakesh Treaty	Marrakesh Treaty to Facilitate Access to Published Works for Persons Who Are Blind, Visually Impaired or Otherwise Print Disabled, 27 July 2013
Paris Convention	Paris Convention for the Protection of Industrial Property of March 20, 1883, as revised at Brussels on December 14, 1900, at Washington on June 2, 1911, at the Hague on November 6, 1925, at London on June 2, 1934, at Lisbon on October 31, 1958, and at Stockholm on July 14, 1967. Geneva: United International Bureau for the Protection of Intellectual Property (BIRPI)
Patent Cooperation Treaty	Patent Cooperation Treaty (Draft Agreement on the European Union Patent Court and draft Statute (Working document), No. prev. doc.: 11270/08 PI 32 COUR 32, 4 November 2008)
Patent Law Treaty	Patent Law Treaty of June 1, 2000, entered into force April 28, 2005, 39 International Legal Matters 1047
Strasbourg Convention	Convention on the Unification of Certain Points of Substantive Law on Patents for Invention [1963] ETS 47 – Unification Law of Patents
TPP	Trans-Pacific Partnership Agreement of 4 February 2016 (not in force)
Treaty of Rome	Treaty Establishing the European Community [2002] OJ C 325
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights of April 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 International Legal Matters 1197 (1994)
UPCA	Agreement on a Unified Patent Court of 11 January 2013 [2013] OJ C 175/1
VCLT	Vienna Convention on the Law of Treaties of May 23, 1969, United Nations, Treaty Series, vol. 1155, p. 331

European Union law

CFR	Charter of Fundamental Rights of the European Union [2012] OJ C 364/1
CPC	Council Convention 76/76/EEC for the European Patent for the Common Market [1976] OJ L 17/1
EC	Convention for the European Patent for the Common Market of 15 December 1976 [1975] OJ L 17/1
EEA	Agreement on the European Economic Area [1994] OJ L 1/3

TEC	Treaty Establishing the European Economic Community [1992] OJ C 224/32
TFEU	Treaty on the Functioning of the European Union [2012] OJ C 326/47
Treaty of Lisbon	Treaty of Lisbon amending the Treaty on European Union and the Treaty establishing the European Community [2007] OJ C 306/1
TUE	Treaty on European Union [1993] OJ L 293
76/76/EEC	Convention for the European patent for the common market (Community Patent Convention)
Reg. 2017/1001	Regulation (EU) 2017/1001 of the European Parliament and of the Council of 14 June 2017 on the European Union trade mark [2017] OJ L 154/1
Reg. 2017/746	Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU [2017] OJ L 117/176
Reg. 2017/745	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC [2017] OJ L 117/1 (Medical Devices Regulation)
Reg. 536/2014	Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use and repealing Directive 2001/20/EC [2014] OJ L158/1
Reg. 608/2013	Regulation (EU) No 608/2013 of the European Parliament and of the Council of 12 June 2013 concerning customs enforcement of intellectual property rights and repealing Council Regulation (EC) No 1383/2003 [2013] OJ L 181/15
Reg. 1260/2012	Regulation (EU) No 1260/2012 of 17 December 2012 of the European Parliament and of the Council implementing enhanced cooperation in the area of the creation of unitary patent protection with regard to the applicable translation arrangements [2012] OJ L 361/89
Reg. 1257/2012	Regulation (EU) No 1257/2012 of the European Parliament and of the Council of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection [2012] OJ L 361/1
Reg. 712/2012	Commission Regulation (EU) No 712/2012 of 3 August 2012 amending Regulation (EC) No 1234/2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and

	veterinary medicinal products (Text with EEA relevance) [2012] OJ L 209/4
Reg. 182/2011	Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers [2011] OJ L 55/13
Reg. 1223/2009	Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products [2009] OJ L 342/59
Reg. 1107/2009	Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC [2009] OJ L 309/1
Reg. 469/2009	Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products [2009] OJ L 152/1
Reg. 207/2009	Council Regulation (EC) No 207/2009 of 26 February 2009 on the Community trade mark (no longer in force) [2009] OJ L 78/1
Reg. 1333/2008	Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives [2008] OJ L 354/16
Reg. 1234/2008	Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products [2008] OJ L 334/7
Reg. 216/2008	Regulation (EC) No 216/2008 of the European Parliament and of the Council of 20 February 2008 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency, and repealing Council Directive 91/670/EEC, Regulation (EC) No 1592/2002 and Directive 2004/36/EC [2008] OJ L79/1
Reg. 1394/2007	Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 [2007] OJ L 324/121
Reg. 1907/2006	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing

	Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC [2006] OJ L 396/1
Reg. 1901/2006	Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004 [2006] OJ L 378/1 (Paediatric Products Regulation)
Reg. 816/2006	Regulation (EC) No 816/2006 of the European Parliament and of the Council of 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems [2006] OJ L 157/1
Reg. 507/2006	Commission Regulation (EC) No 507/2006 of 29 March 2006 on the conditional marketing authorisation for medicinal products for human use falling within the scope of Regulation (EC) No 726/2004 of the European Parliament and of the Council [2006] OJ L 92/6
Reg. 726/2004	Regulation (EC) 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency [2004] OJ L 136/1
Reg. 1085/2003	Commission Regulation (EC) No 1085/2003 of 3 June 2003 concerning the examination of variations to the terms of a marketing authorisation for medicinal products for human use and veterinary medicinal products falling within the scope of Council Regulation (EEC) No 2309/93 (Text with EEA relevance) [2008] OJ L 334
Reg. 6/2002	Council Regulation (EC) No 6/2002 of 12 December 2001 on Community designs [2002] OJ L 3/1
Reg. 2245/2002	Commission Regulation (EC) No 2245/2002 of 21 October 2002 implementing Council Regulation (EC) No 6/2002 on Community designs (OJ EC No L 341 of 17.12.2002, p. 28) amended by Commission Regulation (EC) No 876/2007 on 24 July 2007 amending Regulation (EC) No 2245/2002 implementing Council Regulation (EC) No 6/2002 on Community designs following the accession of the European Community to the Geneva Act of the Hague Agreement concerning the international registration of industrial design [2007] OJ L 193/13
Reg. 1592/2002	Regulation (EC) No 1592/2002 of the European Parliament and of the Council of 15 July 2002 on common rules in the

	field of civil aviation and establishing a European Aviation Safety Agency (Text with EEA relevance) [2008] OJ L 79/1
Reg. 178/2002	Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety [2002] OJ L 31/1
Reg. 141/2000	Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products [2000] OJ L 18/1
Reg. 1610/96	Regulation (EC) No 1610/96 of the European Parliament and of the Council of 23 July 1996 concerning the creation of a supplementary protection certificate for plant protection products [1996] OJ L 198/30 (Plant Protection Products Regulation)
Reg. 2100/94	Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights [1994] OJ L 227/1
Reg. 2309/93	Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products [1993] OJ L 214
Reg. 1768/92	Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products (no longer in force) [1992] OJ L 182/1
Reg. 2655/82	Commission Regulation (EEC) No 2655/82 of 1 October 1982 laying down rules for implementing the import arrangements for 1982 for products falling within subheading 07.06 A of the Common Customs Tariff originating in third countries other than Thailand and amending Regulation (EEC) No 950/68 on the Common Customs Tariff (no longer in force) [1982] OJ L 290/31
Reg. 1182/71	Regulation (EEC, EURATOM) NO 1182/71 of the Council of 3 June 1971 determining the rules applicable to periods, dates and time limits [1971] OJ L 124/1
Dir. 2016/943	Directive (EU) 2016/943 of the European Parliament and of the Council of 8 June 2016 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure (Text with EEA relevance) [2016] OJ L 157/1 (Trade Secrets Directive)
Dir. 2015/2436	Directive (EU) 2015/2436 of the European Parliament and of the Council of 16 December 2015 to approximate the

	laws of the Member States relating to trade marks (Text with EEA relevance) [2015] OJ L 336/1
Dir. 2014/114	Directive 2014/104/EU of the European Parliament and of the Council of 26 November 2014 on certain rules governing actions for damages under national law for infringements of the competition law provisions of the Member States and of the European Union (Text with EEA relevance) [2014] OJ L 349/1 (Damages Directive)
Dir. 2007/46	Directive 2007/46/EC of the European Parliament and of the Council of 5 September 2007 establishing a framework for the approval of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles (Text with EEA relevance) [2007] OJ L 263/1
Dir. 2005/28	Commission Directive 2005/28/EC of 8 April 2005 laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products (Text with EEA relevance) [2005] OJ L 91/13
Dir. 2004/48	Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights [2004] OJ L 195/16
Dir. 2004/27	Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use [2004] OJ L 136/34
Dir. 2003/94	Commission Directive 2003/94/EC of 8 October 2003 laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use (Text with EEA relevance) [2003] OJ L 262/22
Dir. 2001/83	Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use [2001] OJ L 311/67
Dir. 2001/82	Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products [2001] OJ L 311/1
Dir. 2001/92	Commission Directive 2001/92/EC of 30 October 2001 adapting to technical progress Council Directive 92/22/EEC on safety glazing and glazing materials on motor vehicles and their trailers and Council Directive 70/156/EEC relating to the type-approval of motor vehicles and their trailers (no longer in force) [2001] OJ L 291/24

Dir. 2001/20	Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use [2001] OJ L 121/34
Dir. 98/79	Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices [1998] OJ L 331/1
Dir. 98/44	Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of biotechnological inventions [1998] OJ L 213/13 (Biotech Directive)
Dir. 93/42	Council Directive 93/42/EEC of 14 June 1993 concerning medical devices [1993] OJ L 169/1
Dir. 93/41	Council Directive 93/41/EEC of 14 June 1993 repealing Directive 87/22/EEC on the approximation of national measures relating to the placing on the market of high-technology medicinal products, particularly those derived from biotechnology (Date of entry into force unknown (pending notification) or not yet in force) [1993] OJ L 214/40
Dir. 91/414	Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (no longer in force) [1991] OJ L 230/1
Dir. 90/385	Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices [1990] OJ L 189/17
Dir. 87/22	Council Directive 87/22/EEC of 22 December 1986 on the approximation of national measures relating to the placing on the market of high-technology medicinal products, particularly those derived from biotechnology (no longer in force) [1987] OJ L 15/38
Dir. 75/319	Council Directive 75/319/EEC of 20 May 1975 on the approximation of provisions laid down by Law, Regulation or Administrative Action relating to proprietary medicinal products (no longer in force) [1975] OJ L 147/13
Dir. 75/318	Council Directive 75/318/EEC of 20 May 1975 on the approximation of the laws of Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of proprietary medicinal products [1975] OJ L 147
Dir. 65/65	Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by Law, Regulation or Administrative Action relating to proprietary medicinal products [1965] OJ 369/65

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INTRODUCTION

1 PURPOSE AND METHODOLOGY OF THE STUDY

1.1 THE MANDATE OF THE EUROPEAN COMMISSION

The purpose of this Study is to provide the Commission with a legal assessment of the EU system on supplementary protection certificates (hereinafter: SPCs). Furthermore, the Study will analyse the interaction between the SPC legislation and the Unitary Patent Package as well as the options for creating a unitary SPC. Finally, it will examine the impact of the UPCA on the *Bolar* exemption and the options for creating a manufacturing waiver for SPCs.[1]

Pursuant to the specifications of the Call for Tender, the tendered Study should provide the Commission with "an evaluation of the SPC regulation from a legal perspective", present "a comprehensive legal review of the EU SPC system", and analyse whether the existing EU legal framework for SPCs is "legally sound" and "fit for its purposes". Against this background, the Study is of purely legal nature. It provides a review of the legislation and case law, and on the basis of this analysis identifies critical issues and suggests possible solutions. Accordingly, the Study does not address the economic effects which the SPC Regulations may have had in the European market since their entry into force. Furthermore, it does not review the changes, if any, that may have occurred in the innovation structure of the respective industries since 1992 and 1994.

At the same time the Call for Tender requires the provision of conclusions on "the legal effectiveness" and "efficiency" of "the legal SPC framework in the EU". Based on this assessment, the Study should propose changes to existing rules where appropriate. This aspect requires some clarification.

1.2 ON THE EFFECTIVENESS OF THE SPC LEGISLATION. LIMITATIONS OF THE STUDY

Effectiveness denotes the ability of a provision or a set of provisions to achieve their intended purposes. With respect to the SPC legislation, the question of effectiveness would require the Study to identify the purposes that the drafters of this legislation had in mind and to answer the question whether or not these purposes were achieved.

The evaluation of a law's effectiveness is one of the most difficult tasks of a legal, sociological and economic analysis. The reasons are well known. On the one hand, the purposes a lawmaker pursues can be manifold and may not always have been clearly stated in the law concerned. On the other hand, the law operates in the context of various other regulations, factual influences and additional factors. Even if specific developments can be empirically proven after the enactment of a law, this does not imply a cause-effect relationship with the enactment or the amendment of that specific regulation. In the field of IP law, the difficulties for this type of research are even greater. This is also due to the fact that the companies operating in a specific market can also benefit from the protection offered and existing in foreign markets

[1] The scope of the *Bolar* exemption with respect to third-party suppliers was part of the tendered Study, since pursuant to the Tender Specifications the subject of the Case C-661/13 *Astellas Pharma Inc v Polpharma SA Pharmaceutical Works* ECLI:EU:C:2014:588 (withdrawn case) shall be considered.

relevant to their activity. Thus, for instance, patent protection available in the US market may be as effective in fostering innovation in Europe as patent protection in Europe itself. Further, the evidence that may be obtained concerning the effects of an IP regulation is not conclusive. For instance, the mere fact that the system's users resort to patent or SPC filings does not necessarily mean that the law pursuant to which such rights are granted is effective. As a consequence, from a mere legal analysis, no definitive conclusions can be drawn on questions of effectiveness and efficiency.

The same conclusion is valid for the SPC system. We are in a position to identify the purposes the legislature had in mind when it enacted the SPC legislation. The main purpose was to foster research in new active ingredients. However, we cannot assess whether the Regulation has achieved this goal and stimulated innovation that – all else being equal – would not have taken place without SPCs in Europe. For the same reasons, we cannot answer the question whether the term of the SPC is adequate for this purpose or could be reduced without affecting innovation. The same holds true for the question whether some other measures, such as a manufacturing waiver, would be economically sound.

This does not mean that the Study has neglected these aspects. What the Study addresses is, however, only the "perceived effectiveness", i.e. how the stakeholders evaluate the SPC Regulations, and whether and to what extent they make use of the system. To this purpose we have collected some data from secondary literature and we have asked the stakeholders themselves. These data and information do not constitute evidence that makes it possible to answer the questions of whether the regulations have effectively served the purposes for which they were enacted starting in 1992.

1.3 METHODOLOGY

The study combines legal analysis with a fact-finding process. The purpose of the legal analysis and of the fact-finding process is to verify the hypotheses formulated in the preparatory phase. Furthermore, both are aimed at identifying issues not considered in that phase.

1.3.1 Legal analysis

The Study focuses on the relevant case law of the Court of Justice of the European Union (CJEU). In this regard, we collected all relevant decisions of the CJEU as well as relevant judgments of courts from EU Member States. We also investigated the granting practice of several National Patent Offices (NPOs).

1.3.2 Fact finding

The fact-finding process for the present Study is based on a combined quantitative and qualitative approach. This allows, on the one hand, for comparability of the responses and the inclusion of a large number of stakeholders, while on the other hand providing sufficient flexibility and time to discuss certain issues in greater depth with stakeholder experts.

The fact-finding is structured as follows:

1.3.2.1 MPI Questionnaire for the NPOs

We conducted questionnaire-based qualitative interviews with the competent officers at the national patent-granting authorities of all EU Member States and two EPC States.[2] We received responses from the following Offices:

- Austria (AT)
- Czech Republic (CZ)
- Germany (DE)
- Denmark (DK)
- Spain (ES)
- Finland (FI)
- France (FR)
- Greece (GR)
- Croatia (HR)
- Hungary (HU)
- Ireland (IE)
- Italy (IT)
- Lithuania (LT)
- Luxembourg (LU)
- Latvia (LV)
- Netherlands (NL)
- Poland (PL)
- Portugal (PT)
- Romania (RO)
- Serbia (RS)
- Switzerland (CH)
- Slovak Republic (SK)
- Sweden (SE)
- United Kingdom (UK)

1.3.2.2 Stakeholder survey

Further, a stakeholder survey was conducted by the Institut für Demoskopie Allensbach (hereinafter: the Allensbach Survey). The details of the Allensbach Survey are described in Annex III to this Study. The details on how we created the list of stakeholders which were then contacted by the Allensbach Institute are explained in Annex IV to this Study.

As explained there, the stakeholders consulted by the survey cannot be considered a representative population. On the one hand, an official and reliable list of stakeholders is not available. On the other hand, some specific groups within the participants to the survey are likely overrepresented (companies), while others (universities, research institutions) are underrepresented. In addition, in geographical terms, the distribution of the stakeholders is not uniform. Therefore, when we refer in the analysis to the prevailing view of the stakeholders, we intend herewith only the stakeholders that were consulted in the course of the Study. Such opinions may, but do not necessarily, reflect the views of the majority of the generics or originator industry in Europe. The same is true, *a fortiori*, for other groups of stakeholders equally affected by the operation of the SPC system that could be involved only to a limited extent.

1.3.2.3 MPI workshop with the NPOs and stakeholders on 20-21 March 2017

In order to have the opportunity to discuss the most relevant issues regarding SPCs at an early stage of the Study, we organised a two-day workshop with the support of the German Patent and Trade Mark Office in Munich. Stakeholders, including professional and industry associations, law firms and companies, were invited for the first day of the workshop. A total of 190 individual participants signed up for the workshop, in some cases with several individuals representing the same stakeholder. The presentations and discussions were recorded with the consent of the participants for the purpose of this Study. On the second day, representatives from the SPC granting

[2] See Annex VI of this Study.

authorities were invited exclusively for a discussion on the granting practice of the NPOs. Eighty individual participants signed up for the discussion round. As on the first day, the discussion was recorded with the consent of the participants.

1.3.2.4 Stakeholder interviews

To supplement the quantitative Allensbach Survey, we conducted 14 additional qualitative interviews. The stakeholders were selected on a non-representative basis but mainly based on presumed experience in the field of SPCs and availability for the interview. Most interviews were conducted by a team of two MPI researchers. The participants received a list of questions prior to the interview. This list was used as a guideline for the actual interview. All interviews were conducted on an anonymous basis and lasted between 60 and 120 minutes.

1.3.2.5 Stakeholder seminar on 11 September 2017

An additional seminar specifically designed for industry stakeholders was held on 11 September 2017 at the MPI in Munich. Representatives of the European Commission and stakeholders from both the originator and generics industries in the field of pharmaceuticals and plant protection products attended the seminar. The following industrial associations were represented:

- European Federation of Pharmaceutical Industries and Associations (EFPIA)
- European Confederation of Pharmaceutical Entrepreneurs (EUCOPE)
- European Association for Bioindustries (EuropaBio)
- Medicines for Europe
- European Crop Protection Association (ECPA)
- European Crop Care Association (ECCA)

While this meeting was not originally planned for the present Study, a group of industry associations involved with the Study expressed their wish to have an additional opportunity to present their position and concerns on the Survey conducted by the MPI and the Allensbach Institute. The MPI addressed this wish by planning the additional seminar. Furthermore, participants were given the opportunity to address further issues, which they deemed to be relevant in written submissions.

1.4 OUTLINE OF THE STUDY

The Study is divided into six parts. Part One lays out the legal background of the SPC regime. In this part we present the purposes of the SPC legislation (Chapter 2), its origin and development (Chapter 3), some relevant notions of regulatory (Chapter 4) and patent law (Chapter 5), and finally the interplay of SPC protection with other instruments provided under EU law that are able to protect the results of pharmaceutical research (Chapter 6).

Part Two of the Study addresses the question of the effectiveness of the SPC Regulations. This part assesses to what extent patent holders make use of the system (Chapter 7), and how, according to the answers collected by the Allensbach Survey of the consulted stakeholders, they perceive the functioning of the system (Chapter 8).

Part Three includes a legal analysis of Reg. 1610/96 and Reg. 469/2009 (hereinafter: the SPC Regulations). This part aims at identifying critical points of the current legal framework. It combines input obtained from the data collected through the qualitative interviews and quantitative surveys with the analysis of the relevant case law (Chapters 9–20).

Part Four concerns the impact of the Unitary Patent Package on SPCs. It will address the issues *de lege lata*, in particular whether SPCs may be granted by designating a European patent with unitary effect, what the legal effect of the grant is, and how SPCs relate to the UPC Agreement (Chapter 21). This part will further address issues *de lege ferenda*, and in particular the issue of whether and how a unitary SPC could be implemented (Chapter 22).

Part five of the Study offers some comparative insights (Chapter 23). It is based on national reports on patent extension models provided by selected extra-European jurisdictions (Annex II of the Study). Part Six, finally, provides the European Commission with a summary (Chapter 24) and some recommendations (Chapter 25). The Study includes following Annexes:

- Annex I "National Reports EU" contains information on the practice of some EU NPOs (hereinafter: Annex I);
- Annex II "International Reports" contains reports on patent term extensions or SPCs available in selected extra-European jurisdictions (hereinafter: Annex II);
- Annex III contains the Allensbach Survey – "Survey on the Legal Aspects of Supplementary Protection Certificates in the EU" (hereinafter: Annex III);
- Annex IV "Fact Finding Methodology" includes information on the participants in the survey and on the interviews (hereinafter: Annex IV);
- Annex V includes some "SPC Statistics to Chapter 7" (hereinafter: Annex V);
- Annex VI, "Questionnaire for the National Patent Offices of the EU Member States", reproduces the MPI questionnaire for the NPOs (hereinafter Annex VI).

1.5 CHRONOLOGY OF THE STUDY

The preliminary draft of the Study was submitted in August 2017. Following comments by the European Commission in October 2017, the Final Report of the Study was completed in November 2017. The Commission provided the MPI with further comments and questions on specific parts of the Study in February and May 2018. We considered this feedback in drafting the reviewed Final Report, which was submitted in May 2018. However, the Study could not consider adequately literature and case law published after November 2017.

PART ONE:

BACKGROUNDS AND PURPOSES OF THE SPC REGULATIONS

2 THE PURPOSES OF THE SPC REGULATIONS AND THE NATURE OF SPCS

The legal analysis in Part Three of the Study depends, *inter alia*, on the legal objectives underpinning the SPC Regulations as well as on the nature of the rights created thereby. This chapter embarks on an investigation of the relevant issues.

2.1 THE PURPOSES OF THE MEDICINAL PRODUCTS REGULATION (REG. 1768/92)

2.1.1 Premise

The purposes of the SPC Regulations have been addressed in several Advocate General opinions and some CJEU judgments as a basis for interpreting the legislation. Furthermore, the purposes of the SPC Regulations form the yardstick for assessing – as we are requested to do in this Study – whether the legislation has been effective.

The relevant benchmark for this inquiry is provided by the recitals of the SPC Regulation and the Explanatory Memorandum[3] of the European Commission. Regarding the latter it has been argued that the text is no longer relevant for interpreting the legislation. Indeed, the Proposal for a Council Regulation of 3 April 1990 was amended and the wording of Reg. 1768/92 is not identical to the wording of the Proposal.[4] However, this argument is valid only with respect to provisions amended in the course of the process that led to the adoption of Reg. 1768/92. The rules governing the conditions for granting the certificate as well as the relevant recitals remained the same throughout the parliamentary process. They were also incorporated in the subsequent Reg. 1610/96 on plant protection products and are reproduced in Reg. 469/2009.

The Medicinal Products Regulation was adopted on the basis of the provisions concerning the free movement of goods and the functioning of the internal market.[5] Consistent with this legal basis the primary justification for enacting the Medicinal Products Regulation was to prevent a heterogeneous development of the national law of the Member States. As is common for Union regulations creating EU IP rights or harmonising existing national rights, this common-market-based motivation was not the only purpose pursued by the lawmaker and likely not even the most important one.[6]

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3 European Commission, Explanatory Memorandum to the Proposal for a Council Regulation (EEC), of 11 April 1990, concerning the creation of a supplementary protection certificate for medicinal products (COM(90) 101 final – SYN255), para. 3.

4 See UK IPO, BL 0/138/05 *Knoll AG,* Decision of 19 May 2005, paras. 8-11.

5 Art. 100a Treaty Establishing the European Economic Community [1992] OJ C 224/32.

6 Colin Birss et al, *Terrell on the Law of Patents* (18th edn, Sweet & Maxwell 2016), paras. 6-26 et seqq.; Case C-350/92 *Spain v Council* [1995] ECR I-1985; joined Cases C-207/03 and C-252/03 *Novartis and others* [2005] ECR I-3209, Opinion of AG Colomer, para. 42 ("An analysis of the preamble to the regulation shows that the legislature's main motivation in adopting the legislation was not to guarantee the free movement of medicinal products but to create the conditions necessary to ensure that pharmaceutical research is profitable and to deter firms in that industry from leaving the Union, without failing to have regard to other interests worthy of legal protection, such as public health, the interests of consumers and those of the generic medicines industry. The unimpeded trade in medicinal products within the Community is an indirect result of that main objective, so, with the aim of

Indeed, in the *travaux préparatoires*, the goals pursued by the historical lawmaker – in addition to securing the functioning of the internal market – are defined as follows:

- offering adequate protection to pharmaceutical research;
- putting the European industry on equal footing with the US and Japanese industry
- preventing a relocation of research centres from Europe to extra-European jurisdictions;
- ensuring a balance of all interests concerned;
- creating a transparent and simple system for granting certificates.

With the exception of the latter, all these purposes or interests are also reflected in the recitals of the SPC Regulations.

2.1.2 Preserving the integrity of the common market

Pursuant to Recital 7 Reg. 469/2009,[7]

> "a uniform solution at Community level should be provided for, thereby preventing the heterogeneous development of national laws leading to further disparities which would be likely to create obstacles to the free movement of medicinal products within the Community and thus directly affect the establishment and the functioning of the internal market."

This was a common justification for legal acts adopted under Art. 100a EEC.[8] The European Union (or Community) had and has no direct competence in the field of intellectual property. Such competence can be based only on the provisions related to the functioning of the common market. The background of Recital 7 Reg. 469/2009 was the initiative of some Member States, such as Italy and France, to adopt their own system of SPCs with different terms and requirements of protection, and the risk that other EU Member States might follow their example.[9] This would have led to a situation where the same active ingredients would be patent-free in some countries and protected in others, thus resulting in a fragmentation of the common market.

In order to preserve the integrity and the functioning of the common market, Reg. 1768/92 established a uniform system for granting SPCs. This system replaced national rules in the states where certificates already existed and prevented the enactment of autonomous domestic legislation in Member States where certificates were not provided for. Being uniform law, the EU Regulation aimed at preventing a heterogeneous development not only of the written law, but also of the case law. In tension with this objective, however, Reg. 1768/92 did not create an unitary title of protection granted by a central office, but a national right granted by the national authorities. As a consequence, the applicant must file a bundle of national SPC applications in any country of interest, and the NPOs of each country will have to make their own decisions on the existence of the requirements for protection.

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preventing the internal market from being partitioned as a result of divergent national laws, a uniform set of rules has been imposed. It is true that primary importance was attributed to those secondary reasons in order to provide justification for the Community's competence and to situate its legal basis in Article 100a of the EC Treaty (now, after amendment, Article 95 EC), but that does not mean that the substance and provisions of the rules are to be observed exclusively from the point of view of the establishment and functioning of the common market, whilst any other reasons which were decisive in adoption of the rules are to be disregarded").

7 See also Recital 6 Reg. 1610/96.

8 Later Art. 95 EC, and now Art. 114 TFEU.

9 Joined Cases C-207/03 and C-252/03 *Novartis and others* [2005] ECR I-3209, Opinion of AG Colomer, para. 42.

Furthermore, it follows from SPCs being national rights that actions for revocation must be brought in the national jurisdictions where the right shall be removed, and that the holder of the SPCs must likewise enforce them separately in each jurisdiction. This may lead to the situation that the same product is protected in one jurisdiction and not protected in another, because the competent authorities reached diverging conclusions on eligibility or the scope of protection. It is true that the CJEU ultimately decides on the interpretation of the Regulations. However, the CJEU cannot apply the law to a specific set of facts. The Court and the referral system under Art. 267 TFEU can only prevent that diverging decisions originate from a diverging interpretation of the Regulation.

Without doubt, the SPC Regulations were successful insofar as they have prevented a heterogeneous development of the law in the EU Member States. Domestic legislation interfering with the Regulations or covering products outside the scope of the Regulations has not been adopted anywhere. Certificates based on Italian and French legislation were no longer granted once the transitional period expired. The question of whether the SPC Regulations and the CJEU have also prevented the development of heterogeneous practices in the Member States is more complex. In Chapter 7 we provide some data on the differences in the granting rates of the NPOs. We also asked the question to the stakeholders and NPOs (Chapter 8). When interpreting those data and the responses received, one must however be cautious. Different granting rates do not necessarily signal a heterogeneous interpretation of the SPC Regulations. They do not mean that one and the same application would be evaluated differently. Granting rates may be impacted by the fact that the examination of Art. 3(c) and Art. 3(d) Reg. 469/2009 is optional in some countries and in mandatory in others.[10] The same can result from whether the examination is of a substantive or rather formal character. These aspects are not related to the interpretation of the law, but to the institutional context in which the law is applied.

2.1.3 Adequate protection of pharmaceutical research

2.1.3.1 Premise

The recitals of the Medicinal Product Regulation point out that pharmaceutical research plays a decisive role in the continuing improvement in public health. Pursuant to Recital 3 "Medicinal products, especially *those that are the result of long, costly research*, will not continue to be developed in the Community and in Europe unless they are covered by favourable rules that provide for sufficient protection to encourage such research".[11] The Regulation states that "the period that elapses between the filing of an application for a patent for *a new medicinal product* and authorisation to place the medicinal product on the market makes the period of effective protection under the patent insufficient to cover the investment put into research".[12] As a result, Reg. 1768/92 assumed that a lack of protection which penalises pharmaceutical research in Europe exists.[13] The purpose of the Medicinal Products Regulation was and is therefore to ensure adequate protection for the results of pharmaceutical research, or in the words of an Advocate General Colomer, "to

10 See Art. 10(5) Reg. 469/2009.
11 Recital 3 Reg. 469/2009 (emphasis added).
12 Recital 4 Reg. 469/2009 (emphasis added). The original proposal referred to the time between the discovery of a new medicinal product and the authorisation to place it on the market.
13 Recital 5 Reg. 469/2009.

create the conditions necessary to ensure that pharmaceutical research is profitable".[14] The reasons why this was seen as necessary for the pharmaceutical sector are expounded in Reg. 1768/92 and in the Explanatory Memorandum.

On the one hand, "the holder of a patented medicinal product must refrain from using it until he has obtained authorization from the health authorities to place the product on the market".[15] Such authorisation procedure requires the pharmaceutical industry to demonstrate "the quality, safety and efficacy" of "new medicinal products".[16] This reduces the effective period of exclusivity granted by the patent, indeed:

> "an average period of 12 years between the discovery of a new medical product, at which time the patent application is filed, and its being made available to patients is currently necessary, the effect of which is to reduce the exclusive exploitation period under the patent to only 8 years."[17]

On the other hand, the industry cannot defer the application for a patent after an invention is made. The requirement of absolute novelty and the first-to-file principle would expose the company to the risk of creating prior art quotable against the patent application or of losing the patent race to a competitor.

The patent erosion resulting from these two factors – the pressure for early patent filing and the delay of the invention being ready for exploitation – could lead, in the view of the EU legislature, to a situation where pharmaceutical research would not be profitable anymore. All these assumptions were made with respect to "new medicinal products".[18]

Despite this clear starting point, the Medicinal Products Regulation presents some ambiguities. First, it is unclear what *type of research* the Regulation intends to foster, and second, which achievements within that type of research entitle a beneficiary to the SPC.

2.1.3.2 What kind of research does the Regulation intend to foster?

Pharmaceutical research can have many purposes. It may be aimed at identifying a new receptor and a causal link between said receptor and a specific disease, selecting an adequate candidate for blocking a receptor concerned when it is known to play a role in a specific disease and in doing so screening existing molecules for such use, improving manufacturing methods for a specific compound with known pharmacological properties, identifying the active enantiomer of a racemate already authorised as medicinal product, or screening existing compounds already authorised as drugs for new indications, identifying derivatives of known compounds with improved pharmacodynamics or improving properties of known compounds (new formulations to e.g. increase shelf-life).

The patentable results of this research may vary accordingly: they can consist in the identification of a new receptor linked to a disease and a screening method for

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14 Case C-350/92 *Spain v Council* [1995] ECR I-1985; joined Cases C-207/03 and C-252/03 *Novartis and others* [2005] ECR I-3209, Opinion of AG Colomer, para. 42

15 European Commission, Explanatory Memorandum to the Proposal for a Council Regulation (EEC), of 11 April 1990, concerning the creation of a supplementary protection certificate for medicinal products (COM(90) 101 final – SYN255), para. 2.

16 *Ibid*., para. 2.

17 *Ibid*.

18 *See infra* passages from the Explanatory Memorandum cited in Section 1.1.4.

identifying therapeutic candidates, in a new class of compounds as therapeutic agents, or in a new method for manufacturing known compounds. They can further consist in new formulation or new uses of old compounds already disclosed in the prior art as medicinal agents. Sometimes, a new use may require a new formulation and is possible only because of the new formulation.

The variety of goals that the research may pursue and of results it may reach raise the question of what kind of research the Regulation intends to foster. Two well-known and often quoted lines of the Explanatory Memorandum provide that "all research, whatever the strategy or final result, must be given sufficient protection"[19], and that "all pharmaceutical research provided it leads to a new invention which can be patented (…) must be encouraged without any discrimination"[20].

Further, Art. 1 Reg. 1768/92 stipulates that patents designated as a basic patent may consist of a patent for a process, a patent for a use and a patent for a method for manufacturing the active ingredient. Thus, it would be reasonable to assume that since the purpose of the SPC legislation is to foster pharmaceutical research without any discrimination, an SPC is available whenever a pharmaceutical invention is made and patented, and an MA for the exploitation of this invention has been requested and granted.

However, in our view, these conclusions are historically and legally unfounded. The purpose of the SPC legislation as conceived by the EU legislature was not to reward any research resulting in a patentable invention and a patented medicine, but only research that led to "new active ingredients", that is, substances that had never been authorised before for a medicinal purpose. The Regulation intended to address an assumed decline in the development of new molecules for medicinal use.[21] Only for this category of products the necessity exists to conduct full clinical trials, which the Regulation and the Explanatory Memorandum consider critical and decisive for granting compensation. Consequently, the purpose of the SPC Regulations was to supplement the protection that these new active substances already enjoyed under the data protection rules. Other pharmaceutical research may benefit from patent protection, but not from SPC protection. This opinion is based on the following arguments:

First, the Regulations make clear that the SPC may be granted only on the basis of the first MA in the state concerned (Art. 3(d)) and on the basis of an application filed within six months after the award of that MA (Art. 7). Further, only one SPC may be granted for this product (Art. 3(c)). The combined effect of these provisions is that an SPC is granted only for substances that were authorised for the first time as a medicinal product. If the product was already authorised in the past, and the applicant has identified new uses or a new formulation of the product and obtained a more recent MA, an SPC will not be possible for two reasons. If the application is based on the more recent MA, it will not comply with Art. 3(d) Reg. 469/2009, because it is not the first MA for the product; if the application for a certificate is based on the older MA, the application will be late under Art. 7 Reg. 469/2009.

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19 European Commission, Explanatory Memorandum to the Proposal for a Council Regulation (EEC), of 11 April 1990, concerning the creation of a supplementary protection certificate for medicinal products (COM(90) 101 final – SYN255), para. 12.

20 *Ibid.*, para. 29.

21 Robert Wenzel, *Analoge Anwendung der Verordnung über das ergänzende Schutzzertifikat für Arzneimittel auf Medizinprodukte?* (Nomos 2017) pp. 136-141.

Second, several statements in the Explanatory Memorandum demonstrate that the above-mentioned combined effect of the two provisions is indeed intended (emphases added):

> "Prior authorization procedures for medicinal products were first introduced in the industrialized countries following the experience with thalidomide. Since then, the public authorities have required the pharmaceutical industry to demonstrate the *quality, safety and efficacy of new medicinal products*. These prior controls, which are essential for the protection of public health and which are beyond question, involve considerable scientific and technical effort and expenditure."**[22]** (…)
>
> "In 1980, the Commission took the view that it was necessary to protect innovating firms. Directive 87/21/EEC therefore introduced, without prejudice to patent protection, a mechanism which, in particular for "high-technology" medicinal products, prevents a second applicant for marketing authorization from presenting a smaller-scale application for a period of 10 years from the first authorization for marketing of the product in the Community. The Commission takes the view that it is time to protect further *new medicinal products*."[23] (…)
>
> "Far from being a discriminatory measure in favour of a particular sector, the present proposal for a Regulation alms at guaranteeing laboratories working to develop *new medicinal products* a level of protection equal to that enjoyed by research in other sectors."[24] (…)
>
> "The proposal for a Regulation therefore concerns *only new medicinal products*. It does not involve granting a certificate for all medicinal products that are authorized to be placed on the market. Only one certificate may be granted for any one product, a product being understood to mean an active substance in the strict sense."[25] (…)
>
> "The system established by the proposal does not apply to all *patented* medicinal products placed on the market, but only to those which consist in *new medicinal products*. A large proportion of the medicinal products sold on the market have only few innovative features, or none at all. These are not covered by the scope of the proposal. Each year, only *about 50 new medicinal products* are authorized worldwide. It is these that are covered by the proposal for a Directive."[26] (….)
>
> "The certificate is designed to *encourage research into new medicinal products* so that the duration of protection it affords, together with the effective duration of protection by patent, is sufficient to enable the investments made in the research to be recovered."[27] (…)
>
> "Furthermore, it need not be feared that applications for a certificate will be routinely and systematically filed each time authorization to place a product on the market is given, since the conditions laid down in Article 3 for obtaining the certificate are strict and *allow only one certificate per product corresponding to the first authorization given in the State concerned*."[28]

In the language of the Explanatory Memorandum the term "new medicinal product" does not refer to the formulation of the medicine, but to the active ingredients. Indeed, when the Explanatory Memorandum refers to the medicine including the product, it uses the term "proprietary medicinal product":

> "What is authorized to be placed on the market is referred to as a "proprietary medicinal product", i.e. "any ready-prepared medicinal product placed on the market under a special name and in a special pack" (Article 1.1 of Directive 65/65/EEC).
>
> However, it may be the medicinal product that is patented, meaning the active ingredient, the process by which the medicinal product is obtained, or an application or use of the medicinal product.
>
> For the purposes of the certificate, which lies at the interface of the two systems, the terms "product" has been chosen as a common denominator. The exact meaning given to it is defined in Article 1, which is based on the definition of a medicinal product laid down Directive 65/65/EEC. However, the qualifier "active" is added to the term "substance" in order to include the concept of an "active ingredient or "active substance" used in patent law.

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22 European Commission, Explanatory Memorandum to the Proposal for a Council Regulation (EEC), of 11 April 1990, concerning the creation of a supplementary protection certificate for medicinal products (COM(90) 101 final – SYN255), para. 2.

23 *Ibid*., para. 3.

24 *Ibid*., para. 4.

25 *Ibid*., para. 11.

26 *Ibid*., para. 24.

27 *Ibid*., para. 36.

28 *Ibid*., para. 46.

> Consequently, the term "product" is not understood to mean a proprietary medicinal product or a medicinal product in the wider sense, but in the narrower sense of product used in patent law which, when applied to the chemical and pharmaceutical field, means the active ingredient."[29]

Third, the Economic and Social Committee pointed out in the process leading to the adoption of Reg. 1768/92 that the Proposal for a Regulation should be restricted to "pharmaceutical discoveries which genuinely involve a basic innovation".[30] The Explanatory Memorandum also refers to "innovative" products, suggesting that not every patented proprietary product is an innovative one for the purpose of the Proposal. In answering a question before the European Parliament shortly after Reg. 1768/92 was enacted on how the Regulation ensures such result the Commission pointed out:

> "So far as the definition of "innovative pharmaceutical products" is concerned, the Commission would point out that the certificate can only be used for a product – i.e. an active ingredient used in a medicinal product – covered by a patent. Under all the Member States current legal rules on patentability, this can only be a product, new world-wide, resulting from a specific inventive activity. The patent in question must also be valid and should be at the end of its legal term. In addition the pharmaceutical use of the active ingredient is demonstrated by the fact that the latter must have received administrative authorisation, issued under Community law and intended to certify the quality, effectiveness and safety of the product as a medicinal substance.
> Lastly, the Commission would emphasize that the limit laid down by the Regulation — only one certificate to be granted per active substance (Article 3 (c)) — provides an additional guarantee that a relatively small number of certificates will be issued, not exceeding the number of new active substances authorized to be placed on the market as medicinal products (barely 50 a year)."[31]

The Commission's suggestion that the only products that are SPC-eligible are compounds that are "world-wide new" at the time of filing the application for a patent is of course not quite correct, as also process and use patents may constitute basic patents within the meaning of Art. 1(c). However, what is clear from the observations of the Commission is that it was intended to protect only new active ingredients in the sense that they had not been authorised before. This is the sense of the reference to 50 medicinal products authorised each year – an estimation that is given in several publication at that time – and this is also confirmed in the same answer when the Commission states – though addressing another question – that "for the purpose of the Regulation, the only relevant authorizations are those which cover for the first time in each Member State an active ingredient protected by a patent in force in that State".[32] These were the innovative pharmaceutical products that the European Commission had in mind when drafting the Proposal.

Fourth, the fact that the historical purpose of the Regulations was to address the assumed decline in the development of new molecules in Europe[33] is also confirmed by the studies and documents provided by the industry that underpinned the Proposal. The "Memorandum on the Need of the European Pharmaceutical Industry for Restoration of Effective Patent Term for Pharmaceuticals"[34] to which the European

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29 *Ibid.*, paras. 28-29.

30 Opinion on the proposal for a Council Regulation (EEC) concerning the creation of supplementary protection certificate for medicinal products [1991] OJ C 69/22; Robert Wenzel, *Analoge Anwendung der Verordnung über das ergänzende Schutzzertifikat für Arzneimittel auf Medizinprodukte?* (Nomos 2017) p. 135.

31 Joint answer to Written Questions Nos 2367/92, 2368/92 and 2370/92 given by Mr Bangemann on behalf of the Commission, 26 November 1992 [1990] OJ C 61/30, para. 2.

32 *Ibid.*

33 Robert Wenzel, *Analoge Anwendung der Verordnung über das ergänzende Schutzzertifikat für Arzneimittel auf Medizinprodukte?* (Nomos 2017) p. 135.

34 EFPIA, Memorandum on the need of the European pharmaceutical industry for restoration of effective patent term for pharmaceuticals, 1988.

Commission likely[35] intended to refer in the Explanatory Memorandum deals with the assumed decline of the share of new chemical entities (NCEs) developed in Europe. The same is true of the study by *Suchy*,[36] to which *Schennen* refers as the document on which the European industry based its position. This study concerned only new pharmaceutical active ingredients approved for the first time for human medicine by the German Health Agency between 1979 and 1986. It is in respect to these new active ingredients – and not new formulations or new indications – that the *Suchy* study calculates an average effective patent term of 9.5 years (assuming a – at that time still fictitious – 20-year patent term).[37]

Finally, the understanding of the German Ministry of Justice and of the German Government of the purposes of the Reg. 1768/92 confirms the present analysis. In the transcription of the German Ministry of Justice's discussion of the Proposal the following understanding of Art. 3 Reg. 469/2009 is recorded:

> „Artikel 1 bezieht alle patentgeschützten Erzeugnisse, soweit sie arzneimittelrechtlich zugelassen sind, ein, unabhängig davon, ob es sich um ein Stoffpatent, ein Verfahrenspatent oder um ein Verwendungspatent handelt. Dieser umfassende Ansatz wird begrüßt. Er wird aber eingeschränkt dadurch, daß nach Artikel 3 Abs. 1 i.V.m. Artikel 1a VO-E nur für jeden Wirkstoff ein Zertifikat erteilt werden kann. *Damit wird die Zahl der verlängerbaren Patente im Ergebnis auf die Anzahl der neuen Wirkstoffe begrenzt.* Es ist zu prüfen, ob diese Einschränkung dem Ziel der Regelung gerecht wird."[38] (Emphasis added).

Accordingly, in the Explanatory Memorandum to the German law implementing the Regulation, the German Government expresses the opinion that SPC will be granted only for "neue, erstmals im Bereich der Europäischen Gemeinschaften zugelassenen Wirkstoffe oder Wirkstoffzusammensetzungen",[39] that is, new active ingredients or new combinations of active ingredients that have for the first time been authorised in the European Community.

In this perspective, the Regulation was intended to offer protection for the same subject matter as is the subject of data exclusivity, that is, an active substance authorised for the first time as a medicinal product (NCEs).

The fact that all categories of patents can be selected for obtaining an SPC does not affect the soundness of our reasoning. It is possible – and this is referred to in the Explanatory Memorandum – for an active ingredient to be the subject of different patents with a different scope. In that case, the patentee is free to select the patent designated as the basic patent in an SPC application. There is no obligation to choose

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35 The European Commission's Explanatory Memorandum to the Proposal for a Council Regulation (EEC), of 11 April 1990, concerning the creation of a supplementary protection certificate for medicinal products in para. 3 refers to a Study of EFPIA entitled "Memorandum on the Necessity to restore the effective duration of patents for pharmaceutical products". The only EFPIA study that is at our disposal in this regard is entitled "Memorandum on the Need of the European Pharmaceutical Industry for Restoration of Effective Patent Term for Pharmaceuticals". We assume that the latter study is intended by the European Commission.

36 Herbert Suchy, `Effective Patent Term of New Pharmaceutical Active Ingredients Approved in Germany´ [1988] IIC 337, and Herbert Suchy, `Patentrestlaufzeit neuerer pharmazeutischer Wirkstoffe´ [1987] GRUR 268.

37 Katarzyna Zbierska, *Application and Importance of Supplementary Protection Certificates for Medicinal Products in the European Union* (Shaker 2012) p. 192.

38 Aufzeichnung des Bundesjustizministeriums vom 15.10.1990 zum Vorschlag der Kommission der Europäischen Gemeinschaften für eine Verordnung des Rates über die Schaffung eines ergänzenden Schutzzertifikats für Arzneimittel (Kommissionsdokument KOM (90) 101 endg., Rats-Dokument 6033/90, Bundesrats-Drucks. 309/90. The record was published in [1991] GRUR Int. 32.

39 See 'Begründung Patentänderungsgesetz', BT-Drs. 12/3630; see also the analysis of Robert Wenzel, *Analoge Anwendung der Verordnung über das ergänzende Schutzzertifikat für Arzneimittel auf Medizinprodukte?* (Nomos 2017) p. 135.

the chronologically senior patent granted for the product. However, irrespective of the patent selected, the requirements of Art. 3(d) Reg. 469/2009 must be met. The patentee cannot choose the MA, which must be "the first chronologically given in the State concerned" for that active ingredient. For this reason, process patents and use patents can be the basis of an SPC only when the active ingredient to which the patent relates had not been authorised before as medicinal product. This could be the case, for instance, because the owner of a possible product patent granted for the active ingredient decided not to invest in developing a medicine including that active ingredient, as Advocate General Sir *Jacobs* with respect to process patents correctly observed in *Basf*[40] and *Schennen*[41], the representative of the German Government, correctly confirmed with respect to use patents in his commentary. Such scenario could also occur when a product patent was not possible because a disclosure anticipated the subject matter of the product claim. It can also occur that the same entity is awarded several patents with a different priority date relating to the same substance, and the owner of these patents decided for any reason to designate for the purpose of the procedure for granting a certificate not the priority older product patent, but a process or use patent relating to the same substance.

Summing up, in our view Reg. 1768/92 had the main purpose of fostering research in new molecules never authorised before, for whose exploitation as medicinal products a full-dossier MA was needed, that is, data concerning the safety and efficacy of the product. For these products the need to file a stand-alone MA before marketing reduces the patent life, an effect that led to the assumed lack of protection motivating the Regulation. Patents for new manufacturing process, new formulations and new indications of substances already described in the literature could benefit from the SPC regime as well. This should be possible, however, under the general conditions for granting the certificate. The MA must be the first one granted for the active ingredient in that country (and not only for that specific formulation and indication).[42]

The above considerations answer the question of what kind of research the Regulations – in the intention of the historical lawmaker – intend to foster, namely "research in new medicinal products". However, they do not answer the question of whether it is the disclosure of an patentable invention, or the development of a marketable product which is to be rewarded as the result of this research. The answer to that question depends on who is the intended beneficiary of the legislation.

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40 Case C-258/99 *BASF AG v Bureau voor de Industriële Eigendom (BIE)* [2001] ECR I- 03643*,* Opinion of AG Jacobs, para. 49 ("It is true that process patents are covered by the definition of a basic patent in Article 1(9) of the Regulation and that process patent holders may therefore benefit from the SPC regime. However, in order to benefit from that regime, the substantive conditions laid down in Article 3 of the Regulation must be fulfilled. The fact that those conditions - combined with the definition of product in Article 1(8) - may in practice exclude many process patents from the SPC regime is not contrary to the wording of Article 1(9). For, as the Commission points out, process patent holders may still be granted SPCs in cases where the relevant active substance has not been the subject of a previous marketing authorisation. That might happen in a situation in which the proprietor of a product patent decided not to go through the costly process of applying for a marketing authorisation because the relevant product could not be produced and sold with a profit on the basis of the production process known at the time").

41 Detlef Schennen, *Die Verlängerung der Patentlaufzeit für Arzneimittel im Gemeinsamen Markt* (Bundesanzeiger 1993).

42 As a consequence, old ingredients already authorised in the past as medicinal products could not become the subject of an SPC granted on the basis of subsequent patents granted for a specific formulation or indication or a new process for their manufacturing, because Art. 3(d) could not have been met by the application.

2.1.3.3 The achievement to be rewarded by the SPC: the disclosure of an invention or the development of a marketable product?

All industrial property rights reward a specific achievement and have an intended beneficiary. The achievement may consist in a creation that exhibits a qualitative advance in existing knowledge. Examples of this type of right are patents, plant variety rights or design rights. But the achievement can even consist in the mere fact that specific investments were made. This is the case for data bases or topographic conductors. The entity that benefits from legislation creating IP rights is the entity that has made the achievement that the law intends to protect.

For most IP legislation it is clear which achievement the IP right is meant to reward and who the intended beneficiary is. This seems not to be so for SPCs. *De lege lata*, as we will see in more details in Chapter 13, two interpretations of the SPC legislation can be equally proferred possible.

First, SPCs in their capacity of patent extension could be considered as instruments to create longer patent protection in a field where products are subject to regulatory approval. In this view, patent extensions, or SPCs, have the same justification and perform the same function as patents. They reward an inventor for having made and disclosed a patentable invention.[43] By contrast, it is not the task of SPCs or patent extensions to protect and reward the results of research done *after* an invention has been made, the patent application has been filed and the basic patent has been granted. Therefore, according to this approach, it does not matter who has invested in obtaining a marketable pharmaceutical product and the authorisation for that product. If the latter product is protected by the patent, the patentee is entitled to obtain the SPC. As a consequence, the intended beneficiary of the supplementary protection is the same as that of the original patent protection: the inventor or its assignee.

Under the second theory PTEs or SPCs are intended to create an incentive to bring a product subject to an MA to the market. For this reason, SPCs should also recompense for the efforts made *after* the invention is made, or even *after* the patent is granted, to develop a marketable medicinal product and obtain the MA. The intended beneficiary of the right is the entity that has directly or indirectly invested in the relevant research for obtaining the respective MA. As a consequence, an SPC is only justified if the patent holder or his/her licensee is the entity that was directly or indirectly involved in this development and approval process. As such, the intended beneficiary is not any patentee, but only the patentee that has invested time and money directly or indirectly in developing a marketable product. If patent holder and MA holder are the same entity, the issue is irrelevant. But if patent and MA are in different hands, a contractual relationship must exist.[44]

It is clear that whatever theory is adopted has implications for the question of whether and to what extent the patentee may refer to a third-party's MA.

[43] More precisely, a patentable invention that is partly or fully subject to an authorisation procedure.

[44] For this reason, the grant of an SPC would reasonably benefit both the patent owner and the MA holder.

2.1.4 Putting the European Union at the same level of protection as the US and Japan

A further purpose of the Regulation – as mentioned in the Explanatory Memorandum to the Proposal and explained in the subsequent Plant Protection Products Regulation – is to establish a level of protection that is consistent or equivalent with the level of protection provided under US law and Japanese law. The implicit assumption of the lawmaker is that inequalities in the level or scope of protection would entail competitive disadvantages for the companies located in Europe *vis-à-vis* companies located in the US or Japan. Of course this must not lead to discrimination; as acknowledged in the Explanatory Memorandum to the Proposal for a Plant Protection product Regulation,[45] in compliance with Art. 3 TRIPS it must be ensured that firms from outside the EU have equal access to the certificates.[46]

In order to assess whether this purpose was achieved, we have collected reports on patent term extensions (PTEs) under US and Japanese law.[47] One could argue that from an analytical point of view such a comparison has certain weaknesses. The evaluation of whether two IP systems provide equivalent incentives must include further data, such as the size of the market and the price level of the medicines. If the size of the markets is identical, a longer term of protection combined with a lower price level may be less advantageous for the companies than a shorter term of protection combined with a higher price. The regulatory environment and other forms of exclusivities affect the comparison as well. This criticism would be well justified. However, while the drafters of the Regulation were well aware of the relevance of the factual aspects mentioned, their aim was simply to offer a legal protection regime matching the protection available in the US or in Japan. Therefore, our efforts are equally limited to a comparison of the legal features of the respective regimes.

2.1.5 Preventing the relocation of research centres

Pursuant to Recital 6 the SPC legislation is intended to prevent a relocation of research centres from Europe to foreign jurisdictions. It is questionable whether the availability or non-availability of patent or SPC protection may really affect the decision of companies to locate research facilities in one or the other jurisdiction. Other factors may be far more relevant. Even if one limits the analysis to patent law, other aspects of the legislation than the rules on patent term extension seem to be more relevant in attracting research centres to or away from a certain location, such as the rules on employee inventions or the scope of the research exemption. Despite that, the argument that the absence of protection could lead to a relocation of research centres is periodically stated each time case law or provisions reduce the protection available for innovators in a specific area. This occurred for instance with respect to the decision of the CJEU or several decisions of the EPO that limited the patentability of embryonic stem cell-related inventions. The same argument was suggested by the industry and adopted by the Commission with respect to SPCs, while it met with scepticism from observers.

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45 European Commission, Explanatory Memorandum to the Proposal for a European Parliament and Council Regulation (EC), of 9 December 1994, concerning the creation of a supplementary protection certificate for plant protection products (COM(94) 579 final), para. 55.

46 European Commission, Explanatory Memorandum to the Proposal for a Council Regulation (EEC), of 11 April 1990, concerning the creation of a supplementary protection certificate for medicinal products (COM(90) 101 final – SYN255), para. 2.

47 See Annex II of this Study, International Reports.

We are not in a position to answer the question whether the Regulation has achieved this goal to prevent relocation. Counterfactual evidence is not available. In accordance with the task of the Study, we collected some data on the location of the inventors designated in the basic patents for which SPCs were granted. Furthermore we have asked the opinion of the stakeholders. Some of them criticised the very fact that the question was even posed, as in their opinion this demonstrates a lack of insight into the business reality of the pharmaceutical industry, where – as pointed out above – many other factors are relevant in determining where to locate research centres. From that reaction one might conclude that the expectation expressed by the historical lawmakers about the impact on (re)location of research centres was somewhat unrealistic from the beginning.

2.1.6 A balanced system

The lawmaker intended to build a balanced system that would put the pharmaceutical industry in the same position as other industries. To this purpose, the Regulation limited the maximum term to 5 years after the expiration date of the patent and to 15 years from the first marketing of the active ingredient. It also provides that only one SPC can be granted for the same product, and that the grant of this SPC must occur on the basis of the first MA granted for the active ingredient concerned. If these tenets were consistently observed, the number of SPCs could not exceed the number of new active ingredients authorised (c. 50); the grant of multiple SPCs with a different scope and term based on the same active ingredient would be prevented.

But in fact, some of these principles were changed by case law based on a teleological approach.[48] This triggers the question – which this Study cannot answer – whether the balance of interests originally intended has been preserved.

2.1.7 A simple system

The SPC legislation intended to establish a system for granting that is as transparent and simple as possible.

The assessment of eligibility for SPC protection was to have been based only on two documents, the basic patent and the MA. Even the indication of the product was not necessary: the latter would be identified by the MA supplied in support of the application for a certificate (Art. 8 Reg. 469/2009). Value judgments such as those of assessing inventive step in patent law or judging distinctiveness in trade mark law were not required. The same was true of prior-art searches or evidence of scientific statements.

The appropriateness of this objective could be questioned. The majority of patents are valueless: nobody infringes them, nobody uses them, nobody licenses them. In spite of that we maintain a sophisticated system of examination where the examiner must search for prior art and has to make a value judgment based on a hypothetical abstract notion, the "person skilled in the art". The NPOs must further assess whether the same person skilled in the art, on the basis of the information available at the filing date, could work the invention without inventive efforts. This examination in is mandatory under the EPC for all patent applications. In contrast to patents, the

[48] See Chapter 11, Section 11.3.2 and Chapter 12, Section 12.1.2.2.

overwhelming majority of SPCs are valuable and affect many socially relevant interests. One might therefore wonder why the system for granting SPCs must be kept simple while the system for granting patents can or should be complex. The reasons for this decision are not expressly mentioned in the SPC Regulations, but they can be inferred from the Explanatory Memorandum: the crucial aspect lies in the fact that the Regulations have charged the NPOs with the task of granting SPCs. Some NPOs were, and today still are, simply registration offices – a circumstance of which the European Commission was likely aware – and were not equipped to perform complex technical examinations. For this reason, the conditions to be fulfilled by SPC applications were supposed to be based on simple and objective data easy to verify. The SPC Regulations were not meant create a burden for the NPOs.

2.2 THE PURPOSES OF THE PLANT PROTECTION PRODUCTS REGULATION

The purposes of the Plant Protection Products Regulation are very similar to those provided for the Medicinal Products Regulation.[49] This Regulation likewise intends to create a balanced system, and it also intends "to place European industry on the same competitive footing as its North American and Japanese counterparts".[50] However, US law does not provide for PTEs for plant protection products. In the Explanatory Memorandum it is explained that the US companies benefit from a different method of calculation, because the duration of patents is 17 years from the date on which the patent is granted. However, with the implementation of the 20-year patent term provision of the Uruguay Round Agreements Act this advantage was eliminated in 1995. In this respect, it is also of interest to note that European applicants – unlike their US counterparts – can benefit from internal priority rules at the European as well as at the national level, with the result that the patent expiration date for the same subject matter can be extended to 21 years after the priority date of the first patent application disclosing that subject matter. For this reason the German government proposed a 4-year term and not a 5-year term for SPCs for medicinal products.

2.3 NATURE AND FUNCTION OF THE SPCS

Under European law SPCs are independent *sui generis* IP rights. Their existence requires both a patent and a marketing authorisation (MA). But these rights are formally separate from the patent and the MA on which they are based.

SPCs are meant to provide the patentee with a supplement to protection. The structure of the protection is parallel to that of a patent (*jus excludendi alios*): it consists in the entitlement to exclude others from using, selling or manufacturing a specific product protected by the basic patent for every pharmaceutical purpose authorised in the Member States that have granted the SPC. However, SPCs do not extend the term of the basic patent. The patent regularly expires whether or not an SPC has been requested or granted.

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[49] See also the analysis by Colin Birss et al, *Terrell on the Law of Patents* (18th edn, Sweet & Maxwell 2016), para. 6.89.

[50] Recital 7 Reg. 1610/96.

From a functional perspective, the SPC is intended to "compensate the proprietor for the effective loss of patent term caused by the need to obtain a marketing authorisation before the product can be marketed".[51] To this end, the SPC grants an exclusivity right that is narrower in scope but identical in nature to the patent right. As the critical dates for calculating the time compensation, the legislature has pointed to the filing date of the patent and the granting date of the MA. That construction could be open to two objections. First, under international[52] and European[53] law patents are only negative rights. They confer the power to exclude others from practising the invention. This right can be exercised whether or not the subject matter of the invention is subject to regulatory approval.[54] Therefore, the time needed to obtain regulatory approval – unlike the time needed to grant the patent – does not reduce the legal term of the *jus excludendi.* Second, even if one accepts the concept of SPCs as a form of compensation, it is not justified to include in the calculation time periods in which the SPC applicant did not have any right at all, such as between the filing date and the publication of the application, or time periods in which the SPC applicant only enjoyed an indemnification right, as between the publication of the application and the grant of the patent. By including those periods the SPC also offers compensation for delays resulting from the granting proceedings, which affect all technical fields and all patent applications alike.

Against these objections it can be argued that although is true that patents are only negative rights, the actual purpose of the right is to provide the inventor with a marketing opportunity by reducing competition in the market for the patented product or services. In this way, the patentee has three different options to benefit from the patented invention:

- By directly marketing the product incorporating the invention.
- By licensing the invention and participating in the income obtained by the licensor.
- Finally, the patentee can remain inactive but claim compensation for the use of the invention made by third parties.

If neither the patentee nor the licensor nor the competitor may lawfully bring any product to the market, no remuneration is possible for the patentee, whether in the form of direct income, licensing revenue or damages compensation. *De facto*, the existence of pre-marketing approval requirements reduces the period in which the *jus excludendi* can generate revenue. It is therefore correct to assume that the function of the SPC is to compensate for such a reduction of the period in which the patent ensures a real marketing opportunity. Such compensation is appropriate to the extent that the time loss is due to a decision of the lawmakers and not to the negligence of the patentee in pursuing product approval.

As concerns the decision to consider as the critical date the date of the application and not the date of the patent, as is the case in most jurisdictions, this is a more

[51] As observed by Justice Arnold, the rationale of the SPC is "to compensate the proprietor for the effective loss of patent term caused by the need to obtain a marketing authorisation before the product can be marketed".

[52] Art. 28 TRIPS.

[53] Art. 28 UPCA; see also Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions [1998] OJ L 213/13, Recital 14.

[54] The patent proprietor can enforce the patent against any third party. It can prevent third parties from producing the compound for third markets where a marketing authorisation exists or where the sale of the compound is otherwise allowed.

problematic aspect indeed that has been discussed for some time in the literature. The relevant discussion is considered in Chapter 13.

2.4 SUMMARY

The SPC legislation pursued several goals, which reflect the multiple interests touched by the exclusivity rights created thereby.

Firstly, in accordance with the Art. 100 EEC, the Reg. 1768/92 intended to improve the functioning of the internal market by removing or preventing different SPC regimes in the Member States.

Secondly, the main purpose of the Medicinal Products Regulation is to offer adequate protection to pharmaceutical research. While this teleos is clearly stated in principle, the implementation raises two questions, and precisely the question of what type of research the Regulation intends to foster, and second, which achievements within that type of research entitle a beneficiary to the SPC.

As to the first of these issues, the lawmakers intention was to foster research in "new medicinal products", that in the specific language of the Explanatory Memorandum means "new active ingredients". To achieve this goal, the lawmakers intended to allow only one certificate pro active ingredient on the basis of the chronologically first MA obtained for that active, see Art. 3(d) and Art. 3(c). The intended effect of these provisions was to limit SPC protection to active ingredients that are brought to the market for the first time as active substances of a medicinal product.

While the kind of innovation to be rewarded by an SPC appears to be clearly defined, the specific activity for which the reward is intended remain unclear. There are two possible rationales for SPC or PTE. On the one side, patent extension can just reward the research that lead to the disclosure of a patentable invention. On the other side, patent extension can reward the investments and activities done after an invention is made, to obtain an MA and bring a product to the market. In the first case, the function of the SPC would be similar to that of the basic patent, namely to reward the inventive activity that led to the invention. In the second case, the function of the SPC would be more similar to that of data exclusivity protection. It would reward the investments that have led to the MA. This issue has an impact on the question who is the intended beneficiary of the legislation and to what extent the patentee can rely on an MA issued to an unrelated entity (see Chapter 13).

Another goal of the Regulation was to ensure an equivalent protection in Europe as existed at the relevant time in the US and Japan. This was meant, *inter alia*, to prevent relocation of research centres to those jurisdictions (or to any jurisdiction providing for a better protection than Europe). It is questionable, however, whether the assumption by the historical lawmaker, that the availability of SPCs and the conditions for their protection would have a substantial impact on companies' decisions as to where research facilities are located, was ever backed up by reality.

Furthermore, the Regulation intended to establish a balanced system. The two main pillars of this system were the provisions aimed at preventing the grant of multiple SPCs for the same product (Art. 3(d) and Art. 3(c)) and to ensure that only the first

MA could support the grant of this single certificate. Multiple SPCs for the same active ingredient based on the same or different MAs was in this way excluded.

Finally, the Regulation was aimed at establishing a simple and transparent system for granting SPCs. This purpose demonstrates the intention to avoid encumbering the NPOs with tasks they are not prepared for, than reflecting the actual importance of SPCs and the complexity of issues potentially involved in their grant.

3 THE RELEVANT SOURCES OF LAW FOR SPCS IN EUROPE

3.1 INTRODUCTION

The legal regime of SPC protection is highly complex due to a number of rather unique features.

First, the legal acts that create and govern SPCs are directly applicable EU Regulations, as in the case of Community designs, EU plant variety rights or trademarks. However, the resulting rights are not EU titles of protection. They are also not necessarily national IP rights. Regarding the scope of protection and the rights conferred by the SPC, the SPC Regulations refer to the law governing the designated basic patent.[55] If the designated patent is a national right, the SPC will be a national IP right and be subject to national law. If it is a unitary IP right, it might follow that the SPC will be a unitary right. The issues connected therewith are discussed in Chapter 21, Section 21.2.3.2.

Second, SPCs are autonomous *sui generis* rights. However, their existence and validity postulate the existence of a further title of protection – the patent – and the existence and validity of a further administrative act – the MA. Both the patent and the MA are issued pursuant to and governed by provisions that are external to the SPC Regulations.

Third, SPCs are a peculiar feature of EU law. Other legal systems have opted for an extension of the patent term instead of creating a new type of IP right.[56] As a consequence, the status of SPCs in international IP law is not easy to ascertain. On the one hand, SPCs are rarely mentioned in the international sources of IP law. On the other hand, SPCs grant the holder of the basic patent a patent-right like position. As a consequence, they are deemed to be subject to some of the international provisions governing IP rights.[57] However, it is not clear what these provisions are and to what extent they apply to SPCs.

The hybrid nature of SPCs makes the task of defining the sources of law governing SPCs rather complex. Some of that complexity is reflected in the structure of the EU Regulations, which include several references to external sources of law.

The purpose of this Chapter is to expand on the details of that complex system of legal rules. We start with the international framework (3.2), turning then to the relevant secondary Union law (3.3) and finally to national law (3.3). Some of the references in regard to national law include the Unitary Patent Court Agreement (UPCA), which is part of the legal order of the EU States that have ratified it. However, the impact of the "Unitary Patent Package" on SPCs will only be analysed in the section of the Study specifically dedicated to it.[58]

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55 See Art. 4 and Art. 5 of the SPC Regulations.

56 See Chapter 23, Section 23.2 and Annex II of this Study.

57 European Commission, Explanatory Memorandum to the Proposal for a European Parliament and Council Regulation (EC), of 9 December 1994, concerning the creation of a supplementary protection certificate for plant protection products (COM(94) 579 final), paras. 55-56.

58 See Chapter 21, Section 21.2.3.2 of this Study.

3.2 SPCs AND INTERNATIONAL LAW

3.2.1 Qualification of SPCs as rights falling under the Paris Convention and TRIPS

The fundamental principles governing international intellectual property protection are set forth in the Paris Convention (PC) and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). TRIPS was concluded as an annex to the Agreement on the World Trade Organisation (WTO), to which the EU as well as its Member States have acceded. All EU Member States are also members of the PC. While the EU could not join the PC directly, it is bound by the substantive rules in Arts. 1–12, 19 PC by virtue of Art. 2 TRIPS. Beyond the provisions enshrined therein the PC is also binding for special agreements concluded on the basis of Art. 19 PC, such as the Patent Law Treaty (PLT; see below, 3.2.4). TRIPS obligations must be observed in bilateral free trade agreements addressing issues that are covered by the Agreement.

Before considering the impact of those rules on SPCs, the question must be asked whether or not SPCs, as rights *sui generis*, fall under the notion of intellectual property rights to which the PC and TRIPS apply. That qualification does not derive automatically from the fact that SPCs are an acknowledged form of intellectual property in the EU context. This is demonstrated by the example of *sui generis* rights in non-original databases: while such rights are an established category of intellectual property in the EU, their being subject to the principles of international protection, in particular concerning the obligation to grant national treatment, at least initially has been widely disputed.

The Paris Convention provides a definition of "industrial property" in Art. 1(2) that does not list SPCs. It is true that Art. 1(3) PC specifies that "[p]atents shall include the various kinds of industrial patents recognized by the laws of the countries of the Union, such as patents of importation, patents of improvement, patents and certificates of addition, etc.". Thus it is made clear that a broad interpretation of what constitutes a patent is warranted. However, the different kinds of rights listed in Art. 1(3) PC are still comprised under the broader notion of what, under national legislation, actually constitutes a "patent",[59] whereas that is not the case with regard to SPCs.

On the other hand, insisting on SPCs being exempted from the Paris Convention does not adequately reflect the nature of the right granted. This becomes apparent when SPCs are juxtaposed with corresponding instruments applying for instance in US[60] or Japanese[61] law: those jurisdictions have chosen to actually extend the lifetime of patents granted for (*inter alia*) pharmaceuticals and have therefore placed their respective protection regimes within the established framework of intellectual property rights. The fact that a different route was chosen in the EU does not detract from the fact that the purpose and (generally speaking) the structure of protection are the same as or closely related to those other regimes.[62] Postulating that a fundamental

[59] See Sam Ricketson, *The Paris Convention for the Protection of Industrial Property: A Commentary* (Oxford University Press 2015), para. 7.33.
[60] See Annex II of this Study.
[61] *Ibid.*
[62] For the reasons why a patent term extension could not be implemented in EU law at the relevant time see below, Chapet 3, Section 3.3.2.2 of this Study.

difference exists between the respective instruments in regard to their qualification as industrial property rights falling within the scope of the *Paris Convention would appear to overstate the impact of the black letter* as compared to the spirit and objectives of the Agreements. This also complies with the fact that the European Commission never left any doubt that the basic tenets of international intellectual property law, in particular the principle of national treatment, must be respected with regard to SPCs.

As SPCs are comprised in a broad interpretation of the term "patents" in the meaning of the Paris Convention, they also fall into the ambit of TRIPS. It is true that TRIPS contains its own definition of intellectual property rights in Art. 1(2) TRIPS, spelling out that "the term 'intellectual property' refers to all categories of intellectual property that are the subject of Sections 1 through 7 of Part II" of the Agreement. As SPCs are not mentioned in any of those sections, their inclusion in the TRIPS Agreement might appear doubtful. However, as was confirmed by the WTO Appellate Body in *Havana Club*[63], by making reference to the Paris Convention in Art. 2(1), the obligations under the TRIPS Agreement in regards of the principles enshrined in Part I also pertain to intellectual property rights encompassed by the Paris Convention, though not expressly mentioned in TRIPS. Thus, it follows that SPCs fall under TRIPS as well, at least insofar as the general obligations are concerned. Whether they also conform to the specific notion of a "patent" in Art. 27 TRIPS is a different matter (see below, 3.2.3.3 (c)). Furthermore, it follows as a matter of course from the absence of any express provisions pertaining to SPCs in the PC or TRIPS that there is no obligation under those Agreements to grant some form of patent term extension.

3.2.2 Implications of the Paris Convention

All rights falling under the Paris Convention are subject to the obligation of Paris Union member states to grant national treatment (Art. 2 PC). Hence all beneficiaries of the Paris Convention must be granted the same benefits as accrue under the law to persons or companies domiciled or established in the EU. As the SPC Regulations do not contain any specific requirements concerning nationality or seat/establishment in the EU, that condition is clearly fulfilled. This is not changed by the fact that the basic patent on which the SPC is grounded must be a European patent or a national patent of an EU Member State: if no such patent is granted in the EU, there is no time loss resulting from the MA proceedings for which the SPC could compensate. Thus, the restriction to national or European patents is a consequence of the basic tenets of the system that does not run counter to the principle of national treatment.

None of the other requirements in the Paris Convention are at issue here. In particular, the priority principle under Art. 4 PC does not play a role as SPCs are only granted after the grant of the basic patent, so priority issues are no longer virulent at this stage.

[63] Appellate Body Report, United States-Section 211 Omnibus Appropriations Act of 1998, WT/DS176/AB/R (August 6, 2001).

3.2.3 Implications of TRIPS

3.2.3.1 National treatment

The remarks made above concerning the principle of national treatment in Art. 2 PC are also true with regard to the same principle enshrined in Art. 3 TRIPS. It must be observed, though, that Art. 3 TRIPS is somewhat stricter as regards the reservation made concerning formalities: whereas the Paris Convention makes a reservation for provisions "relating to judicial and administrative procedure and to jurisdiction, and to the designation of an address for service or the appointment of an agent" (Art. 2(3) PC), Art. 3(2) TRIPS qualifies the same reservation in that it only applies "where such exceptions are necessary to secure compliance with laws and regulations which are not inconsistent with the provisions of this Agreement and where such practices are not applied in a manner which would constitute a disguised restriction on trade" (emphasis added). Furthermore, what is owed under TRIPS is not "the same protection", but treatment "no less favourable". This would apply to legislation which grants equal treatment *de jure*, but which discriminates *de facto* between foreign right holders and domestic ones with regard to the availability, scope of protection or administration of IP rights.[64]

As was pointed out with regard to the Paris Convention the SPC Regulations do not contain any discrimination as to seat or nationality. Regarding procedural issues, the specifics of SPC proceedings are subject to national law. Insofar as the national systems were investigated in the course of this Study, there are no discriminatory regulations under the standards of either the PC or TRIPS.

3.2.3.2 Substantive law: overview

Provisions concerning patents are found in Part II Section 5 (Arts. 27–34) TRIPS. Of these articles the following are of potential relevance, directly or indirectly, for SPCs: Art. 27(1) (non-discrimination as to field of technology); Art. 28 (rights conferred); Art. 30 (exceptions); Art. 33 (minimum duration). Also of interest for the interpretation of those articles are the principles and objectives of TRIPS, as set forth in Arts. 7 and 8. This is of relevance in particular for evaluating the flexibility afforded to legislatures in formulating or amending their laws and regulations so as to enable the adoption of measures necessary to protect public health and other important policy goals.

Like most international treaties in the field of intellectual property, TRIPS only sets minimum standards for protection.[65] As pointed out in Art. 1(1), second sentence, TRIPS, this means that members may implement in their law more extensive protection than is required by TRIPS, provided that such protection does not contravene the provisions of the Agreement.

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[64] According to the WTO Panel in *Canada – Patents*, *de facto* discrimination is found if an "ostensibly neutral measure transgresses a non-discrimination norm because its actual effect is to impose differentially disadvantageous consequences on certain parties, and because those differential effects are found to be wrong or unjustifiable". Canada - Patent Protection of Pharmaceutical Products - Complaint by the European Communities and their Member States - Report of the Panel, WT/DS114/R, para. 7.101.

[65] The only exemption so far from that scheme is the Marrakesh Treaty to Facilitate Access to Published Works for Persons Who Are Blind, Visually Impaired or Otherwise Print Disabled, 27 July 2013.

For the issues considered in this Study, the substantive provisions of TRIPS could be of relevance in two aspects. First, regarding the principle of non-discrimination between fields of technology, and second, concerning the three-step test. The first issue could be of *general relevance* for the current system insofar as SPCs are only available in specific fields of technology, namely pharmaceuticals and plant protection products.[66] The second issue is of *specific interest* for the question whether the introduction of a so-called manufacturing waiver is compatible with international law.[67]

Disputes arising between WTO member states over the interpretation of TRIPS provisions are submitted to *ad-hoc* panels established in the framework of the WTO dispute-settlement scheme.[68] The closest scrutiny of issues that are relevant for this Study was provided in the dispute between the (then) EC and Canada concerning exceptions anchored in Canadian patent law.[69] The Panel report on the dispute is therefore presented below, while the pertinent issues – non-discrimination in the meaning of Art. 27 TRIPS and compatibility of a manufacturing waiver with Art. 30 TRIPS – are discussed in the respective Chapters.[70]

3.2.3.3 Canada – Patents

(a) *Background and arguments of the parties*

The dispute between Canada and the EC before the WTO concerned the following provisions of Canadian patent law: Art. 55(2) No 1 of the Canadian Patent Act contained the so-called regulatory or *Bolar* exemption that allows manufacturers of generic medicines to produce samples of drugs for the sole purpose of submitting them for regulatory approval; Art. 55(2) No 2 of the same act concerned the so-called stockpiling exception that allowed the production and storing of pharmaceuticals intended for sale after expiration of the patent.

The EC had argued that allowing for commencing regulatory approval procedures during the term of the patent protection amounted to *de facto* curtailment of the patent protection period that lasts, pursuant to Art. 33 TRIPS, 20 years from filing. Furthermore, as the exception only applied to pharmaceuticals, the EC deemed this to constitute an illegitimate discrimination *vis-à-vis* products in other fields of technology that likewise require marketing authorisation. To this Canada responded that vice versa, if generic companies could only initiate regulatory approval procedures after the lapse of a patent, this would result in a *de facto* extension of market exclusivity, thus altering the bargain between the patentee and society and giving the patent holder a "windfall" period of protection. Furthermore, regarding discrimination by field of technology, Canada disputed the view that legal provisions, including limitations, in the patent field must necessarily apply "across the board"; instead, the decisive

66 See for the relevance of the prohibition of discrimination with respect to medical device Chapter 18, Section 18.6.

67 See Chapter 15, Section 15.3.2.3.

68 The rules governing such procedures are set forth in the "Understanding on Rules and Procedures Governing the Settlement of Disputes" (DSU), available at https://www.wto.org/english/docs_e/legal_e/28-dsu_e.htm (last accessed 4 September 2017).

69 Canada - Patent Protection of Pharmaceutical Products - Complaint by the European Communities and their Member States - Report of the Panel, WT/DS114/R, available at https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S009-DP.aspx?language=E&CatalogueIdList=23317,41942,43207,105793,13125,9352,37857,29169,66513,50308&CurrentCatalogueIdIndex=7&FullTextHash=&HasEnglishRecord=True&HasFrenchRecord=True&HasSpanishRecord=True (last accessed 4 September 2017).

70 See respectively Chapter 18, Section 18.6 and Chapter 15, Section 15.3.2.3.

question should be whether or not the legal requirements of Art. 30 are met. As a third party in the dispute, the US had pointed in that context to the distinction between "differential" and "discriminatory" measures: while the latter were prohibited under Art. 27(1), including in the context of limitations falling under Art. 30, they could in principle be justified to restore "parity of enjoyment", for instance by granting a PTE.[71]

(b) *The Panel report*

The Panel delivered its report on 17 March 2000. Regarding discrimination the Panel disagreed with Canada's position on Art. 27(1) and its relationship with Art. 30 TRIPS. The report states that "Article 27(1) prohibits discrimination as to enjoyment of 'patent rights' without qualifying that term."[72] Considering the *de jure* discriminatory effect of the regulatory exception, the Panel declared that the EC had not presented evidence rebutting the assurance by Canada that the exception was legally available to every product that was subject to marketing approval requirements.[73] The Panel proceeded to examine whether the provision resulted in *de facto* discrimination, which would be found if an "ostensibly neutral" provision has "differentially disadvantageous" consequences that are wrong or unjustifiable[74]. It had been submitted by the EC that Art. 55(2) in effect only applied in the pharmaceutical sector. However, the Panel found that no evidence had been adduced that this was a consequence of the impugned provision, or that the provision had been designed with discriminatory intent[75].

The Panel then examined the compatibility of Art. 55(2) No 1 and No 2 of the Canadian Patent Act with the three-step test set forth in Art. 30 TRIPS. On the first step ("limited exception") it was found that the stockpiling exception was not "limited" enough to satisfy the requirements of the first step, due to the fact that during the last six months before expiry of the patent the manufacturing of protected goods was permitted without any quantitative restrictions. Having failed the first step, the exception was discarded from further examination, because, according to the Panel, all steps must be examined separately and cumulatively.[76] The regulatory exception, however, passed the first step of the test and was examined in more detail for compliance with the second and third steps. On the question of whether the regulatory exception unreasonably conflicts with a normal exploitation of the patent right (step two), the Panel accepted the view advanced by Canada that exploitation of the patent during the *de facto* extension period is not "normal" in the sense that it constitutes a consequence which is necessarily inherent in the exclusive rights conferred on the patentee. For assessment of the third step, relating to whether the regulatory exception unreasonably prejudiced the legitimate interests of the right holder, the decisive question was whether in view of the curtailment of actual market exclusivity experienced by patent holders in the pharmaceutical sector, the interests of patentees in receiving some form of compensation, at least in the form of insisting on full *de facto* post-patent exclusivity, had to be regarded as "legitimate". In support of that argument the EC had pointed to the number of jurisdictions that provide for patent term restoration or other instruments ensuring that patent holders who are subject to

71 See *ibid.,* p. 69.
72 See *ibid.,* para. 7.91.
73 See *ibid*., para. 7.99.
74 See *ibid*., paras. 7.94, 7.101.
75 See *ibid*., paras. 7.102-7.104.
76 See *ibid*., para. 7.38.

specific regulatory requirements receive additional time to make up for the reduction of the exclusivity period. However, the Panel found that such legislation and the objectives on which it is founded "was neither so compelling nor so widely recognized that it could be regarded as a 'legitimate interest' within the meaning of Article 30 of the TRIPS Agreement".[77]

(c) *Consequences for the issues discussed in this Study*

The consequences possibly arising from the substantive provisions of TRIPS as interpreted by the WTO Panel depend, *inter alia*, on the question whether (or to what extent) the specific obligations enshrined in Art. 27 et seq. TRIPS are likewise applicable to SPCs. The answer to that question is not prejudicated by the fact that, as pointed out above, SPCs form part of intellectual property in the meaning of TRIPS and must therefore comply with Part I of the Agreement. Unlike the Paris Convention to which Art. 2(1) TRIPS refers, the definition of what constitutes a patent in the meaning of Art. 27 is more detailed and precise, and SPCs do not conform to that definition in various features. The consequences of that discrepancy are of particular importance for assessing the compatibility of a manufacturing waiver with the three-step test in Art. 30[78]. As a matter of principle, the same applies to the precept of non-discrimination. However, as unequal treatment of like matters is prohibited under EU law anyhow, the effects of whether or not Art. 27 TRIPS must be applied to SPCs are not very substantial (see Chapter 18, Section 18.6).

3.2.4 The Patent Law Treaty

The Patent Law Treaty (PLT) was concluded in 2000 under the auspices of WIPO with the declared aim of "harmonizing and streamlining formal procedures with respect to national and regional patent applications and patents and making such procedures more user friendly".[79] As its centrepiece the PLT contains in Art. 5 a list of elements that member states may require as conditions for according a valid filing date. While other provisions in the PLT are fairly limited, meaning that treaty members are free to provide for requirements which are more favourable from the viewpoint of applicants and owners (Art. 2.1 PLT), Art. 5 imposes a binding standard that must be observed in all member states alike.

The provisions in the PLT have no bearing on SPCs where they concern the specifics of filing patent applications. More relevant are the provisions dealing with representation, communication and notification, and in particular those concerning procedural remedies, namely relief in respect of time limits (Art. 11 PLT) and reinstatement of rights (Art. 12 PLT). The latter provision is of special interest because, unlike the other provisions mentioned which are of a rather general and mostly optional character, Art. 12 contains a binding (minimum) requirement: in case of failure to comply with a time limit for an action in a procedure which directly causes loss of rights, reinstatement must be granted upon request of the affected party if the necessary actions are taken and documents are filed within a prescribed time period, and if it is found that the failure to comply with the time limit occurred in spite of due care required by the circumstances having been taken or, at the option of the contracting state, that any delay was unintentional. Further details are fleshed out in Rule 12 of the Regulations

[77] See *ibid.,* para. 7.82.
[78] See Chapter, Section 15.3.2.3(b).
[79] WIPO website: http://www.wipo.int/treaties/en/ip/plt/ (last accessed 10 November 2017).

to the PLT, which declares, *inter alia*, that contracting states can require that all necessary actions and filing of documents must be carried out together with the filing of the request for reinstatement.

This raises the question of whether the stipulations in the PLT, in particular Art. 12, should be observed also in regard to SPCs. It is true that the PLT applies only to patents in a strict sense (Art. 1(iii) in conjunction with Art. 3 PLT); however, as was stated earlier (1.1), it is submitted here that SPCs for the purpose of examining their compatibility with international norms are treated the same as instruments with corresponding effects that are anchored in the patent system itself, such as patent term restoration. However, even then the PLT is not directly binding on the EU, as the latter has not acceded to the Treaty. The same is true for the Member States of the EU, although they, together with the European Patent Organisation, are among the signatories of the PLT.

A binding effect might nevertheless arise if the substantive obligations laid down in the PLT have become part of EU law by virtue of inclusion in free-trade agreements (FTAs) concluded between the EU and its trading partners. The issue will therefore be reconsidered after addressing the contents of those agreements.

3.2.5 Free-trade agreements concluded by the EU

3.2.5.1 Overview

The EU negotiates and concludes a large and growing number of FTAs, often in the form of Economic Partnership Agreements (EPAs).[80] Such agreements often include a chapter on intellectual property rights outlining the mutual obligations regarding the protection granted and the standards to be fulfilled.

The scope of the EU's competence to conclude such treaties has been a subject of contention. The CJEU considered the issue in its Opinion 1/94, dealing with the competence of the EU to conclude (*inter alia*) TRIPS. Based on the provisions of the (then applicable) EC Treaty it was found that the EU has exclusive competence to enter into agreements with third countries that include provisions on trade-related aspects of intellectual property rights (only) to the extent that it has already exercised its power to legislate in the respective area. In the TFEU, exclusive competence to negotiate and conclude such agreements is assigned to the EU in Art. 207(1), with the procedures being governed by Art. 207(3) in conjunction with Art. 218 TFEU. However, competence may be shared between the EU and its Member States if an agreement covers aspects that are not "trade-related" in the meaning of those provisions.[81] This applies also to agreements including provisions relating to investment dispute procedures, like the Canadian-EU Trade Agreement (CETA).

A (relatively) early example of an EPA is the CARIFORUM EPA, which was signed in 2008 between the EU and 15 Caribbean countries.[82] Another treaty was concluded

[80] In the following, "EPA" and "FTA" are used as synonyms.

[81] For details see CJEU Opinion 2/15, 16 May 2017, ECLI:EU:C:2017:376 concerning competence to conclude the EU-Singapore FTA.

[82] Antigua and Barbuda, The Bahamas, Barbados, Belize, Dominica, Grenada, Guyana, Jamaica, Saint Lucia, Saint Vincent and the Grenadines, Saint Kitts and Nevis, Surinam, Trinidad, Tobago, and the Dominican Republic. Haiti signed the agreement in December 2009, but does not yet apply it, pending ratification.

with Peru and Colombia, and was more recently joined by Ecuador;[83] an updated version of a trade agreement with Mexico is currently under consideration.[84] So-called Stepping Stone EPAs are currently in force between the EU and several African countries, with negotiations about more far-reaching regional agreements still ongoing.[85] In Asia, FTAs were signed with Korea[86] and Singapore, with the latter agreement still awaiting ratification in the EU.[87] FTA negotiations with Vietnam were concluded in 2016[88], and a major FTA with Japan was finalized in December 2017[89]. Furthermore, FTA negotiations have reached an advanced stage with Vietnam. Within Europe,[90] FTAs are in place with Georgia[91] and Moldova.[92]

The manner and extent to which obligations pertaining to intellectual property rights are addressed in such treaties differ widely, depending on the actual situation in the country or region concerned, and also on the character and main objectives of the treaty. The most comprehensive IP chapter so far is found in CETA, which was signed by the EU and Canada in October 2016, but which needs ratification at the national and EU level.

For the purposes of this Study it is not necessary to embark on a comprehensive analysis of the different ways in which intellectual property in general and patents in particular are dealt with in FTAs. The following remarks only refer to the CARIFORUM EPA, the Singapore and Korea FTAs, the Peru/Colombia/Ecuador FTA, the FTA with Japan and CETA, and they only relate to the obligation to observe, or accede to, international treaties, and to special rules concerning SPCs or similar instruments.

3.2.5.2 International treaties referred to in FTAs (in particular: reference to the PLT)

Most of the FTAs screened for this Study make reference, in an initial provision in the patent chapter, to observing international obligations, in particular those deriving from the Patent Cooperation Treaty (PCT). In addition, reference is also made to the PLT, often in formulations that reflect an intention to comply, and not a binding obligation. Thus, Art. 10.33 of the EU-Korea FTA (EUKFTA) declares that "Parties shall make all reasonable efforts to comply with articles 1 through 16 of the Patent Law Treaty (2000)".

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83 The Agreement has been provisionally applied since 1 March 2013 with Peru, and since 1 August 2013 with Colombia. The extension to Ecuador was signed in November 2016, and Ecuador has joined the Agreement on 1 January 2017.

84 EU proposal of EU-Mexico Free Trade Agreement, November 2016; available at http://trade.ec.europa.eu/doclib/docs/2016/december/tradoc_155173.pdf (last accessed 18 December 2017).

85 See e.g. the proposal for an updated version of the trade agreement with Tunisia, last version of 26 April 2016; available at http://trade.ec.europa.eu/doclib/docs/2016/april/tradoc_154486.pdf (last accessed 18 December 2017).

86 On 14 May 2011.

87 Ratification on behalf of the EU was delayed due to the question of legal competence being referred to the CJEU for an opinion. See CJEU Opinion 2/15 of 16 May 2017, which confirmed that the Agreement cannot be concluded by the EU alone.

88 Available at http://trade.ec.europa.eu/doclib/docs/2016/february/tradoc_154223. institutional - GIs 6.5a3 6.11wg rev2 - for publication.pdf (last accessed 18 December 2017).

89 See http://trade.ec.europa.eu/doclib/press/index.cfm?id=1684 (last accessed 14 March 2018).

90 In addition to FTAs concluded with individual (Eastern) European states see also the comprehensive Agreement on the European Economic Area (EEA) which obliges the participating EFTA states Iceland, Norway and Liechtenstein to adapt their domestic legislation to the Community *Aqui,* [1994] OJ L 1/3.

91 [2014] OJ L 261.

92 [2014] OJ L 260.

A similar formulation is found in Art. 20.20 CETA: "Each Party shall make all reasonable efforts to comply with Articles 1 through 14 and Article 22 of the Patent Law Treaty, done at Geneva on 1 June 2000" and in Art. 230 (2) of the EU-Peru/ Colombia/Ecuador FTA (EU-PCE FTA): "The European Union shall make all reasonable efforts to comply with the Patent Law Treaty, adopted at Geneva on 1 June 2000 (hereinafter referred to as the 'PLT')".

Article 11.29 of the EU-Singapore FTA (EUSFTA) reflects an even more cautious approach: "The Parties … shall, where appropriate, make all reasonable efforts to comply with Article 1 to Article 16 of the Patent Law Treaty … in a manner consistent with their domestic law and procedures."

In contrast to those somewhat meek formulations, Art. 147.1 CARIFORUM EPA states clearly and unambiguously that "[t]he EC Party shall comply with … (b) The Patent Law Treaty (Geneva 2000)". [93] Based on that formulation the argument can be made that the EC (now: the EU) has committed to observation of the substantive requirements in the PLT, notwithstanding the fact that it has not acceded to that treaty. Furthermore, by virtue of the most-favoured-nation clause in Art. 4 TRIPS the obligation resulting therefrom can also be invoked by other WTO member states. The fact that this effect is not reflected in the subsequent FTAs, which appear to be based on the position that nothing binds the EU to observing the obligations under the PLT, does not alter the legal effects of its earlier commitment.

It is true that the commitment made in the CARIFORUM EPA is not binding internally in the sense that it has become part of the law that must be applied in the EU. The CJEU denied that effect in its Decision C-146/96 – *Portugal v Council*, paras. 42-47, regarding bilateral agreements concluded in the WTO framework with third countries on market access for textiles. However, as was confirmed in Joined Cases C-300/98 and C-392/98 – *Dior v Assco*, in spite of TRIPS provisions not being directly applicable, they must inform the interpretation of EU law to the best possible degree (paras. 43, 47). Thus, any legislation by the EU dealing with procedures for the grant of, *inter alia*, SPCs would have to be interpreted and applied in the light of the PLT. To avoid any frictions in that regard it is therefore recommendable that the legislation itself be closely modelled on that treaty.

3.2.5.3 SPCs and similar instruments

(a) *Overview*

With the exception of the CARIFORUM EPA, all FTAs screened for this Study address the issue of compensation of patent owners for curtailment of protection caused by regulatory approval. Thus, Art. 10.35 EUKFTA declares:

> "1. The Parties recognise that pharmaceutical products and plant protection products protected by a patent in their respective territories are subject to an administrative authorisation or registration procedure before being put on their markets.
>
> 2. The Parties shall provide, at the request of the patent owner, for the extension of the duration of the rights conferred by the patent protection to compensate the patent owner for the reduction in the effective patent life as a result of the first authorisation to place the

[93] The same formulation is found in Art. 9.1 of the proposal for an updated EU/Mexico FTA.

> product on their respective markets. The extension of the duration of the rights conferred by the patent protection may not exceed five years."[94]

In a similar fashion Art. 11.31 EUSFTA provides that:

> "[t]he Parties recognise that pharmaceutical products protected by a patent in their respective territories may be subject to an administrative marketing approval process before being put on their respective markets. The Parties shall make available an extension of the duration of the rights conferred by the patent protection to compensate the patent owner for the reduction in the effective patent life as a result of the administrative marketing approval process. The extension of the duration of the rights conferred by the patent protection may not exceed five years."

Details of the procedure are left to the contracting parties to organise, in compliance with international obligations applying in the field.

Chapter 14, Art. 35 of the EU – Japan FTA (EUJFTA) stipulates that

> "With respect to the patent which is granted for an invention related to pharmaceutical products or agricultural chemical products, each Party shall, subject to the terms and conditions of its applicable laws and regulations, provide for a compensatory term of protection for a period during which the patented invention cannot be worked due to marketing approval process. As of the date of signing this Agreement, maximum of such compensatory term is stipulated as being five years by the relevant laws of each Party".[95]

Different from other FTAs referred to above, Art. 230(4) EUPCFTA mentions the adoption of a system for extending the patent term only as an option ("may" instead of "shall"). On the other hand the legal effects of such protection are regulated quite strictly:

> "(4) With respect to any pharmaceutical product that is covered by a patent, each Party may, in accordance with its domestic legislation, make available a mechanism to compensate the patent owner for unreasonable curtailment of the effective patent term resulting from the first marketing approval of that product in that Party. Such mechanism shall confer all of the exclusive rights of a patent, subject to the same limitations and exceptions applicable to the original patent."

For a better understanding of that provision, the preceding paragraph, Art. 230(3) EUPCFTA must be taken into account as well, which reads:

> "(3) When the marketing of a pharmaceutical or agricultural chemical product in a Party requires to obtain an authorisation by its competent authorities in such matters, such Party shall make its best efforts to process the corresponding application expeditiously with a view to *avoiding unreasonable delays*. The Parties shall cooperate and provide mutual assistance to achieve this objective (emphasis added)."

The most elaborate form of regulation is contained in Art. 20.27 CETA, dealing with "sui generis protection for pharmaceuticals". The article is modelled on the current EU SPC regulation, but elaborates on some of the perceived deficiencies in that legislation.

Article 20.27.3 CETA makes provisions for reigning in patent owners' lifetime management options. Thus, contracting parties may deny *sui generis* protection altogether if the first application for MA was not submitted within a "reasonable time

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94 The article also contains footnotes (omitted in the quote above) relating to the definition of "pharmaceutical products" and "plant protection products". Furthermore, a footnote at the end of the provision clarifies that the limitation to five years applies without prejudice to a possible extension for paediatric use, if provided for by the parties.

95 Similar to the EUKFTA, the definitions of "pharmaceutical products" and "plant protection products" as well as the reservation for further pediatric extension are addressed in footnote which are omitted in the text quoted above.

limit" to be prescribed by the parties (Art. 20.27.3 lit. a CETA). In addition, the maximum time period between the grant of the first MA and the submission of the request for *sui generis* protection can be fixed at (no less than) 60 days (Art. 20.27.3 lit. b CETA; instead of six months, as in Art. 7 No 2 SPC Reg.).

Article 20.27.4 CETA addresses the situation where the product for which an MA is obtained is protected by more than one basic patent. Contrary to the current situation in the EU, a contracting party can prescribe that an extension of the protection period is only granted once. If the patents are in the hands of the same person, it is that person who chooses the patent to be extended; if the patents are in the hands of different persons they must, in the case of conflicting demands, find a compromise by agreement (Art. 20.27.4 second sentence lit. a and b).

Finally, Art. 20.27.8 CETA stipulates that

> "within the limits of the protection conferred by the basic patent, the sui generis protection shall extend only to the pharmaceutical product covered by the marketing authorisation **and for any use of that product as a pharmaceutical product that has been authorised** before the expiry of the sui generis protection. Subject to the preceding sentence, the sui generis protection shall confer the same rights as conferred by the patent and shall be subject to the same limitations and obligations. (Emphasis added)."

In line with the legal objective thus described, Art. 20.27.9. CETA includes the option of introducing a comprehensive waiver of rights pertaining to the making, using, offering for sale, selling or importing of products for the purpose of export during the period of protection.

(b) *Evaluation and preliminary conclusions*

The provisions addressing SPCs and similar mechanisms in the FTAs related above can be roughly grouped into three different categories. Most frequent are provisions declaring in a general form that an extension of the duration of the patent rights shall be granted at the request of right holders as a compensation for time delays caused by regulatory procedures in specific product sectors. CETA with its explicit reference to the option for introducing a manufacturing waiver belongs in another category. The third category distinguished here concerns Art. 230(4) EUPCFTA, which addresses optional patent term extensions meant to compensate for "unreasonable delays" in regulatory proceedings.

Whether or not the different forms of commitments made in bilateral agreements place any limitations on the EU legislature's freedom to introduce manufacturing waivers applying to SPCs must be assessed on the basis of an interpretation "in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose", as prescribed in Art. 31 VCLT. The issue is considered in more detail in Chapter 15, Section 15.3.2.4.

3.2.6 Summary

While SPCs constitute a right *sui generis* that is not directly addressed in the Paris Convention or TRIPS, the obligations stipulated in those Conventions must nevertheless be fully observed insofar as general principles, in particular the principle of national treatment are concerned. This does not mean, however, that the specific provisions anchored in Part II of TRIPS apply to SPCs in the same manner and with

the same result as in case of measures pertaining to patents. The issue is addressed in more detail in Chapters 15. Section 15.3.2.3 (concerning a manufacturing waiver for SPCs) and Chapter 18, Section 18.6 (concerning the question of SPC-eligibility of medical devices).

Regarding procedural issues, the EU has made a clear commitment to observe the PLT (Art. 147.1 CARIFORUM EPA). This commitment should pertain to SPCs as well.

3.3 UNION LAW

3.3.1 Primary Union law

Primary Union Law does not contain any provision dealing with patent rights. Nonetheless, the EU Charter of Fundamental Rights (CFR),[96] applicable to national authorities when implementing EU law, expressly states in Art. 17(2) that intellectual property shall be protected. The SPC, as a *sui generis* intellectual property right created by an EU Regulation, is covered by such provision. This may have some practical implications in the case in which a change of the SPC Regulations would tighten the conditions for granting an SPC. Unless transitional rules are provided, such a reform would have as a consequence that SPCs granted and valid under the old regime would not be valid anymore under the new law. This would raise the question of whether and to what extent the protection of acquired rights guaranteed by Art. 17(2) CFR shields SPCs against retroactive effects of amendments made to the SPC Regulations. If the answer is in the affirmative, then at least SPC applications filed before the coming into force of the reform must remain subject, insofar as the SPC eligibility of the product is concerned, to the old regime.[97]

3.3.2 The SPC Regulations

3.3.2.1 The Medicinal Products Regulation (Reg. 1768/92)

The Commission tabled a first proposal for a supplementary protection certificate for medicinal products in 1990,[98] which led to the adoption in 1992 of the Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products. [99] During the legislative process the Commission's original proposal was changed to some extent. The most significant of those changes concerned the deletion from the final text of a provision mandating the Commission with the task of issuing implementing provisions,[100] the elimination of the definition of "product" from Art. 1[101], the extension of the protection conferred by the certificate under Art. 4 Reg. 1768/92 to uses as medicinal product authorised before the expiration of the certificate. The original version of the provision

96 Charter of Fundamental Rights of the European Union [2012] OJ C 364/1.

97 For a corresponding result derived from the property clause in the European Convention on Human Rights, see Decision of 11 January 2007 by the European Court of Human Rights (ECtHR), Grand Chamber, *Anheuser-Busch v Portugal*, Application No. 73049/01 (concerning trademark rights).

98 Proposal for a Council Regulation (EEC) concerning the creation of a supplementary protection certificate for medicinal products, COM (90) 101 final [1990] OJ C 114, 10.

99 Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products [1992] OJ L 182/1.

100 *Ibid.*, Art. 14. See also *infra*, 3.3.2.4.

101 *Ibid.*, Art. 1.

limited the scope to uses of the product as medicinal product that have been authorised before the expiration of the *patent*. This change is significant, but its implications have not been considered in *Neurim*.

3.3.2.2 Why SPCs and not patent extensions?

At the pertinent time, a normative model for supplementary protection could be found in US and Japanese law, which both provide for an extension of the patent term.[102] The same holds true for Korea, the other country contemplating patent term restoration for medicines at that particular time.[103]

However, the EU legislature decided not to follow these models, but rather to adopt a new and separate legal title, the supplementary protection certificate. This solution already existed in France[104] and Italy[105]. However, the reasons for choosing this approach were not purely technical; in particular, the decision was not motivated by an assumed superiority of a *sui generis right*-model over a patent extension-model. Rather, it was the result of considerations based on the binary structure of European patent protection, that is, the coexistence of European patents granted by the EPO with national patents granted by the national authorities.[106]

If EU lawmakers had opted for a patent extension model by obligating the Member States to extend the term of national patents, this would have distorted the balance between national and European patents. In the technical fields qualifying for patent extension, a national patent would have been more valuable than a European patent. This would have caused pharmaceutical companies to file a bundle of national applications instead of a single European application, at least in the jurisdictions where double protection is prohibited.[107]

On the other hand, if in order to avoid such effects the obligation to grant a term extension would have pertained not only to national patents, but also to European patents protected in the respective Member States, this would have been in conflict with Art. 63 EPC 1973. The provision in force in 1992 read as follows:

> "Article 63. TERM OF THE EUROPEAN PATENT
> (1) The term of the European patent shall be 20 years as from the date of filing of the application.
> (2) Nothing in the preceding paragraph shall limit the right of a Contracting State to extend the term of a European patent under the same conditions as those applying to its national patents, in order to take into account a state of war or similar emergency conditions affecting that State"

There was no doubt that the list of cases in which the Member States could extend the term of the European Patent under Art. 63 EPC 1973 was exhaustive.[108] It was equally uncontested that the need to undergo a regulatory approval before an invention could

[102] See Annex II of this Study.
[103] See Annex II of this Study.
[104] *Supra* note 61.
[105] *Supra* note 60.
[106] That situation is alien to federal states such as the US, where the creation of federal rights largely coincided with the abolition of state patents.
[107] See Art. 139(3) EPC.
[108] See Hans Peter Kunz-Hallstein, `The compatibility of a community "Certificate for the Restoration of Protection" with the European Patent Convention´ [1990] EIPR 209.

be commercially exploited did not count as an "emergency condition affecting the State" within the meaning of Art. 63 (2) EPC 1973.[109]

Finally, if the legislature had obligated the EU Member States to amend Art. 63 EPC and to introduce SPCs after such an amendment, the legislation would have been considerably delayed. The amendment would have required a revision of the EPC by the Contracting States in the framework of a diplomatic conference, followed by a ratification of the revised text by the Contracting States in accordance with their domestic constitutional law.[110]

The creation of a *sui generis* right appeared as the solution to all these problems. From a legal point of view SPCs were considered not to be an extension of the European patent, but an *aliud*. As a consequence, the SPC Regulations could apply to European patents without triggering a violation of Art. 63 EPC, and a revision of the EPC was not necessary[111]. It is true that some national governments – among them Germany – pointed out that SPCs were practically just patent extensions by another name,[112] and that their creation amounted to a circumvention of Art. 63 EPC. In order to dispel any misgivings in that regard, the EU Member States initiated a procedure under Art. 172 EPC 1973 for amending Art. 63 EPC.[113] However, this did not delay the implementation of supplementary protection. The Medicinal Products Regulation was enacted and applied to European Patents several years before the amendment of Art. 63 EPC entered into force.

3.3.2.3 The Plant Protection Products Regulation (Reg. 1610/96) and the consolidated version of the Medicinal Products Regulation (Reg. 469/2009)

Already in the Explanatory Memorandum of the Medicinal Products Regulation reference was made to other fields where products are subject to a system of prior approval before being placed on the market.[114] Expressly mentioned in that regard were medical devices and agrochemical plant protection products. It was not surprising, therefore, that following the introduction of SPCs for medicinal products, in 1996, a second SPC Regulation, Reg. 1610/96,[115] was enacted for plant protection products. The substantive provisions of the two Regulations are almost identical, but the Reg. 1610/96 contains some provisions and recitals not provided by Reg. 1768/92. Some of these recitals and rules are intended to be valid, *mutatis mutandis*, also for the interpretation of Reg. 1768/92. Recital 17 Reg. 1610/96 reads as follows:

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109 *Ibid*.

110 See Art. 172 EPC 1973; see *also supra* note 71, 210.

111 See Hans Peter Kunz-Hallstein, `The compatibility of a community "Certificate for the Restoration of Protection" with the European Patent Convention´ [1990] EIPR 209, endorsing the approach followed by the legislature.

112 See Detlef Schennen, *Die Verlängerung der Patentlaufzeit für Arzneimittel im Gemeinsamen Markt* (Bundesanzeiger 1993) pp. 33-35.

113 See the Act Revising Article 63 EPC of 17 December 1991, which entered into force on 4 July 1997 [1992] OJ EPO 1.

114 European Commission, Explanatory Memorandum to the Proposal for a Council Regulation (EEC), of 11 April 1990, concerning the creation of a supplementary protection certificate for medicinal products (COM(90) 101 final – SYN255), para. 3.

23 See Regulation (EC) No 1610/96 of the European Parliament and of the Council of 23 July 1996 concerning the creation of a supplementary protection certificate for plant protection products [1998] OJ L 198/30.

> "Whereas the detailed rules in recitals 12, 13 and 14 and in Articles 3 (2), 4, 8 (1) (c) and 17 (2) of this Regulation are also valid, mutatis mutandis, for the interpretation in particular of recital 9 and Articles 3, 4, 8 (1) (c) and 17 of Council Regulation (EEC) No 1768/92"

This way of stipulating interpretative or supplementary rules with regard to previous legislation is somewhat unusual. Advocate General Fennelly raised the question of whether "the Community legislature is entitled to seek to influence the judicial interpretation of a legislative measure through the inclusion of interpretative 'rules' in later legislation which does not purport to amend the earlier measure".[116] However, declaratory or interpretative rules are not foreign to the constitutional traditions of the EU Member States. Similar legislation has often been adopted in Italy, the UK and France, for instance.[117] Of course, there are some constitutional limitations to such legislative practice. The understanding adopted by the interpretative law must be covered by the wording of the older legislation that is the object of interpretation. Legitimate expectations justified by a consolidated case law or agency practice must be taken into account.

The CJEU has considered Recital 17 Reg. 1610/96 relevant and valid in interpreting the provisions of Reg. 1768/92.[118] The application of Recital 17 Reg. 1610/96 to Reg. 1768/92, even if sometimes objected to by the parties affected, has also been approved by the NPOs[119].

A further problem with the recitals adopted is that they are not binding provisions, and they are only meant to serve the interpretation of the binding part of the respective regulations or directives. A recital cannot override or amend a provision set forth in the binding part of a regulation or a directive.

There were other evolutions in the SPC legislation after the enactment of Reg. 1610/96. Reg. 1901/2006 of 12 December 2006 on medicinal products for paediatric use (hereinafter the Paediatric Products Regulation)[120] introduced an extension for paediatric indications. Such extension is possible under European law only when an SPC has been granted. In 2009, a consolidated version of the Regulation was enacted that coordinated the text of Reg. 1768/92 with the Paediatric Products Regulation.[121] The consolidated version took account of some modifications of Reg. 1768/92 due to the entry of new Members into the EU.[122] However, this consolidated version did not incorporate Art. 3(2) Reg. 1610/96 or the recitals of Reg. 1610/96 that shall apply to medicinal products as well.

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116 Case C-392/97 *Farmitalia* [1999] ECR I-5553, Opinion of AG Fennelly, para. 33.

117 See Victor Thuronyi, Comparative Tax Law, p. 76 with further references.

118 See Case C-392/97 *Farmitalia* [1999] ECR I-5553, para. 20, where the ECJ observes: "Moreover, it should be borne in mind that the 13th recital in the preamble to Regulation (EC) 1610/96 of the European Parliament and of the Council of 23 July 1996 which, by virtue of the 17th recital, is also valid, mutatis mutandis, for the interpretation *inter alia* of Article 3 of Regulation No 1768/92, states that the certificate confers the same rights as those conferred by the basic patent, with the result that, where the basic patent covers an active substance and its various derivatives (salts and esters), the certificate confers the same protection."

119 See for instance the decision *of* UK IPO, BL 0/138/05 *Knoll AG,* Decision of 19 May *2005*; *Chiron Corp's And Novo Nordisk A/S's SPC Application* [2005] R.P.C. 24, 587.

120 Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004 (Paediatric Products Regulation) [2006] OJ L 378/1.

121 Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products, COM (90) 101 final [2009] OJ L 152/1.

122 *Ibid.*, Annex I.

3.3.2.4 The absence of soft law and implementing rules in the SPC Regime

If one compares the SPC Regulations with other pieces of legislation in the field of either EU intellectual property law or antitrust law, a striking difference appears in the structure of sources of law and in the institutional design of their application.

Like the EU Regulations establishing unitary IP rights, the SPC Regulations create private rights through directly applicable Union rules. Like the EU provisions governing competition (Arts. 101 and 102 TFEU), the SPC Regulations are applied by national institutions and courts. However, unlike unitary rights regulations or antitrust law, there is no EU agency or institution that applies the provisions of the Regulations instead of, or alongside, national agencies or courts.

Secondly, and again unlikely the system of unitary IP rights or antitrust or regulatory law[123], there is no accompanying binding legislation or soft law that supplements the SPC Regulations. Contrary to the original proposal of the Commission, the SPC Regulations did not delegate the power to the European Commission to adopt implementing rules.[124] In addition, the European Commission did not issue communications or other forms of soft law that could promote a uniform interpretation at the national level. All these factors may have contributed to some of the shortcomings of the current SPC regime reported by some stakeholders and NPOs.

3.3.2.5 The interpretation of the SPC Regulations

The provisions of the SPC Regulations are an integral part of Union law. Their construction is therefore subject to the interpretative criteria of the Union legal order. The CJEU does not apply the Vienna Convention on the Law of Treaties (VCLT) to the interpretation of secondary acts of Union law; instead, it has developed its own set of interpretative criteria.

Among these criteria, much emphasis is placed on the teleological and systematic approach. Consistently with this approach, the provisions of an EU Regulation "*must not be interpreted solely on the basis of its wording, but also in the light of the overall scheme and objectives of the system of which it is a part*".[125] Of course, the objectives and purposes of the Regulations cannot provide a basis for supplementing the SPC Regulations with additional revocation grounds, or for arbitrarily extending the scope of the legal provisions. However, application by analogy or application *ante litteram* of provisions of secondary acts were found admissible in the case law of the CJEU. It is even possible to extend the scope of application of a regulation to fields not covered

123 In the field of antitrust law, for instance, the Commission has adopted a number of implementing rules and soft law. Implementing rules have also been adopted in a multitude of other areas, such as food, chemicals, customs control etc. Such guidance, whether by implementing rules or soft law, may contribute to a uniform application or interpretation of the Union rules by national agencies or national courts. Also in the case of unitary IP rights, the European Commission has been entitled to adopt sub-legislative acts in the form of implementing rules or delegated acts. In addition, the IP agencies entrusted with the grant of unitary rights have adopted guidelines for the examinations. A corresponding scheme applies in the patent system, where national authorities and the EPO apply the same substantive provisions of the EPC governing the validity of the patent. When the former interpret the EPC, they take account of the guidelines adopted by the EPO that in turn codify the case law of the Boards of Appeal, for instance regarding the problem-solution approach.

124 See *supra*, 3.3.2.1, with reference to Proposal for a Council Regulation (EEC) concerning the creation of a supplementary protection certificate for medicinal products [1990] OJ C 114, 10, Art. 14.

125 See for instance Case C-292/00 *Davidoff* [2003] ECR I-389, para. 24.

by the regulation itself, when it is necessary to take into account primary law or international obligations. So in C-165/84, concerning the scope of Reg. 2655/82,[126] the CJEU formulated the following principles:

> "The scope of a regulation is normally defined by its own terms and it may not in principle be extended to situations other than those which it envisaged. The position may be different in certain exceptional cases. Thus, traders are entitled to rely on an application by analogy of a regulation which would not normally be applicable to them if they can show that the rules applicable to their case, on the one hand, are very similar to those which it is sought to have applied by analogy and, on the other hand, contain an omission which is incompatible with a general principle of community law and which can be remedied by application by analogy of those other rules."

The main task of the CJEU in the field of SPCs is to provide, in cooperation with the national courts, a uniform interpretation of the SPC Regulations. While it was emphasised by some stakeholders consulted in the framework of this Study that in principle the CJEU performs its task in an adequate manner, there are also critical voices contending that CJEU case law has caused some of the perceived deficiencies of the current system[127]. That criticism is based on the following points:

- The approach and principles adopted by the CJEU are not completely consistent with the principles and institutional design of patent law. This concerns for instance the distinction between products that are specified in the claims and products that are not specified in the claim, which does not have a basis in patent law.
- By invoking a teleological approach the CJEU has adopted decisions that are not in line with the wording of the Regulations and the intention of the lawmakers.[128]
- The CJEU very often rephrases the questions asked by the court, and the answer provided to the reformulated questions does not always answer in a comprehensive way the questions originally asked.

This Study cannot address the question whether the criticism is justified or not. Any changes in the rules concerning referral procedures – for instance, giving the parties in the underlying litigation a better standing so as to prevent a rephrasing of questions – would have to be of a general character. As such, they do not concern only the SPC regime.

3.3.2.6 The structure of references to regulatory and patent law

In both SPC Regulations, determining the applicable law is relevant in two situations: first, regarding the law governing the grant and the validity of the MA, and second, regarding the law governing the basic patent. To some extent, the Regulations contain explicit references to the applicable law; in other cases, the Regulations are not clear as to which law controls the meaning of a specific term or legal concept.

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126 Commission Regulation (EEC) No 2655/82 of 1 October 1982 laying down rules for implementing the import arrangements for 1982 for products falling within subheading 07.06 A of the Common Customs Tariff originating in third countries other than Thailand and amending Regulation (EEC) No 950/68 on the Common Customs Tariff [1982] OJ L 280/14.

127 Also some NPOs were critical of at least some aspects in CJEU case law. The opinion that CJEU jurisprudence has caused some of the perceived problems of the system was articulated in the statement of one particular NPO. For more details see *infra*, Chapter 8, Section 8.4.

128 This argument was made by the representatives of generic companies at the Stakeholder Seminar in Munich, 11 September 2017.

3.3.2.7 References to regulatory law

The SPC Regulations include several references to regulatory law. Pursuant to Art. 2 Reg. 1610/96, "any product protected by a patent in the respective territory and being subject, prior to commercialisation as a plant protection product, to an administrative authorisation procedure as laid down in Art. 4 of Dir. 91/414/EC, may be the subject of a certificate". Pursuant to Art. 2 Reg. 469/2009, "any product protected by a patent in the territory of a Member State and subject, prior to being placed on the market as a medicinal product, to an administrative authorisation procedure as laid down in Dir. 2001/83 or Dir. 2001/92/EC", may be the subject of a certificate. Whether the product requires an MA and whether the MA submitted in support of the application for a certificate is an MA granted in administrative procedure as laid down in Council Directive 91/414/EEC (Dir. 91/414) must be answered on the basis of the law governing the MA. However, the application of regulatory law or of the plant protection product law to supplement the SPC framework is not always simple. For instance, the regulatory framework provides for several types of authorisation and modifications of existing authorisations. The question of whether the variation of an existing MA is an authorisation within the meaning of Arts. 2 and 3(1)(b) Reg. 1610/96 or Art. 2 and Art. 3(b) Reg. 469/2009 cannot be answered only on the basis of regulatory law.

The sources of law governing marketing authorisation for medicinal products and plant protection products are briefly described in Chapter 4 of this Study.

3.3.2.8 References to patent law

The SPC Regulations do not contain a general reference to the law governing the basic patent. A provision such as the one included in Art. 2(2) EPC with respect to the European patent is lacking in the SPC legislation. By contrast, the references to the law governing the basic patent are specific and limited in scope. In theory, this could be lead to lacuna in the applicable regulatory regime. In practice, we are not aware of practical issues in this regard. In some countries, as for instance UK, the lawmakers in implementing the SPC legislation has made reference extensively to the provisions applicable to patents or patent application. Likely, despite the absence of specific legislation this is also the practice in the other EU Members.

Both SPC Regulations includes explicit and specific references to patent law in Art. 4 and 5 Reg. 469/2009, Arts. 16 and 18 Reg. 469/2009.

Articles 4 and 5 Reg. 469/2009 declare that the law governing the basic patent is applicable in defining what is the scope and what are the rights granted by a certificate. In the case of Art. 4, the scope resulting from such law is limited to the product and uses authorised. Since both provisions formulate a dynamic reference to the law applicable to the basic patent, agreements adopted pursuant to Art. 149a EPC, such as the Unified Patent Court Agreement, which defines the right conferred by the European Patent, can apply directly to the SPCs granted on the basis of a European patent.

Second, Art. 18 Reg. 469/2009 provides that the decisions granting or refusing the SPC application are subject to the same remedies as decisions concerning the patents of the Member State concerned.

Finally, Art. 19 Reg. 469/2009 declares applicable the procedural provisions that apply to the basic patent, unless the SPC Regulations provide otherwise. This wording gives rise to certain problems. First, the reference must also comprise the procedural provisions that apply to the patent *application* and not only the provisions that apply to the granted patent. Second, NPOs granting an SPC on the basis of a European patent are obviously not in a position to apply the procedural rules pertaining to European patent applications and european patents. Third, although Art. 19 Reg. 469/2009 seems to be limited to the rules governing administrative proceedings before the granting authorities, it must also constitute a legal basis for applying the provisions concerning the *enforcement* of patents. A narrower reading would create a lacuna that the lawmaker did not intend to leave open.

The sources of law that are relevant for the basic patents on which the SPC relies and some notions of patent law that are relevant for the understanding of this Study will be addressed in Chapter 5 of this Study.

3.4 NATIONAL LAW

One of the tasks of the Study is to report on the national implementing rules and practices of the EU States in the field of SPCs. For this purpose, the Study has selected some countries whose legislation, institutions and practices dealing with SPCs will be the subject of a specific analysis. We refer to Chapter 20 and Annex I of this Study.[129]

[129] Annex I includes national reports on the practice of some EU NPOs (national reports) drafted by representatives of the NPOs.

4 OVERVIEW OF THE DIFFERENT MA PROCEDURES

4.1 INTRODUCTION

Article 2 Reg. 469/2009 provides that an SPC can only be issued for products that are subject, prior to being placed on the market as medicinal product, to an administrative procedure as laid down in Dir. 2001/83 regarding medicinal products for human use or Dir. 2001/82/EC regarding medicinal products for veterinary use. Art. 2 Reg. 1610/1006 provides a similar rule for plant protection products with reference to administrative authorisation procedure as laid down in Art. 4 Dir. 91/414/EEC.[130]

The purpose of this Chapter is to provide a brief overview of the procedures for granting MAs in the EU, the types of MAs available and the applicable sources of law. The exposition is confined to those aspects of the legislation that are directly relevant for SPC practice.

4.2 MEDICINAL PRODUCTS

4.2.1 Procedural routes to obtaining an MA for medicinal products

Under Union and national legislation MAs for medicinal products can be obtained via four different routes:

- Centralised procedure (CP) as set out in Reg. 726/2004;
- Mutual recognition procedure (MRP) as set out in Arts. 28 *et seqq*. Dir. 2001/83 and Arts. 31 *et seqq*. Dir. 2001/82;
- Decentralised procedure (DCP) as set out in Arts. 28 *et seqq*. Dir. 2001/83 and Arts. 31 *et seqq*. Dir. 2001/82;
- Purely national procedures subject to the domestic provisions implementing Dir. 2001/83 and Dir. 2001/82.

Irrespective of the procedural route selected, the provisions governing the required clinical and other data and identifying the situations where such data are either not necessary or are required to a more limited extent, are uniform, since they are all laid down in the Medicinal Products Code (Dir. 2001/83) and in the Veterinary Products Code (Dir. 2001/82/EC). The only exception concerns the so-called conditional marketing authorisation. Indeed, this type of MA is provided by Reg. 726/2004, and not by Dir. 2001/83 or Dir. 2001/82, and therefore also not by the national law implementing Union law.

A major difference between the different routes relates to the legal effect of the MAs granted. The centralised procedure leads to the grant of an MA that is valid for all EU Member States (European or Union marketing authorisation),[131] whereas within the

[130] As we explained in Section 4.3, the directive was repealed by Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC [2009] OJ L 309/1.

[131] Art. 13(1) Reg. 726/2004.

MRP, DCP and purely national procedures national permissions are granted. The MRP and the DCP allow a national MA to be obtained in more than one Member State.

The scope of the different procedures is not co-extensive: for some medicinal products only a centralised procedure is available; for others only MRP, DCP or national procedures are possible, while for others still, both Union and national authorisations are possible. In the course of this Study several stakeholders have referred to this feature of the regulatory framework as an argument for also admitting national authorisations as a basis for granting a unitary SPC.[132]

4.2.1.1 Centralised procedure (CP)

(a) *Concept of CP*

Since 1 January 1995, an MA can be obtained for all EU Member States via a centralised procedure. Applicants, accordingly, only need to pursue a single MA procedure in order to obtain approval for a medicinal product which allows for the uniform right to market the respective product in all EU Member States. The legal basis in this regard is Reg. 726/2004,[133] having replaced Reg. 2309/93[134] with effect as of 20 May 2005 (except for those provisions explicitly provided for in Art. 90(2) Reg. 726/2004 where a derogation is provided for).

The main reason for establishing a centralised procedure was to improve the functioning of the internal market in the pharmaceutical sector.[135] At the same time, the European pharmaceutical industry was to be strengthened *vis-à-vis* the US pharmaceutical industry by implementing a "one-stop shop" MA procedure. The centralised approval was intended to avoid the disadvantages caused by the need to coordinate different national regulatory procedures in parallel.[136]

(b) *Legal effect*

An MA granted within the centralised procedure is valid throughout the EU and as such can be relied upon by pharmaceutical companies to market the relevant medicinal product in all EU Member States.[137]

Vice versa, if an application submitted within the framework of the centralised procedure is rejected, the corresponding medicinal product may not be placed on the market within the territory of the EU. National agencies are prevented from granting an authorisation for the product concerned. This also applies to the products for which the centralised procedure is only optional. The reason is that the refusal to grant an MA applied for within the centralised procedure constitutes a prohibition on the placing on the market of that medicinal product throughout the Union.[138]

132 See Chapter 22, Section 22.3.4 of this Study.
133 [2004] OJ L 136/1.
134 [1993] OJ L 214/1.
135 *Ibid.*
136 Christian Roger Fackelmann, *Patentschutz und ergänzende Schutzinstrumente für Arzneimittel im Spannungsfeld von Wettbewerb und Innovation* (Heymanns 2009) p. 22.
137 Maria Isabel Manley, Marina Vickers (eds), *Navigating European Pharmaceutical Law* (Oxford University Press 2015), para. 3.40; Arts. 13(1), 38(1) Reg. 726/2004.
138 Arts. 12(2), 37(2) Reg. 726/2004.

(c) *Scope*

The centralised procedure is in some cases mandatory, in others optional, in others excluded.

(i) Mandatory use of the centralised procedure

The centralised procedure was initially mandatory only for pharmaceuticals developed by biotechnological methods.[139] Reg. 726/2004[140] has broadened the class of medicinal products that requires central approval. CP is now mandatory for:[141]

- medicinal products developed by means of specific biotechnological processes (recombinant DNA technology, controlled expression of gene coding for biologically active proteins in prokaryotes and eukaryotes including transformed mammalian cells, or via hybridoma and monoclonal antibody methods);
- advanced therapy medicinal products (gene therapy medicinal products, somatic cell therapy medicinal products or tissue engineered products as defined in Art. 2 Reg. 1394/2007142);
- medicinal products for veterinary use intended primarily for use as performance enhancers in order to promote the growth of treated animals or to increase yields from treated animals;
- medicinal products for human use containing a new active substance which, on the date of entry into force of Reg. 726/2004, was not authorised in the Community, for which the therapeutic indication is the treatment of
  - acquired immune deficiency syndrome,
  - cancer,
  - neurodegenerative disorder,
  - diabetes,
  - auto-immune diseases and other immune dysfunctions, or
  - viral diseases;
  - orphan medicinal products.

(ii) Optional use of the centralised procedure

The centralised procedure is optional when one of the following conditions is fulfilled:[143]

- the medicinal product in question contains an active substance which, on the date of entry into force of Reg. 726/2004, was not authorised in the Community; or
- the applicant shows that
  - the medicinal product constitutes a significant therapeutic, scientific or technical innovation; or
  - the granting of an authorisation in accordance with Reg. 726/2004 is in the interest of patients or animal health at the Community level.

139 Reg. 2309/93, Annex A.
140 See note 1 above.
141 Art. 3(1) Reg. 726/2004 and Annex to Reg. 726/2004.
142 Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation 726/2004.
143 Art. 3(2) Reg. 726/2004.

In addition, MAs for immunological veterinary medicinal products for the treatment of animal diseases that are subject to Community prophylactic measures may also be centrally issued.[144]

The application for a medicinal product that is a generic of a centrally authorised reference medicinal product has (optional) automatic access to the centralised procedure. The same holds true for hybrid applications or biosimilar applications.[145] Also, multiple or duplicate applications for medicinal products including an active substance or a combination of active substances that are already under assessment in a procedure pending before the EMA have automatic access to the CP.[146]

(iii) Exclusion of the centralised procedure

If the preconditions set out in Art. 3(1) and (2) Reg. 726/2004 are not met, the medicinal product is not eligible for evaluation under the centralised procedure. The applicant must resort to the national procedures, to the DCP or the MRP.

(d) *Procedure and content of the application*

An application for a central European MA has to be filed with the EMA.[147] Before filing, the applicant must submit a so-called eligibility request to clarify whether the medicinal product in question falls within the scope of the centralised procedure.

The eligibility request is always made to the EMA, regardless of whether the application for marketing authorisation falls within the mandatory or optional scope or would have "automatic access" to the CP or has access to it in accordance with the Paediatric or Advanced Therapy Regulation. After the EMA has notified the applicant that the medicinal product is eligible for an evaluation under the CP, the applicant can submit the application.

If the medicinal product in question includes an active ingredient not previously authorised, the applicant will have to submit a full-dossier application, that is, an application including the data set out in Art. 8(3) Dir. 2001/83 or Art. 12(3) Dir. 2001/82/EC.[148]

As explained below, there are situations where the application need not include all the data set out in Art. 8(3) Dir. 2001/83. This is possible when the medicinal product is a generic of a centrally authorised reference product, or the medicinal product is not a generic, but the requirements of Art. 10(3) Dir. 2001/83 are met, or else the medicinal product is a biosimilar within the meaning of Art. 10(4), or finally the medicinal product includes a combination of actives previously individually authorised (Art. 10(b) Dir. 2001/82). It is important to note that in the situations addressed by Art. 10(1), 10(3), 10(4), 10a, 10b, 10c, the decision to submit either a stand-alone

144 Art. 3(2) second sentence Reg. 726/2004.
145 See EMA, *European medicines Agency pre-authorisation procedural advice for users of the centralised procedure*, 30 August 2017, EMA/821278/2015 p. 35.
146 *Ibid.*
147 Reg. 726/2004, Art. 4(1) in conjunction with Art. 6 et seqq.
148 See Art. 6(1) Reg. 726/2004.

application (Art. 8(3) Dir. 2001/83) or a generic, hybrid or biosimilar application or a fixed combination application is at the discretion of the applicant.[149]

Irrespective of its legal basis, the application is first assessed by the EMA's Committee for Medicinal Products for Human Use ("CHMP"). The CHMP is required to issue an opinion within 210 days of receipt of the complete application in which it recommends granting or rejecting the authorisation for the medicinal product in question. The legislation provides for the option of a clock-stop in specific situations, and a period of 15 days is provided for transmitting the complete opinion (including required translations) to the European Commission.

In the second step, the European Commission has to draft a decision within 15 days of receipt of the CHMP's opinion. A final decision then has to be taken within a period of a further 15 days following the completion of the procedure referred to in Art. 87(3) Reg. 726/2004, which takes another 22 days.

As was pointed out at the MPI Stakeholder Seminar in Munich on 11 September 2017, it is not possible for the applicants to delay the procedure that leads to the grant of a European MA. After the application is filed, the "regulatory procedures to obtain a marketing authorisation are precise and subject to clear deadlines; there is therefore no room for lack of diligence".[150] Further, the companies have "an interest in placing their product on the market as soon as possible".[151]

However, the question whether the SPC duration should be open to correction on the basis of lack of diligence rules such as those laid down in US law is more complex. On the one hand, the decision when to file an application for starting clinical trials, the timing of these, and the decision when to start the pre-submission phase and then file an MA application with the EMA are all at the discretion of the companies concerned. On the other hand, the duration of the certificate as provided for under Art. 13 Reg. 469/2009 takes into account not only the time needed for obtaining the MA, but also the time needed for completing the clinical trials and non-clinical studies and any other time between the filing date of the basic patent and the notification date of the relevant MA. Finally, the pressure for companies to bring the medicinal product to market as soon as possible may vary according to the category of the products concerned (monotherapy products, fixed-combination products including actives already marketed by the same company as monotherapy products, modified or improved variants of the monotherapy or combination products already on the market).[152]

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149 Of course, the exercise of this discretion is connected with a significant increase or reduction of costs. However, because the applicant is free to choose the legal basis under which it seeks authorisation for a medicinal product, any approach that would either rule out or affirm infringement of a certificate according to the procedural route through which the alleged infringing product was authorised is problematic.

150 EFPIA, *EFPIA Submission – Study on the legal aspects of the SPCs in the EU*, 25 September 2017, p. 5; the text was submitted at our request after the Stakeholder Seminar, and it sums up some of the considerations made by EFPIA representatives at the MPI Stakeholder Seminar in Munich, 11 September 2017.

151 *Ibid*.

152 See also Chapter 16 of this Study.

(e) *Duration*

Once granted, a central MA is valid for a period of five years, except in cases where the applicable legislation stipulates differently (i.e. in the case of conditional marketing authorisation).[153]

4.2.1.2 Mutual recognition (MR) and decentralised procedure (DP)

(a) *Legal effect*

An MA granted within mutual recognition or decentralised procedures is valid in those EU Member States which the applicant has included in the application process and which have accordingly granted the relevant MA. The territory covered by MAs granted within mutual recognition and decentralised procedures is generally, though not necessarily, narrower than that covered by MAs granted within the centralised procedure.

(b) *Scope*

The mutual recognition and the decentralised procedure are regulated in Arts. 28-34 Dir. 2001/83 for medicinal products for human use and in Arts. 31–43 Dir. 2001/82/EC for veterinary medicinal products. The mutual recognition procedure and the decentralised procedure are applicable to all medicinal products for which the centralised procedure is not mandatory. The mutual recognition procedure is available and mandatory if an applicant is already the holder of a national MA issued for the medicinal product concerned.[154] The decentralised procedure is applicable when no previous national MA was granted, but the holder intends to apply for an MA for the same medicinal product in more than one Member State.[155] The use of the decentralised procedure is mandatory if applications for MAs for one medicinal product are filed in two or more Member States. Also, if a Member State is informed that another MA application for the same medicinal product is being examined in another Member State, the Member State concerned must decline to assess the application and refer the applicant to the decentralised or mutual recognition procedure.

The different national applications must be based on an identical dossier, in the case of mutual recognition as well as in the case of decentralised procedures.[156] The MAs granted will have the same wording and SmPC in the different languages. This aspect is relevant for the question whether or the not the lawmakers may admit MAs granted within the DP or MRP as the basis for a unitary SPC.

(c) *Procedure and duration*

The mutual recognition and the decentralised procedure aim at facilitating access to the single market by relying on the principle of mutual recognition.[157] Accordingly, the

153 Art. 14(1) Reg. 726/2004; note that extensions are possible pursuant to Art. 14(2) et seqq. Reg. 726/2004.
154 Art. 28(2) Dir. 2001/83/EC, Art. 32(2) Dir. 2001/82/EC.
155 Art. 28(3) Dir. 2001/83/EC, Art. 32(3) Dir. 2001/82/EC.
156 Art. 28(1) Dir. 2001/83/EC, Art. 32(1) Dir. 2001/82/EC.
157 European Commission, Notice to Applicants, VOLUME 2A, Procedures for MA, Chapter 2, Mutual Recognition, February 2007, p. 1, available at https://ec.europa.eu/health/sites/ health/files/files/ eudralex/vol-2/a/vol2a_chap2_2007-02_en.pdf (last accessed 19 May 2017).

assessment of an application for the grant of an MA is only conducted by one Member State (reference Member State). That assessment, in principle, has to be recognised by the concerned Member States named by the applicant. It is only on the grounds of potential serious risks to public health that the concerned Member States can deny the approval of the reference Member State's assessment.[158] In terms of timing, the procedures must be completed within 210 days after the submission of a valid application.[159]

An MA granted within mutual recognition or decentralised procedures is, similar to a centralised European MA, initially valid for a period of five years[160], and is renewable.

4.2.1.3 Purely national procedure

Purely national MAs are relevant in cases where the medicinal product is only intended to be placed on the market in one single EU Member State. The respective procedures are regulated in the national laws of the EU Member States implementing Dir. 2001/83 and Dir. 2001/82/EC.

4.2.2 Types of marketing authorisation

4.2.2.1 Full MA and submission of clinical trial data

Authorisation procedures for medicinal products that include a new active ingredient not previously authorised require the applicants to submit an extensive amount of clinical, non-clinical and pharmaceutical data. Such data must demonstrate the safety and efficacy of the medicinal product in question.[161] The conduct of the necessary trials and tests requires significant investment on the part of the applicant. The time and resources that have to be invested are a major reason why the requirement of the MA leads to a significant reduction of the patent term, more so than the length of the granting procedure itself. Indeed, the conduct of clinical trials is complex and highly regulated by statutory provisions and accompanying guidelines.[162] Generally, clinical trials are conducted in different phases (phases I to IV). Depending on the relevant phase, a different number of study subjects are involved for different test and study purposes. As the trial proceeds to the confirmation of the therapeutic effect of a new drug in phase III, more patients have to be enrolled and tested.

The legal basis for the conduct of clinical trials is Reg. 536/2014, the so-called Clinical Trials Regulation, which will apply as of 2019.[163] The main purpose of the Clinical Trials Regulation is to create an environment that is favourable for conducting clinical trials, with the highest standards of patient safety, for all EU Member States.[164] For

158 Art. 29(1) Dir. 2001/83/EC, Art. 33(1) Dir. 2001/82/EC.
159 Art. 17(1) Dir. 2001/83/EC, Art. 21(1) Dir. 2001/82/EC.
160 Art. 24(1) Dir. 2001/83/EC, Art. 28(1) Dir. 2001/82/EC; note that extensions are possible pursuant to Art. 24(2) Dir. 2001/83/EC and Art. 28(2) Dir. 2001/82/EC.
161 Note that this does not apply with regard to generic applications for medicinal products pursuant to Art. 10(1) Dir. 2001/83/EC or Art. 13(1) Dir. 2001/82/EC.
162 European Commission, <https://ec.europa.eu/health/human-use/clinical-trials/information_en#ct1> and <https://ec.europa.eu/health/documents/eudralex/vol-10_en> (both last accessed 19 May 2017).
163 Reg. 536/2014, repealing Dir. 2001/20/EC. Note that the latter will continue to apply until Reg. 536/2014 comes into force.
164 European Commission, <https://ec.europa.eu/health/human-use/clinical-trials/information_en#ct1> (last accessed 19 May 2017).

this reason, clinical trials may only be conducted subject to prior approval.[165] The corresponding approval process requires an in-depth description of the planned study on the basis of a detailed study protocol as well as clearance by ethics committees.[166]

As for the duration of a clinical trial, no statutory deadline or fixed timeline exists. Since the conduct of clinical trials very much depends on the design of the respective study and the successful recruitment of a sufficient number of study subjects, the duration can vary significantly from case to case.[167] Based on publicly available research papers clinical trials can last from months up to several years.[168]

Therefore, it is important for the review of the SPC regime from a policy-making perspective to bear in mind that for calculating the time lost in effective patent protection as a consequence of the need to have a medicinal product authorised prior to market launch, not only the time invested in the MA procedure as such, but also the time spent on the required clinical trials, non-clinical tests and other product development activities must be taken into account. Also, the associated costs in terms of the investments made need to be considered in the general assessment of the legislation.[169]

4.2.2.2 Conditional MA

According to Art. 14(7) Reg. 726/2004 and Arts. 4 and 5 Reg. 507/2006,[170] an MA may be granted based on less comprehensive data than normally required, subject to specific obligations (so-called conditional MA).[171] Under the legislation in force, only the EMA can grant conditional MAs.

Conditional MAs can be available for seriously debilitating or life-threatening diseases, in emergency situations as a response to public health threats and for orphan drugs.[172] While conditional MAs can be granted if the applicant has not yet provided all clinical data required to demonstrate the safety and efficacy of the relevant medicinal product, still the requirements set out in Art. 4 Reg. 507/2006 must be met. According to this, it is necessary that

- there be a positive risk-benefit balance for the medicinal product in question,
- unmet medical needs will be fulfilled and
- the benefit to public health of the immediate availability of the relevant medicinal product on the market outweighs the risk inherent in the fact that the clinical data on safety and efficacy is not yet complete.

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165 Recital 2 Reg. 536/2014.
166 Art. 4(2) Reg. 536/2014.
167 See e.g. Rosa M Abrantes-Metz et al, 'Pharmaceutical Development Phases: A Duration Analysis' [2004] FTC Bureau of Economics working paper No 274, pp. 9-10, listing the duration of clinical trials in relation to different diseases.
168 Christopher P Adams, Van V Brantner, 'Estimating the Cost of New Drug Development: Is It Really $802 Million?' [2006] Health Affairs 420, Exhibit 4, 425 indicates that for all three phases of clinical trials the duration could range between 4.4 and 8.8 years; see further Rosa M Abrantes-Metz et al, 'Pharmaceutical Development Phases: A Duration Analysis' [2004] FTC Bureau of Economics working paper No 274, p. 8.
169 Publicly available data indicate that average costs for phase I trials are around US$ 3.4 million, for phase II trials US$ 8.6 million and for phase III trials US$ 21.4 million; see Linda Martin et al, 'How much do clinical trials cost?' [2017] 16 Nature Reviews Drug Discovery.
170 Reg. 507/2006.
171 Maria Isabel Manley, Marina Vickers (eds), *Navigating European Pharmaceutical Law* (Oxford Univeristy Press 2015), para. 3.122.
172 Art. 2 Reg. 507/2006.

Also, it must be likely that the applicant will be in a position to provide the comprehensive clinical data. According to Art. 5 Reg. 507/2006, the conditional MA is granted subject to specific obligations to be met by the applicant (such as the obligation to complete ongoing studies or carry out additional studies).

Conditional MAs constitute a specific compromise for particular situations where certain medicinal products are to be made available for patients before an applicant has collected all clinical data on safety and efficacy of the relevant medicinal product. In consideration of the risk inherent in incomplete clinical data, conditional MAs are only valid for a period of one year. Consequently, they need to be renewed on an annual basis.[173] Once the applicant has fulfilled the specific obligations requested in the conditional MA, the MA may be granted unconditionally.[174]

The conditional MA entitles its holder to place the product on the market, and in this respect it is not qualitatively different from a normal MA. Within the first ten years of application of Reg. 507/2006, a total of 30 conditional MAs have been granted.[175] One question of practical relevance to be addressed in Chapter 9[176] is whether a conditional MA fulfils the notion of MA within the meaning of Art. 2 Reg. 469/2009, and therefore may support the grant of a certificate under Art. 3(b) Reg. 469/2009, and whether it counts as first MA for the purposes of Art. 3(d) and triggers the deadline for filing the application under Art. 7 Reg. 469/2009.[177]

4.2.2.3 MAs granted under exceptional circumstances (Art. 14(8) Reg. 726/2004 and Art. 22 Dir. 2001/83)

If the applicant is not able to provide comprehensive data and it is not likely that it will be able to do so in a short time frame, a conditional MA is not possible. However, the Union legislation provides that in exceptional circumstances a marketing authorisation can be granted, even if the applicant will never be able to submit the data required under Art. 8 Dir. 2001/82 for a normal marketing authorisation. The legal basis for awarding an MA under exceptional circumstances is laid down in Art. 14(8) Reg. 726/2004 in conjunction with Art. 22 and Annex I, Part II of Dir. 2001/83. More precisely, according to Art. 14(8) Reg. 726/2004 and Art. 22 Dir. 2001/83 a marketing authorisation may be granted in exceptional circumstances, "provided that specific procedures are introduced". As one can infer from Annex I, Part II of the Dir. 2001/83, such exceptional circumstances exist where the inability of the applicant to provide the data required for a normal MA is due to the fact that:

- the therapeutic indications for the medicinal product in question are so rare that the applicant cannot be expected to provide comprehensive evidence for safety and efficacy;
- in the present state of scientific knowledge, comprehensive information is not possible;

[173] Art. 6 Reg. 507/2006.
[174] Art. 7 Reg. 507/2006.
[175] EMA, Conditional marketing authorisation, Report on ten years of experience at the European Medicines Agency, p. 8, available at <http://www.ema.europa.eu/docs/en_GB/ document_library/Report/2017/01/WC500219991.pdf> (last accessed 14 August 2017).
[176] Chapter 9, Section 9.3.3.1.(c).
[177] For example, the relevant MA relied upon for the grant of an SPC (here: in Austria) in the CJEU's decision of 6 October 2015, Case C-471/14 *Seattle Genetics* [2015] EU:C:2015:659, was a conditional MA.

- even if it were possible, it would be contrary to generally accepted principles of medical ethics to collect such data.

A corresponding instrument is provided under Art. 39(7) Reg. 726/2004 and Art. 26(3) Dir. 2001/82 for veterinary products. It is important to note that also in the case of MAs granted under Art. 14(8) Reg. 726/2004 or Art. 39(7) Reg. 726/2004 the applicant is entitled to place the product on the market, albeit a restricted one.

4.2.2.4 Generic, hybrid and biosimilar marketing authorisations

(a) *Premise*

In specific situations laid down in Art. 10 Dir. 2001/83 and Art. 13 Dir. 2001/82 it is possible to obtain an MA for a medicinal product for human or veterinary use without submitting an application that contains all the clinical and pre-clinical data required under Art. 8 Dir. 2001/83.

(b) *Generic applications (Art. 10(1) Dir. 2001/82)*

The first situation occurs when the medicinal product is the generic of a medicinal product already authorised. Provided that the period of regulatory data protection has expired, third parties will be allowed to file an application without the data required by Art. 8 Dir. 2001/83. They can refer to the results of pre-clinical tests and clinical trials included in the MA for the reference product. This is true even if the MA granted for the medicinal product concerned is expired or withdrawn.

Pursuant to Art. 10(2)(b) Dir. 2001/83 a generic medicinal product is "a medicinal product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies". The applicant is required to submit data that can adequately demonstrate the bioequivalence of the generic medicinal product and the reference product.

Usually, in the field of small molecules, the generic companies will seek an authorisation for a medicinal product that employs exactly the same pharmaceutical form, and more particularly the same free base or derivative form of the active(s) as the reference product. It can happen, however, that the generic company decides for some reason to bring to market a medicinal product including a different salt or ester or derivative of the same active ingredient. This occurrence, which is not frequent at all according to the information obtained in the course of the Study, does not automatically exclude the applicability of the abridged procedure. Under Art. 10 Dir. 2001/83, indeed, "the different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance shall be considered to be the same active substance, unless they differ significantly in properties with regard to safety and/or efficacy". If the last requirement is not met, the applicant will have to submit additional data, as provided by Art. 10(3) Dir. 2001/83, or even seek a normal MA for the medicinal product employing the specific form of the active substance under Art. 8 Dir. 2001/82. In the latter case, it will also be possible that the salt or derivative concerned will receive the status of new active substance, if claimed by the applicant, and will enjoy its own data protection period under Art. 10(1) Dir. 2001/82.

(c) *Hybrid applications (Art. 10(3) Dir. 2001/83)*

As already mentioned in the previous sub-section, if the medicinal product does not fulfil the concept of generic medicinal product or "the applicant was unable to demonstrate the bioequivalence or introduced some changes in the active substance(s), therapeutic indications, strength, pharmaceutical form or route of administration, vis-à-vis the reference medicinal product", the application will have to include "the results of the appropriate pre-clinical tests or clinical trials". However, such application can still rely on the information and results of clinical trials included in a previous stand-alone marketing authorisation. Therefore, such applications are defined hybrid. Indeed, they include supplementary data, but not full data as would a stand-alone application. Such cases can occur not only when the medicinal product employs a different salt than the reference product, but also when a new indication has been developed for the same form of the old active ingredient. Hybrid applications may become relevant for the SPC legislation, for instance in the case of a *Neurim*-style application for a certificate.

(d) *Biosimilar applications (Art. 10(4) Dir. 2001/83)*

As explained in more detail in Chapter 18, Section 18.2, biological products, such as antibodies, cell lines and proteins, are, within the regulatory framework, all products that are manufactured employing a living system or biological material. For the purposes of the Union legislation, therefore, even products that are not biological material within the meaning of Art. 2 Dir. 98/44 such as polypeptides, are biological products and subject to the specific provisions concerning the latter, since they are manufactured by a biological process.

Biological products in this sense present a higher molecular complexity than so-called small chemical molecules, that is, substances manufactured by chemical synthesis. Furthermore, their features and characteristics are also strongly influenced by the process and the biological material employed for their manufacture. As a consequence, it is accepted that a slight change in the manufacturing process or in the structure of the biological product may have a significant impact on the efficacy, safety and quality of the medicinal product. Also, with the technology currently available, it is not possible to reproduce identically the biological product, but only a product that is similar to the result of a specific biological process.

The legislation takes account of these differences between traditional chemical compounds and products manufactured by biological processes. Biological products are not available in principle for a generic authorisation under Art. 10(1) Dir. 2001/83. Due to the complexity of products manufactured by a biotechnological process, the European Commission do not consider the submission of evidence for the bioequivalence of the biological product sufficient.[178] As a consequence, lawmakers have created a specific route in Art. 10(4) Dir. 2001/83, according to which:

> where a biological medicinal product which is similar to a reference biological product does not meet the conditions in the definition of generic medicinal products, owing to, in particular, differences relating to raw materials or differences in manufacturing processes of the biological medicinal product and the reference biological medicinal product, the results of appropriate pre-

[178] Dev Kumar, Lauren Wilks, *Biological medicinal Products and Biosimilars* in Maria Isabel Manley, Marina Vickers (eds) in NAVIGATING EUROPEAN PATENT LAW (Oxford University Press 2015), pp., 227, 234; see also Case T-15/04 *Sandoz GmbH v Commission of the European Communities* [2006] ECLI:EU:T:2006:212.

> clinical tests or clinical trials relating to these conditions must be provided. The type and quantity of supplementary data to be provided must comply with the relevant criteria stated in Annex I and the related detailed guidelines. The results of other tests and trials from the reference medicinal product's dossier shall not be provided.

In the practice of the EMA, the applicant is required to produce evidence that may demonstrate the "similar nature, in terms of quality, safety and efficacy" of the biosimilar and the reference product.[179] The data that must be generated to support the biosimilar application are set out in more details in the guidelines adopted by the EMA.

This different regulatory pathway for biosimilars of biological products has already influenced the SPC practice, and it is possible that it will affect the scope of the granted certificates. Thus, for instance, while some NPOs in the field of small molecules admit a product definition including all salts and derivatives of the small molecule that is the subject of the MA submitted in support of the certificate, definitions of the product that go beyond the product covered by the MA are rejected in the field of biological products. We refer for more details to Chapter 18, Section 18.2.

4.2.2.5 Variations to the terms of the MA

(a) *Introduction*

Medicinal products may only be placed on the market in line with the corresponding MAs. All amendments concerning e.g. the manufacturing process, the composition of the substances, the therapeutic indications as well as the labelling, the package leaflet or the expert information, have to be indicated to the competent authorities. Certain amendments are subject to prior approval, while others require notification only.

Commission Regulation (EC) No 1234/2008 provides a uniform framework that applies to all MAs issued within the CP, MRP, DP or national procedures. Each variation of the terms of an MA requires a submission of the MA holder. Within the genus "variation" the Regulation makes a distinction between major variations of type II, minor variations of type I A, minor variations of type I B, and extensions.

While extensions of existing MAs always have to be evaluated in accordance with the same procedure as for the initial MA to which they relate, the procedure to be complied with for variations set out in Reg. 1234/2008 depends on the nature of the change and the procedural framework within which the initial MA was granted. Authorisations granted for extensions are from a procedural perspective identical with a new MA. From a formal perspective, extension can either be granted as a new MA or will be included in the initial MA to which it relates.

[179] See EMA, Guideline on similar biological medicinal products, 3 October 2014 CHMP/437/04 Rev 1, Committee for Medicinal Products for Human Use (CHMP), 1 et seq.

(b) *Type of variations*

For the SPC practice, extensions and major variations of type II are more relevant.

An extension is defined as "variation which is listed in Annex I and fulfils the condition laid down therein". Pursuant to Annex I the following changes fulfil the notion of extension:

- Changes to the active substance(s) of a medicinal product (e.g. "replacement of a chemical active substance by a different salt/ester complex/derivative, with the same therapeutic moiety, where the efficacy/safety characteristics are not significantly different", use of a different isomer or mixture of isomer where the efficacy or replacement of the biological active substance with one with a different molecular structure, provided in both cases that the replacement does not affect significantly the efficacy or safety of the medicinal product)[180];
- Changes to strength, pharmaceutical form and route of administration[181]
- Other changes specific to veterinary medicinal products to be administered to food-producing animals such as the change or addition of target species.[182]

Major variations of type II are variations which are not an extension, and therefore do not concern one of the changes listed in Annex I, and at the same time "may have a significant impact on the quality, safety or efficacy of the medicinal product concerned". An example of major variation of type II that has become relevant for the SPC practice is the addition of a new therapeutic indication.

Minor variations of type I A are e.g. variations that have no impact, or a minimal one, on the safety and efficacy of the medicinal product, as for instance changes of purely administrative nature concerning the details of the MA holder, the manufacturer, or in the packaging material which is not in contact with the finished product.[183] Minor variations of type IB[184] are all variations that are neither minor variations of type IA, nor major variations of type II nor extensions.

(c) *Procedural aspects*

(i) Variations of European MAs granted in the centralised procedure

If the applicant intends to introduce variations into a central European MA, a corresponding request has to be filed with the EMA in accordance with Chapter III Reg. 1234/2008. The application for an extension is subject to the same procedure as the marketing authorisation to which it relates, and will require a corresponding approval according to the same principles and with the same steps. With the other variations, by contrast, two procedures apply, depending on the nature of the variation:

- Notification procedure for minor variations of types IA[185] and IB[186];
- 'Prior Approval' procedure for major variations of type II[187].

180 Annex I.1 Reg. 1234/2008.
181 Annex I.2 Reg. 1234/2008.
182 Annex I.3 Reg. 1234/2008.
183 Annex II, 1 Reg. 1234/2008.
184 Article 3(2) Reg. 1234/2008.
185 Art. 14 Reg. 1234/2008.
186 Art. 15. Reg. 1234/2008

The major difference in this regard is that while for variations of types IA and IB a mere notification suffices and approval by the EMA may be assumed if within a time period of 30 days no negative opinion is received, type II variations require a prior explicit approval.

(ii) Variations of MAs granted in the mutual recognition or decentralised procedure

Variations of MAs granted under the mutual recognition or decentralised procedure have to be authorised in accordance with Chapter II Reg. 1234/2008. Other than for MAs granted in the centralised procedure, applications for variations relating to MAs granted in the mutual recognition or the decentralised procedure have to be submitted with all relevant authorities of the Member States.[188] Similar to the variations of MAs granted within the centralised procedure, different procedural steps have to be complied with depending on the type of variation. Accordingly, for type IA and IB variations a notification procedure is sufficient[189] as well, while for type II variations a prior approval has to be obtained[190]. There also is a possibility of an abridged procedure if the variation relates to a human influenza vaccine. The abridged period of time for the assessment of the application is in this case further reduced to 45 days.[191]

(iii) Amendments to national MAs

Variations to national MAs are covered by Reg. 1234/2008 as amended (Chapter 2a) as well. To the extent that Reg. 1234/2008 does not apply, national MAs are subject to the specific national rules applicable in the respective Member State. In view of the broad scope of application of Reg. 1234/2008, however, national rules play a subordinate role only.[192]

(d) *Challenges for SPC legislations*

The option of the MA holder to submit a request for the variation of the granted MA raises at least two legal questions for SPC practice and legislation. On the one hand, one can wonder whether the amendments to the terms of MA originally submitted in support of the application for a certificate may or shall have an impact on the scope of the granted certificate under Art. 4 Reg. 469/2009. On the other hand, it is not clear whether or to what extent variations must be considered a new and independent MA for the purposes of Art. 3(d), Art. 7 and Art. 13 of SPC legislation.

187 Art. 16 Reg. 1234/2008.
188 Art. 8(1), 9(1) Reg. 1234/2008
189 Art. 8, 9 Reg. 1234/2008.
190 Art. 10 Reg. 1234/2008.
191 Art. 12 Reg. 1234/2008.
192 In Germany, e.g., Sec. 29 of the Medicinal Products Act provides for an obligation to inform the competent authorities of amendments to existing medicinal products or information provided for patients in this regard and holds that certain amendments are subject to an authorization requirement. A corresponding authorisation requirement applies if the composition of the active substances either in type or quantity is changed, if there is a change in the pharmaceutical form, if the therapeutic indications are extended, and in the case of the introduction of manufacturing procedures using genetic engineering; see Art. 29 (3) Medicinal Products Act.

4.3 PLANT PROTECTION PRODUCTS

4.3.1 Introduction

Similar to medicinal products, plant protection products (PPPs) may only be placed on the market in the EU subject to an MA based on an in-depth *ex ante* assessment carried out by certain administrative state authorities. The MA procedure for PPPs is regulated in Reg. 1107/2009,[193] which has repealed Dir. 79/117/EEC and Dir. 91/414/EEC. Article 2 Reg. 1610/96 still refers to Dir. 91/414/EEC. However, Art. 83 Reg. 1107/2009 specifies that "references to the repealed Directive shall be constructed as references to this Regulation".

As is the case for MA procedures required before the launch of medicinal products, an assessment of an application for the grant of an MA for a PPP is completed on the basis of extensive documents and information to be provided by the applicant. The applicant is in particular obliged to provide, *inter alia*, test and study reports to demonstrate the safety of the respective PPP.[194] The goal of said regulation is to make sure that only such PPPs are produced and used in the EU which do not have any immediate or delayed harmful effect either on human health, on plants and plant products, on vertebrates or on the environment.[195]

4.3.2 Zonal authorisation system pursuant to Reg. 1107/2009

With the entry into force of Reg. 1107/2009 on 14 June 2011, applications for MAs for PPPs are to be assessed within a so-called zonal authorisation procedure. To this end, the EU Member States were divided into three zones:[196]

- Zone A: North (including Denmark, Estonia, Latvia, Lithuania, Finland, Sweden);
- Zone B: Centre (Belgium, Czech Republic, Germany, Ireland, Luxembourg, Hungary, the Netherlands, Austria, Poland, Romania, Slovenia, Slovak Republic, United Kingdom);
- Zone C: South (Bulgaria, Greece, Spain, France, Italy, Cyprus, Malta, Portugal).

Unlike for medicinal products, the applications cannot be assessed by a specific central European Agency with a central and unitary effect for the territory of the whole EU. Rather, MAs for PPPs are assessed and granted by individual EU Member States on behalf of other Member States in their zone and sometimes on behalf of all zones within a mutual recognition system.[197] The European Commission has, however, created an electronic management tool to support applicants and help them manage the application process. This so-called Plant Protection Product Authorisation Management System (PPPAMS) shall enable users to create applications for PPPs and submit these to the relevant Member States for evaluation. Member States then

193 Regulation (EC) N1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC, [2009] OJ L 309/1
194 Art. 7(1), 8(1) lit. b) and c) Reg. 1107/2009.
195 See Art. 4(2), (3) Reg. 1107/2009.
196 Annex I, Reg. 1107/2009.
197 See Art. 7 Reg. 1107/2009.

manage and conclude these applications within that system, granting or refusing the requested MA.[198] The first PPP MA is valid for a period of ten years.[199]

The basic procedure for authorisation of new PPPs and subsequent Mutual Recognition in other EU Member States is as follows:[200]

- An application is made to the EU country/countries where the PPP is intended to be placed on the market. A zonal Rapporteur Member State (zRMS) is selected for each zone where the PPP shall be authorised (some uses including greenhouse uses, post-harvest treatments, treatment of empty storage rooms or containers and seed treatments are assessed by a single Member State on behalf of all zones[201]);
- The zRMS carries out an assessment of the application.
- Other Member States in the same zone comment on the zRMS's evaluation.
- The zRMS makes a decision on whether to grant or refuse an authorisation.
- Other Member States make a decision to grant or refuse an authorisation.

If an authorisation is issued and later the applicant wishes to place the same product on the market in another Member State(s), an application is made for 'mutual recognition' of the product in the concerned Member State. The same principles apply in relation to an amendment of a PPP MA.[202]

198 Details on the PPPAMS available at <https://ec.europa.eu/food/plant/pesticides/authorisation_of_ppp/pppams_en> (last accessed 7 May 2017).

199 Art. 5 Reg. 1107/2009. Renewals may be granted for a period of max. 15 years: Art. 14(2) Reg. 1107/2009.

200 See <https://ec.europa.eu/food/plant/pesticides/authorisation_of_ppp/application_procedure_en>; an overview of the detailed steps of the granting procedure is further provided by the European Commission at <https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_auth-ppp_app_procedure_first_ authorisation_of_ppp_en.pdf> (last accessed 7 May 2017).

201 Art. 3 No. 17 Reg. 1107/2009.

202 See Arts. 7(1), 33(1) Reg. 1107/2009.

5 SOME NOTIONS OF EUROPEAN PATENT LAW RELEVANT TO THE ANALYSIS OF THE SPC CASE LAW

5.1 PREMISE

The purpose of this Chapter is to address some aspects of patent law that have relevance to the object of the Study. The patent-law-related aspects referred here form the basis for understanding some of the problems following the CJEU case law. They are also relevant for assessing the impact of some reform options the MPI was requested to consider, such as the manufacturing waiver.

5.2 NATIONAL AND EUROPEAN PATENTS

5.2.1 The two basic ways to get patent protection in the EU

At the moment, there are two ways to get patent protection in the EU. The first one is to file for a national patent at the national patent office (NPO). The second one is to file for a European patent at the European Patent Office (EPO).

In examining the patent application, the competent NPO applies national law, including those provisions that implement Union law, such as the Directive on the legal protection of biotechnological inventions 98/44/EC (hereinafter: Dir. 98/44[203]) or the TRIPS Agreement.[204] The EPO applies and operates on the basis of the EPC. In view of the fact that the EU is not a contracting party to the EPC, the EPC itself does not form part of the Union legal order. This holds true, as well, for the provisions of the EPC that adopt the wording of some articles of Dir. 98/44/CE.[205]

5.2.2 Examining and non-examining offices

At the national level, there are different traditions in the way the NPO examines and processes applications for patents. Some offices – so-called examining offices – perform a prior art search and a full examination of all substantive requirements. Other offices – so-called non-examining offices – do not perform a search for prior art and do not examine novelty and inventive step, but rather only assess whether the claimed subject matter is a technical invention and, if so, whether an exception to patentability applies. The EPO, like most of the NPOs within the EU, is an examining office.[206]

This difference between examining and non-examining NPOs *prima facie* appears not to have been considered by the legislators of the SPC Regulations. The SPC Regulations oblige the NPOs to examine at least two of the conditions for granting an

[203] Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions [1998] OJ L 213/13.

[204] The TRIPS Agreement is an integral part of the Union legal order. This is also true for the provisions governing patents; see Case C-6/11 *Daiichi Sankyo* [2011] ECR I-12255.

[205] See Rule 26 *et seqq* of the Implementing Regulations to the Convention on the Grant of European Patents of 5 October 1973 as adopted by decision of the Administrative Council of the European Patent Organisation of 7 December 2006 and as last amended by decision of the Administrative Council of the European Patent Organisation of 14 October 2015.

[206] See Art. 94 EPC.

SPC laid down in Art. 3 Reg. 469/2009 and Reg. 1610/96, namely the requirement that the product is protected by the basic patent and the requirement that the MA has been granted for that product.[207] The examination of these two requirements, however, did not require research and assessment of the prior art and related technical matters. This was true at least when one considers the intention of the lawmakers as anticipated by the Explanatory Memorandum.[208] The case law of the CJEU has partly changed this.[209]

As regards the territorial reach, NPOs can only grant national patents, whose legal effect is limited to the territory of the country granting them, unless a bilateral agreement signed with other countries provides for a broader reach or automatic mutual recognition.[210] By contrast, the EPO grants a European patent that has effect in each contracting state designated in the European patent application. The legal effect of a European patent within the respective designated contracting state is subject to the applicable national law, unless otherwise provided in the EPC. It must be noted in this respect that European patents in the post-grant phase cannot be entirely assimilated as national patents, i.e. they do not have the status of purely national rights which are entirely subject to national law. They rather maintain their nature as European patents and enjoy normative autonomy from national patents. Indeed, according to Art. 2(2) EPC, a European patent shall, in each of the contracting states for which it is granted, have the effect of and be subject to the same conditions as a national patent granted by that state, *unless the EPC provides otherwise*. The EPC provides otherwise for the most important aspects of the patent. It adopts uniform provisions with regard to the invalidity grounds,[211] the extent of protection,[212] the effect of a process claim[213] and the binding version of the patent.[214] Consequently, in national proceedings concerning the infringement or the validity of a European patent, the national courts must apply these uniform provisions of the EPC rather than the corresponding provisions of the national patent acts.

5.2.3 Substantive aspects

Even though there are two ways to obtain patent protection in the EU, the substantive provisions governing national patents, on the one hand, and the substantive provisions governing European patents, on the other hand, have mostly identical wording. The reasons for this convergence of national patent laws and the EPC are complex. Historically, they all go back to the conventions stipulated in 1970 by the European States.[215] For an analysis of the SPC legislation and case law it is important, but at the same time sufficient, to point out the following in this regard:

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207 See Art. 10(2) and Art. 10(5) Reg. 469/2009 and Reg. 1610/96.

208 See European Commission, Explanatory Memorandum to the Proposal for a Council Regulation (EEC), of 11 April 1990, concerning the creation of a supplementary protection certificate for medicinal products (COM(90) 101 final – SYN255), para. 16.

209 See Chapter 10, Section 10.2.3.2 (c) and Chapter 11, Section 11.3.1.6 (c) of this Study.

210 As an example of a corresponding bilateral agreement, see Art. 43 of the Convenzione di amicizia e buon vicinato tra l'Italia e San Marino, WIPO, http://www.wipo.int/wipolex/en/other_treaties/details.jsp?treaty_id=836 (last accessed 18 August 2016).

211 Art. 138 EPC.

212 Art. 69 EPC.

213 Art. 64(2) EPC.

214 Art. 70 EPC.

215 Convention on the Unification of Certain Points of Substantive Law on Patents for Invention of 27 November 1963, ETS 47 – Unification Law of Patents; Council Convention 76/76/EEC for the European Patent for the Common Market of 15 December 1975 (Community Patent Convention) [1976] OJ L

- The requirements for protection provided in European and national patent law are identical. The wording of these provisions is taken from the Strasbourg Convention[216] which was subsequently incorporated in the EPC.
- The scope of protection of national and European patents is also governed by provisions with identical wording in all Member States. These provisions are aligned with Art. 69 EPC and Art. 8 of the Strasbourg Convention.
- The right to prevent the direct use of an invention is governed by provisions aligned in all EU States with Art. 28 TRIPS and Art. 27 Convention for the European patent for the common market (CPC).[217]
- The requirements under which a European patent may be amended and limited are identical in Europe, since they are governed by Art. 105a, Art. 138 and Art. 123 EPC. Furthermore, most of the EU Member States have incorporated in their national law provisions whose wording is identical to Art. 123 EPC and that apply to the limitation of national patents in *ex parte* or *inter partes* proceedings.

As a consequence, for the purposes of SPC legislation, reference to national or European patent law, at least as far as the rules governing the extent of protection or infringing acts are concerned, would not imply that diverging provisions would apply to the SPC.

5.3 SUBJECT MATTER ELIGIBLE FOR PROTECTION

All laws on registered or unregistered industrial property rights require and do in fact contain a set of provisions that define the subject matter that is in principle eligible for protection.[218] The subject matter that is in principle patentable is laid down in Art. 52 EPC and the corresponding provisions of the national patent acts implementing Art. 27 TRIPS. All these provisions state that only "*inventions in the field of technology*", i.e. technical inventions, are patentable.

In view of an SPC's nature as a *sui generis* IP right, a set of provisions to define the subject matter eligible for protection by a certificate was equally needed. This set of provisions is spelled out under Arts. 1 and 2 of the SPC Regulations. According to these provisions, the subject matter eligible for protection by SPCs is a product for which an MA granted under Dir. 2001/82 and Dir. 2001/83 or under Dir. 91/414 (now: Reg. 1107/2009) is required to place it on the market. The product in this regard is the relevant active ingredient of a medicinal product (Art. 1(b) Reg. 469/2009) or active substance of a plant protection product (Art. 1(3) Reg. 1610/96).

17/1; Convention on the Grant of European Patents (European Patent Convention) of 5 October 1973 [1974] 13 International Legal Matters 268

216 Convention on the Unification of Certain Points of Substantive Law on Patents for Invention of 27 November 1963, ETS 47 – Unification Law of Patents ; see in particular Arts. 3 and 4 of the Strasbourg Convention. These provisions regulate the content of the prior art citable against the patent, the requirements of novelty, inventive step and industrial applicability.

217 Council Convention 76/76/EEC for the European Patent for the Common Market of 15 December 1975 [1976] OJ L 17/1.

218 With regard to trademark law, this function is fulfilled by Art. 4 Council Regulation (EC) No 207/2009 of 26 February 2009 on the Community trade mark [2009] OJ L 78/1. In design law the pertinent provision is formulated in Art. 3(a) Council Regulation (EC) No 6/2002 of 12 December 2001 on Community designs [2002] OJ L 3/1. In relation to plant varieties, Art. 5(1) Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights [1994] OJ L 227/1 has to be applied in this regard (Regulation on Community plant variety rights).

5.4 REQUIREMENTS FOR PROTECTION

In order to be *in concreto* eligible for protection as a patent, a technical invention must be novel, inventive and industrially applicable.[219] These conditions are set out in Arts. 54 to 57 EPC. As already mentioned, identical conditions apply to national patents in all EPC contracting states.[220] In relation to SPCs, the conditions for granting a valid title of protection are set out in Art. 3 of the SPC Regulations.

5.5 EXCEPTION FOR MEDICAL METHODS. FIRST AND FURTHER MEDICAL INDICATIONS

European patent law excludes medical methods from patent protection. The purpose of such exclusion is to protect the freedom of medical doctors to choose the therapy or surgery that better fits the needs of the patient. Article 53(c) EPC reads as follows:[221]

> European patents shall not be granted in respect of:
> (…)
> (c) methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods.

As the second sentence of said provision states, products that are used in any of the medical methods excluded can be the subject of a patent. Products in this regard can be chemical substances, biological materials, medical devices and other instruments.

To be eligible for patent protection, such products must be novel and inventive; in this case a product claim will be possible. However, if the respective compound or device is known, a product claim directed to them will not be possible, even if the applicant has disclosed a new and inventive method for using them. Indeed, a new use does not confer novelty to a known item under European patent law. Therefore, if the patent application has disclosed a new and inventive method for using such products for a therapeutic or diagnostic purpose, a corresponding use claim directed to such subject matter would clash with the exclusion from patentability for medical methods under Art. 53 EPC.

However, in relation to substances the rules concerning second and further medical indications as set out in Art. 54(4) and (5) EPC may provide for the patentability of pharmaceutical uses of such substances.[222] Indeed, Art. 54 EPC reads as follows:

> (1) An invention shall be considered to be new if it does not form part of the state of the art.
> (2) The state of the art shall be held to comprise everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application.
> (3) Additionally, the content of European patent applications as filed, the dates of filing of which are prior to the date referred to in paragraph 2 and which were published on or after that date, shall be considered as comprised in the state of the art.
> (4) Paragraphs 2 and 3 shall not exclude the patentability of any substance or composition, comprised in the state of the art, for use in a method referred to in Article 53(c), provided that its use for any such method is not comprised in the state of the art.

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219 In this regard, see in particular Arts. 54-57 EPC. These requirements for protection are mentioned by Art. 27 TRIPS and had already been harmonised previously in Europe by the Strasbourg Convention.
220 See Section 5.2.3 in this Chapter and accompanying footnotes.
221 The national patent laws of EU Member States provide for a similar exception to patentability.
222 Corresponding provisions may be found in all national patent acts; see Annex I of this Study.

> (5) Paragraphs 2 and 3 shall also not exclude the patentability of any substance or composition referred to in paragraph 4 for any specific use in a method referred to in Article 53(c), provided that such use is not comprised in the state of the art.

Consequently, the substance and the composition, even if known, are considered patentable as such, if the patent application discloses a use of such substance or composition for one of the methods referred to in Art. 53(c) EPC and such use is not comprised in the state of the art and is not made obvious by said prior art. However, in this case the patent may only be granted in respect of the use of the substance or composition for the purpose of the methods excluded from patent protection under Art. 53(c) EPC. European patent law allows the drafting of a product claim directed to the substance where – if the exclusion for medical methods were not to apply – only a use claim would be possible, but the allowed patent claim is purpose-bound. That is, the substance is only protected with regard to the medical uses. This means that *vice versa* the use of such a known substance for other purposes is not protected by the patent.

Article 54(4) and (5) EPC in this regard differentiate between the first medical use and further medical uses of the known substance. As regards the first medical indication, the substance can be protected with respect to all uses in a method referred to in Art. 53(c) and Art. 54(4) EPC. As for further medical uses, the substance can be protected only for the *specific use* in a method referred to in Art. 53(c) EPC disclosed in the patent. In practice, this allows for first-medical-use claims structured as follows:

> "Pharmaceutical product comprising the compound Y" or "compound Y for use as a pharmaceutical"

Further-medical-use claims must, by contrast, be limited to the specific use and can be worded for example as follows:

> "Compound Y as a diuretic" or "use of compound Y as a diuretic"

The following additional three remarks are relevant for the further analysis of this Study:

First, the concept of a second medical indication as patentable subject matter is not limited to inventions that teach how to use the known compound for treating a different disease from the disease(s) already identified in the prior art. By contrast, the EPO allows for claims where the only new feature of the use claimed is a new dosage, a new regimen for administration or a new subgroup of patients that can be treated with the compound.[223]

Second, since the wording of Art. 54(4) and (5) EPC allows for protection of the second and further medical indication of *substances* or *compositions* only, while Art. 53(c) EPC refers to products, it is established case law that medical devices cannot benefit from the legal fiction provided in Art. 54(5) EPC. Accordingly, the use of a known medical device for a new therapeutic, surgical, or diagnostic purpose, even if inventive, is not eligible for protection if such use implies a direct interaction with the human body. However, the case law makes an exception to this principle when the medical devices claimed are implantable and are used for the administration of a therapeutic compound. In this case the EPO applies Art. 54(5) EPC to the respective

[223] See EPO (ed), *Case Law of the Boards of Appeal of the European Patent Office* (8th edn, 2016) p. 141 et seqq.

medical device and allows for a second-medical-use claim.[224] As we will see, this distinction could also become relevant to SPC law.[225]

Third, some of the claims recently admitted for second medical indications can only be *directly* infringed by medical doctors. This is true for patent claims covering a specific regime of administration of a certain pharmaceutical. The Board of Appeal of the EPO has excluded that corresponding patents could limit the freedom of physicians or nurses, because it has assumed that the national laws of EPC contracting states have a provision or a doctrine that protects doctors from being sued for infringement when they prescribe or administer a compound in the course of a therapy for a patented indication.[226] At the moment, however, the national laws of the EU Member States do not provide for a corresponding exemption or defence.[227] The same holds true for the UPCA.

5.6 DISCLOSURE: TWO CONCEPTS UNDER EUROPEAN LAW

With respect to the interpretation of Art. 3(a) Reg. 469/2009, the literature and case law sometimes refer to a so-called disclosure theory[228] as an alternative to an infringement test.[229] However, the term "disclosure" is ambiguous in this context. Indeed, two different concepts or standards of disclosure exist in European law.

5.6.1 The concept of disclosure under Art. 83 EPC

A first standard of disclosure has been developed with respect to Art. 83 EPC.[230] According to this provision, a European patent application shall disclose the invention in a manner that is sufficiently clear and complete for it to be carried out by a person skilled in the art. The purpose of this provision is to ensure that the patent is granted in return for disclosure of new technical knowledge and the scope of the patent is proportionate to such disclosure. The provision does not have the consequence, however, that the applicant is prevented, in drafting the claim, from generalising the technical teaching that it has developed to ensure adequate protection. Patent claims may cover many embodiments of the invention that are not mentioned in the original patent application. Under European patent law, a patent claim may include functional features that "may generically embrace the use of unknown or not yet envisaged possibilities, including specific variants which might be provided or invented in the

224 Markus Meyer et al, 'Patentability of Known Medical Devices with a New Medical Use – Case Law of the European Patent Office' [2016] GRUR Int. 109.

225 See Chapter 18, Section 18.6.

226 EPO, Case T 1020/03 *Method of administration of IGF-I/GENENTECH INC*. [2004] ECLI:EP:BA:2004: T102003.20041029, Reasons for decision No. 16.

227 A proposal for exempting doctors from infringement for acts committed during the treatment of a specific person or animal, for instance prescribing a pharmaceutical product for an indication covered by a patent, is currently being discussed in Switzerland, see Felix Addor, Christine Vetter, 'Der Schutz der medizinischen Behandlungsfreiheit vor patentrechtlichen Verletzungsklagen' [2014] sic! Zeitschrift für Immaterialgüter-, Informations- und Wettbewerbsrecht 245-250.

228 See for instance Christopher Brückner, *Supplementary Protection Certificates with Paediatric Extension of Duration* (2nd edn, Heymanns 2015).

229 See Chapter 10, Section 10.2.4.2.

230 It should be noted that provisions with identical wording exist in the patent acts of all EU Member States; see e.g. Sec. 34(4) of the German Patent Act as published on 16 December 1980 (Federal Law Gazette 1981 I p. 1), as last amended by Article 2 of the Act of 4 April 2016 (Federal Law Gazette I p. 558).

future". It is sufficient for satisfying Art. 83 EPC that the person skilled in the art can perform the invention in the claimed scope without undue effort.[231]

The following examples clarify the implications of this approach:

- If a patent discloses a new class of receptors, a claim directed to agonists that are able to bind on the cloned receptors can include agonists that were never identified by the applicant at the priority date and still be considered valid under European law.
- If the claim discloses a new class of proteins, and a claim is directed to antibodies that may bind to this protein, even if the patent specification does not disclose all the variants of antibodies covered by the claim or does not even disclose a single example of such an antibody, the patent claim can still be considered valid if a person skilled in the art can obtain such an antibody without undue effort.
- If the patent discloses a new class of compounds, it is possible to draft a claim including several variants and sub-alternatives, even if a significant number of potential members of this group of compounds were not mentioned in the application as filed and may even be the subject of subsequent patent applications, provided that a person skilled in the art, at the priority date of the patent, could work the invention without undue effort across the claimed scope on the basis of the information included in the application as filed and common general knowledge.

5.6.2 The concept of disclosure under Arts. 87, 123(2), 54 EPC

Contrary to Art. 83 EPC, a stricter disclosure standard applies pursuant to Art. 87 EPC, Art. 123(2) EPC and Art. 54 EPC. This uniform standard has been defined by the Enlarged Board of Appeal (EBA) with respect to Art. 123(2) EPC in the following terms:[232]

> "the test to be applied is whether the skilled person would, using common general knowledge, regard the remaining claimed subject-matter as explicitly or implicitly, but directly and unambiguously, disclosed in the application as filed".

To satisfy this standard an individual disclosure of the chemical compound is necessary. So, as already mentioned, a single claim comprising many alternative compounds that share a specific structure, i.e. a so-called "*Markush claim*",[233] can still be sufficient under Art. 83 EPC, even if only some of the compounds claimed are mentioned in the application, if a person skilled in the art can work the invention across the whole claimed scope without undue effort. However, this does not imply that all compounds covered by such claims are to be considered anticipated under Art.

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231 This interpretation is also one of the reasons why a so-called selection invention or a dependent invention may be patentable and still be covered by an older priority (and valid) patent. A selection invention is a technical teaching that selects individual elements, sub-sets, or sub-ranges, which have not been explicitly mentioned, within a larger known set or range that can also be the subject of a previous patent or patent application or publication, EPO, Guidelines for Examination, Part G, Chapter VI, No. 8. In such cases, the disclosure of a correspondingly selected embodiment together with unexpected advantages can then turn out to be novel and inventive, even if the previous patent covering such embodiment is sufficient and valid under Art. 83 EPC. The requirements for a selection invention to be patentable are quite complex and depend on the circumstances of the individual case. For details, see EPO, Guidelines for Examination, Part G, Chapter VI, No. 8.

232 See EPO, Case G 0002/10 *Disclaimer/SCRIPPS* [2011] ECLI:EP:BA:2011:G000210.20110830.

233 A typical Markush claim recites alternatives in a format such as e.g. "selected from the group consisting of A, B and C".

54 EPC and, if claimed in a subsequent application, shall be considered as comprised in the state of art. Furthermore, it does not imply that the patentee could limit the independent claim of the patent application to each of the compounds covered by the *Markush* claim without infringing Art. 123(2) EPC. Indeed, to consider a specific compound anticipated by said patent application (if claimed in a later application) or to consider it admissible to limit a patent claim of said patent application to one specific compound covered by the *Markush* formula it is necessary that a person skilled in the art could derive the compound in question directly and unambiguously, even if implicitly, from the application as filed. To assess this standard the concept of *individualized disclosure or description*[234] or *disclosure or description in individualized form* is sometimes used,[235] a terminology that has also been adopted and discussed in the SPC case law.

5.6.3 "Disclosure test" under SPC Regulations

When in connection with SPCs the literature refers to a disclosure test or something similar with respect to national case law (*Takeda*[236]) or CJEU case law (*Medeva*[237]), this terminology causes two problems. On the one hand, it is not clear whether the concept of disclosure under Art. 83 EPC, the concept of disclosure that applies to Arts. 87, 123(2), 54 EPC or a third, SPC-specific concept is intended. On the other hand, disclosure is a term that in patent law refers to the whole content of the patent and not to a specific claim.[238]

5.7 SCOPE OF PROTECTION AND RIGHTS CONFERRED BY THE PATENTS

5.7.1 Extent-of-protection rules versus infringing-act rules

All intellectual property right systems need a set of rules that define, first, what is protected and, second, which acts related to this subject matter can be prohibited. With respect to patents, the rules answering the question of what is protected are incorporated in Art. 69 EPC and corresponding provisions of the national patent acts. All such provisions adopted the wording of Art. 8 Strasbourg Convention.

The question of how the subject matter is protected, i.e. which acts may be prohibited (using, manufacturing, offering for sale, etc.), is answered by the provisions implementing Art. 28 TRIPS in national law.[239] These national provisions also apply to European patents pursuant to Art. 64(3) EPC.[240]

234 See *Dr Reddy's Laboratories (UK) Ltd v Eli Lilly & Co Ltd* [2009] EWCA Civ 1362 [2010] RPC 9.
235 See EPO (ed), *Case Law of the Boards of Appeal of the European Patent Office*(8th edn, 2016) pp. 125-127; EPO, Case T 296/87 *Enantiomers* [1988] ECLI:EP:BA:1988:T029687.19880830, Reasons for decision No. 6.1.
236 See Chapter 10, Section 10.2.4.2 (iii).
237 Case C-322/10 *Medeva* [2011] ECR I-12051.
238 See on these issues Chapter 10, Section 10.2.4.
239 In UK law this provision is Section 60 Patent Act, in German law Section 14 PatG, in Italian law Art. 66 it. CPI.
240 A significant exception applies with regard to the right conferred by a process claim. In this regard, Art. 64(2) EPC stipulates that when the subject matter of a European patent is a process, the protection conferred by the patent shall also extend to the products directly obtained by such process.

The distinction between these two sets of rules was drawn very clearly in Opinion G2/88 of the Enlarged Board of Appeal of the EPO with the following explanations:[241]

> "As touched upon previously in paragraph 2.5 above, the protection conferred by a patent is to be determined by interpretation of the terms of the claims, and the rights of the patent proprietor flow from the protection which is conferred. There is a clear distinction between the protection which is conferred and the rights which are conferred by a European patent, however. The protection conferred by a patent is determined by the terms of the claims (Article 69 (1) EPC), and in particular by the categories of such claims and their technical features. In this connection, Article 69 EPC and its Protocol are to be applied, both in proceedings before the EPO and in proceedings within the Contracting States, whenever it is necessary to determine the protection which is conferred. In contrast, the rights conferred on the proprietor of a European patent (Article 64(1) EPC) are the legal rights which the law of a designated Contracting State may confer upon the proprietor, for example, as regards what acts of third parties constitute infringement of the patent, and as regards the remedies which are available in respect of any infringement."

Justice Arnold has called the provisions governing the scope of protection "extension of protection" rules and the provisions governing the right conferred by the patent "infringing act" rules.[242] We will adopt this terminology within this Study for the sake of clarity.

As regards the relevance to SPCs, two points are to be noted in this section. Both concern the case law related to Art. 3(a) SPC Regulations. First, the CJEU pointed out that the law of infringement – including the "extension of protection rules" as well as the "infringing act rules" – is not harmonised in Europe. However, as already mentioned, this statement requires some clarification.

As far as the rules defining the extent of protection of patents are concerned, such rules are identical in all EU Member States. Article 69 EPC applies to all European patents; provisions with identical wording and implementing Art. 8(3) Strasbourg Convention apply to national patents. However, these provisions are not part of the Union legal order. Therefore, it is accurate to state that such provisions are harmonised, but not on the basis of EU rules.

Regarding the "infringing act rules", these provisions are equally identical in Europe, since national law has adopted the wording of Art. 28 TRIPS. The latter provision is an integral part of the Union legal order, and as such even subject to the interpretative jurisdiction of the CJEU.[243] Therefore, in this regard, it is accurate to state that such provisions are harmonised and that this harmonisation is based on EU rules.

Second, and again in relation to Art. 3(a) SPC Regulations, the CJEU has introduced a distinction between products specified in the claim of the basic patent and products *not* specified in the claim of the basic patent.[244] Now, if we consider the rules on the extent of protection as set out in Art. 69 EPC and corresponding national provisions, such provisions allow for the following three distinctions:

- between a product that falls under the extent of protection of the basic patent and a product that does not fall under the extent of protection of the basic patent;
- between a product that is literally infringing and a product that is infringing under the doctrine of equivalence; this distinction has a normative basis in the

241 EPO, Case G2/88 *Friction reducing additive* [1993] ECLI:EP:BA:1989:G000288.19891211.
242 *Teva UK Ltd. et al v Gilead Sciences Inc.* [2017] EWHC 13 (pat), para. 35 et seqq.
243 Case C-6/11 *Daiichi Sankyo* [2011] ECR I-12255.
244 For details in this regard see Chapter 10, Section 10.2.4.2 (b).

EPC, and more precisely in Art. 2 of the Protocol on the interpretation of Art. 69 EPC[245] according to which the national courts, in determining the scope of protection of a European patent, must take account of any element that is equivalent to an element *specified* in the claim;

- between a product that infringes the basic patent and is individually disclosed in the patent, so that the patent could be limited to such product, and a product that infringes the patent, but is not individually disclosed in the patent.[246]

The distinctions may be deduced from the provisions of the EPC and national patent acts and may be based on such provisions. A distinction between a product that is specified and a product that is not specified in the patent claims of the basic patent has no basis in Art. 69 EPC or any other provisions of the EPC, unless one of the former three distinctions is meant. Still, the EU legislature is free to establish and provide for autonomous legal requirements for granting SPCs which may not be in line with the law applicable to the basic patent.

5.7.2 Domestic production of a compound for sale after the patent has expired or for export to patent-free countries – "Manufacturing Waiver"

A further topic to be dealt with in this Study is the so-called manufacturing waiver.

If the basic patent concerns a substance as such, it confers upon its owner absolute product protection. This means that the manufacture of the corresponding substance infringes the patent directly whatever the purpose for which the substance shall be sold and used. Whether the patented substance is then packaged to be sold within or outside the territory of protection of the patent does not matter. Therefore, the production of patented substances to sell them after the patent has expired[247] or to export them to foreign patent-free countries[248] amounts to an infringing act. The same holds true if the patent concerns a method for manufacturing the substance, since the patent in this case confers a derivative absolute product protection.[249]

The situation is less clear with respect to claims for the first or second medical use of a known compound as provided for in Art. 54(4) and (5) EPC. Such claims confer a purpose-bound product protection.

In the case of the first medical indication (Art. 54(4) EPC), the relative patent claim protects the substance for *any pharmaceutical use*. In the case of a patent claim for a second medical indication, according to Art. 54(5) EPC, the claim protects the specific use of the substance only. The patent claim is thus directly infringed only when in the territory of protection the alleged infringer uses the patented technical teaching as

[245] See Protocol on the Interpretation of Art. 69 EPC of 5 October 1973, as revised by the Act revising the EPC of 29 November 2000, OJ EPO 2001, Special edition No. 4, p. 55.

[246] In case of a compound that infringes a patent claim and is individually disclosed in the patent, the granted patent may be limited to that embodiment in line with Art. 123(2) and (3) EPC. In case of a compound that infringes the claim, but is not individually disclosed or mentioned in the original content of the patent application, such limitation would extend the content of the patent beyond the content of the original patent application. It may be consistent with Art. 123(3) EPC, but it would violate Art. 123(2) EPC.

[247] See BGH, *Simvastatin,* X ZR 76/05 [2007] GRUR 221.

[248] For Germany, see Georg Benkard, *Patentgesetz* (11th edn, Beck 2015) sec. 9 para. 11.

[249] See Art. 28 TRIPS.

recited in the claim. If the use for the purpose indicated in the patent claim occurs outside the territory of protection of the respective patent, then it seems difficult to assume that such activity constitutes an infringement of the respective patent.

In this regard it is necessary to distinguish among (i) the mere production of the active ingredient for export, (ii) the production plus the formulation of the active ingredient in a medicinal product, and (iii) the production of the substance, its formulation in a medicinal product and the application of a label that is, however, directed to a foreign market in which the medicinal product shall be exported.

In Germany, the case law assumes that infringement of a second medical indication only exists when there was a manifest preparation of the substance (*sinnfällige* or *augenfällige Herrichtung*) for the patented use. The mere production of the active ingredient does not represent an infringement of the patent.[250] A manifest preparation, in the case of second medical indications, exists when "the composition is manifestly prepared for the therapeutic application protected, for example as a result of formulation, manufacture, dosage, outer packaging or instructions for use accompanying the product".[251] This could imply that an infringement shall be denied in the case that a competitor only manufactures the active ingredient in the country of protection and export it abroad, in a patent-free jurisdiction. The last example (iii), namely the production of the substance, its formulation in a medicinal product and the application of a label for export, could by contrast amount to an infringement, even if the labelling is directed to the law of the country in which the product must be exported and is different from the labelling requested for the country of production for which the asserted patent is in force.

As regards first medical indications, to the best of our knowledge there is no published case law. In our view, in this case an infringement would exist if there is a manifest preparation of the substance for *any* medical use. Whether this medical use occurs in the territory for which the patent is in force or abroad is not relevant, as far as the alleged infringer manufactured in the country of protection a medicinal product including the active ingredient. However, the mere production of the bulk substance, without manifestly preparing it for a medicinal purpose, does not infringe upon the patent for the first medical indication.

The above considerations are relevant in the context of SPCs. Pursuant to Art. 4 Reg. 469/2009, SPCs only cover the pharmaceutical uses authorised in the country that granted the SPC. This is also true when the basic patent covers a substance as such and confers absolute protection. Therefore, the protection conferred by an SPC issued on the basis of a product patent that covers the active ingredient as such[252] is broader than the protection granted by a second-medical-use patent, but narrower than the protection granted by a first-medical-use patent.

The protection is broader than a second-medical-use patent, because the latter covers only the specific use claimed by the patent, while the SPC covers all uses that are authorised with respect to the substance in the territory of the Member State concerned before the expiration date of the certificate.

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250 See Hubertus Schacht, *Therapiefreiheit und Patentschutz für die weitere medizinische Indikation* (Nomos 2014) p. 297 for further references.

251 Thomas Kühnen, *Patent Litigation Proceedings in Germany* (7th edn, Heymanns 2015), para. 268.

252 That is a patent that confers an absolute product protection, because it includes a claim directed to the substance as such without indicating any purpose.

The protection conferred by the SPC is narrower than the protection conferred by a first-medical-indication patent, because the latter covers all medical uses, whether authorised or not in the country in which the patent is in force, while the SPC covers only the uses authorised in the granting EU Member State.

Against this background, different outcomes in assessing whether a specific activity infringes an SPC or a patent for the first or second medical indication are possible. The following scenarios deserve consideration:

> **Scenario I**: Company X manufactures the raw compound that is subject to a European MA and SPCs in Europe for *indication A*, and exports this compound to the US where it is formulated for the same *indication A*.
> **Scenario II**: Company X manufactures a final formulation of a medicinal product that in Europe is subject to SPCs and a European MA for *indication A*; such compound will then be packaged in the US for the US market for *indication A*.
> **Scenario III**: Company X manufactures a final product (including the active ingredient covered by SPCs in Europe) for *indication A*, which is authorised in the US; the only authorised use in Europe is for *indication B*.

Scenario I was considered in two national proceedings, one before Belgian courts and the other before Italian courts.

In the Belgian proceeding,[253] the plaintiff was the holder of a basic patent covering the active ingredient vinorelbine ditartrate which was authorised in Belgium for use against cancer. The active ingredient was protected by an SPC. The defendant had manufactured vinorelbine ditartrate in Belgium in its raw form to export to the US, where the compound was used for producing a final medicinal product for the same indication authorised in Europe and protected by the SPC. The defendant argued that manufacturing the raw compound for export could not infringe the SPC. The latter covered only the use of the active ingredient as a medicinal product. The plaintiff argued by contrast that the only purpose of the expression "for any use of the product as a medicinal product" is to prevent that use of the compound in sectors other than the pharmaceutical one remains subject to the monopoly extended by the SPC. Further, the plaintiff invoked Reg. 816/2006 for support.[254] According to the interpretation of the plaintiff, Reg. 816/2006 also requires an authorisation for the export of the active ingredient as a raw compound, which implies that such manufacturing and export would infringe upon the supplementary certificate. The Tribunal of Brussels concluded that the certificate was infringed by manufacturing the raw compound for export to a country where the compound would be used for preparing medicine for the same indication authorised in Belgium.

In the Italian proceedings, the plaintiff was a competitor of the certificate holder. It initiated an action before the Tribunal of Milan directed to obtaining a declaration of non-infringement with respect to the active ingredient fluvoxamine maleate.[255] Fluvoxamine maleate was the active ingredient of the medicine Dumirox, which was authorised in Italy for treating depressive disorders. Based on such authorisation, a national certificate was granted under Law No 349 of 19 October 1991 and Art. 4*bis* of

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253 [2009] 31(6) EIPR, N41-42. See also the report in SPC Blog, 'Belgian SPC case', available at http://thespcblog.blogspot.de/2009/02/belgian-spc-case.html (last accessed 1 September 2017).

254 Regulation (EC) No 816/2006 of the European Parliament and of the Council of 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems [2006] OJ L 257/1.

255 Tribunal of Milan, Decision of 17 September 1998, Giurisprudenza annotata di diritto industriale 1999, No. 3945, p. 622 et seqq., *Vis Farmaceutici – Istituto Scientifico delle Venezie S.p.A. v Duphar International Research BV.*

the Italian Patent Act in force at that time. The proposed activity, which should be the subject of the declaration, consisted in:

(i) manufacturing in Italy the raw active ingredient fluvoxamine maleate for exporting it to the US and other third countries, where no patents were in force, and

(ii) supplying it to pharmaceutical companies that would have used the bulk active ingredients to manufacture a medicinal product for sale in those patent-free countries.

The plaintiff maintained that such activities would not have infringed the national certificate for two reasons. First, the national certificate – unlike the basic patent – does not cover the substance as such, but only the specific medicinal product (the formulation) covered by the marketing authorisation, that is, the use of the substance for the medicinal purposes covered by the authorisation. Second, the manufacture of the substance for export to countries where no patent protection exists does not amount to an infringement of the exclusivity rights following from the certificate.

The Tribunal of Milan did not agree with these arguments and found the proposed activity infringing on the basis of the assumption that

(i) the national certificate shall confer the same rights as the basic patent: since the patent on the substance confers the right to exclude others from the domestic manufacturing of the substance, even if the use shall take place abroad, the same conclusion shall be valid for the certificate;

(ii) the certificate covers the active ingredient and not just the specific formulation covered by the MA;

(iii) national law shall be interpreted in accordance with Reg. 1768/92, and the certificates granted under the Medicinal Product Regulation confer the right to oppose the production for export of the bulk active ingredient.[256]

The Court of Appeal of Milan,[257] by contrast, considered that is was not clear whether a certificate grants the right to prevent a competitor from manufacturing the raw active ingredient in the country of protection if the manufactured raw materials (bulk active ingredients) would then only be exported without affecting the market with respect to which the certificate was granted. Further, it was of the opinion that Reg. 1768/92 also did not provide a clear answer to this question. Since the Court of Appeal considered itself bound to follow an interpretation of domestic law consistent with Art. 4 Reg. 1768/92, it referred the following question to the CJEU:

> "Va rimessa alla Corte di Giustizia CE ai sensi dell´art. 234 CE l´interpretazione pregiudiziale dell´art. 4 del Regolamento n. 92768/CE per stabilire se l´ambito di protezione del certificato protettivo complementare istituto da tale Regolamento comprende anche la sola produzione della

[256] Tribunal of Milan, Decision of 17 September 1998, Giurisprudenza annotata di diritto industriale 1999, No. 3945, p. 622 et seqq., *Vis Farmaceutici – Istituto Scientifico delle Venezie S.p.A. v Duphar International Research BV.*

[257] Court of Appeal of Milan, Referral order of 23 November 2000, Giurisprudenza annotata di diritto industriale 2000, p. 490 et seqq., *Vis Farmaceutici – Istituto Scientifico delle Venezie S.p.A. v Duphar International Research BV.*

> materia prima con la quale e´ preparato il prodotto che costituisce la specialità medicinale dell´autorizzazione all´immissione in commercio."[258]

In free translation, the Court of Appeal asked the CJEU to answer the question whether the scope of protection of the certificate also includes the mere production of the raw material – that is, the bulk active ingredient – with which the medicinal product that is subject to marketing authorisation is then manufactured.

In commenting on the referral, the Italian journal "*Giurisprudenza annotata di diritto industriale*"[259] noted that the main element of uncertainty in the case concerned, even if it was not expressly addressed by the Court of Appeal, was the fact that the manufacture of the API was solely intended for export, while the use of the active ingredient to manufacture a medicinal product would occur abroad, in a patent-free country. Since such activity was not subject to the requirement of an MA and did not represent one of the activities that the patentees could not carry out before obtaining said MA, which constitute the reasons for introducing national certificates, it could be argued that such activity indeed infringes the basic (product) patent, but does not infringe the national certificate, since the protection conferred by the latter for the active ingredient – unlike the protection conferred by the basic patent – was limited to medicinal uses of the active ingredient. Such medicinal uses, in the case *sub judice*, would occur abroad.

Unfortunately (for our analysis) the CJEU did not answer the question referred by the Court of Appeal of Milan. The CJEU had no reason to assume that the referring court, by applying national law to the national certificate, would be bound to follow the interpretation of Art. 4 Reg. 1768/92 that the CJEU may have adopted.[260] Therefore, it declared the referall inadmissible.

We have not found any case law for the other scenarios. However, some detailed comments are provided by the Handbook drafted by Thomas Kühnen, Presiding Judge of the Second Civil Senate of the Düsseldorf Higher Regional Court. We report the English translation of a relevant fragment of the Handbook:

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[258] The translation of the referred question published in OJ C 61 from 24 February 2001, p. 3, reads as follows: "Must Article 4 of Regulation No 1768/92 (1) be interpreted as meaning that the scope of protection of the supplementary certificate extends only to manufacture of the raw material from which is prepared the product which constitutes the medicinal product covered by the marketing authorisation?" However, the question of the court was not whether the SPC only extends to manufacture of the raw material, but whether the SPC *also* extends to the *mere* manufacture of the raw material. In this regard, the German translation of the referral seems more accurate ("Ist Artikel 4 der Verordnung (EWG) Nr. 1768/92 (1) dahin auszulegen, dass sich der Schutz des ergänzenden Schutzzertifikats *auch auf die bloße Herstellung* des Grundstoffs erstreckt, mit dem das Erzeugnis zubereitet wird, das die Arzneispezialität darstellt, für die die Genehmigung für das Inverkehrbringen erteilt wurde?") (Emphasis added).

[259] See Giurisprudenza annotata di diritto industriale 1999, No. 4252, pp. 495-496. This journal has the policy of not imputing to a specific author the notes and the comments published together with judgments or decisions.

[260] The CJEU oberserved that according to Art. 20 Reg. 1768/92 "the Regulation shall not apply to certificates granted in accordance with the national legislation of a Member State before the date on which this Regulation enters into force or to applications for a certificate filed in accordance with that legislation before the date of publication of this Regulation in the Official Journal of the European Communities". Further, the national law applicable in the referral proceedings did not make any reference to Reg. 1768/92 in consequence of which the latter Regulation could apply in the proceedings concerning the national certificate. As a consequence, the national court would have been bound by the preliminary ruling of the CJEU, since Art. 4 Reg. 1768/92 was not directly applicable to the proceedings pending before said Court, either directly or in consequence of a reference laid down in the applicable domestic law. See Order of the Court of 26 April 2002 in Case C-454/00, *VIS Farmaceutici Istituto scientifico delle Venezie SpA v Duphar International Research BV* [2002] OJ C 191, p. 13.

> "Rather more theoretical in nature is the scenario in which the product produced in Germany cannot be clearly identified as a medicinal agent from its constitution or can be identified as a medicinal agent but could just as easily be used for a licensed indication as for an unlicensed indication abroad. Under such circumstances, it is up to the plaintiff to present strong evidence of the medical connection of production in Germany according to the licence as is required under Art 4 of Regulation (EC) No 469/2009. If any doubt exists, evidence can be based on statements made in delivery documents provided by the German producer or on the actual use of the unspecific product abroad. Indication may be given here by the end products sold there and their instructions for use (medical product for … or a cleaning agent?), but if applicable also simply the area of business in which the recipient of the product operates (buying and selling pharmaceutical products or cleaning materials)."[261]

If we correctly interpret these considerations, an SPC could be infringed by the domestic preparation of the active ingredient, even if this does not evidently occur for a medicinal use authorised in the country of protection. However, in relation to second-medical-indication patents, according to Kühnen, a "manifest" and infringing "preparation" of the active ingredient exists only if the composition is manifestly prepared for the therapeutic application protected by the patent, "for example as a result of formulation, manufacture, dosage, outer packaging or instructions for use accompanying the product". Therefore, if we correctly understand the considerations above, this author seems to suggest a structural difference between an SPC granted on the basis of a product patent and a patent granted for a medical indication: the SPC remains an exclusive right that protects the substance as such and independent of its (domestic) formulation in any pharmaceutical preparation, provided that a medical use occurs abroad.

In our view, the SPC does not cover the substance as such, but only the uses of the substance authorised in the state that granted the SPC. Therefore, the protection provided by SPCs in our view is always purpose-bound.[262] Consequently, the mere manufacture of the active ingredient shall not be considered to infringe the certificate. The same holds true for the preparation of the substance for a pharmaceutical use not authorised in the country that has granted the SPC. Of course, it remains unclear whether the preparation of the substance for the same medical use authorised in the country granting the SPC, but for export, would equally infringe the SPC. It depends on how a court would interpret Art. 4 Reg. 469/2009. One could argue that Art. 4 Reg. 469/2009 protects the preparation of the substance for the authorised use irrespective of the territory where such use shall occur. Alternatively, one could also be of the opinion that Art. 4 Reg. 469/2009 only covers the preparation for medicinal use in the country where the MA on which the respective SPC is based was granted. If the packaging clearly discloses that the sale (and the use) of the active ingredient as a medicinal product for the protected indication will take place in a foreign market, it is at least questionable whether an infringement exists.

A final assessment, however, is rather difficult in view of the lack of case law concerning SPCs. Also, the case law relating to second medical indications does not provide clear guidance in the case of export of the active ingredient as a raw

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261 Thomas Kühnen, *Patent Litigation Proceedings in Germany* (7th edn, Heymanns 2015), para. 178.

262 District Court of Düsseldorf, *Valsartan,* 4b O 66/11 [2011] ECLI:DE:LGD:2017:0810.4B.O62.16.00. Rudolf Kraßer, *Patentrecht* (6th edn, C.H. Beck 2009) p. 586; Case C-322/10 *Medeva* [2011] ECLI:EU:C:2011:773, Opinion of AG Trstenjak, para. 107: "It follows from both those provisions that the protection conferred by a certificate is always protection for a specified purpose: the extent of protection and protective effect of the supplementary protection certificate are restricted to those uses of the product as a medicinal product for which a marketing authorisation exists" (in the original language of the conclusions the Advocate General used the expression "zweckgebundener Schutz", that is, purpose-bound protection). See also the literature referred to by AG Trstenjak at foonote 36 of the mentioned Opinion.

compound. Furthermore, there are three reasons to assume that also possible case law concerning patents for first medical indications could not be critically considered valid for assessing the infringement of an SPC.

First, the CJEU is competent to interpret the scope of protection as provided by SPCs. It follows from this caveat that the question of whether the manufacturing of a substance represents an infringement in consideration of the limitation under Art. 4 Reg. 469/2009 or Reg. 1610/96 could be referred to the Court of Justice.[263]

Second, as already mentioned, the scope of an SPC is different from the scope of a patent for a first medical indication and different again from the scope of a patent for a second medical indication. The case law that applies to the former or the latter category of patent claims shall not be slavishly applied to SPCs.

Third, there are not only normative indications (Art. 4 Reg. 1610/1996 and Reg. 469/2009), but also teleological arguments for interpreting the scope of an SPC differently from the scope of a purpose-bound patent for a second medical indication or first medical indication.

The rationale of SPCs is that the patentee cannot obtain any revenue in the European market from the product covered by the basic patent before a corresponding MA is granted. The requirement of an MA in the State granting the certificate for the exploitation of the patented product is the reason for the existence of the SPC.[264] Economic activities that are not subject to a prior grant of an MA or are subject to an approval that would not entitle the patentee to an SPC shall not be covered by the certificate. Indeed, they are not delayed by the requirement for an MA.

Now the patentee does not need an MA granted under Dir. 2001/83 to manufacture an active ingredient in Europe and to sell it, for instance, in the US. The same holds true for manufacturing a final medicinal product including that active ingredient, if such medicinal product is placed on the market in the US or other foreign markets. All these activities will require other licences or authorisation than a European MA, such as a manufacturing licence in Europe and a product approval in the USA. However, such activities do not require an MA within the meaning of Art. 2 Reg. 469/2009, and are not delayed by the authorisation procedures mentioned in said Article. Since the patentee and third parties could perform these activities (manufacturing for export; placing the product on the market in a foreign jurisdiction) without the MA that is the justification for the existence of the certificate, there is no reason to extend the protection conferred by the certificate to such activities.

The argument made above has still to be tested by the CJEU. Of course, it cannot provide a conclusive answer to the question of whether the production of an active ingredient for export would be subject to the rights conferred by the SPC. It is only the opinion of the authors of this Study. Further, the mentioned decisions of the Tribunal of Milan and of the Court of Belgium came to the opposite conclusion. However, the argument made in this section remains relevant in assessing the question of whether a

[263] Whether the same applies for purpose-bound product patents and first-medical-indication patents is questionable: this depends on the interpretation of Art. 28 TRIPS in general and in particular on the question of whether this provision matters directly for the question of infringement of such patents.

[264] See Giurisprudenza annotata di diritto industriale 1999, No. 4252, pp. 495-496.

rule expressly allowing manufacturing for export would be consistent with the rationale of the SPC.[265]

5.7.3 Limitations of the rights conferred by a patent

All patent systems in Europe also provide rules concerning specific uses of the subject matter that would in principle amount to an infringement of a patent, but that are exempted for specific public-policy reasons. Corresponding exemptions are neither harmonised within the EU nor prescribed by binding international rules or conventions.[266]

Despite the lack of harmonisation in this field, the law in the EU is mostly uniform. The main reason for this voluntary convergence is to be found in the Convention for the European patent for the common market (CPC).[267] While the CPC never entered into force, its provisions governing the rights conferred by the patent served as a model for national lawmakers. A second reason for this de facto conformity is that some of the exemptions provided under national law have a basis in similar legal sources of EU intellectual property law, e.g. the Community Design Regulation.[268] Therefore, significant uniformity also exists with respect to the limitations of the rights conferred by the patent.

The only formal harmonisation provided for on the basis of Union law that applies in the field of pharmaceuticals is the so-called *Bolar* exemption.[269] Still, Union law in this regard only calls for *minimum* harmonisation. Broader exceptions, provided that they are consistent with the requirements established by the TRIPS Agreement, are admissible. Therefore, national laws implementing the *Bolar* exemption are sometimes diverging. With the UPCA entering into force, one will therefore be confronted with the peculiar situation that the same activity can be allowed or prohibited depending on whether national or UPCA law applies.[270]

5.7.4 Impact of the UPCA

A further patent-law-related aspect which will have a significant impact on the protection of pharmaceutical as well as plant protection products is the upcoming entry into force of the UPCA. This will, however, be addressed in detail in Part Four of this Study.

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265 See Chapter 15, Section 15.3.

266 Art. 31 TRIPS allows for such exemptions under specific conditions, but does not list them. The Strasbourg Convention does not deal with the rights conferred and therefore also not with the limitations to these rights. The same holds true for the EPC.

267 Council Convention 76/76/EEC for the European Patent for the Common Market (Community Patent Convention) of 5 October 1973 [1976] OJ L 17/1.

268 Council Regulation (EC) No 6/2002 of 12 December 2001 on Community designs [2002] OJ L 3/1.

269 See Chapter 15, Section 15.4.1.

270 See *ibid.,* Chapter 15, Section 15.4.1.3.

6 FURTHER INSTRUMENTS TO PROTECT THE RESULTS OF CLINICAL RESEARCH

The results of pharmaceutical research cannot be protected by patents only. In view of the high costs associated with the development of new drugs[271], the legislator rather provides for different and specific incentives to invest in research and development activities in this field. Research and development results can be protected by the provisions concerning trade secrets[272], data and marketing exclusivity[273] and orphan drugs[274].

In order to clarify the interactions with the SPC regulations, this Chapter outlines the aforementioned additional regulations to illustrate the scope and the intended beneficiary of the granted protection.

6.1 TRADE SECRETS PROTECTION

6.1.1 Legal basis

On the international level, trade secrets need to be protected in accordance with Art. 39 TRIPS Agreement.[275] In order to harmonise the relevant national provisions on the protection of trade secrets, the EU has enacted the Trade Secrets Directive which needs to be complied with by the Member States as of 9 June 2018.[276]

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271 Innovative pharmaceutical companies often quantify their average development costs per new drug with a figure around US$ 800 million, e.g. DiMasi et al, `The Price of Innovation: New Estimates of Drug Development Costs´ [2003] Journal of Health Economics 151-181 (US$ 802 million); Ulrich Gassner, `Unterlagenschutz im Europäischen Arzneimittelrecht´ [2004] GRUR Int. 983 (€ 870 million). Recently, respective costs have even been considered to be above US$ 2 billion, e.g. DiMasi et al, `Innovation in the pharmaceutical industry: New estimates of R&D costs´ [2016] Journal of Health Economics 20-33 (US$ 2,558 million). However, these figures are not undisputed. The non-profit organisation Drugs for Neglected Diseases initiative (DNDi) estimates that it can make a completely new drug from scratch at costs between US$ 110 and US$ 170 (see at http://www.nature.com/news/busting-the-billion-dollar-myth-how-to-slash-the-cost-of-drug- development-1.20469, last accessed 4 April 2017).

272 Directive (EU) 2016/943 of the European Parliament and of the Council of 8 June 2016 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure [2016] OJ L 157/1.

273 Art. 10(1) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use [2001] OJ L 311/67, as amended by Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 [2004] OJ L 136/34; Art. 14(11) Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency [2004] OJ L 136/1.

274 Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products [2000] OJ L 18/1.

275 Thus for instance in Germany, trade secrets (among other things) are protected on the basis of both unfair competition law and criminal law; Sec. 17 German Act against Unfair Competition ("*Gesetz gegen den unlauteren Wettbewerb*") in the version published on 3 March 2010, Federal Law Gazette (*Bundesgesetzblatt*) I p. 254, as last amended by Article 4 of the Act of 17 February 2016, Federal Law Gazette I p. 233; Secs. 203, 204, 355 German Criminal Code in the version promulgated on 13 November 1998, Federal Law Gazette I p. 3322, last amended by Article 1 of the Law of 24 September 2013, Federal Law Gazette I p. 3671 and with the text of Article 6(18) of the Law of 10 October 2013, Federal Law Gazette I p. 3799.

276 Art. 19(1) Dir. 2016/943.

6.1.2 Subject matter and purpose of protection

Under the Trade Secret Directive, the notion of trade secrets covers know-how, business information and technological information where there is both a legitimate interest in keeping them confidential and a legitimate expectation that such confidentiality will be preserved.[277]

The purpose of the legislation is to protect undertakings against dishonest practices aimed at misappropriating trade secrets, such as "unauthorised copying, economic espionage or the breach of confidentiality requirements".[278] To this end, the Trade Secrets Directive provides for legal remedies including claims for injunctive relief, recall from the market, destruction of infringing products and damages which are to a certain extent similar to the legal remedies in case of infringements of patents and other intellectual property rights.[279] Other than patents – which are granted in return for the disclosure of the invention – trade secrets are not exclusive rights, and they are only protected against unlawful acquisitions, uses and disclosures.[280] Further, they provide for a protection which is unlimited in time as long as the secrecy of the respective information is maintained. While in this regard the scope of protection appears to be even broader than with regard to patents, trade secrets protection might present some deficiencies. Since no exclusive rights are recognised on trade secrets, both independent discovery of the same information as reverse engineering are considered as lawful ways to acquire a trade secret under the Directive.[281] A further difficulty is that the trade secrets holder is required to demonstrate that the condition of protection (*inter alia* that the information still constitutes a secret or that reasonable steps have been taken to ensure its secrecy) are fulfilled at the enforcement stage.

6.1.3 Beneficiary

According to Art. 4 (1) of the Trade Secrets Directive, the beneficiary of the legal protection is the trade secret holder. Trade secret holder means any natural or legal person lawfully controlling a trade secret.[282] Due to its vagueness, that definition might cause some difficulties in the course of future enforcement actions. While in a scenario of a fully integrated pharmaceutical company running its own research and development department the company as that legal person being in control of the overall research and development process will generally benefit from trade secrets protection[283], the question of the holder of trade secrets becomes much more difficult to answer in the case of multi-lateral research and development projects involving different companies and research and development service providers. Trade secret protection will in such scenarios in particular depend on contractual arrangements to

277 Recital 14 Dir. 2016/943.
278 Recital 4 Dir. 2016/943.
279 See Dir. 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights, in the version of the Corrigendum [2004] OJ L 195/16, in this regard. It should nevertheless be noted, that before ordering any injunctions or corrective measures, the competent judicial authorities are required to undertake a strict proportionality test following Art. 13 Dir. 2016/943.
280 Art. 4 Dir. 2016/943 (Trade Secrets Directive).
281 Recital 16 Dir. 2016/943.
282 Art. 2(2) Dir. 2016/943.
283 Specific legal problems may also arise in this scenario in relation to technical improvement proposals made by employees. In this regard, the question who is in lawful control of the information in dispute has to be answered on the basis of the agreement concluded between the respective company and the respective employee.

be agreed upon with the various stakeholders. Trade secret protection therefore is subject to specific contract-management strategies on the basis of which it has to be decided who the person in lawful control of specific know-how and information is.

6.1.4 Interaction with SPC Regulations

Patent and SPC protection on the one side and trade secrets protection on the other side seems to exclude each other in relation to the technical subject matter in dispute. The grant of a patent requires the disclosure of the invention; the disclosed information cannot be protected anymore as trade secret as of the time of the publication of the corresponding patent application. However, in the practice, the question is by far more complex. It is possible that a specific subject matter is protected by both a patent right and trade secret law. So, for instance, under European patent law, the patentees do not need to disclose the best mode to practice the invention. Under SPC legislation the applicant has to submit the copy of the marketing authorisation, but confidential information included in the MA are not made available to the public by the NPO. For this reason, the technology incorporated by a medicinal product can be protected by both a patent and the associated SPC on the one side, trade secrets law on the other side.

6.2 DATA AND MARKETING EXCLUSIVITY FOR MEDICINAL PRODUCTS

6.2.1 Definition of basic terms

Data exclusivity constitutes the period of time during which a company cannot refer to the clinical trial data of a reference medicinal product in support of an application for an MA for a generic, hybrid and biosimilar medicinal product. Consequently, MAs in this regard cannot be granted by the competent regulatory authority during the data exclusivity period.[284] Marketing exclusivity constitutes the period of time during which a product authorised on the basis of a cross reference to the clinical trial data of a reference medicinal product cannot be placed on the market, irrespective of whether the MA for that product (a generic, hybrid or biosimilar) has been granted by the competent authority already or not.[285]

The main difference between data and marketing exclusivity consequently is the following: the generic, hybrid or biosimilar MA may not be granted during the period of

[284] Zaide Frias, 'Data exclusivity, market protection and paediatric rewards', Presentation at the EMA Workshop for Micro, Small and Medium Sized Enterprises of 26 April 2013, slide 4, available at http://www.ema.europa.eu/ docs/en_GB/document_library/Presentation/2013/05/WC500143122.pdf (last accessed 8 April 2017); European Commission document 'Notice to Applicants', Volume 2A, Procedures for MA, Chapter 1, Marketing Authorisation, December 2016, p. 39.

[285] Zaide Frias, 'Data exclusivity, market protection and paediatric rewards', Presentation at the EMA Workshop for Micro, Small and Medium Sized Enterprises of 26 April 2013, slide 4, available at http://www.ema.europa.eu/ docs/en_GB/document_library/Presentation/2013/05/WC500143122.pdf (last accessed 8 April 2017). For the differentiation between data exclusivity and marketing exclusivity, also refer to Federal Administrative Court, *Decision of 10 December 2015* [2016] NVwZ-RR 504, para. 33, according to which marketing protection means that the competent authorities may process an application submitted on the basis of a reference to clinical trial data of third parties but that the corresponding generic product may not be placed on the market prior to the expiry of the time of protection.

data exclusivity while during the period of marketing exclusivity the authorisation may be granted but the corresponding product may not be placed on the market.

6.2.2 Legal basis

The legal basis of data and marketing exclusivity rights is provided for by the statutory rules governing medicinal products and their MA in the EU.

6.2.2.1 Reference medicinal product approved by NP, DCP or MRP

In case of national MAs granted by an EU Member State on the basis of its national provisions[286] or within the framework of the mutual recognition[287] and the decentralised procedure[288], Art. 10 (1) lit. a (iii) Dir. 2001/83 in its initial form[289] held that an applicant for an MA was not required to provide results of clinical trials if he could demonstrate that the medicinal product was essentially similar to a medicinal product and that this product has been authorised in line with the Community provisions in force for a time period of not less than six years or – at least – a period of ten years.[290]

This time schedule was amended by Art. 1 Dir. 2004/27/EC[291] with effect as of 30 October 2005[292] in that respect that the reference medicinal product must have been authorised for a time period of not less than eight years in a Member State or in the Community. Further, an additional marketing protection period of two years has been implemented. Accordingly, a generic medicinal product shall not be placed on the market until an overall time period of ten years has elapsed from the initial authorisation of the reverence medicinal product. This ten years period, however, can only be extended for an additional year where an application is made for a new indication which, during the scientific evaluation prior to their authorisation, are held to bring a significant clinical benefit in comparison with existing therapies.[293] This new system as in force for reference medicinal products for which an application for authorisation was submitted after 30 October 2005 is therefore commonly referred to as the *"8+2+1"-System*.[294]

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286 See Chapter 4, Section 4.2.1.3.
287 See Chapter 4, Section 4.2.1.2.
288 Ibid.
289 [2001] OJ L 311/67.
290 The 10-year period applies for high-technology medicinal products authorised under Art. 2(5) Dir. 87/22/EEC [1987] OJ L 15/38 (repealed by Dir. 93/41/EEC [1993] OJ L 214/40). Also, a Member State could take a decision to extend the data exclusivity period to 10 years in case it is considered to be necessary for the interest of public health. For an overview which data exclusivity period applies in which Member State with regard to the Dir. 2001/83/EC in its initial form see the European Commission document 'Notice to Applicants', Volume 2A, Procedures for MA, Chapter 1, Marketing Authorisation, December 2016, p. 40.
291 Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use [2004] OJ L 136/34.
292 Art. 3 Dir. 2004/27/EC.
293 Art. 10(1)(4) Dir. 2001/83/EC as amended by Art. 1 Dir. 2004/27/EC. It should be noted that a non-cumulative period of one year of data exclusivity is available on the basis of Art. 10(5), where an application is made for a new indication for a well-established substance, provided that significant pre-clinical or clinical studies were carried out in relation to the new indication.
294 Peter Feldschreiber, *The Law and Regulation of Medicines* (Oxford 2008), para. 13.191; Andreas von Falck et al, `"Life-Cycle-Management" für Arzneimittel und gewerbliche Schutzrechte´ [2015] GRUR 1050, 1058; Nina Schäffner, *Lifecycle Management im Arzneimittelsektor* (Nomos 2015) p. 137.

6.2.2.2 Reference medicinal product approved by CP

In case of MAs granted by the EMA on the basis of the centralised procedure, prior to 20 November 2005 a marketing exclusivity period of ten years applied pursuant to Art. 13 (4) Reg. 2309/93.[295] With effect as of 20 November 2005, according to Art. 14 (11) Reg. 726/2004,[296] the *"8+2+1"-System* also applies within the framework of the centralised procedure.

6.2.2.3 Commencement of the data and marketing exclusivity period: The notion of Global MA

The applicable data and marketing exclusivity periods have to be calculated as of the date of approval of the relevant reference medicinal product, i.e. the relevant protection periods commence with the issuance of the respective MA.

A particularity needs to be taken into account in this regard against the background of the concept of global MA. According to Art. 6(1) Dir. 2001/83, as amended by Art. 1 Dir. 2004/27/EC, any additional strengths, pharmaceutical forms, administration routes, presentations, as well as any variations and extensions shall also be granted a separate MA. For the purpose of calculating the data and marketing exclusivity periods, however, corresponding MAs shall be considered as belonging to the same global MA.[297] MAs granted for any additional dosage, pharmaceutical form, route of administration, presentation or any variation or extension of the original medicinal product, therefore, do not trigger a new data and marketing exclusivity period.[298] In such cases one single data and marketing exclusivity period commences as of the date of issuance of the first MA of the respective active ingredient. In this regard, also new indications form part of the same global MA granted for an already approved active ingredient; new indications amount to a type II variation under Art. 6 Reg. 1085/2003.[299]

As a result, if a company has been granted a first MA, it will benefit from a data-exclusivity period. However, if the same company is granted a second MA for variations, extensions or new indications of the same active ingredient, this company will not benefit from a new data-exclusivity period for this second MA. If the second MA is granted to an unrelated company, the latter will benefit from a separate period of exclusivity.

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295 Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products [1993] OJ L 214/1.

296 Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency [2004] OJ L 136/1.

297 For details see European Commission document 'Notice to Applicants', Volume 2A, Procedures for marketing authorisation, Chapter 1, Marketing Authorisation, December 2016, p. 42. A question to be dealt with under […] of this study is whether for the purpose of determining what the first authorisation to place the product on the market as a medicinal product pursuant to Art. 3 lit. d) SPC Regulation is the specific MA or the global MA concept has to be referred to. The CJEU, however, underlines the different objectives pursued by the SPC regulation on the one side and data and marketing exclusivity on the other side: Case C-527/07 *Generics (UK)* [2009] ECR I-5259, para. 50.

298 Case T-472/12 *Novartis Europharm v Commission* [2015] EU:T:2015:637, para. 46.

299 *Ibid.*, para. 47; European Commission document 'Notice to Applicants', Volume 2A, Procedures for marketing authorisation, Chapter 1, Marketing Authorisation, December 2016, p. 44.

6.2.2.4 *Overview*

The legal situation before and after the introduction of the current *"8+2+1"-System* can accordingly be summarised as follows:[300]

Overview on applicable data-/marketing exclusivity periods		
Submission Date of MA application for the reference medicinal product	CP	NP, MRP, DCP
Before 20 November 2005 (CP) 30 October 2005 (NP, MRP, DCP)	10 years data exclusivity	6 or 10 years data exclusivity
After 20 November 2005 (CP) 30 October 2005 (NP, MRP, DCP)	"8 + 2 + 1"-System	

Table 6.1: Overview on applicable data-/marketing exclusivity periods

6.2.3 Purpose and scope of application

The purpose of data and marketing exclusivity is to compensate an innovative pharmaceutical company's investment into the conduct of clinical trials and in collecting the relevant data on that basis.[301] To this end, the relevant Union legislation protects innovative pharmaceutical companies within a certain limited period of time against the use of data which they have obtained from clinical trials conducted in order to fulfil the preconditions required for the grant of an MA for an innovative medicinal product.[302]

Following the expiry of the relevant data and marketing exclusivity period, generics, hybrids and biosimilars then may be approved by cross-referring to the clinical trial data established by innovative pharmaceutical companies.

Other than patents and SPCs, data and marketing exclusivity rights do not need to be enforced by civil law actions. Rather, third parties such as in particular manufacturers of generic medicinal products are *ex lege* prevented from launching their products prior to the expiry of the relevant data and marketing exclusivity periods.[303]

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300 Inspired by Zaide Frias, 'Data exclusivity, market protection and paediatric rewards', presentation at the EMA Workshop for Micro, Small and Medium Sized Enterprises of 26 April 2013, slide 3, available at http://www.ema.europa.eu/ docs/en_GB/document_library/Presentation/2013/05/WC500143122.pdf (last accessed on 8 April 2017).

301 Pedro Roffe, Geoff Tansey, *Negotiating Health: Intellectual Property and Access to Medicines* (Routledge 2012) p. 170; Christian Roger Fackelmann, *Patentschutz und ergänzende Schutz-instrumente für Arzneimittel im Spannungsfeld von Wettbewerb und Innovation* (Heymanns 2009) p. 470; Peter Feldschreiber, *The Law and Regulation of Medicines* (Oxford 2008), para. 13.189; Christian B Fulda, 'Unterlagenschutz und Marktschutz für Arzneimittel oder: Über die Entfernung von Münster nach Brüssel' [2008] PharmR 589; Nina Schäffner, *Lifecycle Management im Arzneimittelsektor* (Nomos 2015) p. 137.

302 Federal Administrative Court*, Decision of 10 December 2015* [2016] NVwZ-RR 504, 507.

303 Note that in case a generic, hybrid or biosimilar MA should have been granted in violation of the protection provided for by the statutory rules on data and marketing exclusivity, legal remedies are provided for by national and European law; see Case C-104/13 *Olainfarm* [2014] EU:C:2014:2316, para. 40. In Germany, e.g., legal actions can then be filed with the competent administrative courts.

The legal effects resulting from the two different legal regimes, therefore, differ as follows:

- Patent and SPC protection enables the holder of the corresponding right to prevent third parties, from manufacturing and distributing medicinal products that make use of the active ingredient protected for the indication claimed by the basic patent.
- Data and marketing exclusivity enables an innovative pharmaceutical company as holder of an MA of a reference medicinal product to prevent generic competition, irrespective of whether the product is protected by a patent or an SPC.[304]

As a consequence, data and marketing exclusivity rights cannot be relied upon as a legal basis to prevent the launch of a similar product using the patented compound or method and for which the competing company has conducted its own clinical trials. In view of the costs involved in the conduct of clinical trials, this option, however, is rather theoretical in nature.

6.2.4 Beneficiary

The beneficiary of data and marketing exclusivity is the holder of the MA obtained for a medicinal product including a new active substance.[305]

6.2.5 Interaction with SPC Regulations

As anticipated in Chapter 2[306] and as it will be further discussed in Chapter 13, it is not clear whether the SPC may be granted only when the SPC holder is the owner of the MA or the owner of the MA agrees or is a related company. If such a limitation applies, SPC protection and data marketing protection will benefit the same entity or group of entities that has developed a new therapeutic candidate and has performed the clinical trials necessary to bring a product to the market. If by contrast the SPC applicant may refer to a third-party MA without any limitation, then SPC protection and data protection will have different beneficiary and reward different achievements: for the former it will be necessary and sufficient to have developed a patentable pharmaceutical invention, and the applicant will not be required to have performed any investment in order to obtain an MA. In this case the SPC would perform the same function as the basic patent, while the MA would reward the entity that has invested to bring an active ingredient to the market.

Which one of the two options applies has policy implication: if the SPC is to reward and compensate for the time and investment put into obtaining an MA, as assumed for instance by the German Federal Patent Court in *Farmitalia*,[307] then it would be by far closer to data protection rules. This would call for a strict consistency of the two

[304] Manuel Campolini, 'Protection of innovative medicinal products and registration of generic products in the European Union: Is the borderline shifting?' [2003] 25(2) EIPR 91, pointing out that data and marketing exclusivity may in particular become decisive in case of exceptionally long development times or if the medicinal product in question constitutes non patentable subject matter.

[305] Federal Administrative Court, *Decision of 10 December 2015* [2016] NVwZ-RR 504, 505; Higher Administrative Court of Münster, *Decision of 5 October 2011* [2011] Case 13 B 881/11, PharmR 478, 479; Higher Administrative Court of Münster, *Decision of 27 April 2015* [2015] Case 13 B 881/11, PharmR 366, 368.

[306] Chapter 2, Section 2.1.3.

[307] BPatG, *Decision of 15 May 1995*, Case 15 W (pat) 122/93 [1995] BPaTGE 35, 145.

systems, and for avoiding rules that could undermine specific choice made by the lawmaker in one field or the other. We refer to the analysis in Chapter 13 in this regard.

Regarding the term of protection, SPC protection and data protection may overlap, but the former will usually last longer than data protection, unless the MA is issued less than 5 years before the expiration date of the patent.

6.3 ORPHAN DRUGS

6.3.1 Legal basis

Orphan drugs – or technically "orphan medicinal products" – are regulated in Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products. The Regulation sets out the requirements for a medicinal product to be designated "orphan medicinal product" in Art. 3.

6.3.2 Purpose and scope of application

The basic ratio behind the regulation is, according to its Recital 1, the understanding that "some conditions occur so infrequently that the cost of developing and bringing to the market a medicinal product to diagnose, prevent or treat the condition would not be recovered by the expected sales of the medicinal product". Consequently the regulation assumes that "the pharmaceutical industry would be unwilling to develop the medicinal product under normal market conditions".[308]

6.3.3 Beneficiary

According to the wording of Reg. 141/2000 the applicant for the orphan drugs status of a medicinal product is called a *"sponsor"* and can be "any legal or natural person, established in the European Community, seeking to obtain or having obtained the designation of a medicinal product as an orphan medicinal product".[309] The sponsor usually will be but does not have to be also the holder of the general MA for the medicinal product pursuant to Reg. 726/2004. According to Art. 8(1) of Reg. 141/2000 the Community and the Member States may not, for a period of 10 years, accept another application for an MA. Thus, the beneficiary of the orphan drug exclusivity is not the patent or SPC owner, but instead the holder of the MA.

6.3.4 Interaction with SPC Regulation

According to Art. 34(4) Reg. 1901/2006 the six-month paediatric extension of the SPC may not apply to medicinal products designated as orphan medicinal products pursuant to Reg. 141/2000. This means that according to EU law the incentives of a paediatric SPC extension and the additional orphan drugs exclusivity are mutually exclusive and thus cannot be claimed or applied for cumulatively. The ratio for this is explained in more detail in Chapter 17 of this Study.

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308 See Recital 1 Reg. 141/2000.
309 *Ibid.,* Art. 2(c).

6.4 SUMMARY

European law provides for different instruments protecting research and development results in the field of medicinal and plant protection products. While trade secret protection constitutes a separate and independent legal concept for the protection of research and development results, data and marketing exclusivity intend to provide for a compensation for investments made to bring to the market a medicinal product including a new active substance. In view of the different beneficiaries protected by data and market exclusivity on the one side (i.e. the MA holder) and SPCs on the other side (i.e. the patentee) the two legal concepts are generally autonomous and exist independent from each other. However, in scenarios of fully integrated entities where MA holder and SPC holder are identical, the exclusionary effects of both legal concepts overlap significantly. Such overlap is excluded in case of orphan drug exclusivity and paediatric SPC extension.

PART TWO:

THE EFFECTIVENESS OF THE SPC REGULATIONS

7 OVERALL USE OF THE SPC SYSTEM IN THE EU

7.1 INTRODUCTION

As already mentioned in Chapter 2, the lawmaker had five goals in mind when enacting the SPC Regulations:

- Correcting the functioning of the common market by preventing a division of the market in territories where protection is available and territories where protection is either not available or already expired because of different terms or different requirements;
- Fostering pharmaceutical research;
- Providing EU companies with conditions that are competitive with the US and the Japanese legal order;
- Ensuring a balanced system that takes into account all interests;
- Establishing a simple and transparent system for granting extensions.

A legal study cannot answer the question whether some or all these goals were satisfactorily achieved by the legislation, as pointed out in the introduction. For instance for the question whether SPC protection has fostered pharmaceutical research, there are additional complications:

- It is not possible to distinguish the effect of patents from the effect of SPCs.
- It is not possible to distinguish the effect of EU SPCs and patents from the effect of US patents or patent extension, because the effect that a patent system displays on the behaviour of companies depends on the relevance of the market for that company and not on the geographical location of the company.

However, the MPI, while not intending to provide answers to the question of effectiveness, can provide information on the perceived effectiveness of the system, that is, how the stakeholders – e.g. users, competitors, NPOs – assess the functioning of the Regulations.

In this respect, the MPI has adopted two approaches. First, it has reviewed some data concerning the activities within the SPC system. Indeed, one may indirectly infer that if companies invest in and make use of SPCs, the latter are an adequate instrument of protection and a valuable asset. Naturally, this is not an inference in terms of effectiveness, but rather of relevance.

Second, the MPI has conducted a survey and carried out interviews with stakeholders and NPOs concerning the functioning of the system. Again the collected answers provide only information on how the actors involved perceive specific aspects of the legal framework. For this reason, we speak of perceived effectiveness of the SPC Regulations in creating a balanced system of protection for genuine innovation.

7.2 THE OVERALL USE OF SPCS: INSIGHTS FROM PRIOR STUDIES AND SECONDARY DATA

This section will focus on selected empirical facts concerning the perceived effectiveness of the SPC regulations. It should be noted that the findings obtained do not suffice to answer conclusively the questions of whether the regulations have achieved the objective for which they were initially enacted. Instead, this review provides support to the relevance and validation of the subsequent legal analysis in its thematic priorities and basic arguments.

The section is divided into two parts. First, it provides the reader a brief overview of the economic literature on the effects of variation in the strength of IP regimes on the pharmaceutical market. This is followed by empirical findings on SPC activities, namely SPC application filings, SPC granting practices, and SPC enforcement. The latter part draws primarily from recent descriptive studies on SPCs but is complemented by the authors' own empirical analysis. Second, this Chapter also addresses the question of available SPC filing and legal status information in national registers as well as central databases.

7.2.1 Economic literature review

7.2.1.1 Patent rights in the pharmaceutical industry

Developing new drugs is largely seen as a lengthy, risky and costly endeavour.[310] Investment costs for new drugs depend largely on the specific therapy and the development company conducting R&D with little potential to gain from economics of scale.[311] These R&D costs have been growing substantially since 1970 due to demanding regulatory requirements for marketing authorisation leading, for example, to longer clinical trial phases. Currently, 80 per cent of all marketed drugs do not cover their average capitalised development costs.[312]

Patents are considered as an especially important tool for protecting pharmaceutical innovations.[313] Surveyed US R&D executives in the pharmaceutical industry state that a large fraction of drugs would not have been developed in the absence of patent

[310] See, for instance, Joseph DiMasi et al, `The Price of Innovation: New Estimates of Drug Development Costs´ [2003] 22(2) Journal of Health Economics 151-185; Christopher P Adams, Van V Brantner, `Estimating the Cost of New Drug Development: Is it really $802 million?´[2006] 25(2) Health Affairs 420-428; Joseph DiMasi et al, `Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs´ [2016] 47 Journal of Health Economics 20-33. The latter authors argue that the average pre-tax & pre-approval out-of-pocket R&D cost estimate for the development of a new drug or biological based on a self-originated compound amounts to US$ 1,395 million (2013-dollars) including the costs of the unsuccessful project allocated to the marketed product.

[311] Christopher P Adams, Van V Brantner, `Estimating the Cost of New Drug Development: Is it really $802 million?´[2006] 25(2) Health Affairs 420-428.

[312] Frederic M Scherer, *Pharmaceutical Innovation* in Bronwyn H Hall and Nathan Rosenberg (eds), HANDBOOK OF THE ECONOMICS OF INNOVATION (North Holland 2010) pp. 539-574.

[313] See, for instance, Wesley M Cohen et al, `Protecting their intellectual assets - Appropriability conditions and why US manufacturing firms patent (or not)´ [2000] NBER Working Paper No. 7552; Edwin Mansfield, `Patents and Innovation: An Empirical Study´ [1986] 32(2) Management Science 173-181; Richard C Levin et al, `Appropriating the Returns from Industrial Research and Development´ [1987] 3 Brookings Papers on Economic Activity 783-831.

protection.[314] However, more recent surveys show that also secrecy and first-to-market advantages are effective means to protect the development of novel drugs.[315]

The characteristics of patents have implications for the pharmaceutical industry and in particular for the incentives to develop novel drugs. Since the time span between patent filing and commercialisation varies substantially between treatments (e.g. early-stage treatments have longer commercialisation lags), also the effective market exclusivity period to recoup R&D costs depends on the type of treatment. The fixed patent term and lengthy development times may lead therefore to an underinvestment in projects with longer commercialisation lags.[316] However, the speed of commercialisation of new drugs is found to increase with the commercial value of the patent and to reduce with uncertainty over the patent validity.[317]

One pharmaceutical product is often protected by multiple patents. Whereas "primary" patents refer to the protection of an active ingredient (usually filed during the research phase), "secondary" patents protect production methods, modifications, different formulations, dosages, or medical uses in later phases of the drug development process. The ratio between primary and secondary patents is somewhere between 1:4 and 1:7. For pending patents it increases to 1:13, suggesting that secondary patents tend to serve as a measure to create legal uncertainty.[318] If these supplementary patents substitute for the core innovation patent, this is called building patent fences and might strategically protect from imitation or block competing innovations from entering the market (static view). Patent fences are found especially for high selling drugs.[319] Furthermore, originator companies might seek extension of market exclusivity time (dynamic view) by filing "secondary" patents – a practice known as "evergreening".[320] Patent validity challenges are disproportionally targeted at these later expiring patents (presumably secondary patents), limiting the effectiveness of "evergreening".[321]

Patents also serve as an instrument of market coordination. A longer market exclusivity period increases the likelihood of imitative substitutes by subsequent competitors entering the market, which leads to duplicative R&D investments. In turn, originators might reduce R&D efforts in order to avoid the entry of non-infringing

[314] Edwin Mansfield, `Patents and Innovation: An Empirical Study´ [1986] 32(2) Management Science 173-181.

[315] Wesley M Cohen et al, `Protecting their intellectual assets - Appropriability conditions and why US manufacturing firms patent (or not)´ [2000] NBER Working Paper No. 7552.

[316] Eric Budish et al, `Do Firms Underinvest in Long-Term Research - Evidence from Cancer Clinical Trials´ [2015] 105(7) American Economic Review 2044-2085.

[317] Stefan Wagner, Simon Wakeman, `What do patent-based measures tell us about product commercialization? Evidence from the pharmaceutical industry´ [2016] (45)5 Research Policy 1091-1102.

[318] See, for instance, María José Abud et al, 'An Empirical Analysis of Primary and Secondary Pharmaceutical Patents' [2015] 10 PloS ONE 4; European Commission, Pharmaceutical Sector Inquiry. Final Report [2009].

[319] See, for instance, Christian Sternitzke, 'An exploratory analysis of patent fencing in pharmaceuticals: The case of PDE5 inhibitors' [2013] 42 Research Policy 542-551.

[320] As already elaborated, "evergreening" is intended as a legal extension of the exclusivity right for a subject matter already disclosed by a previous patent beyond the 20 years term. This is legally not allowed under the EPC. However, because of peculiar elements of the pharmaceutical market, which involve e.g. the consumer's reliance on doctors' decisions for the choice of products and the regulated access to the market, it is possible to extend an exclusivity position to the market despite the expiration of the basic patent covering the original innovation. This is due to the existence of so-called secondary patents together with other measures such as switching off strategies. How often this happens and how effective so-called secondary patents are in assisting the originator in this strategy is unclear.

[321] C Scott Hemphill, Bhaven N Sampat, 'Evergreening, Patent Challenges, and Effective Market Life in Pharmaceuticals' [2012] 31 Journal of Health Economics 327-339.

substitutes.[322] Moreover, patents may facilitate vertical disintegration. Large pharmaceutical companies tend to in-license molecules discovered by biotech companies or the public sector. Whereas academic groups may have a comparative advantage in discovering molecules, pharmaceutical companies can focus on conducting extensive and expensive clinical trials. For example, it is observed that patents issued in earlier stages of development are frequently assigned to companies other than those that eventually receive the marketing authorisation.[323] Furthermore, the European Commission finds that 35 per cent of originator companies' molecules with pending marketing authorisation were acquired or in-licensed.[324] This is in line with the findings of other studies that most new drugs with a high therapeutic value were developed based on public research input.[325]

7.2.1.2 Patent regime strength in the pharmaceutical industry

Only very few empirical papers have explicitly investigated Supplementary Protection Certificates in Europe and patent term extensions elsewhere.[326] From an empirical perspective, it is difficult to establish the causal effect on firms' behaviour from the introduction of the SPC regime. To the best of our knowledge, there are no studies investigating whether the number of chemical entities developed in Europe has grown in absolute or relative terms, or whether the share of the European industry relative to the global industry has changed. Furthermore, given the global relevance of the EU market protection, the introduction of the SPC regime may have also affected the behaviour of firms located outside Europe, making a direct comparison barely meaningful.

However, in contrast to patent extension and SPCs protection, there is a considerable body of literature studying the effects of variation in the strength of a particular patent regime (by introducing, strengthening or weakening it) in the context of pharmaceuticals in various geographical markets. This section will provide a brief summary of the key findings.

The evidence on the effects of introducing drug product patents on national R&D efforts in developed countries is mixed. Whereas the domestic R&D spending trend in the pharmaceutical industry in Canada increased relative to other industries and other countries after the implementation of patent rights in 1987,[327] the Supreme Court

322 Duncan S Gilchrist, 'Patents as a Spur to Subsequent Innovation Evidence from Pharmaceuticals' [2016] 8(4) American Economic Journal: Applied Economics 189-221.

323 Frederic M Scherer, *Pharmaceutical Innovation* in Bronwyn H Hall, Nathan Rosenberg (eds), HANDBOOK OF THE ECONOMICS OF INNOVATION (North Holland 2010) pp. 539-574.

324 European Commission, Pharmaceutical Sector Inquiry. Final Report [2009] p. 56.

325 Iain M Cockburn, Rebecca M Henderson, *Publicly Funded Science and the Productivity of the Pharmaceutical Industry* in Adam B Jaffe et al (eds), INNOVATION POLICY AND THE ECONOMY (MIT Press 2001) p. 21.

326 See, for instance, Alice de Pastors, SPC-News 29, 'Latest News on Medicinal Product SPCs in Europe' [2015]; Margaret Kyle, 'Economic Analysis of Supplementary Protection Certificates in Europe' [2017] European Commission/MINES ParisTech (CERNA) Working Paper, available at https://ec.europa.eu/docsroom/documents/25621/attachments/1/translations/en/renditions/pdf (last accessed 15 January 2018); Malvina Mejer, '25 Years of SPC Protection for Medicinal Products in Europe: Insights and Challenges' [2017] working paper, available at https://ec.europa.eu/info/publications/25-years-spc-protection-medicinal-products-europe-insights-and-challenges_en?2nd-language=bg (last accessed 15 January 2018).

327 Bohumir Pazderka, 'Patent Protection and Pharmaceutical R&D Spending in Canada' [1999] 25(1) Canadian Public Policy/Analyse de Politiques 29-46.

legitimisation of drug patents in Italy in 1978 had no effect on domestic R&D expenditures,[328] or rather a negative effect on the national innovation trend.[329]

In 1984 the Drug Price Competition and Patent Term Restoration Act, also known as the Hatch-Waxman Act, came into force in the United States. It included a patent term extension, giving an additional period of patent protection of up to five years[330], to compensate for the commercialisation lag due to lengthy clinical trials and the FDA regulatory approval.[331] In early studies, the Hatch-Waxman Act was predicted to foster generic entry and price reductions, but to be unlikely to have an impact on R&D.[332] Indeed, more recent studies show that the Hatch-Waxman Act has extended the effective patent life and at the same time also substantially increased the probability of generic entry.[333] Izhak et al. (2017) conclude that longer and narrower patents raise the likelihood of imitation during the patent period.[334] Furthermore, strengthening patent rights due to the Hatch-Waxman Act has accelerated the launch of new molecules in the US compared to other OECD countries.[335] However, delaying generic entry by longer market exclusivity periods leads to substantial increases in public healthcare expenditures, as shown for example by an increase in US Medicaid spending due to paediatric extensions.[336]

Other studies have investigated the introduction of national patent laws in several emerging and developing countries. In general, national patent reforms seem not to have stimulated domestic R&D efforts in the long run.[337] However, Qian (2007) finds that the introduction of national pharmaceutical patent rights in 26 countries between 1978 and 2002 accelerated domestic innovation specifically in countries with high

328 See Frederic M Scherer, Sandy Weisburst, 'Economic Effects of Strengthening Pharmaceutical Patent Protection in Italy' [1995] 26(6) IIC-International Review of Industrial Property and Copyright Law 1009-1024. The authors have also not found any market shift from emulating drugs developed elsewhere to developing innovative drugs in Italy.

329 See Pablo M Challu, 'Effects of the monopolistic patenting of medicine in Italy since 1978' [1995] 10(2/3) International Journal for Technology Management 237-251. The author finds additionally an increase of prices and an increase of imports (negative trade balance) after 1978.

330 Olena Izhak et al, 'Patent Duration, Breadth and Costly Imitation Evidence from the US Pharmaceutical Market' [2016] Working Paper. The remaining patent term after FDA approval is capped at 14 years.

331 Furthermore, it allowed generic companies to file an Abbreviated New Drug Application (ANDA), so that generic firms do not have to demonstrate safety and efficacy but only bioequivalence of their drug. Both bioequivalence testing and ANDA filings are also possible before the expiration of a new drug patent. See, for instance, Henry Grabowski, Margaret Kyle, 'Generic Competition and Market Exclusivity Periods in Pharmaceuticals' [2007] 28(4/5) Managerial and Decision Economics 491-502; Olena Izhak et al, 'Patent Duration, Breadth and Costly Imitation Evidence from the US Pharmaceutical Market', [2016] Working Paper.

332 Henry Grabowski, John Vernon, 'Longer Patents for Lower Imitation Barriers: The 1984 Drug Act' [1986] 76(2) American Economic Review 195-198.

333 Henry Grabowski, John Vernon, 'Effective Patent Life in Pharmaceuticals' [2000] 19(1/2) International Journal of Technology Management 98-120; Olena Izhak et al, 'Patent Duration, Breadth and Costly Imitation Evidence from the US Pharmaceutical Market' [2016] Working Paper.

334 Olena Izhak et al, 'Patent Duration, Breadth and Costly Imitation Evidence from the US Pharmaceutical Market' [2016] Working Paper.

335 Nebibe Varol et al, 'Does Adoption of Pharmaceutical Innovation respond to changes in the Regulatory Environment' [2012] 34(3) Applied Economic Perspectives and Policy 531-553.

336 Aaron S Kesselheim et al, 'Extensions Of Intellectual Property Rights And Delayed Adoption Of Generic Drugs: Effects On Medicaid Spending' [2006] (25)6 Health Affairs 1637-1647.

337 See, for instance, Yi Qian, 'Do National Patent Laws Stimulate Domestic Innovation in a Global Patenting Environment? A Cross-Country Analysis of Pharmaceutical Patent Protection 1978-2002' [2007] 89(3) Review of Economics and Statistics 436-453; Margaret Kyle, Anita M McGahan, 'Investments in Pharmaceuticals Before and After TRIPS' [2012] 94(4) Review of Economics and Statistics 1157-1172; Simona Gamba, 'The effect of Intellectual Property Rights on domestic innovation in the pharmaceutical sector' [2016] Research Institute for the Evaluation of Public Policies Working Paper.

levels of development, education, and economic freedom.[338] The same applies for compliance with TRIPS[339], which is associated with greater R&D efforts in diseases that affect wealthy countries. The IP implementation in developing countries has however not changed the direction of R&D investments towards diseases that are more prevalent in developing countries.[340] The increase in domestic innovation also disappears in the long run.[341] Moreover, introducing patent rights accelerates the launch of new drugs in low-, middle- and high-income countries.[342] Whereas Duggan et al. (2016) find price increases for molecules receiving a patent, but little effects on quantities sold, profits or the market structure after the Indian compliance with TRIPS,[343] Kyle and Qian (2015) estimate price and sales increases conditional on drug launch in 59 countries when exploiting the differential TRIPS compliance deadlines internationally.[344]

Some papers have specifically focused on the effect of generic competition and validity challenges on various outcomes. Since the Hatch-Waxman Act allowed for Paragraph IV challenges[345] before the expiration of a new drug patent, generics can enter the market even prior to patent expiry. Thus, Paragraph IV patent challenges shorten market exclusivity periods and especially target drugs in large markets.[346] These Paragraph IV challenges have been substantially increasing since 1984, which results in more generic competition early in a drug's market life. This is fostered by first-to-file incentives giving an additional 180-day exclusivity period to the first generic company that successfully challenges the drug patent.[347] Thereby, generic firms disproportionally challenge weak patents that expire later than basic patents.[348] However, a large share of Paragraph IV challenges is settled between the originator

338 Yi Qian, 'Do National Patent Laws Stimulate Domestic Innovation in a Global Patenting Environment? A Cross-Country Analysis of Pharmaceutical Patent Protection 1978-2002' [2007] 89(3) Review of Economics and Statistics 436-453.

339 The TRIPS-Agreement of 1994 mandated a global harmonisation of pharmaceutical patent rights. On the one hand, it led to an introduction of pharmaceutical patent rights in several countries. On the other hand, other countries, e.g. the US, had to extent their patent term to 20 years. The timing of compliance with TRIPS varied substantially between countries. See, for instance, Margaret Kyle, Anita M McGahan, 'Investments in Pharmaceuticals Before and After TRIPS' [2012] 94(4) Review of Economics and Statistics 1157-1172; Margaret Kyle, Yi Qian, 'Intellectual Property Rights and Access to Innovation - Evidence from TRIPS' [2015] Hoover IP Working Paper.

340 Margaret Kyle, Anita M McGahan, 'Investments in Pharmaceuticals Before and After TRIPS' [2012] 94(4) Review of Economics and Statistics 1157-1172.

341 Simona Gamba, 'The effect of Intellectual Property Rights on domestic innovation in the pharmaceutical sector' [2016] Research Institute for the Evaluation of Public Policies Working Paper.

342 See, for instance, Margaret Kyle, Yi Qian, 'Intellectual Property Rights and Access to Innovation - Evidence from TRIPS' [2015] Hoover IP Working Paper; Iain Cockburn et al, 'Patents and the global diffusion of new drugs' [2016] 106(1) American Economic Review 136-164.

343 Mark Duggan et al, 'The Market Impacts of Pharmaceutical Product Patents in Developing Countries: Evidence From India' [2016] 106(1) American Economic Review 99-135.

344 Margaret Kyle, Yi Qian, 'Intellectual Property Rights and Access to Innovation - Evidence from TRIPS' [2015] Hoover IP Working Paper. The authors further state that an increase of prices and at the same time sales suggests pharmaceutical companies investing in efforts to shift the demand outside, e.g. by advertising or establishing distribution channels.

345 "The Hatch-Waxman Act includes a provision where generic firms can challenge the validity of the patents that brand manufactures file with the US FDA. [..] In this case, a generic firm asserts that brand name firm's patent(s) are invalid or non-infringed by the generic's product. The first generic firm to file and prevail under a paragraph IV certification for a particular branded product receives a 180-day marketing exclusivity" in Henry Grabowski, 'Are the Economics of Pharmaceutical R&D Changing? Productivity, Patents and Political Pressures' [2004] 22(2) Pharmacoeconomics 19-20.

346 Henry Grabowski, Margaret Kyle, 'Generic Competition and Market Exclusivity Periods in Pharmaceuticals' [2007] 28(4/5) Managerial and Decision Economics 491-502.

347 See, for instance, Henry Grabowski, 'Are the Economics of Pharmaceutical R&D Changing? Productivity, Patents and Political Pressures' [2004] 22(2) Pharmacoeconomics 19-20; Matthew J Higgins, Stuart JH Graham, 'Balancing Innovation and Access: Patent Challenges Tip the Scales' [2009] 326(5951) Science 370-371.

348 C Scott Hemphill, Bhaven N Sampat, 'When do Generics Challenge Drug Patents?' [2011] 8(4) Journal of Empirical Legal Studies 613-649.

and the generic firm, which in turn delays generic entry.[349] Overall, Paragraph IV challenges yield modest welfare gains, because consumption is only shifted from branded sales to generic sales as shown by a case study on hypertension drugs in the United States.[350] From a dynamic perspective, more generic penetration leads to a decrease in early-stage pharmaceutical research within the same ATC class as well as to a R&D shift towards large-molecule products.[351] However, also biological drugs face competition from biosimilars after the patent expiry. There is a substantial variation across different EU countries depending on country-specific procurement and buyer institutions either discouraging or facilitating biosimilar penetration, which partially result in falling market prices over time.[352]

So far available empirical studies that explicitly investigate supplementary protection certificates (SPC) are rather descriptive in nature and analyse primarily the determinants of SPC usage as well as application outcomes. The first study, conducted by de Pastors (1995), summarises the initial usage of SPCs in 1993 and 1994 and finds a substantial heterogeneity between the number of applications and SPC grants of different countries.[353] De Pastors (2015) provides recent descriptive statistics based on hand-collected SPC data retrieved from the national patent offices. She finds a significant attenuation of differences between EU Member States as SPCs increasingly refer to EP patents and EMA marketing authorisations. However, the remaining differences are still significant, especially with regard to the differential outcome of SPC applications across states.[354] This is confirmed by Mejer (2017) and Kyle (2017). Mejer (2017) further observes an increasing geographic coverage of SPCs, significant differences in the scope of SPC protection (e.g. expiry dates), and an increasing number of multiple SPCs referring to the same medical product.[355] Additionally, Kyle (2017) finds evidence that the likelihood of applying for SPC protection increases with a drug's development time and that products with SPCs face faster generic entry than those without.[356] Both studies conclude that further harmonisation efforts would reduce the uncertainty around the validity of SPC, especially for generic entrants. Due to limited data availability, none of the studies analyses SPCs for plant protection products.

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349 C Scott Hemphill, Bhaven N Sampat, 'Drug Patents at the Supreme Court' [2013] 329(6126) Science 1386-1387.

350 See Lee Branstetter et al, 'Regulation and Welfare: Evidence from Paragraph IV Generic Entry in the Pharmaceutical Industry' [2016] 47(4) The RAND Journal of Economics 857-890.

351 Lee Branstetter et al, 'Starving (or Fattening) the Golden Goose - Generic Entry and the Incentives for Early-Stage Pharmaceutical Innovation' [2014] NBER Working Paper.

352 Scott Morten et al, 'The Impact of the Entry of Biosimilars: Evidence from Europe' [2016] HBS Working Paper No. 16-141.

353 Alice de Pastors, 'Supplementary Protection Certificates. Situation after Two Years of Operation of the EC1768/92 SPC Regulation' [1995] 17(3) World Patent Information 189-192.

354 Alice de Pastors, SPC-News 29, 'Latest News on Medicinal Product SPCs in Europe' [2015].

355 Malvina Mejer, '25 Years of SPC Protection for Medicinal Products in Europe: Insights and Challenges' [2017] working paper, available at https://ec.europa.eu/info/publications/25-years-spc-protection-medicinal-products-europe-insights-and-challenges_en?2nd-language=bg (last accessed 15 January 2018).

356 Margaret Kyle, 'Economic Analysis of Supplementary Protection Certificates in Europe' [2017] European Commission/MINES ParisTech (CERNA) working paper, available at https://ec.europa.eu/docsroom/documents/25621/attachments/1/translations/en/renditions/pdf (last accessed 15 January 2018).

7.2.2 SPC data overview

7.2.2.1 National intellectual property registers

An assessment of the national online intellectual property registers revealed that data on SPC-relevant information are available for all Member States of the European Union (plus Norway and Switzerland) except for Croatia, Cyprus and Malta. The SPC Regulations require the NPOs, pursuant to Art. 9 Reg. 469/2009, to publish the notification of an SPC application. Such publication must include information about the applicant, the basic patent, the title of the invention, the MA and, where relevant, the date and number of the first MA for the purposes of Art. 13 Reg. 469/2009 or whether an extension is also requested together with the grant of the SPC (Art. 9(2) (f) Reg. 469/2009). Further, the NPOs shall publish the notification of the fact that a certificate has been granted, and such publication must include – pursuant to Art. 11 – all the elements mentioned with respect to the publication concerning the existence of SPC application. The same rules apply under Reg. 1610/96 to applications filed for and certificates granted on active substance of a plant protection product. However, there is considerable heterogeneity between the countries with regard to coverage, level of detail and accessibility (see also Table 1 in Annex V for an overview).

- Coverage: Although SPCs were introduced in 1993 (2004 or 2007 respectively), some countries provide information only for a subset of their SPC applications. For instance, data coverage for Italy starts in 2006, for Luxembourg in 1997, and for Portugal in 1998. Furthermore, countries differ as to whether they publish all SPC applications in their registries or only granted SPCs (e.g. Estonia).
- Level of detail: All national registers include information on the product name and the SPC holder/applicant. Most national registers also include information on the basic patent (except Bulgaria and Lithuania), the filing date (except Czech Republic), and the lapse date (except Bulgaria). However, there is considerable variation with regard to information on the usage of an SPC (medical SPC or plant protection SPC), the grant/rejection date, and the underlying MA. Whereas all registers include information on the outcome when an SPC application was granted, several national registries (e.g. Italy, Sweden and Estonia) do not report rejections or withdrawals.
- Accessibility: The majority of countries allow for search queries in order to obtain register information on SPCs. However, some countries only provide single PDF documents (Italy) or aggregated lists (Ireland and Estonia). Furthermore, not all registers allow for a download of the SPC information in a structured format.

The World Intellectual Property Office conducted a survey on the grant and publication of SPCs.[357] It was last updated in 2002, therefore there is no information on the countries that joined in the context of the Eastern Enlargement of the EU after 2002.[358] The results of the survey concerning the level of detail are largely consistent

[357] WIPO, 2002 "Survey on the Grant and Publication of 'Supplementary Protection Certificates' for Medicinal and Phytopharmaceutical Products or Equivalent Industrial Property Rights (SPCs)", available at http://www.wipo.int/export/sites/www/standards/en/pdf/07-07-01.pdf (last accessed 31 October 2017).

[358] The list of surveyed countries concerning SPCs for medical products were AT, BE, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, IE, IT, LU, LV, MD, NL, NO, (PT), (RO), SE. The survey also included non-European

with the findings presented above (all countries: SPC applicant, title of invention (product name), number of basic patent (the above analysis shows missing information only for countries not included in WIPO survey), SPC grant). However, there is considerable discrepancy between the findings of the WIPO survey and the above analysis with regards to marketing authorisation (e.g. AT, DK, EE) and grant date. Differences likely result from the fact that this analysis observes national online registers in 2017, and that not all countries publish their entire SPC information in online databases.[359]

7.2.2.2 PATSTAT legal status database

The legal status data of the EPO Worldwide Patent Statistical Database, also known as PATSTAT, covers information on the events during the lifetime of a patent application, which also extends to SPC-related events if the patent serves as a basic patent. Information on legal events originates from the INPADOC Worldwide Legal Status database and includes the national legal event codes and the event description. In some cases, the information is supplemented by the SPC application number/SPC number, a filing date, and an extension date/expiry date. However, there is a substantial heterogeneity between the coverage of the entries (by country) because national offices voluntarily submit their SPC information to the INPADOC database.[360] Therefore, the EPO does not accept any responsibility for the accuracy of legal status data relating to the post-grant phase (which concerns practically all SPC-related events). The potential lack of accuracy refers to the coverage, fitness and up-to-date-ness of the data. These concerns are justified for two reasons[361]: First, some countries seem to have no SPC-relevant legal event entries (BG, CY, CZ, GR, HR, IT, LV, MT, PT, RO, SL) or have unrealistically few observations (e.g. only seven SPC legal events in Poland).[362] Second, the number of SPC legal events differs substantially between countries which have a similar number of SPC applications (e.g. France and Germany), which is likely related to different (former) reporting practices.

7.2.2.3 Commercial data providers

One database on SPC applications is provided by Cabinet Alice de Pastors (AdP). This database covers information on more than 20,000 SPCs (as of April 2016), which are either published in national patent registers or the official gazettes.[363] The AdP database contains, *inter alia*, information on the country and date of the SPC application, the name of the product, the basic patent, and the first MA in the EU. Furthermore, it includes the application outcome (and dates) provided that the

countries with comparable instruments to compensate for the lengthy period between patent filing and first marketing authorisation, such as AU, JP, KR, and US.

359 See Question 11 a) (ii)), and c) in the WIPO (2002) survey: some countries, like Italy, have only internal databases. Furthermore, for some countries SPC information may only be published in the weekly patent office gazette.

360 INPADOC contains legal status events from over 40 international patent authorities worldwide. For more information, see https://www.epo.org/searching-for-patents/legal/inpadoc.html (last accessed 31 October 2017).

361 This analysis is based on the data retrieved from PATSTAT Legal Status - 2017 Spring Edition. For more information, see https://www.epo.org/searching-for-patents/business/patstat.html (last accessed 31 October 2017).

362 There are more than 1,000 legal SPC events which are not associated with any country (code).

363 It appears to cover more SPCs than those listed in the national online registers and/or PATSTAT. Moreover, the AdP database comprises SPCs according to the EU Regulations as well as SPCs according to national law.

outcome is stated in either the patent gazettes/official documents or the registries.[364] There also exist commercial databases which include information on SPC, e.g. IMS Health or CORTELLIS. The former is used by Kyle (2017) in her economic report on SPCs in Europe for the European Commission. Kyle (2017) shows that more than 90 per cent of the SPC observations included in IMS Patent Focus can be matched to the AdP data. However, some countries like Malta or Cyprus are not covered by IMS.

7.2.3 Selected empirical findings on SPC activities

This section presents selected empirical findings on SPC activities. It hereby draws on primary as well as secondary sources to address some questions concerning the perceived effectiveness of the SPC Regulations.[365] In particular, this section describes trends in SPC filing activities, differences in granting practices between national patent offices, and evidence of SPC enforcement. The section concludes with a discussion of how these findings may serve as potential indicators of the current SPC regime's effectiveness. The two recent studies on SPCs introduced above – Kyle (2017) and Mejer (2017) – represent the main secondary sources in the following paragraphs.

7.2.3.1 SPC application filings

According to the recent study by Mejer (2017), the number of SPC applications (restricted to those filed under the European Union SPC regulation) has considerably increased over the course of the last three decades. With the first MA date as a reference point, the average annual number of SPC applications in the period from 1993 to 2003 was about 500. In the subsequent years, the annual number frequently surpassed the 1,000 mark and reached its peak at about 1,500 applications in 2013.[366] This rise in SPC application filings can be traced back to several factors concerning the extensive margin, i.e. the number of unique medical and plant protection products, as well as the intensive margin, i.e. the number of countries in which applications for SPC protection on a single medical or plant protection product are filed.

First, Kyle (2017) finds that the use of SPCs has generally expanded: Whereas in the 1990s, about 75 per cent of newly authorised drugs had a respective SPC application filed in at least one country, the share has increased to above 85 per cent in more recent years.[367] Furthermore, Mejer (2017) argues that recent medical products based on combinations of active ingredients and complex biological molecules can be associated with multiple patents as well as multiple SPC applications. Taking the same line, there is an apparent trend towards filing multiple SPC applications with varying

[364] The AdP database has been used for annual reports. See, for instance, Alice de Pastors, SPC-News 29, 'Latest News on Medicinal Product SPCs in Europe' [2015]. A part of the database, which covers SPCs for plant protection products, was partly acquired by Enigma Marketing Research in 2015. For more information, see http://news.agropages.com/News/NewsDetail---15375.htm (last accessed 31 October 2017).

[365] The data used cover SPC filings for three countries (DE, FR, UK) as available from the respective national patent register. Comparing SPC filings in their aggregate by country, the numbers seem consistent with the AdP database as presented in de Pastors (2015).

[366] De Pastors (2015) counts the largest number of SPC applications in 2014, namely 1,650. These differences may be due to different reference dates (De Pastors (2015) refers to the filing date, whereas Mejer (2017) refers to the marketing authorisation date).

[367] One reason for this may be that more products fall into the range of development times for which SPCs are relevant; see also Kyle (2017) and the following paragraphs elaborating this argument.

scope, which are based on the same medical product as well as the same basic patent, even if eventually only one of these applications can be granted.

Second, the geographical scope of SPC filings has increased over time. In the early years of the SPC regulation, SPC applications were filed on average in six to seven countries – a number which has increased to about 20 countries in more recent years. The expansion of the European Union, which resulted in additional countries offering SPC protection, as well as an increased tendency to seek centralised marketing authorisation at the European Medicine Agency are seen as the main drivers of this development.[368] The average number of countries in which SPC protection is sought exceeds by far the average number of countries in which a European Patent is validated.[369]

There are several possible reasons why SPC applications for a particular product are filed only in a subset of all possible countries. As de Pastors (1995) notes, reasons for initial variation were mainly found in country-specific patent and SPC laws and different cut-off dates that determined whether an already authorised product can obtain SPC protection. Differences in later years are most likely rather the result of economic considerations.[370] Frequently, the decision whether to file, validate and maintain a patent in a particular country has to be made at a time when the commercial value of the underlying technology is still uncertain. Naturally, some patent holders may decide to restrict patent protection to the economically most significant countries, with the result that the basic patent required for the SPC application may not be available in all countries offering SPC protection. However, more and more patents are filed via the European Patent Office, which comes with lower marginal costs by country filing and a real option to decide on the geographical scope of patent protection only after the centralised grant decision.[371] In fact, differences in the number and set of countries in which SPC applications are filed have largely vanished since 1993.[372]

In total, Mejer counts about 15,000 SPC applications in the years 1993 to 2014. These applications refer to 909 unique products of which medical products represent the predominant majority (891).[373] SPCs for plant protection products can be filed since 1997. According to the author's own data, for the period 1997 to 2015, the average share of SPC applications for plant protection products is ca. 19 per cent in FR (16 per

368 See Malvina Mejer, '25 Years of SPC Protection for Medicinal Products in Europe: Insights and Challenges' [2017] working paper, available at https://ec.europa.eu/info/publications/25-years-spc-protection-medicinal-products-europe-insights-and-challenges_en?2nd-language=bg (last accessed 15 January 2018) p. 6: "In 1996 only 6% of products were covered in medical products authorized centrally by EMA. In 2000 it was 40% and by 2010 the share reached almost 90%." Furthermore, firms increasingly tend to apply for SPCs in smaller markets.

369 Dietmar Harhoff et al, 'Patent Validation at the Country Level – The Role of Fees and Translation Costs' [2009] 38(4) Research Policy 1423.

370 Alice de Pastors, 'Latest News on Medicinal Product SPCs in Europe' [2015] p.2.

371 See Malvina Mejer, '25 Years of SPC Protection for Medicinal Products in Europe: Insights and Challenges' [2017] working paper, available at https://ec.europa.eu/info/publications/25-years-spc-protection-medicinal-products-europe-insights-and-challenges_en?2nd-language=bg (last accessed 15 January 2018) p. 8: "The average geographical scope protection of the basic patent increased from six Member States, for patents filed in 1984, to almost 13 for patents filed in 2004."

372 According to de Pastors (2015), differences in SPCs filings over the last 24 years have greatly decreased since all EU countries are submitted to Reg. 469/2009. After many East European countries joined the EU and were subject to Reg. 1768/92 (codified version Reg. 469/2009), there was greater uniformity in the number of SPCs requested.

373 See Malvina Mejer, '25 Years of SPC Protection for Medicinal Products in Europe: Insights and Challenges' [2017] working paper, available at https://ec.europa.eu/info/publications/25-years-spc-protection-medicinal-products-europe-insights-and-challenges_en?2nd-language=bg (last accessed 15 January 2018) p. 6.

cent in DE, and 15 per cent in the UK). The shares are fairly constant except for a considerable surge in the year when SPCs for plant protection products were introduced (see figures 1-3 in Annex V).

The share of SPC applications with basic patents granted by the domestic patent office instead of the European Patent Office is about 7-11 per cent (8 per cent in FR, 8 per cent in DE, 11 per cent in the UK) for the overall period 1993 to 2015. However, as can be seen from figures 4-6 in Annex V, there is a strong time trend with even fewer SPC applications based on non-EP patents filed in recent years. This decline is paralleled by a strong decline of cited MAs granted by national regulatory bodies instead of the European Medicines Agency.

To shed light on the origin of the SPCs' underlying inventions, figure 7 in Annex V presents distributions of inventor countries among SPC basic patent families over time. The share of EPC member states shows a fluctuating, but overall slightly decreasing, trend from about 50-60 per cent in the 1990s to about 40 per cent in more recent years (with the SPC application filing as reference point).

7.2.3.2 SPC granting practices

Differences in SPC granting practices between patent offices may manifest themselves in various ways. In the following section the focus lies on differences in the granted scope and length of protection as well as in the duration of SPC examination (i.e. grant lag).

From an aggregate perspective, there appears to be substantial variation in SPC grant rates across countries. For instance, while in Luxembourg or Italy nearly all SPC applications have been granted, this only applies for about 80 per cent of applications in Germany or the UK.[374] Mejer also finds some evidence for the incumbent SPC countries that hints at a negative relationship between the number of SPC applications and the grant rate.[375]

However, using aggregate statistics may not be very meaningful in the assessment of whether examination at each patent office follows the SPC regulation in the same manner. In fact, a comparison of SPC granting practices requires all SPC applications referring to one product to be the same across countries. That is, the application has to be based at least on the same MA and basic patent (family) in all countries. This applies for the subset of SPCs based on a common Union MA and national parts of the same EP bundle patent. At least 26 per cent of these "SPC application twins" appear to be subject to divergent grant decisions.[376] Despite all that, SPC applications may still differ considerably in their scope. Furthermore, application outcomes may also differ between countries due to patent office-specific application strategies (multiple SPC applications of varying scope for the same product) and varying exertion of resources by the originator to prosecute the application. Finally, some patent offices may decide

[374] See Malvina Mejer, '25 Years of SPC Protection for Medicinal Products in Europe: Insights and Challenges' [2017] working paper, available at https://ec.europa.eu/info/publications/25-years-spc-protection-medicinal-products-europe-insights-and-challenges_en?2nd-language=bg (last accessed 15 January 2018) p. 12.

[375] *Ibid.*: "There is some evidence, at least for the EU15 that higher volume of SPC applications examined results in lower grant rate."

[376] *Ibid.,* p. 13: "The data shows among 740 products approved between 2004 and 2014 and referring to the same basic patent no decision has been taken with respect to 34. Out of remaining 706 applications, 26% (182) were granted in one Member State but rejected or withdrawn in the other."

during examination to narrow the SPC application with the result that granted SPCs diverge in scope of protection even if the initial SPC applications show no differences. There are more qualitative assessments of how granting decisions across the patent offices on the same product diverge – yet these are limited to a relatively small number of cases.[377]

According to the SPC Regulation, SPCs may provide a maximum of five years of protection – with the date of the first MA as reference date.[378] Early expiration date discrepancies across countries were primarily found in the lack of harmonisation of national laws.[379] However, Mejer (2017) states that, for SPC applications filed between 2004 and 2014, expiry dates are still quite heterogeneous across the Member States. She further argues that in more than half of these cases the discrepancy originates from differences in first MA dates.[380] In fact, prior to recent decisions by the CJEU the day considered as MA date used to vary between countries. For instance, whereas most countries refer to the issue date, Belgium and the UK used to rely on the notification date. As far as European MAs are concerned, the CJEU has clarified the issues and decided that the critical date for calculating the SPC term is the date of the notification of the decision to grant the MA to the applicant.[381] However, this case law does not apply to national MAs. According to the data collected by the MPI, many NPOs still refer to the date on which the decision is made as the critical date, since starting from there the MA has legal effect. However, as Mejer (2017) notes, with the clarification brought by recent case law and an increasing share of SPC applications referring to EMA MA dates, discrepancies in expiry dates are likely to disappear.[382]

Besides variation in the scope and length of SPC protection, further differences in granting practices may relate to the duration from the filing of the SPC application to the final grant decision. In fact, there is considerable heterogeneity in average grant lags. For instance, in France the median length of grant lag is 17 months, whereas in Germany, the median length is 31 months.[383] Underlining this finding, figures 8 and 9 in Annex V show that in France about 60 per cent (in the UK about 80 per cent) of all eventually granted SPC applications received their decision within the first 18 months, whereas in Germany this share is only about 37 per cent. These differences also prevail when rejections are included.[384]

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377 See, for instance: Omkar Umesh et al, 'Comparative Quantitative Analysis of Supplementary Protection Certificates (SPCs) in Europe' [2017] 22(1) Journal of Intellectual Property Law & Practice 16; Alice de Pastors, SPC-News 29, 'Latest News on Medicinal Product SPCs in Europe' [2015].

378 This period may be extended by another 6 months if the underlying medicinal product fulfils the requirements related to paediatric use research.

379 As argued in Alice de Pastors, SPC-News 29, 'Latest News on Medicinal Product SPCs in Europe' [2015].

380 Malvina Mejer, '25 Years of SPC Protection for Medicinal Products in Europe: Insights and Challenges´ [2017] working paper, available at https://ec.europa.eu/info/publications/25-years-spc-protection-medicinal-products-europe-insights-and-challenges_en?2nd-language=bg (last accessed 15 January 2018).

381 Case C-471/14 *Seattle Genetics* [2015] EU:C:2015:659.

382 Malvina Mejer, '25 Years of SPC Protection for Medicinal Products in Europe: Insights and Challenges' [2017] working paper, available at https://ec.europa.eu/info/publications/25-years-spc-protection-medicinal-products-europe-insights-and-challenges_en?2nd-language=bg (last accessed 15 January 2018).

383 The median grant lag is calculated from all SPC applications in Germany (France) filed between 1995 and 2005, which receive a grant decision. Hence, SPC applications, which are not eventually granted but e.g. rejected or withdrawn, are excluded. Including all SPC applications, which receive any form of decision, results in a median "first decision" lag that is slightly larger than the median grant lag. SPC filings after 2005 are excluded in order to account for censoring.

384 However, with respect to France it shall be pointed out that according to the applicable French law a decision over the grant of the certificate must be made within a deadline of 12 months since the filing of the request, and after this deadline the application must be rejected. The French Patent Office is

As prior studies on the duration of patent examination have shown,[385] this grant lag can be a function of the patent office's workload and examination practices, but it may also partly depend on characteristics of the applicant and the underlying application. It can also be the consequence of provisions, like the one laid down in French law, according to which the examination must be concluded within a specific period of time, after which the application is rejected if a decision to grant the SPC is not possible. As Mejer (2017) notes, the grant lag is seemingly unrelated to the volume of applications at a given patent office.[386] Given that the applicant is frequently the same for all SPC applications,[387] it appears reasonable to assume that different examination practices at the national patent offices cause at least part of the observed variation in grant lag.[388]

According to this literature, differences in the examination outcomes at national patent offices and lack of clarity on the provisions of the SPC Regulation lead to significant differences in the scope of SPC protection in the European Union.[389]

7.2.3.3 SPC enforcement

Patent (hence, SPC) litigation can be a costly endeavour. Recent studies estimate that the costs of enforcing an exclusive right before a court may amount to between EUR 50,000 to EUR 4 million, depending on the country.[390] Furthermore, the fragmented system in Europe usually allows enforcement only in the jurisdiction where the patent holder has successfully litigated. This implies that in order to stop Europe-wide infringement, legal enforcement in more than one jurisdiction may be necessary. SPCs frequently cover products with considerable commercial value with the result that the stakes of the litigants go well beyond the usual litigation costs – making litigation more likely. Furthermore, uncertainty about the strength of SPC protection in a particular country for originators and generic producers make (pre-court) settlements less likely, so that a legal resolution before court is needed. Given the lack of uniform and concurrent granting decisions of SPCs across the Member States, one may

required by law to grant or reject the SPC within one year of the request. After this deadline, the application must be rejected. However, the notification of an irregularity interrupts this time period until regularisation, at which point the time period is re-initialised.

385 Dietmar Harhoff, Stefan Wagner, 'The Duration of Patent Examination at the European Patent Office' [2009] 55(12) Management Science 1969.

386 Malvina Mejer, '25 Years of SPC Protection for Medicinal Products in Europe: Insights and Challenges' [2017] working paper, p. 12: "The backlog is not related to the volume of applications received. While Germany, United Kingdom, France and Italy receive very similar number of applications the share of pending applications is four times lower in France and Italy (less than 10 per cent) when compared to Germany or UK (about 40%)." Available at https://ec.europa.eu/info/publications/25-years-spc-protection-medicinal-products-europe-insights-and-challenges_en?2nd-language=bg (last accessed 15 January 2018).

387 As Kyle (2017) notes, SPCs as well as marketing authorisations may be held by different entities across countries.

388 Registration, renewal and invalidation of SPCs are not harmonised under the SPC Regulations. For example, national patent offices may conduct *ex-officio* examination or examine on formalities only. The former requires more resources and is more time consuming than the latter, hence a larger backlog. Furthermore, in cases where there is a pending case in front of a national court concerning the patent for which SPC is applied for, some patent offices will wait with their grant or rejection decision until the court issues a judgment (e.g. UK), while others will not. For those that do, the backlog is expected to be higher. Last but not least availability of pre-grant opposition proceedings could potentially delay the decision to grant.

389 Malvina Mejer, '25 Years of SPC Protection for Medicinal Products in Europe: Insights and Challenges' [2017] working paper, available at https://ec.europa.eu/info/publications/25-years-spc-protection-medicinal-products-europe-insights-and-challenges_en?2nd-language=bg (last accessed 15 January 2018).

390 See Katrin Cremers et al, 'Patent Litigation in Europe' [2017] European Journal of Law and Economics 8.

therefore expect, first, a larger degree of SPC litigation overall, and second, more multi-jurisdictional – parallel – litigation of SPCs as decisions in one jurisdiction do not easily resolve uncertainty of the dispute in another jurisdiction.

Based on SPC litigation data from a commercial case law database, the authors of this Study find 174 litigation cases in European Member States based on SPCs.[391] When these cases are linked via the INPADOC patent families of the SPCs' basic patents, the litigation cases relate to 87 unique patent families. Based on this broad definition of parallel cases, the share of duplicate litigation (i.e. the patent family is litigated in more than one country) is 23 per cent. This figure is not higher than those found in a recent cross-jurisdictional study on patent litigation in Europe.[392] However, this analysis comes with considerable caveats. The available SPC litigation data are restricted to particular countries and years. Furthermore, detailed entries are usually conditional on a published court decision.

In comparison, for Germany, the national patent register lists overall 16 granted SPC applications that have been subject to a revocation action.[393] The revocation action is a validity challenge against the exclusive right and usually part of a dispute between the rights holder and another party. Relative to the overall number of 861 granted SPC applications at the German Federal Patent Office, this amounts to a litigation rate of 1.9 per cent. This litigation rate is higher than for the overall population of granted patents in Europe; however, this comparison falls short when taking into account the considerable commercial value of each SPC, which likely exceeds the commercial value of the average patent.

391 For more information, see Annex V of this Study, Section 1.2 on SPC litigation data.
392 See Katrin Cremers et al, 'Patent Litigation in Europe' [2017] European Journal of Law and Economics 8.
393 For more information, see Annex V of this Study, Section 1.3 on SPC revocation data.

8 THE EFFECTIVENESS OF THE SPC SYSTEM IN THE EU

In assessing the efficiency and effectiveness of a legislation the acceptance and the views of the stakeholders are relevant. In this case we may refer to these views as the ”perceived effectiveness” and “perceived clarity” of the legal framework. To assess these factors from the point of view of stakeholders we conducted a limited number of structured interviews and invited stakeholders to express their experiences and opinions by responding to an online survey. Further we collected additional information in a workshop. While the results of such a survey cannot provide conclusive outcomes, and while the sample is not representative of the European industry for the limitations explained elsewhere[394], the information collected may still reflect accurately the perception of the participating research population.

This Chapter includes the results of those questions that were designed to establish the opinion of participating stakeholders on the effectiveness of the SPC Regulations. Furthermore, it includes some notions regarding the opinions of the NPOs on the effectiveness of the system.

8.1 ALLENSBACH SURVEY

8.1.1 The purposes of the SPC Regulations

As already explained[395], the SPC Regulations pursued different purposes, namely:

- To preserve the integrity of the common market by preventing an heterogeneous development of the legislation.
- To foster research in products eligible for SPC protection, and particularly products for which the development time is longer due to required regulatory approval processes.
- To strengthen the EU as a location for pharmaceutical research by offering standards of protection equivalent to those existing in Japan and the US and in this way preventing a relocation of research centres outside of the EU.
- To balance all the interests involved in the pharmaceutical and plant protection sectors through the existence and extension of exclusivity rights on pharmaceutical and plant protection products.
- To establish a uniform, simple and transparent system for granting SPCs.

To assess the perceived effectiveness of the SPC system, the questionnaire for the Allensbach Survey, to a large extent, mirrored these objectives of the SPC Regulations with the goal in of evaluating whether these objectives were achieved from the point of view of the stakeholders.

Some of the questions gained criticism from some stakeholders. So for instance, it was argued that the existence of SPC protection is not relevant or is only one of the many factors in influencing the decision where to locate a research centre, and that such a question (Q26a) shows little understanding of the pharmaceutical industry.[396] It

394 See Annex IV of this Study.
395 See Chapter 2 of this Study, Sections 2.1 and 2.2.
396 See, for example, response in Annex III of this Study, p. 424.

is true in our view that it is not clear why – being any other factor equal – the absence or existence of SPC protection shall influence the decision of a company in locating a research centre in one country or another. We agree that other factors seem to be more relevant. If at all, the existence of SPC legislation and longer patent protection – in conjunction with a narrow experimental exemption – could lead a company to avoid that jurisdiction and not locate its laboratories there. But there is no doubt that this purpose was one of those at the basis of the SPC legislation. For this reason, in asking the stakeholders whether they think the SPC legislation has reached its goals, we should mention also this purpose; indeed, it is emphasised several times in the relevant material (recitals of Reg. 1768/92, recitals of Reg. 1610/96 and pertinent Explanatory Memoranda).

8.1.2 Attitude towards the present SPC system

Answers regarding the experienced effectiveness of the SPC system can be correlated with the stakeholders' general attitude towards the SPC system. Therefore, we included questions that indicate the general attitudes

The main basis for determining the general attitudes was Q26, which presented several statements, and among those, the following most general statements (from Q26a and 26b, for the complete questionnaire see Annex III):[397]

- "The current SPC regime takes all the involved interests sufficiently into account."
- "The current SPC Regulations work well in most cases and do not result in legal uncertainty."

Of the participating stakeholders 56 per cent agreed or strongly agreed with the statement that the current SPC regime takes all the involved interests sufficiently into account, while 37 per cent disagreed or strongly disagreed.

Regarding the question whether the current SPC Regulations work well in most cases and do not result in uncertainty, 53 per cent of the participants either agreed or strongly agreed with this statement, 44 per cent disagreed or strongly disagreed and three per cent stated that it is impossible to say.

[397] For a detailed analysis of the responses see Annex III, pp. 16-19 and p. 127-156.

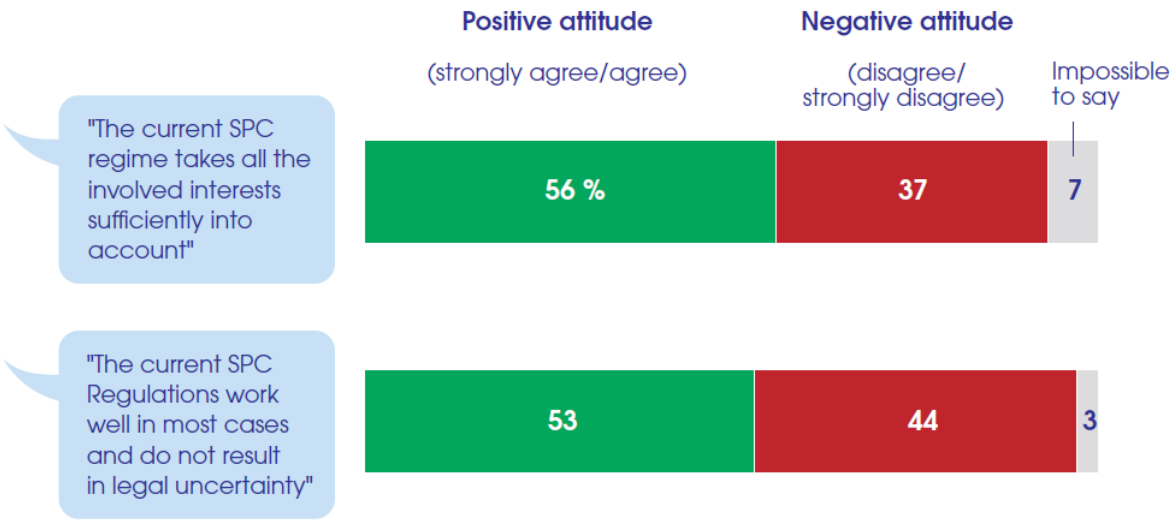

Figure 8.1: Q26 of the Allensbach Survey

8.1.3 Incentive for investment in research

8.1.3.1 General question

Of all respondents, 80 per cent agree/strongly agree in Q26 with the statement that the current SPC regime fosters the investment in research and development (R&D) activities, only 15 per cent of respondents oppose it (disagree/strongly disagree). Clear majorities of two subgroups, (i) the representatives of originator companies and (ii) the representatives of generic companies also agree with that. Of course, the wording of the question does not exclude the possibility that other measures may also foster investment in research and development activities. But as soon as the general attitude toward the SPC system is introduced into the analysis of Q26a additionally, the clear correlation between investment in R&D and a general positive or negative attitude toward the current SPC system becomes visible.

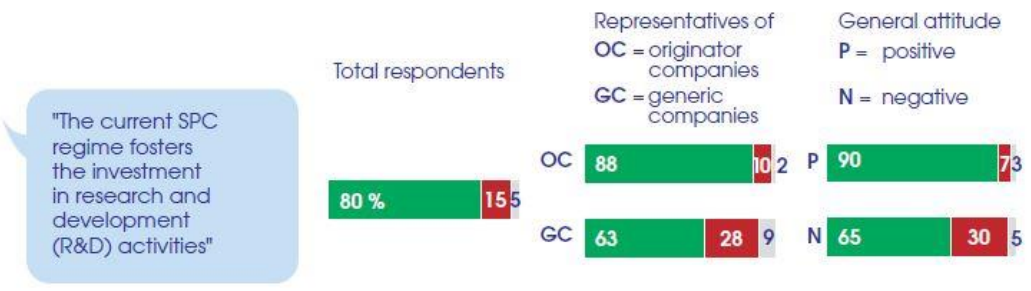

Figure 8.2: Q26 of the Allensbach Survey

8.1.3.2 *Incentive for products with long development time*

More than two thirds (68 per cent) of all respondents agree or strongly agree with a further statement in Q26b that the current SPC Regulations act as an incentive to develop more products for which a longer time is needed until an MA is obtained while 19 per cent disagree or strongly disagree. Interestingly, while there is a large majority among the representatives of generic companies (72 per cent) who agree or strongly agree with this statement, almost 26 per cent give no definite answer. Some participants commented that it was not defined what "longer" meant.[398] The term was included in the question based on economic research suggesting a trend for longer development times.[399] Therefore, it was assumed that "longer" meant a timespan for the development that extends beyond an average development time and also extends at least beyond five years. The time span of five years is relevant insofar as products with a shorter development time will not benefit from the additional SPC term (Art. 13 Reg. 469/2009 EC and Art. 13 Reg. 1610/96 EC). In the data there are no indications that the partial imprecision (which is often inevitable, even necessary to keep a survey question wording simple and short) actually prevented respondents to understand the overall scope of the statement.

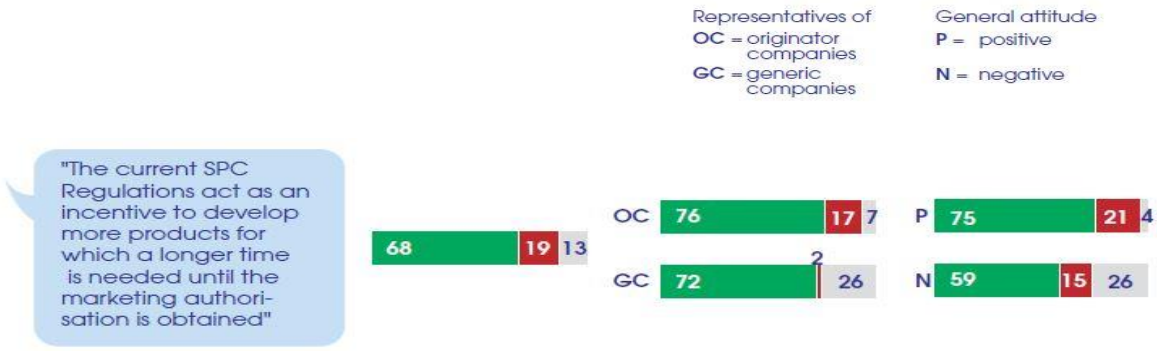

Figure 8.3: Q26 of the Allensbach Survey

8.1.3.3 *Second medical uses*

Second medical uses are sometimes claimed to become equally important for pharmaceutical companies as first medical uses. The mere fact that it is the second use also does not exclude the possibility that substantial time is required for the R&D and MA application processes. Nevertheless, there are differences with respect to first and second medical uses and the question was meant to establish whether the protection for second medical uses is sufficient from the point of view of the participating stakeholders. Asked whether the SPC Regulations as interpreted by the CJEU sufficiently protect new medical uses of known compounds, that is the so-called second medical use (Q26b), a clear majority of two-thirds (63 per cent) of the participants agree or strongly agree with this statement while 23 per cent disagree or strongly disagree.[400]

398 See for example response in Annex III of this Study, p. 412.
399 Tony Rollins, 'How Europe's SPC regime works in practice. Managing Intellectual Property in Practice', 22 June 2016, available at http://www.managingip.com/Article/3560853/How-Europes-SPC-regime-works-in-practice.html (last accessed 6 November 2017). See also Chapter 16, Section 16.2
400 See Annex III of this Study, pp. 16, 18, 151.

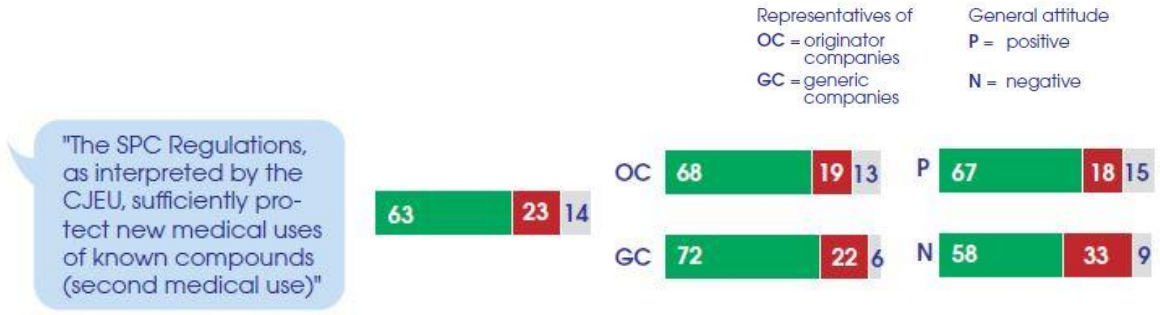

Figure 8.4: Q26 of the Allensbach Survey

8.1.3.4 Combination products

A further statement[401] presented to the stakeholders was whether or not the SPC Regulations as interpreted by the CJEU encourage investment in the development of combination products in Europe (Q26b). The background to this question is a presumed increase in combination products compared to single-compound products. Reasons for such combinations can vary across different products and uses. Vaccines, for example tend to rely strongly on combination products to reduce the number of applications. In other areas combinations may lead to increased effectiveness or simply convenience. Since combination products are based at least on two active ingredients, the focus is on whether the present SPC Regulations as interpreted by the CJEU are adequate in this respect. Opinions on this are divided: 45 per cent of all participants agree with the statement while 31 per cent do not and a considerable number, 24 per cent refrain from stating any particular opinion on that.

Among the representatives of originator companies a relative majority of 44 per cent, agree with the statement while equally 28 per cent oppose it and 28 per cent stay undecided. At the same time a majority of 57 per cent of the representatives of generic companies agree while 26 per cent oppose and 17 per cent stay undecided.

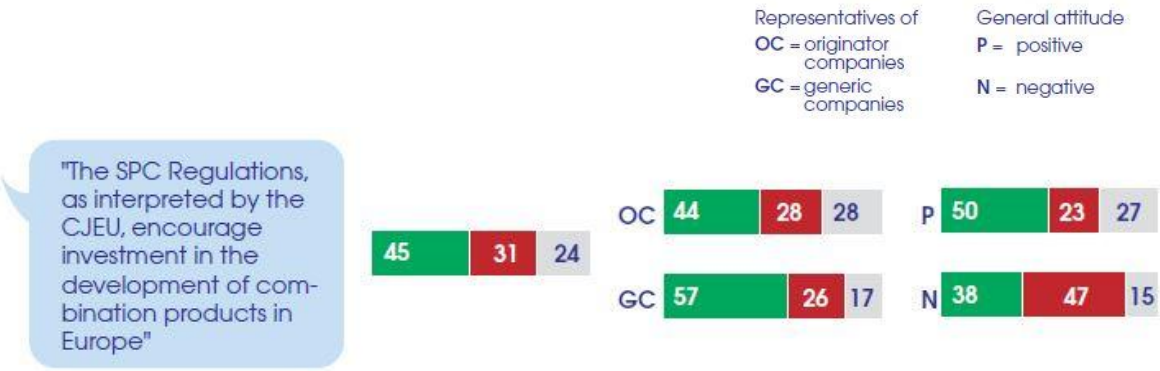

Figure 8.5: Q26 of the Allensbach Survey

[401] See *ibid.*, pp. 17, 148.

8.1.3.5 Biopharmaceutical products

By means of Q29 the stakeholders were asked whether in their opinion Regulation 469/2009/EC needs to be changed or amended in order to better accommodate biopharmaceuticals and products of recombinant DNA technology.[402] According to our qualitative interviews as well as our literature analysis, biopharmaceuticals are gaining a much more important role in the pharmaceutical sector compared to more than 20 years ago when the SPC Regulations were drafted. The question, therefore, is obviously whether or not the Regulations are sufficient for this new technology. After having conducted the qualitative interviews with selected stakeholders it came as a surprise that a vast majority of stakeholders, 73 per cent of those participating in the Allensbach Survey, state that in fact today's Reg. 469/2009 needs to be changed or amended in this respect. Only 13 per cent stated that it does not need to be amended, with 14 per cent having no clear opinion on this. This was the opposite result to our experiences in the structured interviews, in which all stakeholders stated that in their opinion the present rules are sufficient with regard to biological products. This difference may be traced back to different cross sections of stakeholders in both parts of the Study.

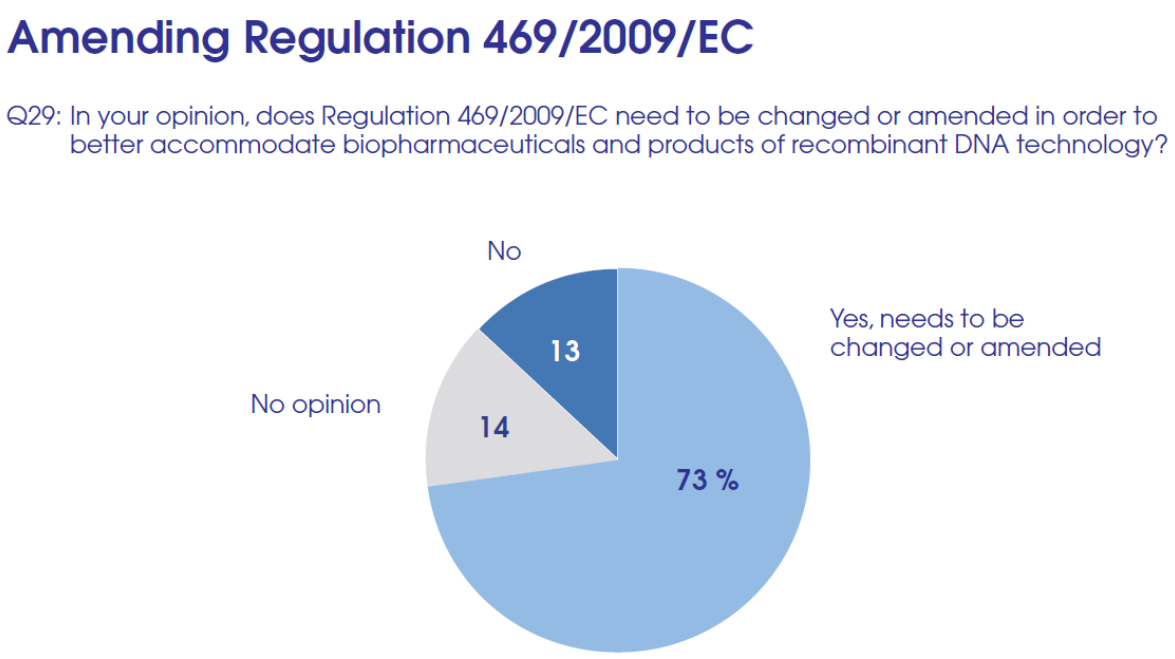

Figure 8.6: Q29 of the Allensbach Survey

8.1.4 Relocation of research centres and generic companies

As described earlier, one of the primary goals of the SPC Regulations is to strengthen the European pharmaceutical industry and to keep research and development in the EU. We asked therefore whether the SPC could have an influence in the decision to relocate research centres outside of the EU as well a negative influence on the decision of generic companies in to locate development or production facilities outside Europe.

[402] See Annex III of this Study, p. 157.

8.1.4.1 *Relocation of research centres*

The picture resulting from the reaction to the next statement of Q26a is not that clear. We asked the stakeholders whether the current SPC Regulations on medicinal and plant protection products effectively prevent research centres situated in the EU Member States from relocating to countries outside the EU. The question was drafted with the goals of the SPC Regulations in mind to prevent the relocation of research centres outside of the EU.[403]

Only at first glance, the distribution of the answers seems to be quite even with 36 per cent of all respondents agreeing and 34 per cent disagreeing. But in the subgroup of representatives of originator companies 52 per cent agree, while 52 per cent of the subgroup of representatives of generic companies oppose it.

Within both subgroups approximately one fourth of the participants (25 and 24 percent, respectively) refrain from choosing a specific answer on that matter.

This perfectly legitimate though,relatively high, share of undecided respondents points to an important conclusion, namely, that it is indeed difficult to attribute any effect directly or solely to the SPC system. Instead a plurality of factors may be decisive. This again, is a topic for further economic research.

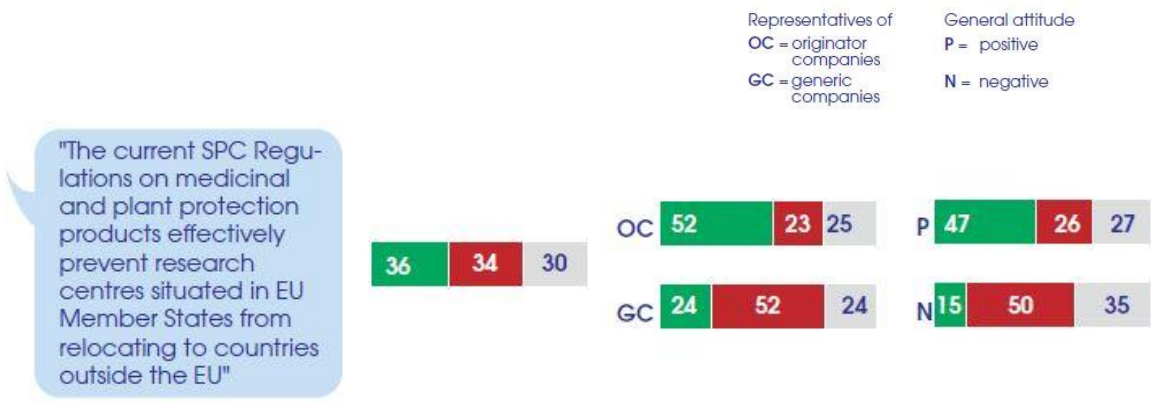

Figure 8.7: Q26 of the Allensbach Survey

8.1.4.2 *Relocation of development or production facilities of the generic industry*

Since the SPC is connected to the patent, it is a tool for supporting the originator industry. However, it is possible that as a side effect, generic companies will move their development and production facilities to countries outside the EU without supplementary protection to avoid the extended term of protection and to be able to manufacture products for foreign markets as soon as the basic patent protection expires. This may also put them in a position to be able to bring products on the EU market immediately after the SPC expires. While these are mainly economic decisions, they are influenced by the law and therefore are included in this Study to a limited

[403] See Proposal for a Council Regulation (EEC) concerning the creation of a supplementary protection certificate for medicinal products, COM(90) 101 final [1990] OJ C 114, 10 para. 7.

extent. We asked participants what effect the SPC system may have on the relocation of generic companies outside of the EU (Q26a).[404]

In total, 38 per cent of all stakeholders are of the opinion that the SPC system as currently practiced encourages European manufacturers of generic medicines to relocate production facilities to countries outside the EU, whereas a relative majority (41 per cent) do not share this view and 21 per cent are undecided. Again, a closer look reveals that a vast majority of 87 per cent of the representatives of the subgroup of generic companies agree with the statement, while only 19 per cent of the respondents on the originator side agree.

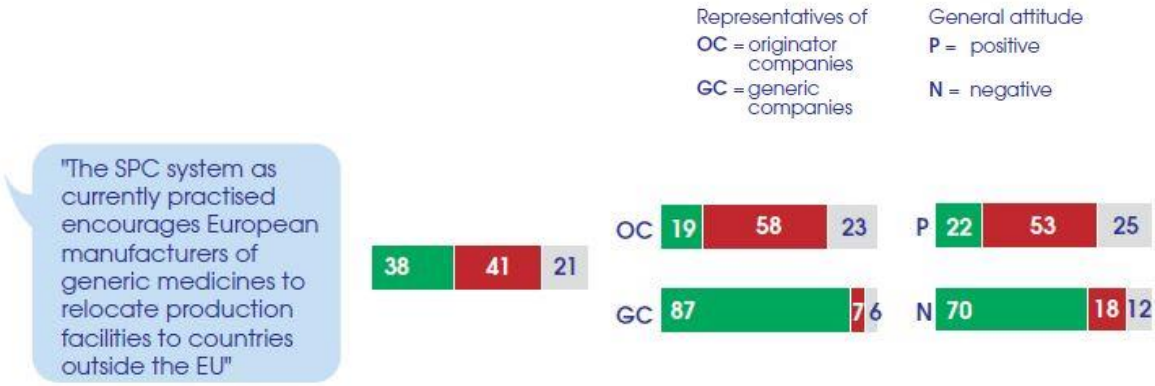

Figure 8.8: Q26 of the Allensbach Survey

8.1.4.3 Effects of the SPC on the decision to manufacture active ingredients

One of the main goals of the SPC Regulations was to prevent companies from moving research on and manufacture of medicinal products outside the EU. Thus the effect of the availability of SPC protection on the decision to manufacture active ingredients in the EU may provide some insights into whether this goal has been met. The responses to question 63, however, do not provide a clear picture since a majority of all stakeholders and particularly of the originators stated that this varies from case to case.[405] Only the generic companies state with a clear majority that the availability of SPC protection has an effect on their decision where to manufacture an active ingredient. Combined with the results from our structured interviews the conclusion may be drawn that while the availability of SPC protection is one decisive factor for originators it is not the only one. As one company representative stated during the interviews, "the overall political climate with respect to pharmaceutical products and IP protection" is important.[406] On the other hand, it can be concluded from the responses of the generic manufacturers that production will take place in countries without SPC protection to allow an early market entry also in countries with SPC protection.

404 See Annex III of this Study, pp. 17, 19, 130.
405 See *ibid.*, pp. 46, 245, 246.
406 Interview summary on file with the authors of the Study.

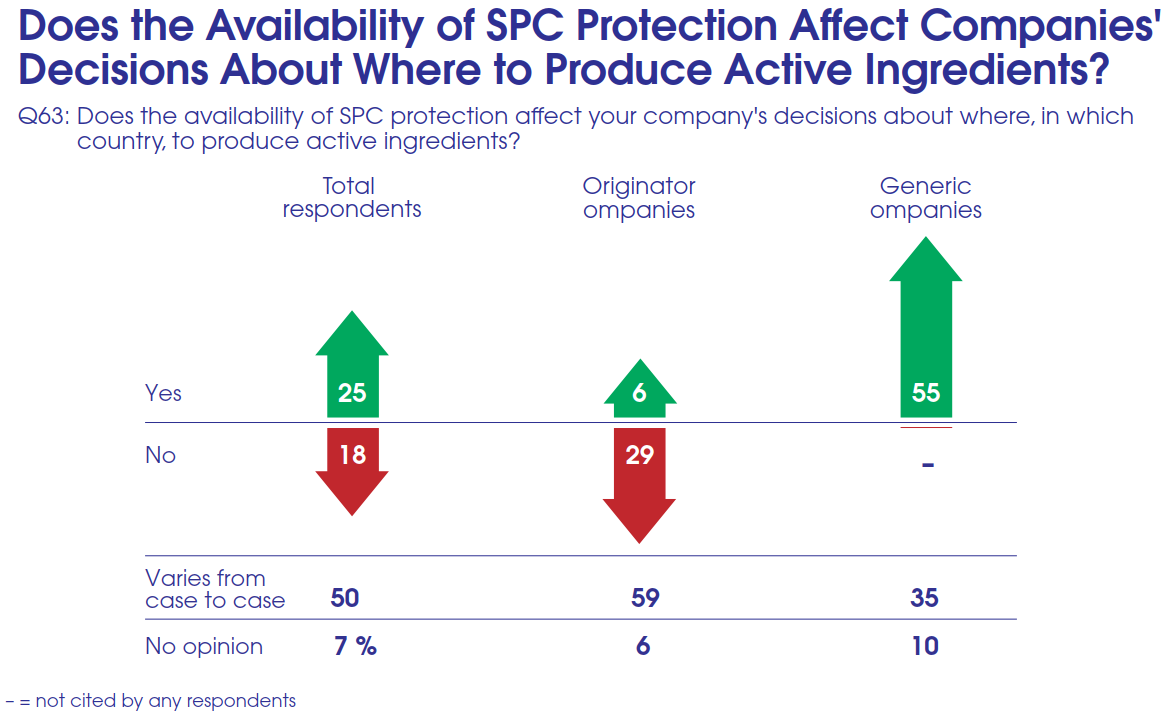

Figure 8.9: Q63 of the Allensbach Survey

8.1.5 Balance of interests

The SPC Regulations intended to create a system of extension that is balanced and takes the interests of the patients and of the generics industry sufficiently into account.[407] To this purpose, several precautions aimed at preventing an excessive extension of the protection were adopted: beyond the general limitation of the extension to five years after the grant of the SPC, it was provided that only SPCs for the product could be granted – irrespective of the identity of the applicant – and that such SPCs would be granted only on the basis of the first MA issued for the active ingredient concerned. These provisions aimed to prevent an evergreening of protection, as mentioned in the case law, that is, to rule out that generic competition with respect to active ingredients could be delayed by obtaining multiple SPCs for the active ingredient. In the Allensbach Survey we asked two separate questions on this matter: a first (Q26a) focused on the general issue of the balance of interests, and a second one (Q31) on the issue of evergreening.

8.1.5.1 General question on the balance of interests

In answering the respective statement in Q26a that focuses the balance of interests, the majority (56 per cent) of all respondents support the view that the current SPC regime takes all the involved interests sufficiently into account while 37 per cent disagree or strongly disagree. Again, we find the pattern of quite opposite opinions of representatives of originator companies and those of generic companies: While among the representatives of originator companies 76 per cent generally are of the opinion

[407] Recital (10) and European Commission, Explanatory Memorandum to the Proposal for a Council Regulation (EEC), of 11 April 1990, concerning the creation of a supplementary protection certificate for medicinal products (COM(90) 101 final – SYN255), para. 25.

that the current SPC regime takes all the interest involved sufficiently into account, this share is only 20 per cent among the representatives of generic companies.

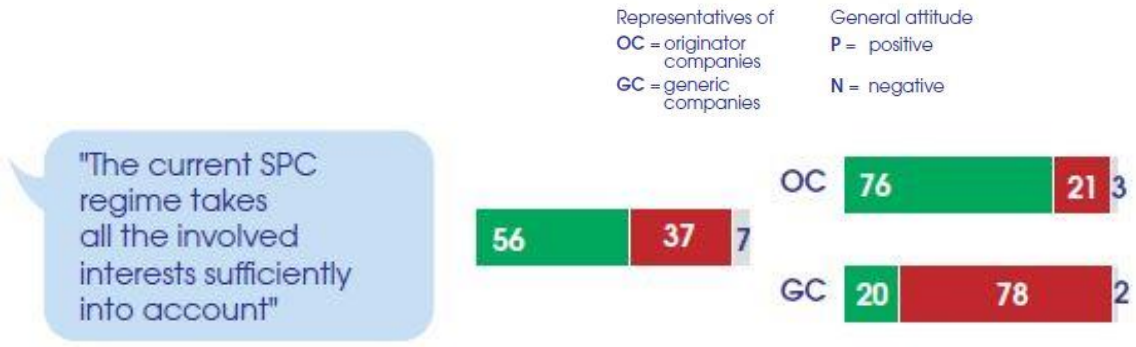

Figure 8.10: Q26 of the Allensbach Survey

8.1.5.2 Evergreening

Legal literature in the past years has addressed a phenomenon labelled "evergreening". Since this is not a genuine concept of patent law, there is also no clear definition. However, in the general and academic discussions, it seems to be clear that "evergreening" includes various types of strategies to extend the protection of pharmaceutical products beyond what is envisioned by the law maker and thus delaying efficient competition.[408]

By Q31, participants were asked whether or not the current SPC Regulations might have encouraged "evergreening" strategies. The wording of the question met some criticism in the respective comment box of the questionnaire as allegedly biased because of the use of the term "evergreening". A significant number of participants themselves argued that the term is not clearly defined. As examples, we present two verbatim responses from the provided comments box:[409]

> "The use of the word "evergreening" is not helpful as there is no shared understanding of what this means. SPCs are based on patents and by their very nature are meant to extend the patent term for the marketed product for a finite and limited period of time. It is not clear what is meant by linking the granting of SPCs to "evergreening" and there is no basis […] are aware of to suggest the SPC regulations have encouraged any such undefined strategies. […]"
> "Evergreening is a perception, not a strategy. What is described as "evergreening" is nothing more than the protection of improvements of products by patents, which improvements are only patentable if they satisfy the patentability criteria. Once a patent on an active ingredient expires (even after SPC), it becomes available to all, including generic companies. Only the further patents on improvements are not yet available, meaning that generic companies do not yet have access to the latest (most-improved) version of the product, but the original one has become available. Moreover, most patents on improvements cover new uses of the product, which themselves are not the subject of SPCs, so SPCs have no effect on the practice of protecting improvements."

As described earlier, a survey like this cannot measure hard facts, but only perceptions. So, if the criticism is directed to the evaluation of the concept of "evergreening" as a perception by market participants, this criticism does not affect the validity of the question itself.

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408 For a discussion of the term and further references see Nina Schäffner, *Lifecycle Management im Arzneimittelsektor* (Nomos 2015) p. 29.
409 See Annex III of this Study, pp. 317 and 319.

Further criticism was expressed regarding the answering categories provided. A number of participants were of the opinion that of the categories

- "Yes, to a great extent",
- "Yes, somewhat", and
- "No, not substantially",

two were in the affirmative and only one on the negative side, while a chance was missing to express a clearly negative opinion. We agree that it may have benefited the wording of Q31 to provide a second, clearly negative option. However, this can be taken into account when analysing the responses.

Overall, 32 per cent of the participants are of the opinion that the current SPC Regulations have encouraged evergreening strategies either somewhat or to a great extent. On the opposite side 61 per cent of participants were of the opinion that this is not the case or at least not substantially. Looking at the numbers in more detail, it can be seen that a majority of the representatives of generic companies see a correlation between the current SPC Regulations and evergreening (76 per cent of them choose "yes, to a great extent" or "yes, somewhat") while a majority of representatives of originator companies (79 per cent) opposed this by choosing "No, not substantially".[410]

It is worth mentioning that a normal to low share of only 7 per cent of all participants stated that it is impossible to say or that they do not have an opinion on this issue and that all participants responded to the question. Therefore, it is fair to say that a vast majority was familiar with the term "evergreening" and could attach a certain meaning to it.

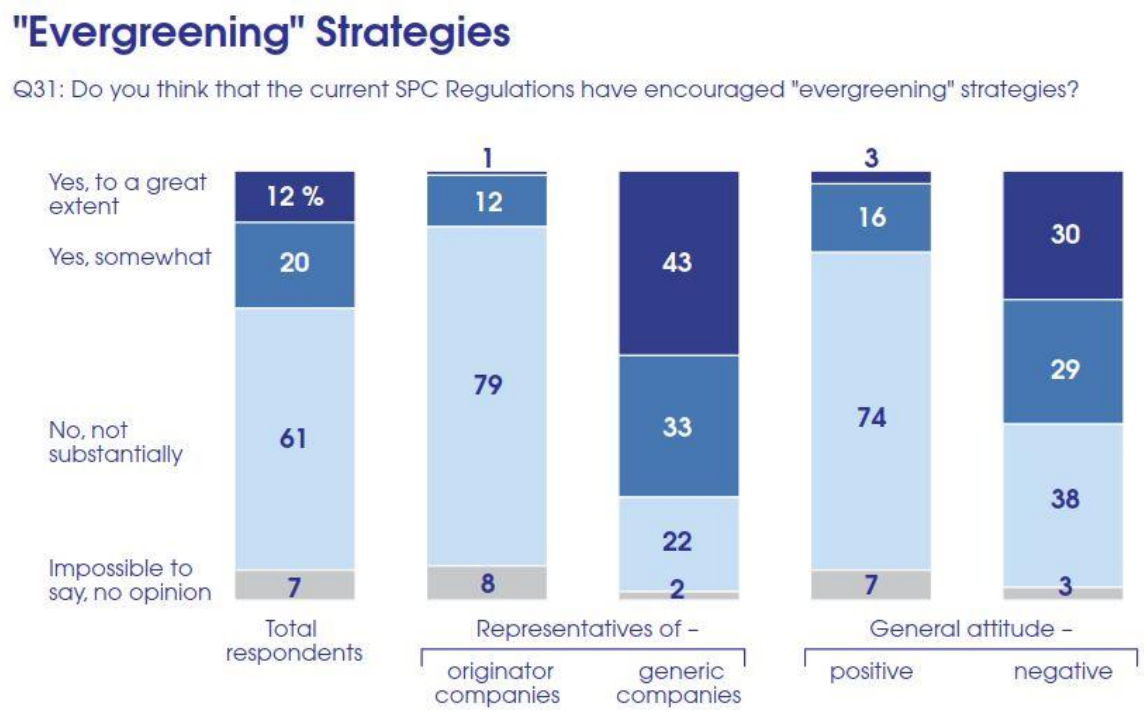

Figure 8.11: Q31 of the Allensbach Survey

[410] See *ibid.*, pp. 21, 163, 164.

In a follow-up question (Q32), we asked those participants who responded either "Yes, to a great extent" or "Yes, somewhat", what specific aspects of the SPC Regulations might have encouraged "evergreening" strategies. We received a total of 44 comments which can be found in Annex III to this Study. Most respondents perceive a lack of clarity and/or ambiguities caused by the wording of the Regulations as well of the case law. One statement may serve as a summary of the majority of responses:

> "In many cases it is the uncertainty in the interpretation of the SPC Regulations that allows the evergreening strategies. This is not only as a result of the specific wording of the SPC Regulations, but also as a result of numerous unclear decisions handed down by the CJEU. These decisions often try to solve one issue of interpretation, but end up creating further uncertainty (because they introduce tests which themselves include ambiguous terms), but also because the decisions only go as far as is necessary to answer the specific question that is asked, rather than giving complete guidance. This is exemplified by the numerous referrals around the meaning of Article 3(a) of Regulation 469/2009."[411]

8.1.5.3 Incentive to increase time span between trials and filing of MA application

Finally we asked participants whether the current SPC Regulation acts as an incentive to increase the time span between the preclinical trial phase and the filing of the MA application. The question is based on the general possibility of prolonging the MA application process to extend the time of legal exclusivity. Other jurisdictions, such as the USA, force the applicant to pursue the clinical trials and the application process in a diligent manner. Our question, therefore, tried to evaluate whether or not such delays have been experienced.

Overall 60 per cent disagreed and 26 per cent agreed with this statement while 14 per cent said that it is impossible to say. Here again the majority – 71 per cent – of the representatives of originator companies disagreed with the statement, while 20 per cent agreed and nine per cent stated that it is impossible to say. On the generic side 48 per cent agreed with the statement while 35 per cent opposed it. 17 per cent stated that it is impossible to say.

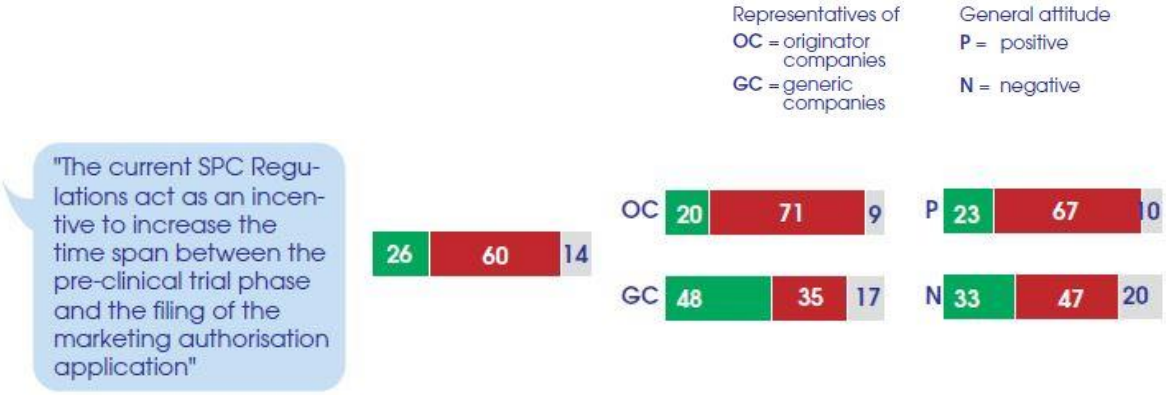

Figure 8.12: Q26 of the Allensbach Survey

We discussed this issue also in our structured interviews and understood that from the point of view of originator companies, being first on the market is sufficient pressure

411 See Annex III of this Study, p. 325.

not to delay the start of clinical trials and the MA application process.[412] Generic companies agreed with this in general but stated that in the case of second generation products and SPCs the market pressure is reduced. This can lead to delay strategies.

8.1.6 Uniformity and legal certainty

8.1.6.1 Premise

Two important goals of the system were also to ensure a uniform system for granting SPCs that could prevent a heterogeneous development of the legislation and were both transparent and simple. Some questions were directed to assess whether in practice these goals were achieved.

8.1.6.2 Differences in national procedures

Since SPCs are granted on the level of the EU Member States and since there are differences in the procedures, this may lead to loss of effectiveness and increased lack of predictability. Therefore, we also addressed the question to the stakeholders regarding the practices of the national offices and differences thereof (Q26b). 62 per cent of the respondents agree or strongly agree with the statement that when it comes to examining SPC applications, the practice and procedures of the national offices in the EU Member States differ significantly in terms of predictability, transparency and quality of the rights granted. While the opinion among the representatives of originator companies was quite balanced, with a relative majority of 48 per cent agreeing, while 41 per cent disagreeing and 11 per cent stateing that it is impossible to say, the picture amongst the representatives of generic companies was much clearer: 83 per cent of the generic participants agree/ strongly agree while only four per cent disagree and 15 per cent state that it is impossible to say.

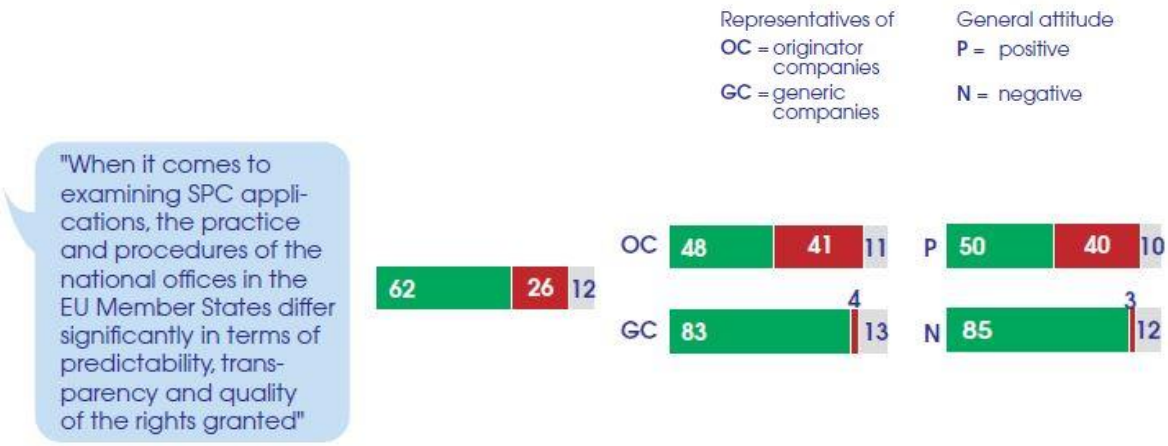

Figure 8.13: Q26 of the Allensbach Survey

8.1.6.3 Legal uncertainty

A similar picture is visible regarding the statement in Q26b whether or not the current SPC Regulations work well in most cases and do not result in legal uncertainty. Legal

[412] Interview summary on file with the authors of the Study.

uncertainty leads on the one hand to increased internal costs for companies that either wish to obtain an SPC or that try to avoid infringing an SPC. Furthermore, legal uncertainty often leads to increased litigation associated with additional costs. Both are signs of a lack of effectiveness. Looking only at the overall picture of the opinions it seems they are divided roughly half and half: 53 per cent of all respondents agree/strongly agree with the statement and 44 per cent of respondents disagree/strongly disagree with it. A closer look, however, shows that a vast majority of 74 per cent of the representatives of originator companies is positive towards the statement, while the vast majority of 78 per cent of the representatives of generic companies dismisses it.[413]

8.1.6.4 Attitudes towards the CJEU case law on Articles 3(a) and 3(b) of the Regulations

One of the issues discussed during our first workshop as well as in the literature is the clarity of the CJEU case law in *Medeva* (C-322/10) according to which a product is protected by the basic patent within the meaning of Art. 3(a) of the SPC Regulations when it is "specified in the wording of the claims of the basic patent". Since the law can only be considered as being effective if the criteria used by the law are clear, we asked the participants whether they perceived the *Medeva*-case law as a clear or unclear criterion. We used a scale from -2 to +2 to measure the pertaining attitude in Q46 of the Allensbach Survey. Overall, the criterion is being perceived as rather unclear with a mean score of -0.15 on the scale. Particularly law firms (-1.03) and representatives of generic companies (-0.30) perceived the criterion as unclear while representatives of originator companies perceived it as clear (0.34).[414]

8.1.6.5 Amendments to Art. 3(a) of the SPC Regulations

If a core element of a regulation is not sufficiently clear and stakeholders advocate a change of the law this lack of clarity may be perceived as a problem. Therefore, we asked the stakeholders whether they would favour an amendment of Art. 3(a) of the SPC Regulation regarding the subject matter of protection of the SPC (Q48). Four options were provided: (1) A definition based on the EPC, (2) the so-called "infringement test", (3) the so-called "core inventive advance test" and (4) no change in the law. 38 per cent of the respondents in total prefer no change in the law while a 51 per cent favour some form of change, but none of the three options received a clear vote as a front runner. Particularly law firms and representatives of generic companies favour changes but the representatives of originator companies and associations oppose changes.[415]

[413] See Annex III of this Study, pp. 14, 17, 19, 145.
[414] See *ibid.,* pp. 35, 198.
[415] See *ibid.,* pp. 36, 204.

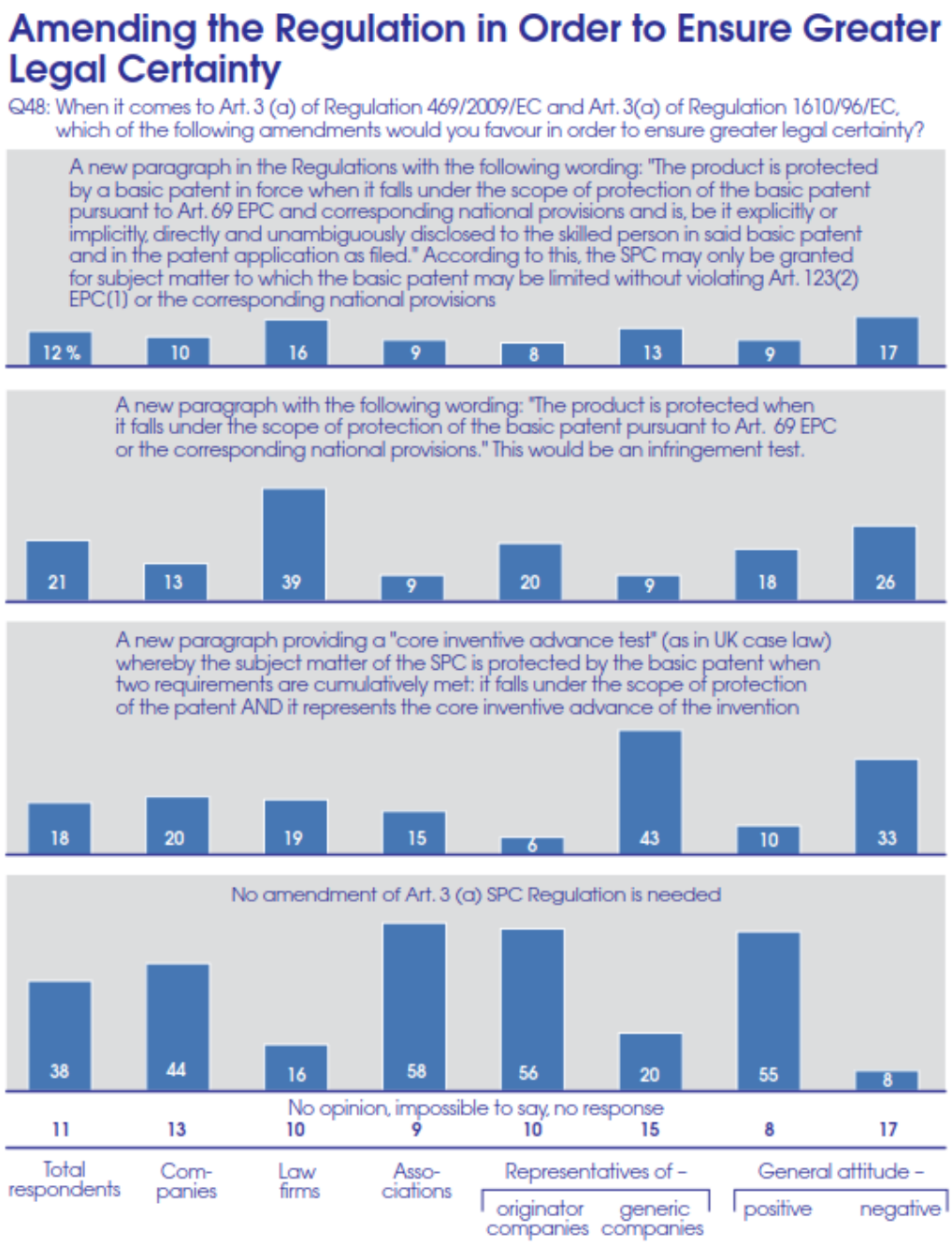

Figure 8.14: Q48 of the Allensbach Survey

A significant number of respondents used the opportunity to provide a more detailed comment in the comment box below Q48. We would like to highlight one particular type of comment that has been provided multiple times and provides a concise summary of a majority of the other verbatim:

> "Article 3(a) is a very short and clear article, which – as acknowledged by many practitioners and patent offices – can hardly be made clearer. Through the CJEU case law, the various questions which have arisen regarding its interpretation have now been answered, providing further clarity and guidance to patent offices. Decisions on the pending references should further add to this clarity. In addition, the case law of the CJEU on SPCs should be considered as a whole and not

> only as single decisions decided based on the specifics of a given case. In addition, we see strong limitations with all the suggested amendments."[416]

It is worth mentioning, that in order to achieve more clarity some participants suggested additional guidelines instead of introducing changes to the Regulations themselves which may create new problems:

> "Instead of amending Art. 3(a) of Regulation 469/2009/EC, EU Guidelines for Examination of SPCs, e.g. such as the Guidelines for Examination of SPCs of the German Patent and Trademark Office, seem to be needed. Guidelines are more flexible than the Regulations and may be further adapted in the future."[417]

8.1.7 Measures to improve the system

8.1.7.1 Harmonisation

Further, we presented the stakeholders with a variety of possible measures that may be introduced into the SPC system and we asked which of them they would expect to have a positive effect. The question was based on the assumption that if stakeholders expected a positive effect then the present situation has room for improvement and thus is not optimal with respect to effectiveness.

A clear majority, at 88 per cent of stakeholders, expects a positive effect on the system if the procedures for granting SPCs are harmonised within the EU. This is in line with our findings from the structured interviews and the discussions during the workshop, where a lack of harmonisation was identified as one of the main problems of the system. A lack of harmonisation may lead to different results and/or delays and thus is a clear characteristic of the lack of effectiveness.

Regarding the other proposed changes there was no clear majority for any of them but a closer look shows that there is a clear divide between originators and generic manufacturers. Therefore, it is difficult to draw conclusions regarding the effectiveness since the results may simply indicate preferences to strengthen or weaken the respective position in the proceedings.

416 See Annex III of this Study, p. 354.
417 *Ibid.*

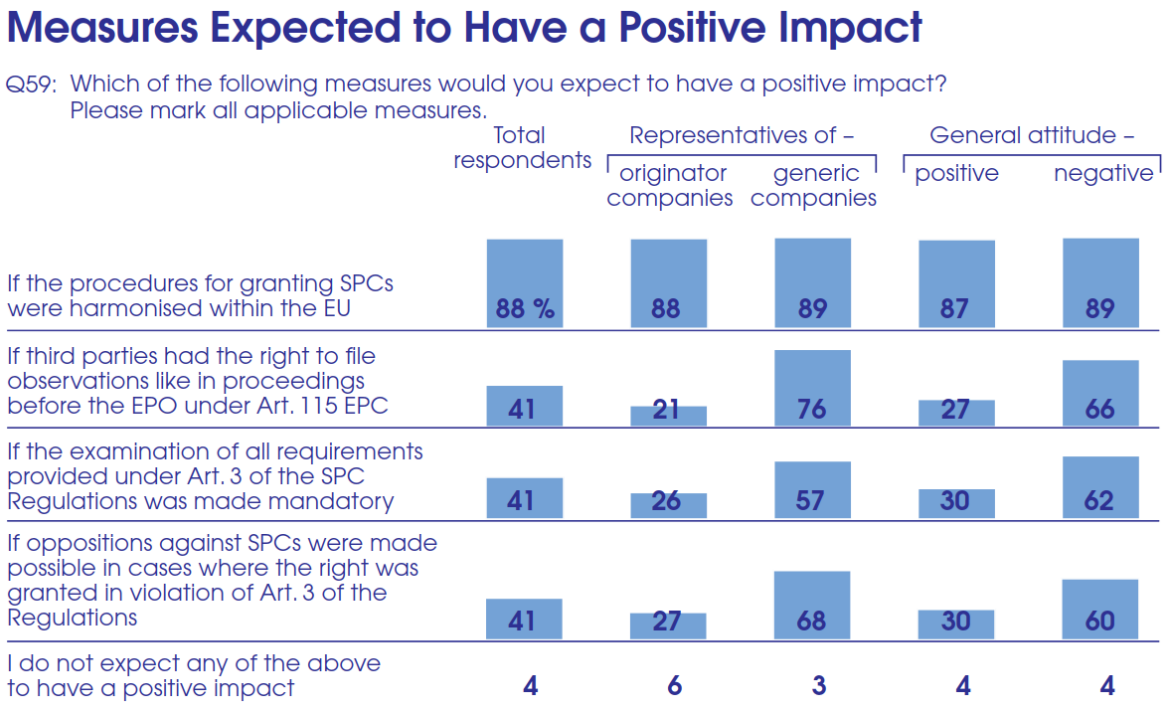

Figure 8.15: Q59 of the Allensbach Survey

8.1.7.2 Need for a Unitary SPC

Finally, we asked stakeholders in Q69 whether there is a need for a unitary SPC. Such a perceived need may indicate that a system made out of national SPCs is being seen as not sufficiently effective.

Three quarters (75per cent) of the stakeholders and similar shares in all subgroups state that there is a need for a unitary SPC. This confirms our findings from the qualitative interviews and the workshop that the lack of harmonisation and the complicated application procedure in numerous Member States are the most significant weaknesses of the current SPC system.

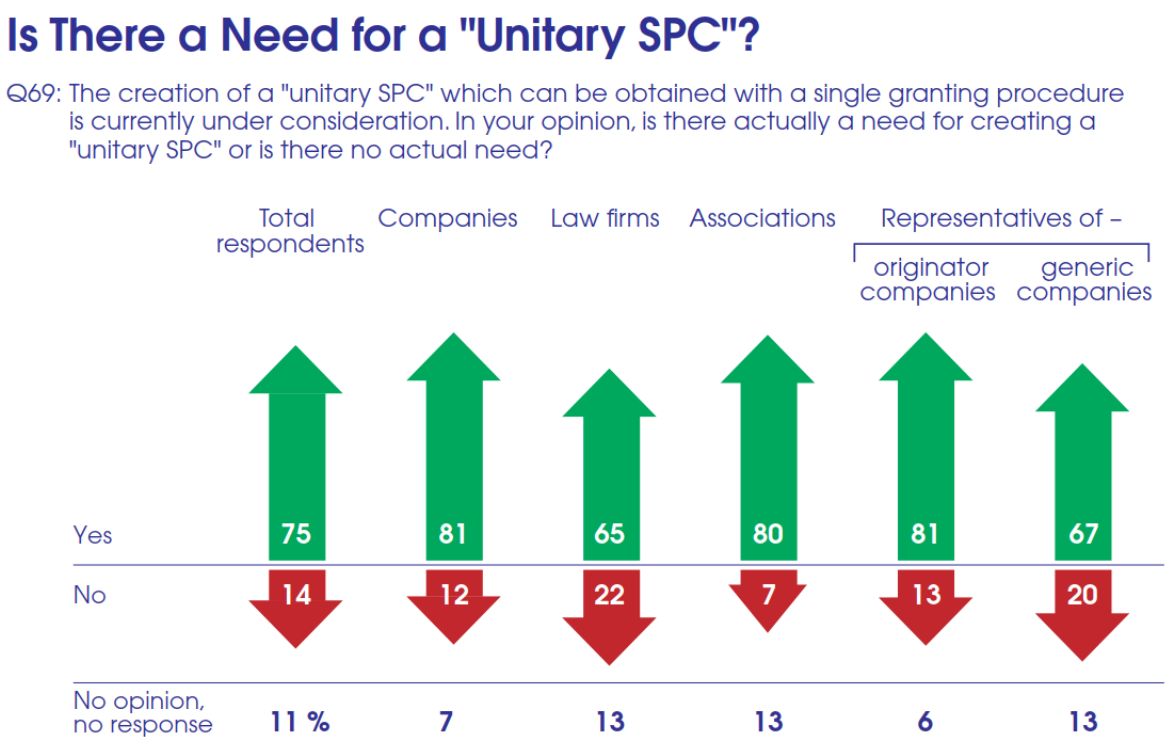

Figure 8.16: Q69 of the Allensbach Survey

It became also clear from the responses to Q70 that experience of the examiners and clear procedures are important factors for the effectiveness of the system. The majority of respondents stated that a Unitary SPC-system must be set up in such a way that it includes experienced examiners from the national patent offices. This could be realised in a "virtual office". We cite one response as an example for what can be seen as the majority opinion:

> "[…] have proposed that unitary SPCs on the basis of European Patents with unitary effect are granted by a virtual body composed of SPC experts from national patent offices. That it is virtual does not mean it does not exist - this virtual office would need to be legally created and embodied, either as a stand-alone institution or hosted by a competent EU agency or body, with the task and responsibilities for granting unitary SPCs entrusted to the (virtual) office and supported by a performing IT system. By being virtual, such a body would be able to retain and rely on the existing expertise at national level instead of trying to build a new agency from scratch. A virtual body would also overcome issues such as forum shopping that might occur with mutual recognition of decisions. Finally, considerations such as the location and associated costs of a new agency are reduced. It is recognised that there might be a need for a small number of administrative staff but it is believed that these needs would be relatively light."[418]

8.1.7.3 Extending SPC protection to other fields

As explained in earlier Chapters, the rationale for granting SPC protection to certain products is the loss of effective protection time on the market after having acquired the necessary MA. While the MA application procedures are particularly long for medicinal products and plant protection products, there are also other fields where permissions from authorities must be granted prior to bringing a new product onto the market. Therefore, the question is, whether SPC protection should be extended to other fields as well. While this question may be answered purely based on an

[418] See Annex III of this Study, p. 402.

evaluation of the length of such authorisation proceedings in other fields, we wanted to see if stakeholders favoured or opposed such an extension thus indirectly establishing whether or not there is a perceived need for this in the industry.

We asked whether they would favour or oppose extending SPC protection to other fields of technology, such as medical devices, cosmetic products, food products and food additives (both for humans and animals). Overall the stakeholders were split on this question with only 28 per cent favouring such an extension of the SPC protection for other fields, 36 per cent opposing it and also 36 per cent stating it is impossible to say or having no opinion. In no single stakeholders subgroup was there an overall majority in favour of such an extension. The strongest support for such an extension was among law firms with 40 per cent in favour and 44 per cent against the extension. The strongest opposition was among the representatives of generic companies with 65 per cent opposing such an extension. Among representatives of originator companies, while 27 per cent were in favour of and only 19 per cent opposed to such an extension, 54 per cent were not able to state a preference either way.

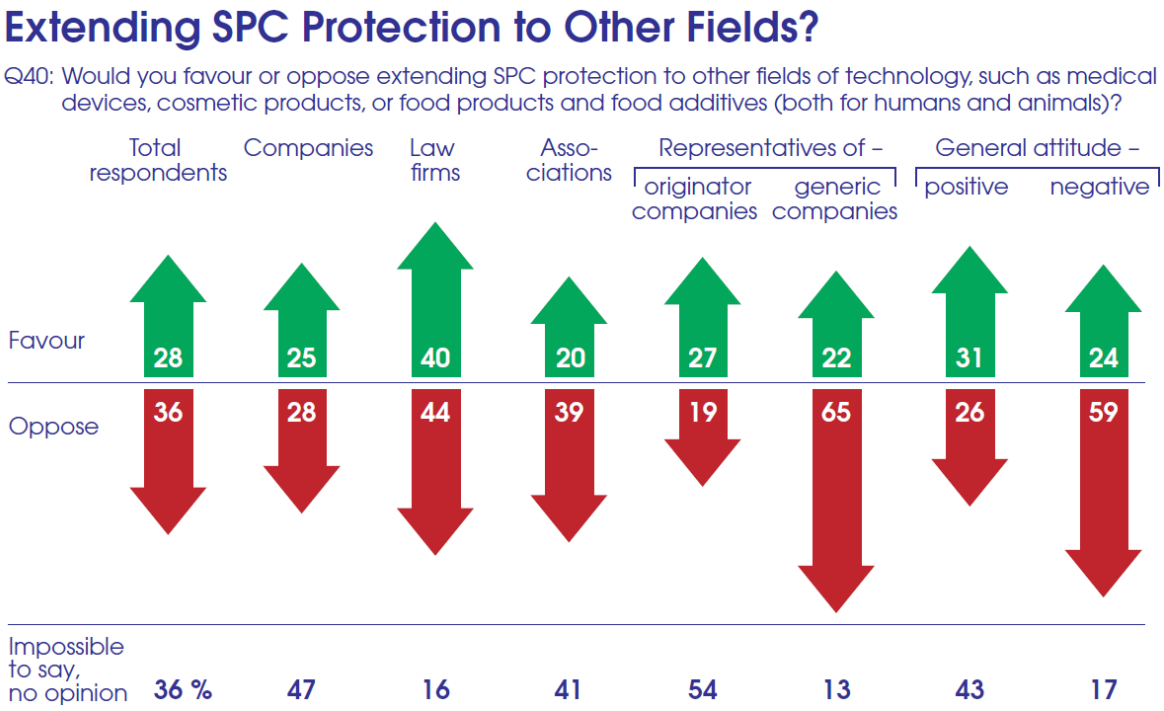

Figure 8.17: Q40 of the Allensbach Survey

We followed up in Q41 with those respondents who were in favour of an extension and asked to what subgroup of possible technology fields they would extend SPC protection. 91 per cent would extend it to medical devices, 43 per cent to cosmetic products, 38 per cent to food additives, 34 per cent to food products and 16 per cent to other fields.

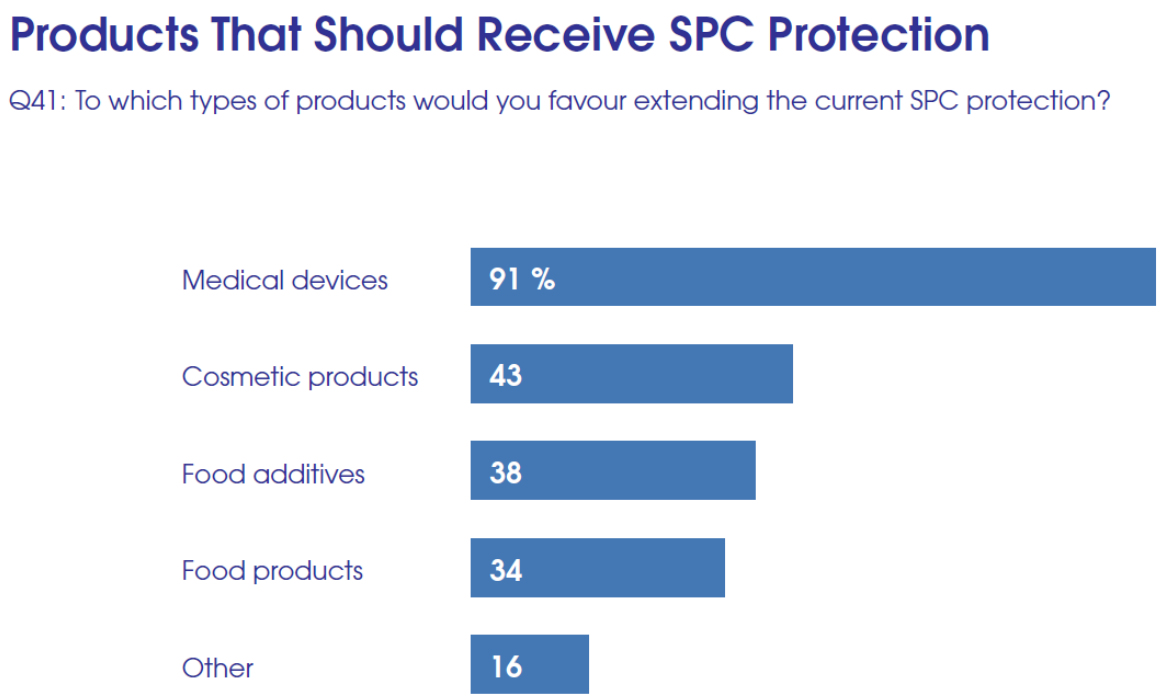

Figure 8.18: Q41 of the Allensbach Survey

8.1.8 Summary and conclusions

Overall, the following, although limited conclusions may be drawn from the Allensbach Survey regarding the effectiveness of the SPC system.

- Overall a majority of stakeholders believes that the current system works well in most cases and fosters investment in research and development activities.
- The differences in procedures in the granting process between the various Member States are one of the main issues identified and a unitary SPC is desirable.
- While amendments regarding biopharmaceuticals, which are already covered by the present Regulations, may be required, there seems to be no need to extend the SPC system beyond pharmaceutical and plant protection products.
- Some changes regarding definition and clarifications of the requirements to obtain an SPC may improve the system.
- There is a division in the perception of the systems between stakeholders that qualify themselves as originators and stakeholders that qualify themselves as generic companies: while the former are fundamentally satisfied with the current legal framework, the generic companies have questioned whether the system takes sufficiently into account all the interests involved and have identified critical issues in the current legal framework and case law.

8.2 STAKEHOLDER SEMINAR

We provided selected stakeholders who raised criticism regarding the methodology of some wording in the MPI Questionnaire for the Allensbach Survey with the opportunity to discuss the questions with us during a workshop in Munich on 12 September 2017.

The participants provided us with written opinions which are discussed in more depth at the relevant parts of the Study. These written opinions and the discussions of the Seminars have not provided any opinion on the perceived effectiveness of the SPC system that were not already collected and identified by the Allensbach Survey.

In particular the invited stakeholders have addressed the effectiveness of the system, the clarity of the case law and possible changes of the Regulation. It became clear that representatives of the originator companies perceive the overall SPC system as functioning and the case law as sufficiently clear. Representatives of the generic industry, on the other hand, perceive the case law as less clear and the possibilities to obtain an SPC for example for new uses of known active ingredients as too broad and contrary to the original rationale of the Regulations. It is also consistent that the representatives of the originators voiced the opinion that changes in the SPC Regulations are not required but that the further development should be left to the case law. This has been particularly stated with respect to third-party MAs issues and biological products. Regarding the introduction of a manufacturing waiver, the opinions are divided. While the representatives of the generic industry would welcome such an exemption, the representatives of the originator industry are of the opinion that it would not be compatible with the purposes of the current SPC Regulations and would not produce the assumed economic benefits. Regarding the introduction of a Unitary SPC both groups, the generic companies and the originators, would welcome such a step in principle.

8.3 QUALITATIVE INTERVIEWS

During the qualitative interviews the focus of the questions on effectiveness was limited since we assumed that this can be addressed better in the online survey. However, we addressed two issues in the course of the interviews. The perspective of the stakeholders on effectiveness in the qualitative structured interviews was mixed.

The originators were of the opinion that the case law of the CJEU is clear enough for them to make business decisions. However, some of them highlighted that differences in the practices of the NPOs exist und lead to uncertainty. Particularly the length of the procedures and the different standards applied were mentioned as critical issue. Also, the issue of late issuance of MAs required for an application for a paediatric extension was highlighted as leading to risks and uncertainties thus making business decisions for both, originators and generics, difficult.

The generic companies explained that the system has become much more complex and unclear criteria created by the case law would make it difficult to predict decisions. At the same time they stated that originally the system was created with patents on a particular compound in mind with one SPC per product. The increase in method patents and combinations as well as multiple SPCs covering the same active ingredient based on several basic patents and several MAs would make the system more complex. In the case of questionable patents or SPCs it would take substantive resources for generic companies to clear the way for market entry.

8.4 OPINIONS OF THE NPOS

Assuming that effectiveness requires legal clarity, we also asked the NPOs not only for their opinion on possible changes to the Regulations and their local practices, but also whether or not the case law of the CJEU and the Regulations are sufficiently clear for them to apply. We assumed that a lack of clarity has influence on the day-to-day work of the offices, thus resulting in reduced effectiveness.

Several NPOs were of the opinion that including a definition of "active ingredient" would increase legal clarity (Q10 of the MPI Questionnaire for the NPOs). However, some of the responses also pointed out that if the definition is too complex, it may add additional uncertainty, thus again reducing effectiveness.

Regarding the case law of the CJEU on Art. 3(a), a majority of the offices were of the opinion that the guidelines of the CJEU regarding the *Medeva*-requirement ("specified" in the wording of the claims of the basic patent) were not sufficiently clear. The terms "specified" and "identified" would still leave a lot of room for interpretation. However, some NPOs acknowledged that the case law has also reduced some uncertainties.

The workshop organised by the MPI on 21 March 2017 with the NPOs presented us with the opportunity to learn more about the experiences and opinions of the NPOs and to gain insight into the perceived effectiveness of the system.

During the workshop representatives of the NPOs stressed that it should be borne in mind that the lawmaker intended to create a balanced[419] and simple[420] system. From the perspective of some NPOs the system, however, has become more complex and implies a significant burden on the NPOs in the granting procedure. The reason for this additional complexity is, according to some views, the development of the case law.

So, one NPO pointed out that, based on the case law, the NPOs are now required to do a core *inventive-advance* based analysis in the context of Art. 3(a) or (c) Reg. 469/2009. Furthermore, even the question what the active ingredient is, is now supposed to be assessed in the granting procedure. This imposes additional burdens on the NPOs that have not been envisaged by the lawmakers.

In addition, it has been observed by one NPO that the balance originally drawn by the lawmakers has been subsequently questioned by the case law. Indeed, the lawmaker had a clear purpose for the SPC system in mind. He was aware that the same active ingredient can be subject of multiple MAs and several patents. Nevertheless, he wanted the product to be protected by only one SPC on the basis of the first MA. The case law, but in part also the legislative development, has changed the system, since multiple SPCs, based on different MAs, each serving as the first MA, are now possible following *Neurim*. The more complex the system becomes, the more difficult it is to manage, particularly by smaller NPOs.

Finally, some NPOs are of the opinion that there is legal uncertainty at the moment. The reason for this legal uncertainty is that the Regulations do not provide the necessary answers for some relevant issues and that the case law of the CJEU, so far,

419 See Proposal for a Council Regulation (EEC) concerning the creation of a supplementary protection certificate for medicinal products, COM(90) 101 final [1990] OJ C 114, para. 10 et seq.

420 *Ibid*., para. 16 et seq.

has also failed to provide clear answers. Particularly the decisions *Medeva* and *Neurim* seem to pose challenge for the implementation by the NPOs. However, several NPOs are not convinced that legislative action would solve the existing issues and warn that any change would lead to new case law. They are of the opinion that the problems created by the case law in the past years should be fixed by the case law. These opinions voiced during the workshop are also supported by some of the responses to the MPI Questionnaire for the NPOs. As a general conclusive comment, one NPO stated:

> "Originally conceived as a simple and transparent system that could be easily applied by interested parties, the system of SPC has proven increasingly complex in practice. The reason is that SPCs are based on several fundamental tensions:
> - The SPC is at the crossroads of two legal systems, each with its own objectives and logic: a patent on the one hand, a monopoly that allows the innovator to earn a return on investment, and the MA regulation on the other, which focuses on the preservation of public health in the general interest.
> - The stated objective of the SPC is to compensate for the period between the filing of the patent and the granting of the MA, which delays its exploitation. However, it can be obtained on the basis of a third party MA. It follows that it does not always constitute actual compensation, assessed in concreto, of the time-limits imposed by the tests necessary to ensure the efficacy and safety of the product, but rather an overall corrective mechanism to the benefit of the pharmaceutical and plant protection industry.
> - The SPC is issued for a product, understood in the strict sense of the active ingredient, and designed as an exceptional protection for "new drugs" and not for those incorporating minor changes in the dosage or dosage form. However, it can be obtained on the basis of any patent protecting the active ingredient including new methods of production, new applications, new compositions of known products.
> - This dichotomy is reflected in the case law of the CJEU and has resulted in changes and complexification in the practices of the national offices.
>
> In order to find answers to some essential points of this questionnaire (ownership of the MA, core inventive, definition of the product ...), it is therefore important to wonder about the fundamental objective of the SPC system: Should it constitute a global tool for encouraging research and investment in pharmaceutical industry, or a real compensation appreciated in concreto?"

As another concise example we present the following response from one of the NPOs:

> "The CJEU is responsible for interpreting the SPC Regulations in response to references from national courts, and it is important to recognise the role and importance of the Court and its judgments in the SPC system. SPCs are valuable rights, and businesses have shown they are prepared to litigate where they see potential for a positive outcome in their favour. Clear judgments from the CJEU on how the Regulations should be interpreted are therefore an important part of the process.
>
> At present, when national courts are uncertain about how a specific provision of the SPC Regulation(s) should be interpreted in order to the facts of a case, it will formulate questions to the CJEU, asking the Court for its views. In considering the referral, the CJEU will often reformulate the questions before giving its interpretation of the legislative provision, and then provides an answer to the question(s). The CJEU judgment then returns to the national referring court, which has to apply it to the specific facts of the case. This can be more difficult to do if the CJEU has not answered the questions it was asked.
>
> In our experience of SPC cases, CJEU judgments usually stop short of providing general guidance on how the Court's interpretation should be applied. Whilst we would not expect the Court to set out how the judgment applies to the case in hand, some guidance would be useful. For example the core inventive advance was a new test/concept in *Actavis v Sanofi* (C-443/12), but the Court gave no indication of how they saw it being applied, which resulted in a lack of legal certainty and clarity as to exactly what "core inventive advance" means. This has in turn led to further references seeking clarity on this point.
>
> Other examples include the tests of "identified or specified in the wording of the claims" in *Medeva* (C-322/10), *Georgetown* (C-422/10), *Daiichi Sankyo* (C-6/11), *Queensland* (C-630/10) and *Yeda* (C518/10) and and the "subject matter of the invention" in *Actavis v Boehringer*, C-577/13.
>
> In some instances, the Court does not distinguish between previous case law/line of reasoning and this also results in legal uncertainty and administrative burden. For example, CJEU decisions *MIT* (C-431/04) and *Yissum* (C-202/09) provided that a therapeutic indication does not form a part of the notion of product, whereas *Neurim* (C-130/11) concerned facilitating SPCs in just such circumstances. No explanation in of the change of direction was provided by the Court.

If the CJEU was able to provide clearer guidance which, in its view, should be considered when applying its judgment(s), we consider a significant amount of time and effort could be saved. For example, the additional work and references to the CJEU seeking to clarify earlier judgments would reduce, and there would be less administrative burden on Member States, the Court of Justice, and stakeholders. Importantly, it would improve legal certainty across the internal market as SPC granting authorities would all be working to the same guidance.

In short, some of the problems this legal review is seeking to address could be solved through clearer and more comprehensive CJEU judgments."

PART THREE:

LEGAL ANALYSIS OF THE SPC REGULATIONS

9 SUBJECT MATTER ELIGIBLE FOR SPC PROTECTION (ARTS. 1 AND 2 REG. 469/2009)

9.1 PREMISE

All systems of registered or unregistered IP rights need a set of rules that define what the subject matter eligible for protection under the applicable law is. In the case of European patents, such rules are contained in Art. 52 EPC, according to which provision all inventions in the field of technology are patent-eligible.

For SPCs, the corresponding rule results from a combined reading of Arts. 1 and 2 Reg. 469/2009 and Arts. 1 and 2 Reg. 1610/96. Pursuant to Art. 2 Reg. 469/2009 any product protected by a patent "that is subject prior to being placed on the market as medicinal product to an administrative authorisation procedure" as laid down in Dir. 2001/83 and Dir. 2001/82/EC may be the subject of a certificate. Pursuant to Art. 2 Reg. 1610/96 a product for which an SPC can be granted is any product protected by a patent that, "prior to being placed on the market as a plant protection product, is subject to an administrative authorisation procedure" as laid down in Art. 4 of Dir. 91/414/EEC" (now Reg. 1107/2009). Products within the meaning of Art. 1(b) Reg. 469/2009 and Art. 1(8) Reg. 1610/96 are, respectively, "an active ingredient or combination of active ingredients" and "active substances and preparations containing one or more active substances".

From those provisions it follows that two things can in principle be eligible for SPC protection: an active ingredient of a medicinal product subject to an administrative authorisation procedure under Dir. 2001/83 or Dir. 2001/82/EC; or an active substance of a plant product subject to an administrative procedure under Reg. 1107/2009.

While the SPC Regulations show significant similarities in content and structure, they have a major difference in this regard: Art. 1(3) Reg. 1610/96 defines the concept of "active substance"; by contrast, Art. 1 Reg. 469/2009 does not further specify the concept of "active ingredient". Neither of the SPC Regulations further expressly defines the concept of MA, while they define the concept of basic patent. Against this background, with a focus on Reg. 469/2009,[421] three topics are addressed in this Chapter.

The first is the question of how the case law interprets the concept of active ingredient, and whether a definition of this term is opportune and, if so, which options are available to the EU lawmakers (Section 9.2). The second topic concerns the concept of MA, and more specifically which administrative act fulfils the notion to which the SPC legislation refers to (Section 9.3). Finally, we address the notion of basic patent within the meaning of Art. 1(c) Reg. 469/2009 (Section 9.4).

[421] Specific issues concerning the Plant Products Regulation are discussed in Chapter 19 of this Study.

9.2 THE CONCEPT OF ACTIVE INGREDIENT

9.2.1 Introduction

Both the Proposal for a Council Regulation (EEC) concerning the creation of a supplementary protection certificate for medicinal products[422] and the adopted Reg. 1768/92 included the concepts of "product" and "medicinal product". The Proposal included a definition of the term "product", meaning "active substance", but not of "medicinal product", while Reg. 1768/92 included a definition of "medicinal product", but not of active ingredient.

The definition of product included in Art. 1(a) of the Proposal of the European Commission reads as follows:

> "*Product* means any active substance or combination of substances presented for treating or preventing disease in human beings or animals and any active substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in humans or in animals."

This wording reproduced the definition of "medicinal product" pursuant to Art. 1, No 2, Dir. 65/65/EEC and supplemented it with the adjective "active", that according to the European Commission explanation was a term used in patent law:

> "What is authorized to be placed on the market is referred to as a "proprietary medicinal product", i.e. "any ready-prepared medicinal product placed on the market under a special name and in a special pack" (Article 1.1 of Directive 65/65/EEC).
>
> However, it may be the *medicinal product that is patented, meaning the active ingredient***,** the process by which the medicinal product is obtained, or an application or use of the medicinal product.
>
> For the purposes of the certificate, which lies at the interface of the two systems, the terms "product" has been chosen as a common denominator. The exact meaning given to it is defined in Article 1, which is based on the definition of a medicinal product laid down Directive 65/65/EEC. However, the qualifier "active" is added to the term "substance" in order to include the concept of an "active ingredient or "active substance" used in patent law.
>
> Consequently, the term "product" is not understood to mean a proprietary medicinal product or a medicinal product in the wider sense, but in the narrower sense of product used in patent law which, when applied to the chemical and pharmaceutical field, means the active ingredient"[423]

The assumption that the term "active ingredient" or "active substance" is a concept of (European) patent law was not accurate at that time, and is still imprecise today. Despite this, it was clear that the "active substance" to which the Proposal referred to was the active constituent or active ingredient of the pharmaceutical product, and that the terms "medicinal product" and "active ingredient" in both the Proposal and the Explanatory Memorandum were used as synonymous. Indeed, when referring to the specific authorised drug, the Explanatory Memorandum employed the term "proprietary medicinal product".

This terminology underwent a slight change in the approval process of the Medicinal Product Regulation. Art. 1 Reg. 469/2009 in force in line with Art. 1 Reg. 1768/82 reads as follows:

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422 See Proposal for a Council Regulation (EEC) concerning the creation of a supplementary protection certificate for medicinal products, COM(90) 101 final [1990] OJ C 114/10.

423 European Commission, Explanatory Memorandum to the Proposal for a Council Regulation (EEC), of 11 April 1990, concerning the creation of a supplementary protection certificate for medicinal products (COM(90) 101 final – SYN255), para. 28. Emphasis added.

> "(a) 'medicinal product' means any substance or combination of substances presented for treating or preventing disease in human beings or animals and any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in humans or in animals;
> (b) 'product' means the active ingredient or combination of active ingredients of a medicinal product."

Therefore, in the language of the Regulation adopted, "medicinal product" is the drug, the specific formulation authorised by the Health agency to be placed on the market, while "product" remained unchanged and designated the "active ingredient" of the drug. As consequence, medicinal product and product do not represent synonymous terms in the binding part of the Regulation. Some recitals and some provisions of the legislation in force, however, still employed the term "medicinal product" in the sense of "active ingredient".[424]

9.2.2 Medicinal product

The definition of medicinal product in Art. 1(a) Reg. 469/2009 is identical to that of Art. 1(a) Reg. 1768/92 and is taken from Dir. 65/65/EEC.[425] Therefore, it does not take into account the definition of medicinal product as laid down in Art. 1(2) of Dir. 2001/83 as amended by Dir. 2004/27/EC[426], which reads as follows:

> "Medicinal product:
> (a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or
> (b) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis."

Such a definition specifies the type of action that the medicinal product exerts. Its purpose, as explained by the CJEU in *Hecht-Pharma*,[427] was "to take account of the emergences of new therapies and of the growing number of so-called 'borderline' products".[428] The case law of the CJEU has already referred to the pharmacological, immunological or metabolic effect of the substance by interpreting Art. 1(b) Reg. 469/2009.[429] Furthermore, the difference in wording of the definition of the medicinal product in both legislations was also discussed in the *Cerus*[430] and *Angiotech*[431] decisions of the UK Patent Office.[432] In both mentioned cases, the applicants considered this difference in wording relevant since substances "which treat diseases by physical means such as products within medical devices" may be a medicinal product within the meaning of Art. 1(a) Reg. 469/2009, since this provision "does not refer to exerting a pharmacological, immunological or metabolic action".[433] However, the Deputy Director acting for the Comptroller, Dr. Lawrence Cullen, did not consider

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424 This is the case, for instance, of Recital 3 and Recital 8 Reg. 1768/92. See also Art. 20 Reg. 469/2009.
425 *Ibid*.
426 [2004] OJ L 311/67.
427 Case C-140/07 *Hecht-Pharma* [2009] ECR I-41.
428 See Katarzyna Zbierska, *Application and Importance of Supplementary Protection Certificates for Medicinal Products in the European Union* (Shaker 2012) p. 65 et seq.
429 See for instance Case C-631/13 *Forsgren* [2015] EU:C:2015:13.
430 UK IPO, BL O/141/14, *Cerus Corporation*, Decision of 31 March 2014.
431 UK IPO, BL O/466/15, *Angiotech Pharmaceuticals Inc. and University of British Columbia*, Decision of 6 October 2015.
432 UK IPO, BL O/141/14, *Cerus Corporation*, Decision of 31 March 2014, para. 67.
433 UK IPO, BL O/466/15, *Angiotech Pharmaceuticals Inc. and University of British Columbia*, Decision of 6 October 2015, para. 83.

these differences in wording material, since only products that have been approved under Dir. 2001/83 are eligible for protection under the SPC Regulation.

While this approach is convincing, an updated definition of the concept of medicinal product seems to be nevertheless opportune and has been taken into consideration in informal communication by the European Commission itself.[434] An updated definition[435] could read, in line with the wording of Art. 1(2) Dir. 2001/83, as follows:

> (a) 'medicinal product' means any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

Such wording would distinguish medicinal products from substances and devices that may have a therapeutic or diagnostic purpose and are applied to the human body, but do not exert a pharmacological, immunological or metabolic action.[436] Further, the provision would continue to exclude from SPC protection substances that are not administered to the human body, even if they may exert a pharmacological, immunological or metabolic action, or serves a diagnostic purpose (for instance, substances used for diagnostic purposes in an *in vitro*-procedure).

9.2.3 Active ingredient

9.2.3.1 Issues

According to the analysis by *Schennen*,[437] the Medicinal Products Regulation did not include a definition of active ingredient because such definition did not seem necessary: indeed, it was clear that active ingredient could be understood only as the substance qualified as "active constituent" in the MA supplied in support of the application for the certificate, in contrast to any other substance that is included in the medicinal product and that is not an active constituent but an excipient. Despite this reasoned interpretation of Art. 1(b) Reg. 1768/92, the concept of active ingredient has led to some case law at european and national level. Several issues have been answered by the CJEU and the national courts, while other questions are still open. Such issues are:

- whether the concept of the "active ingredient" is to be identical to the concept of "active substance" in regulatory law, or whether it is broader;
- if these concepts are identical, whether it is still possible to argue that a product is an active ingredient even if it is not identified as such in the MA;
- whether by the term "product" the SPC legislation means the specific form of the substance that the MA holder may place on the market pursuant to the MA

[434] See Katarzyna Zbierska, *Application and Importance of Supplementary Protection Certificates for Medicinal Products in the European Union* (Shaker 2012) p. 66 and the Herwig von Morze correspondence with the European Commission (DG Internal Market and Services) reported by Jeremy Philips in the SPC blog, 18 October 2010, 'When will the "suitable opportunity" arise for changing an obsolete definition?' available at http://thespcblog.blogspot.de/2010/10/when-will-suitable-opportunity-arise.html (last accessed 18 December 2017).

[435] *Ibid.*

[436] Substances presented as having properties for treating or preventing disease in human beings would be considered medicinal products by presentation under Dir. 2001/83, even if they do not display a pharmacological, immunological or metabolic action.

[437] Detlef Schennen, *Die Verlängerung der Patentlaufzeit für Arzneimittel im Gemeinsamen Markt* (Bundesanzeiger 1993) p. 52.

or whether it can be read broadly as encompassing all forms and derivatives of the free base;
- if "active ingredient" is intended to encompass all the derivatives and forms of this substance, how to distinguish derivatives that are just a variant of the same active ingredient from derivatives that are a different and new product.

It should be pointed out that these issues – according to the information available to the MPI – do not become relevant very frequently.

9.2.3.2 The concept of active ingredient coincides with the notion of active substance

Despite episodic attempts by some applicants to argue that the concept of active ingredient pursuant to Art. 1(b) Reg. 469/2009 is broader than the concept of active substance of the Medicinal Product Code,[438] the CJEU has clarified that only "substances which produce a pharmacological, immunological or metabolic action of their own" fall within the scope of the term "active ingredient".[439] This way, the CJEU has adopted a concept of active ingredient which is consistent with the concept of active substance under Art. 3(a) Dir. 2001/83. This applies also for older decisions where the CJEU has not referred to the regulatory law, but generically to general concepts in pharmacology, for instance C-431/04, where the CJEU maintained that the concept of active ingredient does not include "substances forming part of a medicinal product which do not have an effect of their own on the human or animal body".[440]

In accordance with this understanding, the CJEU has already decided that an excipient or an adjuvant is not an active ingredient within the meaning of Art. 1(b) Reg. 469/2009.[441] The same conclusion applies to the combination of an adjuvant with an active ingredient. Such a combination is not a new product within the meaning of Art. 1(b) Reg. 469/2009.[442]

This interpretation is consistent with the purpose of the SPC legislation for fostering research in new medicinal products, meaning new active ingredients,[443] and with the indication of the Explanatory Memorandum that new formulations of old active ingredients are not considered different active ingredients for the purpose of Art. 3(c) and Art. 3(d) Reg. 469/2009.[444] Indeed, a combination of adjuvant A with an active ingredient B may be novel and inventive in patent law, even if the active ingredient B was already known and used as medicinal product. For the purposes of the SPC legislation, however, such combination is just a new formulation of the active ingredient B.

The interpretation of the CJEU is further consistent with the regulatory framework. As explained by the Comptroller of the UK Patent Office in *GlaxoSmithKline UK Limited v*

438 See for instance UK IPO, BL O/506/12 *GlaxoSmithKline Biologicals, SA*., Decision of 19 December 2012.
439 Case C-631/13 *Forsgren* [2015] EU:C:2015:13, para. 47.
440 Case C-431/04 *Massachusetts Institute of Technology* [2006] ECR I-4089, para. 18.
441 *Ibid.*, para 25 ("in the light of the foregoing, the inevitable conclusion is that a substance which does not have any therapeutic effect of its own and which is used to obtain a certain pharmaceutical form of the medicinal product is not covered by the concept of 'active ingredient', which in turn is used to define the term 'product'.").
442 Case C-210/13 *GlaxoSmithKline Biologicals* [2013] EU:C:2013:762, para. 35.
443 See Chapter 2, Section 2.1.3.2.
444 *Ibid.*

Wyeth Holdings LLC,[445] Dir. 2001/83 distinguishes clearly between excipients (Art. 1(3b) and active substances (Art. 1(3(a))) and "treats an adjuvant as a type of excipient".[446] The regulatory burden – e.g. the amount of clinical testing and data required – for a compound qualified as an adjuvant is smaller than for a compound qualified as an active substance in the application for an MA.[447]

9.2.3.3 The relevance of the MA

While the CJEU case law is clear in considering active substance and active ingredient a consistent notion, the question is what are the criteria for deciding whether or not a substance for which the SPC is requested is an active ingredient within the meaning of the SPC Regulations. Two options are possible.

The first is to require the NPOs make their own assessment independent of the result of the MA granting proceedings. The second option is that the NPOs just follow the indication of the MA.

The two options have practical implications. In the first case, the NPO can decide that a substance, even if not indicated among the active substances in the MA submitted in support of the application, is an active ingredient and can be protected, provided that the other requirements under Art. 3 Reg. 469/2009 are met. In the second case the NPO must just check that the substance for which the certificate is requested is the compound identified as active substance in the MA.

The question was already discussed, but not answered, by the CJEU in *Farmitalia*.[448] Subsequently, it was addressed again in the *Forsgren* case[449] concerning an application for a certificate filed with the Austrian Patent Office. The SPC was requested for Protein D, an IgD binding protein of the *Haemophilus influenzae* bacterium. According to the basic patent designated for the purposes of the procedure, EP 0 594 610 B1, the protein was effective against *Haemophilus influenzae*. The MA supplied for the certificate was granted for a vaccine effective against pneumococci composed of 10 pneumococcal polysaccharide serotypes conjugated to carrier proteins. Protein D was one of the carrier proteins identified in the MA.

The Austrian Patent Office refused to grant a certificate because the protein was not the active substance but an excipient (*Hilfsstoff*) on the basis of the MA. The Board of Appeal confirmed this decision. In the proceedings before the Austrian Supreme Patent and Trade Mark Adjudication Tribunal the applicant argued that Protein D had a pharmacological effect on its own as a vaccine against *Haemophilus influenzae* and was an adjuvant to the substances effective against pneumococci. As a consequence, it was an active ingredient protected by the basic patent and eligible for an SPC. The Austrian Court considered decisive for the outcome of the case whether or not Protein

445 High Court of Justice of England & Wales (Patents Court), *GlaxoSmithKline UK Limited v Wyeth Holdings LLC* [2016] EWHC 1045 (CH).
446 See Annex I, Part I, Module 3 to Dir. 2001/83/EC.
447 See for instance in the field of vaccines EMA, Guidelines on Adjuvants in Vaccines for human use, EMEA/CHMP/VEG/134716/2004, available at http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500003809.pdf (last accessed 1 November 2017).
448 See Chapter 10, Section 10.2.3.2 (a).
449 Case C-631/13 *Forsgren* [2015] EU:C:2015:13.

D is considered an active ingredient and therefore referred the following questions to the CJEU:

> "1. Under Article 1(b) and Article 3(a) and (b) of [Regulation No 469/2009], provided that the other conditions are met, may [an SPC] be granted for an active ingredient protected by a basic patent (in this case, Protein D) where that active ingredient is present in a medicinal product (in this case, Synflorix) as part of a covalent (molecular) bond with other active ingredients but none the less retains an effect of its own?
> 2. If Question 1 is answered in the affirmative:
> (a) Under Article 3(a) and (b) of [Regulation No 469/2009], may [an SPC] be granted for the substance protected by the basic patent (in this case, Protein D) where that substance has a therapeutic effect of its own (in this case, as a vaccine against the *Haemophilus influenzae* bacterium) but the marketing authorisation for the medicinal product does not relate to that effect?
> (b) Under Article 3(a) and (b) of [Regulation No 469/2009], may [an SPC] be granted for the substance protected by the basic patent (in this case, Protein D) where the marketing authorisation describes that substance as a 'carrier' for the actual active ingredients (in this case, pneumococcal polysaccharides), where the substance, as an adjuvant, enhances the effect of those substances, but where that effect is not expressly mentioned in the marketing authorisation for the medicinal product?"

The European Commission in its submission argued that only the active ingredient that is indicated as active substance in the MA is eligible for SPC protection. A separate and independent examination of the issue before the NPOs is not possible. However, this approach was rejected by the CJEU. The headings of the judgement read as follows:

> "1. Articles 1(b) and 3(a) of Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products must be interpreted as not precluding, in principle, the possibility that an active ingredient can give rise to the grant of a supplementary protection certificate where the active ingredient is covalently bound to other active ingredients which are part of a medicinal product.
> 2. Article 3(b) of Regulation No 469/2009 must be interpreted as precluding the grant of a supplementary protection certificate for an active ingredient whose effect does not fall within the therapeutic indications covered by the wording of the marketing authorisation.
> Article 1(b) of Regulation No 469/2009 must be interpreted as meaning that a carrier protein conjugated with a polysaccharide antigen by means of a covalent binding may be categorised as an 'active ingredient' within the meaning of that provision only if it is established that it produces a pharmacological, immunological or metabolic action of its own which is covered by the therapeutic indications of the marketing authorisation, a matter which it is for the referring court to determine, in the light of all the facts of the dispute in the main proceedings."

In the subsequent proceedings[450] the Austrian Supreme Court interpreted these headings in the sense that an SPC can be granted if the product is an active ingredient. In assessing this aspect, it is not decisive whether the substance is identified in the MA as an active substance. It is necessary and sufficient that the substance concerned have on its own a pharmacological effect. However, not any pharmacological effect matters for granting the SPC, but only one that falls under the therapeutic indication of the MA. To this purpose, the Supreme Court referred the case back to the Technical Division of the Austrian Patent Office in order to request and admit specific evidence for such pharmacological, immunological or metabolic action of the protein in the medicinal product Synflorix. The Supreme Court argued further that in the decision on the application the Patent Office must take a position on the existence or non-existence of such effect. If an ascertainment is not possible, the burden of proof lies on the applicant. The application must be rejected.

[450] Austrian Supreme Court, Decision of 22 April 2015, Case No. 4 Ob 20/15t.

9.2.3.4 The opinion of the NPOs

The case law described in the previous sections concerns infrequent situations, but is in the view of the MPI the consequence of a lacuna. Reg. 469/2009 does not define the concept of active ingredient and does not specify expressly the criteria for distinguishing an active ingredient from other constituents of the medicinal product.

As a consequence, in the MPI Questionnaire for the NPOs the MPI raised the issue of whether the definition of the concept of active ingredient could improve the SPC Regulation and ensure higher certainty. The question for the NPOs reads as follows:

> "Reg. 469/2009/EC does not define the concept of "active ingredient". Would the following definition provide more legal certainty? Please comment on the pros and cons of such a definition.
> *"(b) An active ingredient of the medicinal product is the product intended to exert a pharmacological, immunological or metabolic effect of its own with a view to restoring, correcting or modifying physiological functions or to make a medical diagnosis that falls within the therapeutic or diagnostic indications covered by the wording of the marketing authorisation granted under Directive 2001/82/EC and Directive 2001/82/EC to which the SPC application refers."*
> Related Recital
> *"(2) The concept of 'active ingredient' for the purposes of the Regulation only includes the substance indicated as an active substance pursuant to the MA and having an effect that falls within the therapeutic or diagnostic effect covered by the wording of the marketing authorisation. The concept does not include adjuvants or any other substance or ingredient of the medicinal product that, pursuant to the marketing authorisation to which the SPC application refers pursuant to Art. 8(1)(a)(iv) Reg. 469/2009, do not have a pharmacological, immunological or metabolic effect on the human or animal body of their own covered by the wording of the MA."*

The majority of the NPOs have reservations toward the definition considered by the MPI Questionnaire. Three contributions by three different NPOs may sum up adequately the different reactions:

> "We would strongly encourage the use of a reference in the SPC Regulation to the definition of active ingredient that is provided in the relevant Directive relating to medicines for human use i.e. Directive 2001/83/EC (as amended by Directive 2011/62/EC of 8 June 2011). See for example, Article 1(2), 1(3) and 1(3a) of Directive 2001/83/EC as amended which read:
>
> From Directive 2001/83/EC
> "TITLE 1
> DEFINITIONS
> Article 1
> For the purposes of this Directive, the following terms shall bear the following meanings:
> 2. Medicinal product:
> (a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or
> (b) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.
>
> 3. Substance:
> Any matter irrespective of origin which may be:
> — human, e.g. human blood and human blood products;
> — animal, e.g. micro-organisms, whole animals, parts of organs, animal secretions, toxins, extracts, blood products;
> — vegetable, e.g. micro-organisms, plants, parts of plants, vegetable secretions, extracts;
> — chemical, e.g. elements, naturally occurring chemical materials and chemical products obtained by chemical change or synthesis.
> *3a. Active substance: Any substance or mixture of substances intended to be used in the manufacture of a medicinal product and that, when used in its production, becomes an active ingredient of that product intended to exert a pharmacological, immunological or metabolic action with a view to restoring, correcting or modifying physiological functions or to make a medical diagnosis…"*

In the SPC Regulation, Art 1(b) states that "product means the active ingredient or combination of active ingredients of a medicinal product". One could consider including an additional reference here to refer to the definition of active ingredient used in Directive 2001/83/EC.

Rather than include a separate or specific definition of "active ingredient" in the SPC Regulation, it would be possible to take the same approach as, for example, in Art 3(b) of the SPC Regulation to refer to the Directive as the source of the definition. Thus if the Directive is amended or updated in this regard, then this change will also apply to definition of active ingredient in the SPC Regulation.

We would suggest that this has the additional benefit of making clear the link between the IP system and the regulatory approval system for medicines which is fundamental to the SPC regime."

Another NPO observed:

"The authorities that issue the MA have already made a decision whether a substance is qualified as a new active substance, i.e. a substance not previously authorised in Europe. They do so because such determination is relevant for data and market protection rules. The EMA explicitly lists the outcome of this determination in the European Public Assessment Report. It is baffling why such a determination should again be made by another government entity, this time by the national patent office (using the same definitions) while examining SPC applications. Why can't the active ingredient simply be defined as the active ingredient which the medicine agencies already have identified?"

Another NPO observed:

"This wording has the advantage to provide with important precisions concerning:
The nature of effects exerted by the product
The fact that it exerts it "on its own"
The fact that this effect must fall within the therapeutic indications covered by the MA.
Concerning "*covered by the wording of the marketing authorisation":* It could be useful to add that the relevant part of the MA to define the product is the "active substance" list of the "qualitative and quantitative composition" part in the summary of product characteristics, and to specify that other assertions, for example in the scientific discussion part of the EPAR are not to be taken into consideration.
"*does not include adjuvants or any other substance* (…)" could also be usefully amended with some more examples, such as "*excipients*"."

9.2.3.5 The opinion of the stakeholders consulted

The Allensbach Survey includes some questions on the definition of active ingredient. The first question (Q43) was whether including a definition in the Medicinal Product Regulation would be opportune, and the second (Q44) whether a possible definition considered by the MPI could be helpful to secure legal certainty. The proposed definition was based on our understanding of *Forsgren* and reads as follows:

"An active ingredient of the medicinal product is the product intended to exert a pharmacological, immunological or metabolic effect of its own with a view to restoring, correcting or modifying physiological functions or to make a medical diagnosis that falls within the therapeutic or diagnostic indications covered by the wording of the marketing authorisation granted under Directive 2001/83/EC and Directive 2001/82/EC to which the SPC application refers."

The stakeholders showed a varied attitude towards the question of whether a definition would be opportune. 46 per cent of stakeholders do not see any relevant issues regarding the concept of active ingredient, and would not welcome the inclusion of a definition in the Medicinal Product Regulation. With 44 per cent nearly the same share of stakeholders are of the opposite opinion and would favour the inclusion of a definition.

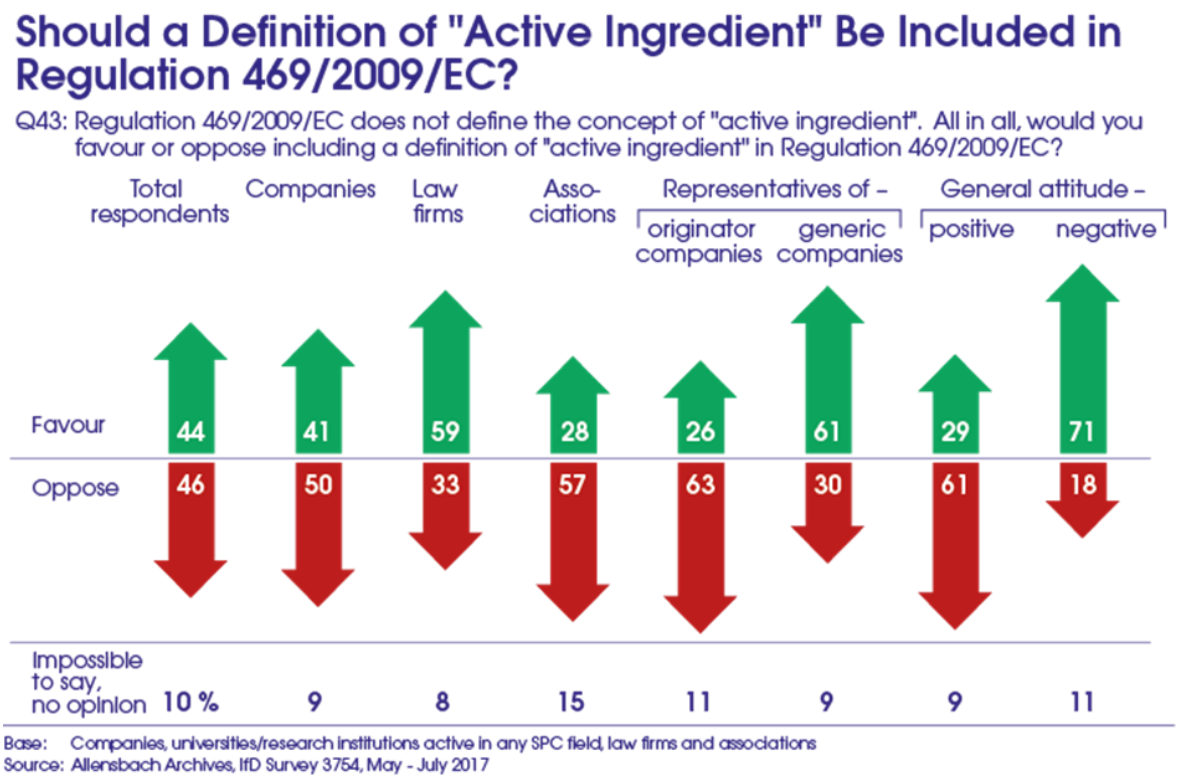

Figure 9.1: Q43 of the Allensbach Survey

Several stakeholders criticise the definition proposed by the MPI as redundant and circular, and argue that it could lead to further case law concerning the meaning of the terms adopted. A majority of the generic companies that answered Q43 would welcome a definition of active ingredient, but not necessarily the one included in the Allensbach Survey. We refer to the comments to Q43 of the Allensbach Survey.[451]

9.2.3.6 MPI opinion and recommendation

If the purpose of the SPC Regulation is deemed to be to offer compensation for a delay that is caused by the prerequisite of the authorisation for placing on the market a new active ingredient, the SPC should be granted only for active substances within the meaning of Dir. 2001/82 and Dir. 2001/83.

The assessment of whether or not a substance is an active ingredient for the purposes of the SPC granting proceedings must be based on the result of the MA granting proceedings and not on the result of a technical discussion conducted before the NPOs.

A provision that is able to translate this opinion into a binding rule must equate the active ingredient under Art. 1(b) Reg. 469/2009 with the active substance identified in the MA submitted in support of the application for a certificate.

This definition would imply that in a situation where the SPC is requested for a substance as such that was identified as a carrier of an active ingredient or as an adjuvant in the MA, the grant of an SPC would not be possible. This result is

[451] See Annex III of this Study, pp. 343-348.

independent of whether or not the applicant can provide evidence that the substance has a pharmacological effect and that this effect falls under the indication of the MA.

For this position we identified three main arguments.[452]

First, the reason for granting the SPC is that the product has undergone a regulatory approval procedure. The implicit premise is that regulatory approval has regarded the substance as an active ingredient and not as an excipient or another constituent of the medicinal product that is not active. This conclusion follows from systematic and historical considerations. Indeed, the SPC protection shall cover "new medicinal products", or new active ingredients in the terminology of the Explanatory Memorandum, that have undergone significant testing concerning their quality, safety and efficacy.[453] Even if a novel excipient or an adjuvant (that represents a subcategory of excipients) can or sometimes must be tested with respect to safety as an active substance, the same is not true for efficacy tests. If one admitted that a product that has been authorised as excipient or carrier of the medicinal product could still show that it has pharmacological effect and that it is an active, this would make room for strategic behaviour. We agree in this regard with the following considerations made by the Hearing Officer of the UK Patent Office in the case BL O/506/12:

> "it would appear that the applicant admits that an active ingredient and an adjuvant are not assessed by the regulatory authorities in the same way and that the process is less onerous for an adjuvant than an active ingredient. If it were nonetheless right that an SPC should be granted, it would mean that there would be different grades of SPC, some wherein the product had not of itself required a rigorous regulatory procedure because the regulatory body did not consider it an active ingredient, and others where it did, but they would all receive the same SPC "reward". Such a system would not be fair."[454]

Second, one purpose of the SPC is to establish a simple system for granting SPCs where the decision to grant or to refuse the certificate is based on two main documents: the MA and the basic patent. This is confirmed by Art. 8 Reg. 469/2009, which identifies the content of the application, and by paragraph 48 of the Explanatory Memorandum.[455] The Regulation does not provide that the examination mandated by Art. 10 Reg. 469/2009 must be based on material or documents other than the documents listed in Art. 8 Reg. 469/2009.

Thirdly, the purpose of establishing a system that is transparent and where any competitor can predict whether or not an SPC will be granted or, if granted, it is valid, on the basis of the documents submitted under Art. 8 Reg. 469/2009 would be jeopardised if one accepted that the NPOs have the task to assess on the basis of evidence submitted by the applicant whether a substance that is not the active substance of the medicinal product according to the MA supplied in support of the

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452 These arguments were partially anticipated by the European Commission in its submission in the proceedings before the CJEU. See Submissions of the European Commission of 17 March 2014, Ref. Ares(2014)802213 (Court Procedural Document).

453 European Commission, Explanatory Memorandum to the Proposal for a Council Regulation (EEC), of 11 April 1990, concerning the creation of a supplementary protection certificate for medicinal products (COM(90) 101 final – SYN255), para. 2 ("since then, the public authorities have required the pharmaceutical industry to demonstrate the quality, safety and efficacy of new medicinal products. These prior controls, which are essential for the protection of public health and which are beyond question, involve considerable scientific and technical effort and expenditure").

454 UK IPO, BL O/506/12 *GlaxoSmithKline Biologicals SA*, Decision of 19 December 2012.

455 "Few documents are required. Apart from the request itself, a copy of the first authorization to place the product on the market in the State concerned is required as this enables the product to be identified. (….) Information enabling the basic patent to be identified must also be provided. The authority empowered to grant the certificate will have to verify that the authorization(s) and the patent refer to one and the same product".

application for a certificate, is an active ingredient within the meaning of SPC law. As pointed out by an NPO in answering the MPI Questionnaire for the NPOs and as also stated by one speaker at the MPI Workshop with the NPOs, a special agency competent for this assessment has already decided on this issue by granting the MA. There is no reason for reopening this technical discussion before the NPOs.

9.2.3.7 Summary

The MPI proposes defining the concept of active ingredient as the active substance identified in the MA. This definition would reflect the case law of the CJEU that denied the status of new active ingredient to adjuvants and excipients, and denied the status of combination of active ingredients to products that associate an active ingredient with an adjuvant that has an increasing or bolstering effect on the therapeutic effect of the active ingredient.

Such definition would be consistent with the division of work between specialised agencies competent for issuing MAs and NPOs competent for issuing SPCs. Further, through the proposed dynamic reference to the regulatory legislation and the health agency assessment, the SPC legislation would be able to include new technological developments in the existing legislative framework.

9.2.3.8 Salts, esters and derivatives of the active ingredient

(a) *The issues*

In the chemical field, not all the substances that are formulated as active substances of medicinal products are neutral – that is, they do not form salts with acids or bases under normal conditions. When the medicinal product is taken by a patient, the active substance is absorbed without further change (although it may subsequently be modified by physiological processes in the body, such as activation or metabolism). Examples of active substances which are neutral include darunavir, lamivudine and olanzapine.

However, the majority of chemical substances formulated as active substances of medicinal products are salts of acids or bases. The INN name is based on the "parent" acid or base. So in the case of idarubicin, idarubacin is the "free" base and idarubacin hydrochloride the salt that the free base forms with hydrochloric acid. In solution, under normal physiological conditions, such salts separate ("dissociate") into their component parts:

$$X.HCl \rightleftarrows XH^+ + Cl^-$$

And in the body, XH^+ may well interact with a receptor in the form X.

X is the part of the chemical substance that is responsible for the activity of the chemical substance. This X may be given different names – e.g. active moiety or active part of the substance – but it is fundamentally a piece of molecule that is shared by several salts and variants of the same compound and is responsible for the physiological or pharmacological action of the drug. Under the INN convention, this equation would be expressed as:

$$X.HCl \rightleftarrows X + HCl$$

Most free bases can form salts with a wide range of acids – and so can exist in many different "forms" – but all will generate X in the body – and so, generally, will have an identical effect, irrespective of the particular salt (or form).

Now the existence of different variants of the same chemical compound raises some legal issues for the SPC system.

The first issue concerns the subject of the certificate. More precisely, the question is whether the product for which the SPC is granted is the concrete form of the substance that the applicant can bring to the market on the basis of the MA supplied or the active ingredient as such in all its possible forms. This question followed from the fact that Reg. 1768/92 as well as Dir. 65/65/EEC did not define the concept of active ingredient, while Dir. 75/318/EEC made a distinction between active ingredient and active moiety,[456] possibly suggesting a legal difference between the two concepts.[457]

The second issue is interrelated with the first one mentioned above, and is the question whether all salts and esters and derivatives of an active ingredient are to be considered the same product, or, if not, what the criteria are for considering a derivative a different and new product *vis-à-vis* the basic form of the same substance. This issue is relevant for deciding whether an application for a certificate complies with Art. 3(c) Reg. 469/2009 or Art. 3(d) Reg. 469/2009 when

- an older certificate has been granted for the basic substance or another salt of the same substance
- an older MA exists for the parent compound or a salt other than the salt for which a certificate on the basis of a younger MA is requested.

But it is also relevant for deciding whether or not a salt falls under the scope of a certificate granted for the parent compound on the basis of an MA covering such parent compound or another salt of such compound. In both cases, indeed, the question is whether or not the free base and the derivative concerned are the same product.

(b) *The subject of the certificate: Farmitalia*

For answering the question whether the active ingredient that is the subject of the certificate is the active substance or a specific form of the latter, and what the implications of this answer are for the scope of the certificate, the judgment *Farmitalia* is relevant. *Farmitalia* was the first judgment of the CJEU to deal with Art. 3(a), but its relevance goes beyond this provision.[458] The facts of the case are as follows. The Italian company was the owner of a national (German) patent for the alpha-anomer of 4-demethoxydaunomycin. The non-proprietary designation of the compound was idarubicin. *Farmitalia* obtained a national MA in Germany for the medicinal product

[456] See Annex, Part 1, 3 of Council Directive 75/318/EEC of 20 May 1975 on the approximation of the laws of Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of proprietary medicinal products [1975] OJ L 147/1.

[457] John N Adams, 'Supplementary protection certificates: the "salt" problem' [1995] EIPR 277, 279, also quoted by AG Fennelly, Case C-392/97 *Farmitalia* [1999] ECR I-5553, Opinion of AG Fennelly, para. 29.

[458] C-392/97 *Farmitalia* [1999] ECR I-5553.

Zavedos 5 mg and Zavedos 10 mg. The product contained as an active ingredient the salt idarubicin hydrochloride, which was also the active substance indicated in the national MA. This substance represents a specific salt of the basic form of the compound idarubicin claimed by the patent. *Farmitalia* filed an application for the certificate in which the product definition reads: "idarubicin and salts thereof including idarubicin hydrochloride".

The SPC requested was not directed to the specific form of the substance for which the MA was granted, but to any forms of that substance. The German Patent and Trade Mark Office and the German Federal Patent Court[459] rejected such a product definition because it did not match the product covered by the MA, which was a specific salt of idarubicin. The German Federal Patent Court admitted the first auxiliary request directed to the specific salt that was covered by the MA. Both were of the opinion that only the product indicated as the active ingredient in the MA could be protected by an SPC. Since only the salt idarubicin hydrochloride was indicated as the active ingredient in the MA, the SPC could not be granted for other forms of the basic substance. *Farmitalia* tried to obtain a broader product definition on the assumption that such definition was material on the scope of the SPC. This assumption seems also to underlie the decision of the German Federal Patent Court.

The case was brought before the German Federal Court of Justice. The court referred two questions to the CJEU. The second question concerned Art. 3(a) Reg. 469/2009 and will be discussed later. The first one related to Art. 3(b) Reg. 469/2009, but it is relevant for the present analysis. The referring court asked whether Art. 3(b) Reg. 469/2009 requires that the product in respect of which the grant of a certificate is sought be described as an "active constituent" in the marketing authorisation form as a medicinal product and, if so, whether Art. 3(b) is not complied with where a single individual salt of an active ingredient is declared in the notice of authorisation to be an "active constituent", but a protection certificate is sought for the free base and/or for other salts of the active ingredient.

Now the answer from the CJEU to this first question may be surprising, because while the referring court was considering the issue of the requirements of protection (Art. 3 (b) Reg. 469/2009), that is, whether and under what conditions the certificate should be granted, the CJEU addressed the question of what the certificate covers, one granted.[460] The first heading of the CJEU judgment reads as follows:

> "On a proper construction of Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products and, in particular, Article 3(b) thereof, where a product in the form referred to in the marketing authorisation is protected by a basic patent in force, the supplementary protection certificate is capable of covering the product, as a medicinal product, in any of the forms enjoying the protection of the basic patent."

The German Federal Court of Justice interpreted this answer in the sense that an SPC may be granted for the product in all its forms even if the MA covers only a specific salt of the product. The CJEU indeed maintained that if the scope of the SPC were limited to

[459] BPatG, *Decision of 15 May 1995*, 15 W (pat) 122/93 [1995] BPaTGE 35, 145.

[460] See Thomas Bopp, *Die Schutzbereichsbestimmung bei ergänzenden Schutzzertifikaten* in FESTSCHRIFT 80 JAHRE PATENTGERICHTSBARKEIT IN DÜSSELDORF (Carl Heymanns Verlag 2016) p. 66.

> "the particular salt form of the active ingredient mentioned as the active constituent in the marketing authorisation, whereas the basic patent protects the active ingredient as such as well as salts thereof, including the one which is the subject-matter of the marketing authorisation, any competitor would be able, after the basic patent had expired, to apply for and, in some circumstances, obtain marketing authorisation for a different salt of the same active ingredient, formerly protected by that patent."[461]

The SPC could not in this case prevent the competitors from bringing to market products which were, in principle, therapeutically equivalent to that protected by the certificate. This would frustrate "the purpose of Regulation No 1768/92, which is to ensure the holder of the basic patent of exclusivity on the market during a given period extending beyond the period of validity of the basic patent".[462]

From this decision it appears to follow that the SPC is granted for the active substance understood as the active moiety. As result, the SPC also covers all forms of the free bases that share the same active moiety. Such coverage would be an automatic effect of granting the certificate. This was at least the implication of *Farmitalia* drawn by the German Federal Supreme Court in the case *Sumatriptan.*[463]

One could infer from this case law that the scope of the SPC may be broader than the product of the MA, which covers only a specific form of the authorised compound. However, this could also be a simple consequence that follows the way the MA granted for *Farmitalia* was issued by the national authorities. The national MA supplied by the Italian company in support of the application for a certificate referred specifically to the salt. The MA granted by the EMA nowadays refers to the active moiety accompanied by the salt or hydrate form, where relevant. The part of the Notice to Applicants relating to SmPCs[464] states with respect to the qualitative and quantitative composition of the medicinal product:

> "The active substance should be declared by its recommended INN, accompanied by its salt or hydrate form if relevant, or the European Pharmacopoeial name if that name represents an established name in Europe.
>
> (...)
>
> Where the active substance is present in the form of a salt or hydrate, the quantitative composition should be expressed in terms of the mass (or biological activity) in International (or other units where appropriate) of the active moiety (base, acid or anhydrous material), e.g. '60 mg toremifene (as citrate)' or 'toremifene citrate equivalent to 60 mg toremifene'."

If the MA supplied in support of the application and the application for a certificate identifies the active ingredient by its INN, then the latter can and shall be interpreted as referring the active moiety of the compound. Provided that the patent protects the latter and not just a specific formulation or a specific salt, a valid SPC may be granted for the substance that will cover all forms and derivatives sharing the same active moiety. This seems to be consistent with the rationale and the conclusion of *Farmitalia* as well as Recital 13 Reg. 1610/96.

Summing up, we infer from this case law that when the patent covers a compound including possible salts of it, the certificate is granted for the active ingredient intended as the active free base or active moiety of the substance, even if the MA

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461 C-392/97 *Farmitalia* [1999] ECR I-5553, paras. 18-19. For sake of completeness, the argument reported in main text was made by the parties, and agreed with by the CJEU, see para. 19.

462 *Ibid.*

463 BGH, *Sumatriptan,* X ZB 12/01 [2002] GRUR 415.

464 European Commission, 'Notice to Applicants - Summary of Product Characteristics', available at https://ec.europa.eu/health//sites/health/files/files/eudralex/vol-2/c/smpc_guideline_rev2_en.pdf (last accessed 13 November 2017) p. 4.

entitles the applicant to bring to market included in the medicinal product authorised only a specific form of such substance. As a consequence, the SPC can in principle cover all salts and esters and derivatives that can be considered to share the same active moiety, unless the latter for any reason must be considered a different product. This leads to the next question, which was not dealt with or answered by *Farmitalia*.

(c) *When is a derivative a different product?*

(i) Premise

Pursuant to Recital 13 Reg. 1610/96, where the basic patent covers an active substance and its various derivatives (salts and esters), the certificate confers the same protection, that is, the certificate covers the derivatives of the active substance. Pursuant to Recital 14 "the issue of a certificate for a product consisting of an active substance does not prejudice the issue of other certificates for derivatives (salts and esters) of the substance, provided that the derivatives are the subject of patents specifically covering them". Recital 13 Reg. 1610/96 establishes a rule that all salts of the same parent compound are to be considered the same product, while Recital 14 formulates an exception to this principle. This exception laid down in Recital 14 can be applied consistently with the binding part of both Regulations only when such salt is considered a different and new active ingredient with respect to the free base compound or other variants of that free base. Only in this case, indeed, will an older MA granted for the free bases or for other salts or variants of these bases be disregarded in applying Art. 3(d) Reg. 469/2009 and the older SPC granted for the free bases or other salts or variants of these free bases will be disregarded in applying Art. 3(c) Reg. 469/2009. Recital 14 Reg. 1610/96, however, does not clarify what the criteria are for deciding when the derivative may be considered a different product than the basic substance or other derivatives of that substance. At least two theories are possible.

According to a first approach, advocated by several stakeholders, the mere existence of a patent and MA is the necessary, but also sufficient, condition for granting the certificate for the salt. The existence of the patent confirms that the salt is novel and inventive over the prior art. The relevant prior art will likely include other salts or the parent compound itself, if previously authorised or disclosed.

According to a second theory, the application for a certificate must meet the conditions laid down in Art. 3 Reg. 469/2009 and must be considered a different product. For this purpose, the existence of a basic patent covering specifically the derivative is a necessary, but not a sufficient, requirement because the grant of the patent could not imply that salts disclosed in the prior art are different products, or have different pharmacological properties. For the sake of completeness, it could not even imply that the derivative is inventive.[465]

[465] See Art. 54(3) EPC. The patent application for a certificate could for instance be filed within a period of 18 months after the application for the general formula including the free base. The older application for the general formula would represent prior art only for examining novelty, but not the inventiveness of the salt disclosed in the later application.

(ii) The case law

The first theory, according to which the existence of a patent and an MA should be considered a sufficient requirement for granting the certificate, seems to have been adopted by the German Federal Court of Justice in the *Escitolapram* decision.[466] In commenting on Recital 14 Reg. 1610/96 the court seemed to be of the opinion that the requirements laid down in the Recital are satisfied when the derivative is covered by a product patent. However, while the consideration of the court may support this reading, they are mere obiter comments, since the certificate was requested for an enantiomer, and the court anyway considers the enantiomer a different product than the racemate, at least in the case where both enantiomers were active. Further, the court considers the racemate to be a combination of two active ingredients, and the enantiomer one member of this combination, and not a derivative of the racemate. Therefore, Recital 14 was not really relevant for that factual scenario.

The approach that the mere existence of a product patent is not sufficient and something more is required in order to consider the derivative a different and new active ingredient for the purpose of the SPC legislation was adopted by the German Federal Federal Court of Justice in the *Doxorubicin-Sulfate* decision.[467] In this decision the court considered doxorubicin-sulfate and doxorubicin-hydrochloride the same substance, because in both cases the pharmacological effect remains identical and is determined by doxorubicin. A further development of this case law was made by the recent decision *Paliperidone palmitate* of the German Federal Patent Court[468]. In this case the court specified further the criteria for deciding whether or not a derivative may be considered a new substance. The court referred to the criteria existing in regulatory law, and particularly Art. 10 Dir. 2001/83, that distinguish the cases when a salt may be considered the same substance as the reference product, so that a generic application is possible, and when it may be considered a new substance, so that only a full dossier application is possible. Similar criteria apply to the question of when a salt may be considered a new chemical entity for the purpose of regulatory data protection. It is worth reporting the reasoning of the courts:

> "Indications of how an active substance and its derivatives are to be classified under certificate law can be derived from Recitals 13 and 14 of Regulation (EC) No 1610/96 (Plant Products Supplementary Protection Certificate Regulation), which by virtue of Recital 17 thereof are also to be taken into account in the interpretation of the Medicinal Products Supplementary Protection Certificate Regulation, Regulation No 1768/92, and from the materials on the latter regulation. Pursuant to Recital 13 of Regulation No 1610/96, an active substance and its derivatives are as a rule to be treated as one and the same product (assumption of product identity). This is in conformity with the materials on Regulation No 1768/92, according to which the Regulation is to be restricted exclusively to new medicinal products and for this reason minor changes to the medicinal product such as the use of a different salt or ester or a different pharmaceutical form does not justify the grant of additional protection certificates (cf. Proposal for a Council Regulation (EEC) concerning the creation of a supplementary protection certificate for medicinal products = COM (90) 101 final, para. 11). This interpretation was confirmed by the ECJ in its Farmitalia decision (ECJ, 2000 GRUR Int. 69), in which, although not explicitly addressing the interpretation of the concept of a product, it nevertheless emphasised within the framework of its interpretation of Art. 3 (b) of Regulation No 1768/92 that "the certificate is capable of covering a product as a medicinal product in any of the forms enjoying the protection of the basic patent if the product in the form referred to in the marketing authorisation is protected by a basic patent in force". Thus the ECJ's interpretation is based on a broad concept of the product, according to which an active substance and its pharmacologically equivalent derivatives are to be regarded as the same product.

466 BGH, *Doxorubicin-Sulfat,* X ZB 4/08 [2009] GRUR 41.
467 *Ibid.*
468 BPatG, *Paliperidonpalmitat*, 14 W (pat) 25/16 [2017] GRUR Int. 961.

> However, Recital 14 of Regulation No 1610/96 makes it clear that it is nevertheless not impossible for an active substance and its derivatives to be regarded as different products if the derivatives in question – as in the present case – are the subject matter of patents specifically covering them. Admittedly, the wording of Recital 14 of this Regulation appears only to refer to the provision of Art. 3 (c) of Regulation No 1768/92, but the underlying idea it contains nevertheless equally applies to the further restriction on grant in Art. 3 (d) of this Regulation (citation omitted), which is likewise based on the aim of preventing the unlawful grant of multiple protection certificates for the same product.
>
> 5. Whether an active ingredient and its derivatives are to be assumed to be identical products or different products is determined according to the criteria developed with respect to Art. 1 (b) of Regulation No 1768/92. This requires the substances under comparison to have different pharmaceutical effects. According to the Forsgren decision, a pharmaceutical effect requires a substance to have its own pharmacological, immunological or metabolic effect (citation omitted). Hence in the present case, it must be determined whether the ester (paliperidone palmitate) is to be regarded as a different product as compared with the free alcohol (paliperidone) in terms of its pharmacological and/or metabolic effect.
>
> Even if the concept of a product in certificate law is to be determined autonomously (citation omitted), principles from pharmaceutical law that are in conformity with those of certificate law can be drawn upon for the interpretation of Art. 1 (b) of Regulation No 1768/92 (citation omitted). The question discussed in the field of certificate law whether and when the different product forms of an active substance are regarded as one and the same active substance was, for pharmaceutical licensing proceedings, decided by the Community legislature in Art. 10 (2) b) sentence 2 of Directive No 2001/83 such that an active substance and its derivatives are to be regarded as the same active substance unless their characteristics differ substantially with respect to safety and/or effectiveness (citation omitted). Accordingly, under certificate law, too, the answer to the question whether two active substances are different products within the meaning of Art. 1 (b) of Regulation No 1768/92 is to be based on whether their material properties differ from each other in such a way that is reflected in a different pharmacological, immunological or metabolic effect."[469]

In the specific case, the application for a certificate was filed for paliperidone palmitate, a fatty acid ester of paliperidone. A previous MA was granted for unmodified paliperidone. On the basis of this previous MA an SPC for paliperidone on the basis of a different basic patent was issued to the same applicant. Despite the fact that paliperidone palmitate is a "pro-drug", which is hydrolyzed *in vivo* to yield the same active moiety paliperidone, the court, based on its own assessment, came to the conclusion that "different material characteristics resulting from the different chemical functionalities" existed between the two forms, and that there were "substantial and not merely minor differences in the pharmacological and metabolic effects of the product paliperidone palmitate at issue in these proceedings and the product paliperidone". As a consequence, the court regarded the two products as "different products within the meaning of Art. 1 (b) of Regulation No 1768/92, with the result that the grant of the supplementary certificate requested is not excluded by virtue of Art. 3 (c) and (d) Reg. 469/2009 of the Regulation".

(iii) Options

The SPC legislation intended to allow only one certificate per active ingredient. This principle shall ensure the balance of the system and prevent multiple extensions for the same product. In accordance with this policy choice, according to the Explanatory memorandum, the substitution of one form of the active ingredient with another form of the same active ingredient shall not lead to the grant of a new certificate. Further, the Explanatory Memorandum suggests that derivatives of the same substance shall be considered as the same substance for the purpose of granting certificates. This conclusion has been put in question by Recital 14 Reg. 1610/96. However, such Recital 14 Reg. 1610/96 does not state clearly whether the mere existence of a patent

[469] BPatG, *Paliperidonpalmitat*, 14 W (pat) 25/16 [2017] GRUR Int. 961.

covering a derivative is sufficient to consider the latter a different product eligible for SPC protection.

Against this background, lawmakers have two options. If they deem the existence of a patent necessary, but also sufficient for the derivative to be considered a new active ingredient, they should clarify this principle in the Regulations. If by contrast they consider that something more is required in order to consider a derivative a new product *vis-à-vis* the free base or other salts or derivatives of the same active, they should spell out these requirements.

If the latter is the option preferred, several approaches are possible in this regard:

- considering the substance a new product only when a stand-alone MA (Art. 8(3) Dir. 2001/83) is supplied in support of the application for a certificate. This would however set a very low bar, since in case two salts are proven to be the 'same substance', then the same clinical studies could be re-submitted for the new Art. 8(3) Dir. 2001/83 application without conducting proper new development.
- Considering the derivative a different product when it was presented by the applicant and considered by the health agency itself to be a new active substance according to the criteria laid down in regulatory law; this approach would not be coextensive with the previous one, since the mere fact that the MA granted for a salt is stand-alone MA does not automatically confer NAs status to the salt;[470]
- spelling out in SPC legislation criteria to assess when a new active ingredient exists; such criteria could be fully consistent with regulatory law, but could require at the same time an independent assessment by the NPO.

The MPI considered a possible provision implementing the latter option in the Questionnaire for the NPOs and in the Allensbach Survey. The wording considered reads as follows:

> "The different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active ingredient shall be considered to be the active ingredient, unless they differ significantly in properties with regard to safety and/or efficacy."[471]

According to this wording, the existence of a patent was not sufficient for considering a derivative a new product. The NPOs must also assess whether the pharmacological properties of the derivative are different from the pharmacological properties of the basic substance or other derivatives of such substance; the criteria governing such assessment were consistent with that laid down in regulatory law, that consider as the same substance all the derivatives that do not differ significantly with regard to safety and or efficacy. Such proposal does not seem to be very distant from the approach taken by the German Federal Patent Court in *Paliperidone palmitate*. Also following such decision, the NPO shall do its own assessment of these criteria, regardless whether such elements were assessed by the EMA or the national agency and such assessment result from the pertinent MA supplied in support of the certificate. The substantive examination of pharmacological effects in the procedure for granting the

[470] See EMA (edn), Reflection paper on considerations given to designation of a single stereo isomeric form (enantiomer), a complex, a derivative, or a different salt or ester as new active substance in relation to the relevant reference active substance, 18 October 2012, EMA/651649/2010, p. 5.

[471] See Art. 10(2)(b) Dir. 2001/83/EC.

certificate appears to be the main problematic aspect of this approach, as the reactions of the NPOs have confirmed.

(iv) Opinion of NPOs

The MPI has asked the NPOs the following question in the MPI Questionnaire for the NPOs[472]:

> "Reg. 1610/96/EC has clarified that the issue of a certificate for a product consisting of an active substance does not prejudice the issue of other certificates for "derivatives (salts and esters) of the substance, provided that the derivatives are the subject of patents specifically covering them", see Recital No 14. Reg. 1610/96/EC has not clarified, however, under which conditions the derivative may be considered a different product within the meaning of Art. 3 Reg. 1610/96/EC or Reg. 469/2009/EC. Consider the following hypothetical provision (inspired by Art. 10 Dir. 2001/83/EC)
>
> 'The different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active ingredient shall be considered to be the same active ingredient, unless they differ significantly in their properties with regard to safety and/or efficacy.'
>
> In your view, would this provision provide criteria that are predictable, ensure sufficient protection for pharmaceutical innovation and reduce the potential for life-cycle strategies?"

While two out of 24 NPOs did not provide an answer to this question at all and four gave a positive answer, the majority of NPOs (18) found that the mentioned provision did not provide predictable criteria or that it could not both ensure sufficient protection for pharmaceutical innovation and reduce the potential for life-cycle strategies (11) or at least expressed their doubts about it (7).

The following comments are exemplary for the doubts or concerns of the NPOs with respect to the provision considered by the MPI Questionnaire:

> "In our practice, a wording such as 'product X in any form protected by the basic patent' in the definition of the product is accepted and may cover the product itself and its salts, asters, etc….
> It seems actually very useful to add a precision that salts, esters, isomers, and mixtures of isomers are to be considered as the same active ingredients, unless they differ significantly. Solvates, hydrates, enantiomers could also usefully be added and, in the biology field, viral strains and other derivatives.
> On the other hand, the wording 'complexes and derivatives' does not seem precise enough.
> It could be useful to add that mutants and variants of a product are not to be considered as the same active ingredient than the product."

> "As far as the specific wording of the hypothetical provision is concerned, it seems unclear:
> 1) whether the list of salts etc. is an exhaustive or non-exhaustive list (caveat with regard to positive definitions applies also here).
> 2) with regard to the meaning of 'derivatives' and 'differ significantly'. This wording is generally regarded as lacking clarity in the context of patent claims.
>
> As far as the intention of the provision is concerned, it appears that a provision of this type would have the potential to ensure sufficient protection for true innovations and to reduce life cycle strategies. Rather than focusing on new patents (as in recital 14 of Reg. 1610/96/EC), a criterion which is specifically directed to safety and/or efficacy seems preferable. Only if new forms of an active ingredient with significant differences in safety and/or efficacy are the subject of new MAs, an SPC should be granted."

> "Hard to see how this provision would make any difference compared with current CJEU case law (C-392/97). Secondly this seems to only cover classic generic derivatives of small organic molecules, not biosimilars.

[472] Q11 MPI Questionnaire for the NPOs, Annex VI of this Study.

Regarding derivatives there are two issues:
1) how to ensure that the SPC also covers therapeutically equivalent derivatives
2) how to allow SPCs for derivatives that are not therapeutically equivalent

Ad 1). In the current system applicants are keen on a broad product description 'A, optionally in the form of a salt, ester or derivative (etc.)'. What is problematic is that there is no clinical data for salts, esters etc. yet available, so only assumptions can be made about which derivatives will be equivalent, and which not. These assumptions may involve a survey of the scientific literature and applicants will challenge NPOs in this regard. A much more effective and efficient solution would be to only allow the grant of the SPC for the authorized ingredient (or active principle), and have the applicants rely on recital 13 to obtain broad protection.

Ad 2). Firstly SPCs for specific salts/esters are fairly rare. Secondly the criterion of recital 14 is the presence of a specific patent covering the product. It is not entirely clear if that means a product patent (i.e. excludes use or process patent). Moreover the derivative may be the subject of a specific patent for reasons that have nothing to do with therapeutic properties (e.g. less hygroscopic, therefore more stable)."

"Our office believes that the word 'derivates' is too generic and that it can apply for very different molecules than the active ingredient. In Reg. 1610/96/EC it is explained that the derivatives are specifically salts and esters and not other substances ('derivatives (salts and esters)'). Therefore the word 'derivatives' should be eliminated from the statement or modified in order to state that 'derivatives' are considered to be (only): 'salts, esters, ethers, isomers, mixtures of isomers or complexes'."

"We would like to draw your attention to the document 'Proposal for a COUNCIL REGULATION (EEC) concerning the creation of supplementary protection certificate for medicinal product' from Brussels, 11 April 1990, which states the following (page 20, second paragraph): 'This calls for a strict definition of the product within the meaning of Article 2. If a certificate has already been granted for the active ingredient itself, a new certificate may not be granted for one and the same active ingredient whatever minor changes may have been made regarding other features of the medicinal product (use of a different salt, different excipients, different pharmaceutical presentation, etc.).' (underline added) [Also explanation of Art. 3 in 'Proposal for a EUROPEAN PARLIAMENT AND COUNCIL REGULATION (EC) concerning the creation of a supplementary protection certificate for plant protection product' from Brussels, 09.12.1994]

Explanation seems required as to whether there is a relationship between the Recital 14 of the Reg. 1610/96 and the cited paragraph of the 'Proposal(s)' and whether it is possible to apply them in consistent way. What was the intention of the legislator? It seems to us that the Recital 14 of the Reg. 1610/96 and cited paragraph of the 'Proposal(s)' have divergent meanings. Taking into account Art. 3(c) and Art. 3.2. (Reg. 1610/96), as well as the decision Farmitalia of the CJEU, the Recital 14 of the Reg. 1610/96 seems to be quite odd and inapplicable pursuant to the (other) objectives of the Regs."

"The definition seems not to suit well for the purposes of Reg. 1610/96/EC and Reg. 469/2009/EC. The patents for specific derivatives (specific salt or ester) of an active substance are usually granted for the reason that the new derivative can be easily processed (better solubility) or is more stable, or is more compatible with excipients etc. Consequently, on the basis of a new derivative it may be possible to provide new pharmaceutical forms (for example oral capsules instead of e. g. ampoules for intravenous injection) containing the new derivative, which are then the subject of further marketing authorizations. Thus, if there are patents specifically covering a specific derivative of a (known) substance, the difference in respect of that substance may not lie solely in safety and/or efficacy."

"An advantage with the hypothetical provision is that the definition of derivative is put in line with the regulations that are governing the marketing authorisations. It is made clear in at least central marketing authorisation if the medical authorities give an active ingredient status as a 'new active substance'. A problem with the provision is the reference to safety and/or efficacy. It is not always the case that medical authorities have been posed with the question if a specific derivative should be regarded as a new active ingredient. If not, should national offices examine if derivatives differ significantly in their properties with regard to safety and/or efficacy? How should this be done? Do all national offices have the qualifications for these types of examinations? It is desirable that the expression 'derivative' is further clarified. The use of the expression derivative in the provision should, if possible, be avoided as the expression is silent regarded the extent of structural similarities that is needed. Can for example a fragment of an antibody be considered as a derivative of an antibody – a fragment of an antibody can differ significantly in the structure without differing significantly in its properties with regard to safety and efficacy. In case derivative is defined in the Regulation, the definition must be carefully drafted taking into account the fast development in the biotechnological sector. The latter part of the answer to question 10 applies also here.[473]

[473] The latter part of the Answer of this NPO to Q10 reads as follow: "As a key concept, it is desirable, that active ingredient is clearly defined within the Regulation. However, such a definition must be

> "The hypothetical provision includes the undefined term 'significantly'. The evaluation of this condition is not within the competency of a patent expert. In addition, it does not add value to the current regulation.
>
> Whether this ensures sufficient protection for pharmaceutical innovation and reduces the potential for life-cycle strategies depends on the definition and legal certainty of the term 'significantly'."
>
> "As currently worded this provision would not provide criteria that are sufficiently predictable as there would always be the opportunity for an applicant to argue that their product differs 'significantly' in its properties. The proposed wording does not appear to be a clear test, that an IPO can readily apply, in particular in situations where a product could be part of a complex formulation. MAs do not provide such comparison data and further evidence would have to be supplied to demonstrate this criteria."

One of the main concerns expressed is the need for the NPOs to make its own assessment of the question whether the derivative is a different active ingredient. Such a concern was also directed against a definition of active ingredient that is independent from the result of the assessment made in the procedure for granting the MA supplied in support of the application for a certificate.

(v) Opinion of the stakeholders

The same question and the same hypothetical provision was the subject of the Allensbach Survey (Q45). The majority of the stakeholders that answered the question did not consider the provision a useful or opportune clarification (48 per cent). Several comments were made in this regard with two main trends.

A first line of comment consider a clarification not needed and deem that the grant of a certificate shall be possible each time a patent and an MA are granted for the derivative. Further, they consider the proposed clarification confusing, and challenging for the NPOs, since they should make an assessment for which they are not well equipped. Further they consider the question poorly drafted. We report some of these comments:[474]

> "One should not be asked to just accept as perfect or reject a single definition provided without any explanatory statement or rationale. The structure of the survey is further inconsistent as a comment box is here provided as opposed to question 27. Patent offices should not have to/cannot assess whether there is a significant difference with regard to safety and efficacy. This is a question for medicines regulatory bodies, not national patent offices. The proposed clarification would introduce a new condition and therefore create uncertainty and lead to more litigation, when there is no lack of clarity in the current law. It is sufficient that a molecule is considered a NCE by the EMA/national authority and there is a patent to that molecule."
>
> "Anything which is covered by a separate patent, should be eligible for SPC protection. - Safety and efficacy criteria are registration requirements and are not suitable for the examination process in patent offices".
>
> "No clarification of the law is required. It is clear that a new salt, ester etc, is considered a new chemical entity and is subject to a patent and a marketing authorisation then an SPC may be granted. Any further analysis with regard to efficacy and/or safety must be considered beyond the competence of the national patent offices."

carefully drafted taking into account the fast development in the biotechnological sector. Which type of products should according to the legislator, in the future, be able to obtain an SPC? The definition must be fit for the purpose. It is always difficult to define something only by indicating what is included, as you must present an exhaustive list. This is even more difficult in a field, such as biotechnology, that is developing rapidly. There is a risk that you regularly need to amend the definition. It is usually more durable to state, in negative terms, what is excluded. A possible option might be to refer to the definition of active ingredient in the Regulations governing marketing authorisation. These seem to be updated more regularly and are following the development within the field."

474 See Annex III of this Study, pp. 348-354.

Other comments seem to agree with the policy intention underlying the provision considered by Q45 – the mere existence of a patent shall not be sufficient to consider the derivative a different product than the basic substance for the purpose of Art. 3 (c) and Art. 3 (d). However, they indicate also some issues with the definition proposed in Q45 and submitted alternative criteria, as making the grant of a certificate dependent from the grant of a stand-alone MA (Art. 8(3) Dir. 2001/83):

> "It would be clearer to close this alley, and simply make the "SPC availability" dependent upon the question whether a full new medical approval is necessary or not. I don't think just because a company figures that an alternative salt works even better, should be awarded with a new SPC, if they can get a new patent on it anyway. Otherwise, we will have case laws on the term "significantly" in this context... Instead I suggest: "The different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active ingredient shall be considered to be the same active ingredient, unless the regulatory authorities consider the application for marketing approval such that it requires the same support with studies and data as a new chemical entity."

> "The idea of including certain derivatives into the SPC directive is going into the right direction, but this should be the exception. Art. 10(2)(b) of Directive 2001/83/EC sets a standard for a generic derivative which I believe is too low. Rather, significant clinical trials should be necessary, i.e. more akin to Art. 10(3) of Directive 2001/83/EC. I would propose to define (by way of fiction) a derivative of a known active ingredient as new active ingredient if it was subject to testing of the safety and efficacy that is substantially equivalent to the standards of annex I of Directive 2001/83/EC (and related guidelines). See also ECJ cases C-195/09 and C-229/09 which set a similar hurdle".

Some consider the clarification not necessary, because its normative content already follows from the link existing between SPC legislation and European pharmaceutical legislation. We refer for more details to the comments on p. 348 ff. of the Allensbach Survey Report.[475]

(vi) Conclusion

The SPC legislation was conceived to foster research on new active ingredients. The number of certificates shall have matched the number of the authorised new active substances (at that time, an average of 50 each year). As such, the SPC was to be issued on the basis of an MA granted after extensive clinical trials directed to assess the safety and the efficacy of the product. This result was ensured by Art. 3(d) Reg. 469/2009, according the MA supplied in support of the certificate shall be the first granted in the Member State concerned (and therefore, a stand-alone MA).

If one considers this approach still valid, then it would be consistent with it to admit an SPC for the derivatives of an active substance that was already authorised in the past for medicinal use and even subject of a previous certificate only when such derivative represents a new active substance under regulatory law, and the corresponding authorisation supplied in support of the application for a certificate was based on complete clinical tests. There are different technical ways for implementing such policy choice, as requesting at least an MA granted under Art. 8(3) Dir. 2001/83 or that the derivative has received the status of new active substance according to the criteria laid down in regulatory law, or requesting the NPOs to make its own assessment on the basis of similar or identical criteria.

If one considers by contrast that the mere existence of a patent specifically claiming the derivative and the grant of an MA for its exploitation shall be the necessary and sufficient requirement for granting the certificate on the derivative, then neither the

[475] Annex III of this Study, pp. 348-354.

status of new active substance nor the requirement of a stand-alone MA shall be required for considering the derivative eligible for a certificate.

Which of the two approaches deserves support is a policy question. The first approach is more consistent with the original purposes of the SPC legislation.

9.3 THE CONCEPT OF MARKETING AUTHORISATION

9.3.1 Introduction

As mentioned, Art. 2 Reg. 469/2009 and Reg. 1768/92 do not define the concept of marketing authorisation. This raises the issue of what MAs, obtained via which routes, can be relied on for the purposes of the SPC procedure. A systematic reading of Art. 8(1)(b) Reg. 469/2009, Art. 2 and Art. 3(b) Reg. 469/2009 suggests that an authorisation must comply with three requirements:

- It must have been granted in accordance with Dir. 2001/82 or Dir. 2001/83;
- It must include the entitlement to place on the market the product;
- It must contain the summary of the product caracteristics required by Art. 8(1)(b) Reg. 469/2009.[476]

9.3.2 Exclusion of authorisations with limited scope and CE markings

9.3.2.1 Manufacturing authorisation for medicinal products

The requirement that the authorisation entitles the owner to place the product on the market implies that administrative authorisations whose scope is limited to manufacture cannot suffice as a basis for the grant of an SPC. As a consequence, manufacturing authorisations to which Dir. 2001/83 or Dir. 2001/82 refer[477] do not entitle the patentee to a certificate.

9.3.2.2 Permission to manufacture, import or supply a product for experimental purposes or for use for clinical trials

The same conclusion drawn in the previous section applies to permission or authorisation granted under national law or under Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use that allows its holder to manufacture, import or supply a product for use in a particular trial or experiment. Such authorisations are not MAs within the meaning of Art. 2 or Art. 7 Reg. 469/2009, since they do not entitle the holder to place the investigational medicinal product on the market.

[476] British Technology Group Ltsd.'s SPC Application, Reports of Patent, Design and Trade Mark Cases, Volume 114, Issue 3, 1 January 1997, pp. 118-124.
[477] See Art. 40 Dir. 2001/83 and Art. 44 Dir. 2001/82.

9.3.2.3 Pricing and reimbursement authorisations

Pricing and reimbursement authorisations cannot be considered an MA within the meaning of the SPC Regulation.[478] This is true also for the interpretation of Art. 19(1) Reg. 1768/92 and even if under national law the marketing of drugs is possible only after such authorisations are issued.[479]

9.3.2.4 Active ingredient authorisation for plant protection products

Active substance authorisations granted following the evaluation of active substances for use in plant protection products pursuant to Arts. 4 *et seqq.* Reg. 1107/2009 cannot be referred to as a legal basis for the grant of an SPC and are not considered the first MA for the substance neither. The scope of corresponding active substance authorisations is limited to the use of the respective active substance as an ingredient of a plant protection product that in turn still requires formal approval within the framework of the so-called zonal authorisation system prior to being put on the market.

9.3.2.5 CE markings

Certain products may only be placed on the market provided that they bear a CE marking.[480] The CE marking does not constitute an authorisation granted within administrative proceedings and does no constitute an authorisation granted under Dir. 2001/82 or Dir. 2001/83.[481] Rather, the CE marking is affixed on the basis of a process of self-declaration by the product manufacturer itself or its authorised representative established within the EU that thereby declares that its product conforms to certain regulatory requirements.[482] The question whether a CE design certificate can support the application for a certificate is relevant for drug/medical devices combinations. Chapter 18, Section 18.6 deals specifically with this issue.

9.3.3 Authorisations to place the product on the market

MAs may be obtained for medicinal products and plant protection products. MAs for medicinal products can be distinguished on the basis of the procedural root and on the type of MA. As to the procedural route, one can distinguish European MAs and national MAs. Both are MAs within the meaning of Art. 2 Reg. 469/2009. Indeed, they are granted in accordance with Dir. 2001/82 and Dir. 2001/83, they include the entitlement to place the product on the market, and they contain the summary of the product's caracteristics required by Art. 8(1)(b) Reg. 469/2009.

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478 See also Colin Birss et al, *Terrell on the Law of Patents* (18th edn, Sweet & Maxwell 2016) marginal note 6.88; Klaus Grabinski in Georg Benkard (eds) PATENTGESETZ (11th edn, C.H. Beck 2015) § 16a, marginal note 21; Marco Stief, Dirk Bühler (eds), *Supplementary Protection Certificate* (C.H. Beck, Hart, Nomos 2016) p. 17, para. 48.

479 Case C-127/00 *Hässle* [2003] ECR I-14781.

480 See for example Art. 20 Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No. 178/2002 and Regulation (EC) No. 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC [2017] OJ L 117/1.

481 Klaus Grabinski in Georg Benkard (ed), PATENTGESETZ (11th edn, C.H. Beck 2015) § 16a, marginal note 25.

482 European Commission, The 'Blue Guide' on the implementation of EU products rules 2016 [2016] OJ C 272/1: "The CE marking indicates the conformity of the product with the Union legislation applying to the product and providing for CE marking".

9.3.3.1 Type of MA

(a) *Stand-alone MA for a new active substance*

An MA granted for a new active substance within the framework of centralised,[483] decentralised or mutual recognition or national procedures in the case of medicinal products, or within the framework of the zonal authorisation system in the case of plant protection products, is the primary example of an MA within the meaning of Art. 2 and Art. 3(b) of the SPC Regulations.

(b) *Provisional MA*

(i) Plant protection products

In relation to provisional authorisations granted for plant protection products,[484] the CJEU has decided that these can be relied upon for the grant of an SPC. The reason given for this is a "link of functional equivalence which exists between the criteria set out in Article 8(1) of Directive 91/414/EEC and those laid down in Article 4 of that directive."[485] The legal rules referred to by the CJEU in this regard are now regulated in Art. 30 and 29 Reg. 1109/2009. However, we see no reason why the CJEU's ruling should not apply to the current legal situation. Art. 30 Reg. 1109/2009 has been implemented upon request of the European Parliament, which intended to maintain the previous system of provisional applications.[486]

(ii) Veterinary medicinal products

Under Art. 8 Dir. 2001/82/EC, Member States may provisionally allow the use of immunological veterinary medicinal products "without a marketing authorisation" in the event of serious epizootic diseases. In such a case, no MA is issued: indeed, the company concerned is not entitle to place the product on the market, and the product can only made be available for the purposes and to the conditions set out by the Member Sate. As consequence, such provisional measure is not an MA within the meaning of Art. 2 and 3 Reg. 469/2009 and does not trigger the deadline of Art. 7 Reg. 469/2009. An SPC cannot be granted on the basis of such provisional authorisation.[487]

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483 Colin Birss et al, *Terrell on the Law of Patents* (18th edn, Sweet & Maxwell 2016) marginal note 6.85.

484 Case C-229/09 *Hogan Lovells International* [2010] ECR I-11335.

485 *Ibid.*, para. 46.

486 European Parliament, A6-0359/2007, Report of 5 October 2007 on the proposal for a regulation of the European Parliament and of the Council concerning the placing of plant protection products on the market (COM(2006)0388 – C6-0245/2006 – 2006/0136(COD)), Amendment 35, p. 187: "Experience to date with Directive 91/414/EEC suggests that the Commission's assumption that active substances can be included in the positive list of active substances within 25 months is unrealistic. So far it has taken an average of 55 months for new active substances to be included in Annex I of Directive 91/414/EEC. The provisional national authorisations which are now possible have proved their value over the last few years and allow users to have early access to innovative and more environmentally friendly plant protection products. Provisional authorisation should therefore be granted at least after the expiry of the deadline proposed by the Commission."

487 EFTA Court, Case E-16/14 *Pharmaq AS v Intervet International*, Decision of 9 April 2015, BV [2015] EFTA Ct. Rep. 212, paras. 57, 66.

(c) *Emergency authorisations, conditional MA and authorisation granted under exceptional circumstances*

(i) Plant protection products: emergency authorisations

In relation to plant protection products for human use, emergency authorisations can be granted on the basis of Art. 53 Reg. 1107/2009.

With regard to the preceding Regulation in Art. 8(4) Dir. 91/414, the CJEU has decided that such an emergency MA cannot be relied upon for the grant of SPCs.[488] According to the CJEU, unlike provisional MAs, an emergency MA is not granted subject to an assessment of the compliance of a plant protection product with the basic granting requirements as set out in Art. 4 Dir. 91/414. The CJEU expressly held:[489]

> "It is apparent from the very definition of the emergency MA laid down in Article 8(4) of Directive 91/414 that it concerns 'plant protection products not complying with Article 4'. That type of MA is therefore not intended to ensure that plant protection products thus authorised meet the same scientific requirements as to reliability as those granted an MA on the basis of Article 4 of Directive 91/414. Thus, Article 8(4) of that directive does not require the Member States to carry out scientific risk evaluations prior to issuing such an MA. That derogating provision does, however, strictly limit the use of that type of MA, stating that it applies only to 'special circumstances', and the issue of an emergency MA for a period not exceeding 120 days must appear 'necessary because of an unforeseeable danger which cannot be contained by other means".

(ii) Conditional MAs

Regarding conditional MAs[490] granted for medicinal products for human use, no case law of the CJEU is available at the moment. The MA relied upon for the grant of an SPC in the CJEU's *Seattle Genetics* decision was a conditional MA.[491] However, the CJEU has not dealt with the question whether a conditional MA can be used as a basis for the grant of SPCs.

At the national level, the NPOs accept conditional MAs as an MA within the meaning of Art. 2 Reg. 469/2009. So for instance, the Netherlands Patent Office has granted Molmed a certificate for the product Holoclar (trade name) on the basis of a conditional MA, and so did the Irish[492], German[493], Swedish[494] and French[495] NPOs for the product panitumumab (INN).

This practice deserves support. Conditional MAs constitute a specific form of MA granted under Reg. 726/2004 within the framework of the centralised procedure which gives the right to place the medicinal product on the market. Therefore can be taken into account as MAs within the meaning of Art. 2 and Art. 3(b) of the SPC Regulation.[496]

In addition, a conditional approval seems also to satisfy the criteria elaborated by the CJEU in the decision in *Hogan Lovells/Bayer CropScience*. In that judgement,

488 Case C-210/12 *Sumitomo Chemical* [2013] EU:C:2013:665, para. 36.
489 *Ibid*.
490 See above Chapter 4, Section 4.2.2.2.
491 Case C-471/14 *Seattle Genetics* [2015] EU:C:2015:659.
492 See SPC No. 2008/005.
493 See DE file number 12 2008 000 009.2.
494 See Application Number 0890006-0.
495 See Application FR08C0006.
496 This view is also taken in the CIPA, *CIPA Guide to the Patents Act* (8th edn, Sweet & Maxwell 2016) p. 1283.

concerning provisional MA for plant protection products, the CJEU argued that there is a link of functional equivalence between the prerequisites to be fulfilled for the grant respectively of a standard MA under Art. 4 Dir. 91/414 on the one hand and of a provisional MA under Art. 8(1) Dir. 91/414 on the other hand. This link of functional equivalence can also be confirmed in relation to Art. 14(7) Reg. 726/2004, Art. 4 Reg. 507/2006. Art. 4 Reg. 507/2006 provides that for a conditional MA there must be a positive risk-benefit balance for the respective medicinal product, i.e. similar to the standard MA granting procedure. The EMA as the competent authority for scientific assessment in centralised procedures has to balance positive therapeutic effects of the medicinal product in relation to all risks affecting the quality, safety or efficacy of the medicinal product as regards patients' health or public health. As can be seen *ex contrario* ex Art. 4(1), second sentence, Reg. 507/2006, the applicant further still needs to provide results of pharmaceutical tests as well as pre-clinical tests. On the basis of that information, the EMA is required to conduct a proportionality test taking into account potential risks and therapeutic benefits.

(iii) MAs granted under exceptional circumstances for medicinal products

In relation to medicinal products for human use as well as veterinary medicinal products, MAs may be granted under exceptional circumstances.[497] As the legislature has pointed out in Recital 6 Reg. 507/2006, MAs granted in exceptional circumstances in accordance with Art. 14(8) of Reg. 726/2004 are distinct from conditional MAs insofar as it "will normally never be possible to assemble a full dossier in respect of a marketing authorisation granted in exceptional circumstances." However, the grant of MAs in exceptional circumstances still requires a valid risk assessment and risk management.[498] While there is no case law of the CJEU for medicinal products for human use in this regard, the EFTA Court has decided with regard to veterinary medicinal products that MAs granted under exceptional circumstances also constitute a valid basis for the grant of SPCs.[499] We share this opinion and, in view of the similarity of the legal provisions for the grant of MAs in exceptional circumstances for veterinary medicinal products[500] and medicinal products for human use,[501] see no reason not to apply this ruling to the latter. However, it would be advisable from a policy-making perspective to consider clarifying this question expressly.

(d) *Variations and extensions*

As mentioned in Chapter 4, Section 4.2.2.5, there is a major difference between variations of types IA and IB on the one side, type II-variations or extensions on the other side: while for the former a mere notification suffices and approval by the competent granting authority may be assumed if within a certain time period no negative opinion is received, type II variations require the completion of a prior approval procedure. In addition, extensions require the conduct of a full approval

497 See above Chapter 4, Section 4.2.2.3.
498 See e.g. the scenario described by the CVMP in its Guideline on Requirements for an Authorisation under Exceptional Circumstances for Vaccines for emergency use against Bluetongue, 17 November 2008, EMEA/CVMP/IWP/220193/2008, pp. 5-7.
499 EFTA Court, Case E-16/14 *Pharmaq AS v Intervet International*, Decision of 9 April 2015, BV [2015] EFTA Ct. Rep. 212, para. 65.
500 Art. 26(3) Dir. 2001/82/EC.
501 Art. 22 Dir. 2001/83/EC; Art. 14(8) Reg. 726/2004.

procedure, while certain documents of previous approval proceedings may be referred to.

Whether variations and extensions can be relied upon for the grant of SPCs is unclear. The wording of the SPC Regulations refer only to the grant of an MA, and not to variations or extension of pre-existing MAs. This is consistent with the principle laid down in Art. 3(d) to admit the grant of a certificate only on the basis of the first MA granted for an active ingredient. Indeed, if only the first chronological given MA for an active ingredient may support the grant of the certificate, variations and extensions of older MAs can never be considered as relevant under Art. 3(d) because they can cover only the addition of new indications or the replacement of a salt with another salt, but never the substitution of an active ingredient covered by the original term of the MA with a new active ingredient authorised for the first time. Further, variations and extensions can also not be used in order to transform an MA granted for a monotherapy product in an MA covering a fixed combination product.

However, in *Neurim*, as we will see in Chapter 11, Section 11.3.1 of this Study, the CJEU has introduced the principle that an MA is relevant for a specific application for a certificate under Art. 3(d) only when it falls under the scope of the basic patent designated for the procedure for granting the certificate. Such decision allows according to the practice of most NPOs to grant a certificate for new indications of old active ingredients. The CJEU in *Neurim* did not take a position on the question whether a variation of an existing MA can support the application for a certificate. This issue was not relevant for the factual scenario discussed in the referall proceedings.

From a legal point of view, we believe that type IA and IB variations will not qualify as MA for the purposes of SPC legislation, since no prior approval procedure take place and since they do not cover changes or amendment that could matter for granting an SPC. By contrast, type II-variations and extensions may be qualified as an MA that triggers autonomous deadline for filing an application for a certificate under Art. 7 Reg. 469/2009 and may be submitted in support of the application for a certificate. In both cases, indeed, the modification of the terms of the MA is subject to a prior approval procedure. The situation is similar to the grant of a new MA. Further, at least type II-variations and extensions[502] may cover modification to the terms of the authorisation that are relevant under *Neurim*. Finally, from a policy perspective, what the SPC Regulations requires is a permission to place the product on the market granted in accordance with Dir. 2001/83 and Dir. 2001/82. We do not see any reason why a distinction shall be drawn between the situation where such permission has the form of a new and independent MA and the situation where the permission results from an amendment to an existing MA.

This opinion is supported by a decision of the Higher Regional Court of Vienna, that admitted the filing of an application for a certificate on the basis of II-type variation of an older MA. Such variation extended the scope of the MA to an indication covered by the basic patent and was the first permission covering such indication and falling under the scope of the basic patent. The Court considers therefore the date of the notification of the decision to admit the variation as the critical date under Art. 7 Reg. 469/2009 and the implemented variation as an MA for the purposes of Art. 3 Reg.

[502] Also extension of an MA can become relevant for granting a certificate under *Neurim*. Indeed, if the new indication from a clinical perspective requires a new pharmaceutical form, strength or route of administration, such change will require an extension of the MA.

469/2009. Such conclusion is also supported by the information collected from the NPOs. The majority of NPOs in reply to Q37 of the MPI Questionnaire for the NPOs seem to accept the possibility of granting SPCs where a type II-variation has been submitted as first MA within the meaning of Art. 3 (d) Reg. 469/2009 for a new medical indication. The majority of NPOs took the view, by contrast, that type IA and IB variations could not be referred to as a basis for the granting of a certificate. However, whether or not a II-type variations shall matter for the purposes of the SPCs depends on whether or not the principles stated in *Neurim* shall apply also to situations where a first MA has been issued for a use of the active ingredient as medicinal product for human treatment, and the variation concerns a new indication. The dictum in *Neurim* concerns only the case where the first MA was for a veterinary product and the second for a medicinal product for human use including the same active ingredient. It is clear that in this case a new stand alone application for an MA must be filed under Dir. 2001/83.

Beyond the context of *Neurim*-style applications for a certificate, it is questionable whether the issue whether a variation shall be treated as a new and independent MA can become relevant. This also applies to situations where a first MA is granted for a monotherapy product, and the patentee intends to bring to the market a combination including such product. In this case, a new MA granted under Art. 10(b) Dir. 2001/83 is necessary for bringing a fixed combination product including the active ingredient already authorised. However, if the CJEU shall decide in *Abraxis* that *Neurim* applies also to the situation where a new patented formulation is authorised for the first time, then the cases where a variation of an MA could be relevant for the purposes of Art. 3(b) Reg. 469/2009 would become more frequent.

For sake of completeness, we reproduce in the following table the answers of the NPOs to the questions whether and if, to what extent variations and extension of pre-existing MAs may support the application for a certificate.

NPO	Q35 (extension of a marketing authorisation)[503]	Q36 (II-type variations under Reg. 1234/2008/EC)[504]	Q37 (type II variations and *Neurim*)[505]
Austria	Yes. See answer to Question 34[506]		
Croatia	No, in view of Croatian NPO such an extension should not be a new MA for the purposes of Art. 3(b) Reg. 469/2009/EC. Croatian NPO thinks that in case indicated in Rec.l 14, Reg. 1610/96/EC (q11 of this questionnaire) would be justified to consider it as a new MA	Croatian NPO thinks that variation related to the addition of a new therapeutic indication may constitute a new MA for the purposes of Art. 3(b) and (d) Reg. 469/2009	In Croatian NPOs opinion, a type II MA variation is sufficient to meet the requirements for a "different application of the same product" as set out in the answer to Q1 and 3 in the decision by the CJEU in *Neurim*
Czech Republic	Only new indication seems to constitute "new MA for granting SPC" according to CJEU´s decision C-130/11	The proper variation could be considered as relevant with respect to CJEU´s decision C-130/11. Changes to introduce a new therapeutic use are processed as Major Variations (Type II)	Yes
Denmark	The DKPTO has taken the decision in *Neurim* into account when examining SPC applications for second-medical use. It is possible to obtain a second medical use certificate whether one goes from a veterinary product to a human product (or vice versa) or from a human product to another human product. Furthermore, it is possible to obtain a second medical use certificate based on an updated marketing authorisation if the update contains a new therapeutic application. In this case it is the date of variation which is the date of the marketing authorization. The first marketing authorisation in the Community is the marketing authorisation mentioning the therapeutic application which the SPC is applied for. However, all applications are examined case-by-case on the basis of the following criteria:		

503 Q35 MPI Questionnaire for the NPOs, Annex VI to this Study, reads as follows: Certain changes to an MA, however, are so relevant that it is not possible to follow the variation procedure. These changes, listed in Annex I to Reg. 1234/2008/EC, must be introduced through an extension of the MA application. In your view should such an extension be a new MA for the purposes of Art. 3(b) Reg. 469/2009/EC? If your answer is no, when do you think that it would be justified to consider it a new MA for the purposes of Art. 3(b) and (d) Reg. 469/2009/EC?

504 Q36 MPI Questionnaire for the NPOs, Annex VI to this Study, reads as follows: Reg. 1234/2008/EC refers to three types of variation which have different implications depending "on the impact of the change on the quality, safety or efficacy of the medicinal product". This includes type II variations, that is major variations that do not constitute "an extension and which may have a significant impact upon the quality, safety or efficacy of the medicinal product concerned" (Art. 1(3) Reg. 1234/2008/EC). Does any application for a type II variation constitute a new MA for the purposes of Art. 3(b) and (d) Reg. 469/2009?

505 Q37 MPI Questionnaire for the NPOs, Annex VI to this Study, reads as follows: Is a type II MA variation sufficient to meet the requirements for a "different application of the same product" as set out in the answer to Questions 1 and 3 in the decision by the CJEU in *Neurim* (see especially paras. 25-27)?

506 Answer to Q34 MPI Questionnaire for the NPOs, Annex VI to this Study: "According to the Austrian jurisdiction Type II variations (new therapeutic indications) were considered as a new MA (Higher Regional Court Vienna/ Oberlandesgericht Wien, 34 R 104/15m). But some SPC applications are still pending concerning the question which variations of an MA shall be considered a new MA".

	1. Scope of the basic patent 2. The marketing authorization 3. New therapeutic indication		
Finland	Yes	Finish NPO has not yet resolved this issue	
France	No by a matter of principle. The office will duly examine if this MA is extended to a new product, or an authorization of the same product for a new medical use	Not by a matter of principle. It may constitute a new MA, under certain circumstances, in particular if this variation consists in adding a new medical use	Not by a matter of principle. The office shall duly examine whether the "different application", i.e. a new medical use, this notion being strictly appreciated
Germany	Extensions are not regarded as a new MA for the purposes of Art. 3(b) and (d) Reg. 469/2009/EC Currently no circumstances can be imagined which would justify considering an extension as a new MA	See answer to Q34[507]	
Greece	Yes	---	---
Hungary	In most cases an extension needs to be considered a new MA, however, it depends on the nature of the extension. For example, if the change only concerns the substitution of a salt or an ester of the active ingredient, then it falls within the scope of protection of the original SPC and it need not be considered a new MA	Yes. See our answer to Q34. Answer to Q34: In most cases a variation need not be considered a new MA, however, it depends on the nature of the variation. For example, in the case of "the addition of a new therapeutic indication or the modification of an existing one" within the meaning of Reg. 1234/2008/EC the variation needs to be considered a new MA	Only in the case of a different indication
Ireland	[MA extensions include inter alia "Different salts/esters etc where safety/efficacy not significantly different" "Changes to strength, pharmaceutical form and route of administration"	Possibly consider a new Type II variation for a new indication as the basis for a *Neurim*-type indications	

[507] Answer to Q34: "In view of CJEU C-130/11 *Neurim* only a new therapeutic indication in a type II variation may be considered as a new MA for the purposes of Art. 3(b) and (d) Reg. 469/2009/EC if the new marketing authorisation required a full application in accordance with Article 8(3) of Directive 2001/83/EC".

	etc.] Substituting one salt for another, for example, where safety/efficacy is not significantly different should not lead to a new SPC, unless that new salt is the subject of a patent in its own right. We would have to evaluate on a case by case basis		
Italy	Yes, such an extension should be a new MA for the purpose of Art. 3 (b) Reg. 469/2009	It depends on the kind of variation	Yes, it is but only for the variation related to the addition of a new therapeutic indication
Latvia	We have not faced such extensions of MAs. We are familiar only with variations of MAs. We cannot answer this question definitely without deep knowledge of granting procedure of MAs and their different forms. However, the general thinking would be the same as for variation MAs	As we answered before we would ask/search what these variations are. If it is new therapeutic indication, we would accept it as a new MA	This is not yet a sufficiently clear situation. In the *Neurim* case "different application of the same product" was a new therapeutic indication and new target patient group (animals/people). This was a rather extreme case from which different conclusions could be reached. Because under patent law practiced by the EPO "different application" may be a new invention eligible for another patent and may mean a lot of things, like different formulation of a medicine, different dosage, different value range, etc. For the purposes of SPCs currently we accept a new therapeutic indication as a "different application". However, some cases are under appeal
Lithuania	No practice	Yes	Yes
Luxembourg	N.A.		
The Netherlands	The same answer as Q34. Answer to Q34: These are clearly political questions.		This is the subject of a pending court case in the Netherlands. In our view the teaching of *Neurim* is limited to the dictum of the CJEU, i.e. cases

	It is our view that the original proposal of the current SPC regulation is based on a strict interpretation of the concept of first marketing authorization.	where the first MA is for a veterinary product	
Poland	The MA should be considered as a new MA only for the patents, which protect new applications	Only variations which lead to the new application in accordance with the basic patent	It is difficult to say, because the phrase "different application of the same product" is unclear. We do not know what a "different application" exactly means. Does it mean new medicinal condition, new dosage form or something else?
Portugal	No	No	No
Romania	_____		
Serbia	Variations related to the addition of a new therapeutic indication or to the modification of an existing one could be considered a new MA as long as it relates to the subject matter of the basic patent. We would like to draw your attention to the fact that a new specific use of the known active substance is usually embodied through a new medicinal product with new trade name and, as far as we know, with a new MA (for example Eylea® and Zaltrap® with aflibercept as the active substance). The question that arises here is: how "far" should a "new" therapeutic indication be from the "old" one to be considered a "different application of the same product" according to the *Neurim* decision C-130/11 (for example, an active substance used for treatment of some kinds of cancers has been found useful in treatment of other types of cancer or the same type of cancer but at different stages … - in all the cases, a new patent will be granted …)? What investments are necessary for the related clinical research for an application for a variation of an MA? It seems that a use of the active substance in a "new" therapeutic indication can justifiably be considered a "different application of the same product" when the new therapeutic indication is "far enough" from the "old" therapeutic indication as much as it causes "significant" investment in specific clinical trials (there is a need to define "far enough" and "significant"). Did an MA require a full application in accordance with Article 8(3) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use?		
Slovak Republic	This is a complex question and should be the subject of further discussion on an expert level		
Spain	In line with our answer to question 34, such an extension cannot be considered a new MA for the purposes of Art. 3(b) Reg. 469/2009/EC. It would be very difficult for a Patent Office to	No, it does not. See answers to questions 34 and 35	No, in accordance with our practice, a type II MA variation is not sufficient to meet the requirements for a "different application of the same product"

	evaluate how relevant a variation or an extension of the MA is. The SPC system is a mere administrative procedure that should not be conditioned by a scientific or medical discussion Answer to Q34: In our view, the variation of an MA cannot be considered a new MA. The amount of investment is not an objective approach to decide whether a variation of an MA might be considered a valid MA in the sense of Art. 3(b) Reg. 469/2009/EC		
Sweden		No	Yes, it may be sufficient if it relates to addition or modification of the therapeutic indication
Switzerland	NO, only major variations involve new procedural effort. This is not the case for variations of purely administrative nature or related to - the deletion of any manufacturing site, or - to minor changes, or - to changes made to the specification, or - to packaging material, or - to the tightening of specification limits	Yes	Yes
United Kingdom	Yes - An extension application is still a variation and the points raised above in Q34 are relevant. In medicines legislation, the incentives are confined to new therapeutic indications and not the other changes (active substance, form etc.)	Only in some cases – see answer in relation to Q34 and Q35 above Under the Variation Regulation such type II variations include "variations related to the addition of a new therapeutic indication or to the modification of an existing one" (see	Yes – but only in so far as it identifies a new therapeutic indication. If it is a modification of an existing indication, it is not clear how the applicant will be able to show that this meets the requirement "for a different application of the same product" as

	that can be submitted as an 'extension' application. Please also see answer to Q34 above in relation to getting balance right in terms of rewards available to MA holder	example (a) in Annex II of this Regulation). As mentioned above, it is when the variation relates to a new therapeutic indication that it should qualify as an MA for the purposes of the grant of an SPC. Not all type II variations relate to new therapeutic indications – see Annex II of Reg 1234/2008, examples (b)-(k)	set down in CJEU decision in *Neurim* (C-130/11). However, it may take a little effort to work out if the variation to the MA is for a new therapeutic indication or is a modification to an existing one – this is a matter that the competent bodies for granting MAs usually deal with, it is only something that the national competent bodies that grant Patents and SPCs have had to consider and get to grips with since the judgment from the CJEU in *Neurim*. (see discussion (in English) of decision (34 R 104/15) from Higher Regional Court of Vienna, Austria)

Table 9.1: Variations of an MA and Art. 3(b) Reg. 469/2009

(e) *Marketing authorisation granted under Art. 10(1) and Art. 10(3) Dir. 2001/83*

The SPC legislation does not state that only an MA issued in accordance with Art. 8(3) Dir. 2001/83/EC may support the grant of a certificate. Such limitation or clarification was likely considered to be superfluous by the drafters: if only the first MA could be the basis for granting the certificate under Art. 3(d) and only one certificate could be granted for the active ingredient under Art. 3(c), it was clear that the only relevant MA under Art. 3(d) Reg. 469/2009 was an MA filed in accordance with Art. 8(3) Dir. 2001/83. This conclusion finds support in the Explanatory Memorandum.[508] In unrelated contest, the case law of the CJEU has maintained that only products that have been subject to an administrative authorisation procedure which included safety and efficacy testing could be the subject of an SPC.[509]

Now, the case law – and particularly *Neurim* – has made it possible to grant an SPC on the basis of a more recent MA for active ingredients that were already authorised in the past for medicinal use. As correctly pointed out by the literature, under *Neurim* a generic MA granted under Art. 10(1) Dir. 2001/83 or a hybrid MA granted under Art. 10(3) Dir. 2001/83/EC could become relevant for granting an SPC.[510] Under the

[508] European Commission, Explanatory Memorandum to the Proposal for a Council Regulation (EEC), of 11 April 1990, concerning the creation of a supplementary protection certificate for medicinal products (COM(90) 101 final – SYN255), para. 3.

[509] Case C-452/06 *Synthon* [2008] ECLI:EU:C:2008:565.

[510] Mike Snodin, Michael Pears, 'A brave new world for supplementary protection certificates?`[2012] Life Sciences Intellectual Property Review 26-28.

wording of Art. 3 and Art. 8 Reg. 469/2009 there is no reason to question the ability of a generic or abridged MA to support the application for a certificate. The latter complies with all requirements that we have inferred from Art. 2, Art. 3 and Art. 8 Reg. 469/2009 for the existence of an MA within the meaning of the SPC legislation. Indeed, the generic MA includes a summary of the product characteristics within the meaning of Art. 8(1)(iv)(b). It is granted in accordance with Dir. 2001/82 or Dir. 2001/83. Finally, it entitles the holder to place the medicinal product on the market.

(f) *Global MA and SPC*

According to Art. 6(1) Dir. 2001/83, as amended by Art. 1 Dir. 2004/27, "any additional strengths, pharmaceutical forms, administration routes or, presentations, as well as any variations or extensions of an MA concerning a specific active ingredient" shall also be granted an MA. For the purpose of calculating the data and marketing exclusivity periods, such MA shall be considered as belonging to the same global MA. This is true even if the MA is requested by another company, provided that the holder of the first MA and the holder of the second MA are related entities.

The concept of global MA does not affect the application of the SPC legislation, since such legal notion treats different MAs or variations as belonging to the same (global) MA only for the purpose of limiting the data exclusivity period. As a consequence, MAs belonging to the same global MA remain separate MAs for the purposes of the SPC legislation (Art. 3(b), Art. 7 and Art. 13). This also seems to be the tendence of the NPOs. This aspect is relevant particularly for *Neurim*-style application for a certificate.

9.3.3.2 Recommendations

A clarification of what MA is relevant for the purpose of Art. 7, Art. 3 and Art. 13 Regulations was likely considered not necessary by the lawmakers, since only the first MA matters under Art. 3(d) for granting a certificate and the legal regulatory framework at that time was relatively more simple. Therefore, it was clear that such an MA was a stand-alone MA granted for the active ingredient.

The case law as well as changes to the regulatory framework (for instance, the introduction of new types of MAs as the conditional MA, etc.) has made it less obvious to assess what a relevant MA is for a specific active ingredient and an application for a certificate. An type-II variation would not have been relevant for granting a certificate if the case law had followed a literal interpretation of Art. 3(d) denying any relevance to the scope of the basic patent for determining the first MA for a specific active ingredient. A variation concerning the use of a different salt would not be relevant either, if all derivatives of the same active ingredient were considered to be the same product for the purpose of Art. 3(c) and Art. 3(d). Against this background, a clarification of what types of MA or variations of MA shall be considered to fulfil the concept of MA under Art. 2 and Art. 3 Reg. 469/2009 and what types are not is useful and opportune. From a policy perspective, if the lawmakers agree with the principle stated in *Neurim*, we do not see any reason why the law should draw a distinction between the situation where an indication is authorised through the variation to an existing MA or through the grant of a new MA. In both cases the holder of the MA is entitled to place on the market the active ingredient concerned for the new indication.

In our view, all the MAs granted under the Dir. 2001/82 and Dir. 2001/83 are a valid basis for granting an SPC. However, the assumption of the drafters of the SPC legislation was that only MA issued in consequence of extensive clinical trials directed to test the safety and the efficacy of the active ingredients could justify SPC protection. Against this background, as also suggested by a speaker at the MPI Workshop on 20 March 2017, the lawmakers could specify the policy purposes of the SPC protection by defining what MA is required for granting a certificate.

One approach would be to admit the grant of a certificate only when in order to bring to market a medicinal product including the active ingredient for which the SPC is requested a stand-alone application is necessary. This approach was also one of the options referred to the CJEU in *Neurim*. It is clear that such reform would be meaningful only if the intended purpose of the SPC is to reward the investments made for obtaining the MA. The addressed question is of a policy nature, and is interrelated with further policy questions, such as whether the intended beneficiary of the SPC is any patentee or only the patentee that made investments to bring a product implementing the patented invention to market (and obtaining the fullstand alone MA necessary for this purpose), and whether the SPC protection shall cover any patented medicine or only active ingredients that are authorised for the first time for medicinal use. Therefore, the MPI has no recommendation.

9.3.4 Summary

- The applicable regulatory law provides for different types of MAs. Further it provides for the option to modify an existing MA. Against this background, a definition of what types of MA can and shall be the basis of an SPC is appropriate.
- The drafters of relevant legislation have likely omitted such a definition because only the first MA was intended to be the basis for granting an SPC (Art. 3(d) Reg. 1768/92), and only one SPC per product could be granted (Art. 3(c) 1768/92). As a consequence, only those MAs based on a full dossier were the basis for granting an SPC. These principles have been relativised by the case law (Chapter 11, Section 11.3.1). The definition of what types of MA to use as the basis for granting an SPC can contribute to defining the purposes of the SPC Regulations. If the purpose is to compensate the patent holder for having invested directly or indirectly in the research and clinical trials that are necessary for bringing a new active substance to market for the first time, then the category of MA that may support the application should be limited to a full dossier or stand-alone MA.

9.4 THE CONCEPT OF "BASIC PATENT"

9.4.1 Introduction

The SPC Regulations contain a definition of the term "basic patent". Pursuant to Art. 1(c) Reg. 469/2009, basic patent "means a patent which protects a product as such, a process to obtain a product or an application of a product, and which is designated by its holder for the purpose of the procedure for grant of a certificate". From this provision one can infer that even if a patent does not claim an active ingredient as

such, but only one use of it or one method for manufacturing it, then such patent may still protect the product within the meaning of Art. 3(a) Reg. 469/2009.

Article 1(c) Reg. 469/2009 does not include further clarification with respect to the concept of a basic patent. However, according to Recital 8 Reg. 469/2009 "the provision of a supplementary protection certificate granted, under the same conditions, by each of the Member States at the request of the holder of a national or European patent relating to a medicinal product for which marketing authorisation has been granted is necessary". Further, pursuant to the Explanatory Memorandum to the Proposal for a Medicinal Products Regulation, the SPC Regulation may not disturb the functioning of the European patent system. This would be the case if it were possible to obtain a certificate only for a product protected by a national patent. Indeed, this would create an incentive for national filings to the detriment of European filings.[511] The notion of basic patent pursuant to Art. 1(c) Reg. 469/2009 includes therefore both national and European patents.

The concept of European patent is not defined by Recital 8 Reg. 469/2009. Consistent with Art. 2(1) EPC, the term applies to all patents granted by the EPO pursuant to the procedure laid down in the EPC. However, even if the drafters intended both Regulations to apply to European, Community and national patents, some of the provisions are not properly coordinated with the European patent system alongside a national patent system.

Article 19(1) Reg. 469/2009 provides, indeed:

> In the absence of procedural provisions in this Regulation, the procedural provisions applicable under national law to the corresponding basic patent shall apply to the certificate, unless the national law lays down special procedural provisions for certificates.

Such reference must include both the law applicable to the pending patent application and to the granted patents; otherwise some lacuna would result for the process and the examination of the application for a certificate. It is obvious that the reference of Art. 19(1) Reg. 469/2009 is clear only with respect to national patents, but not with respect to European patents and European patent applications, which are also subject to the EPC provisions. The same holds true for Art. 16(2) Reg. 469/2009, which reads:

> Any person may submit an application for revocation of the extension of the duration to the body responsible under national law for the revocation of the corresponding basic patent.

Under Arts. 100-101 and Art. 105a EPC the body competent for the "revocation" of a European patent is also the EPO. Reference to national law of the EU States can include also the EPC, because the latter after ratification become part of the legal order of the Contracting States.

9.4.2 European patent with unitary effect

Unitary Patents are European patents within the meaning of Art. 2(1) EPC and therefore may be designated for the purposes of granting an SPC before the NPOs.

[511] See European Commission, Explanatory Memorandum to the Proposal for a Council Regulation (EEC), of 11 April 1990, concerning the creation of a supplementary protection certificate for medicinal products (COM(90) 101 final – SYN255), para. 20.

Article 16 and Art. 19 Reg. 469/2009 however need some amendments in order to take into account the existence of the UPCA and the Rules of Procedure enacted on the basis of Art. 44 UPCA.

9.4.3 Utility models and SPCs

In some jurisdictions, such as Germany, utility models may be granted for chemical and pharmaceutical inventions.[512] *De lege lata* and *de lege ferenda* one could ask whether a utility model should qualify as a basic patent within the meaning of Art. 3 Reg. 469/2009.

De lege lata, the answer to this question is no. The concept of a patent is defined within SPC Regulations and must therefore be interpreted autonomously. The recitals of both Regulations do not mention utility models. The *travaux préparatoires* make clear that the legislators only had ordinary patents in mind. Further, an interpretation that considers a utility model to be a patent within the meaning of Art. 3 Reg. 469/2009 would face systematic and teleological concerns. The assumption of the Regulation is that a patent term is not sufficient to cover the investments necessary for bringing a new pharmaceutical product to the market. For this reason, a period of supplementary protection is provided. If, for whatever reason, the patentee has decided to file for a utility model and to give up the longer protection provided by patents, it would be contradictory to let it benefit from a longer protection under the SPC Regulation.[513]

9.4.4 Summary and recommendation

The MPI suggests defining the category of patents that are eligible for SPCs and coordinating the provisions of the SPC Regulations with the European and unitary patent system. Accordingly, Art. 16 and Art. 18 Reg. 469/2009 should be re-drafted. The wording of the provisions must take into account the existence of the EPO as granting authority and of the unified patent system.

[512] See BGH, *Arzneimittelgebrauchsmuster,* X ZB 7/03 [2006] GRUR 135.

[513] Presuming the requirements for protection provided under utility model law were different from the requirements for protection provided under patent law, such an interpretation would allow the holder of a utility model to obtain a longer protection than the ordinary ten-year term provided in the majority of national legal orders for subject-matter that is obvious or not eligible for a patent within the meaning of patent law. This result would likely interfere with the policy decisions of national lawmakers, which the Regulations did not intend to do.

10 CONDITIONS FOR GRANTING AN SPC: ART. 3(A) REG. 469/2009

10.1 INTRODUCTION

Article 3 Reg. 469/2009[514] fulfils the same function within the SPC system that Arts. 54–57 EPC fulfil within the patent system. This article defines the requirements for protection that subject matter eligible for an SPC must satisfy in order to be *in concreto* protectable by an SPC.

There are four cumulative requirements:

a) The product is protected by a basic patent which is in force;
b) A valid authorisation to place the product on the market as a medicinal product has been granted;
c) The product has not already been the subject of an SPC;
d) The authorisation referred to in b) is the first authorisation to place the product on the market as a medicinal product.

Article 3 Reg. 469/2009 is one of the most referred-to provisions of the EU IP legislation. At the moment, there are four referrals pending before the CJEU.[515] Three of them[516] concern the first requirement – Art. 3(a) Reg. 469/2009 – on which this Chapter focuses.

10.2 PROTECTED BY A BASIC PATENT IN FORCE

10.2.1 Premise

The first requirement provided under Art. 3(a) Reg. 469/2009 is that the product is protected by a basic patent in force. While emphasising the ancillary nature of the SPC, the provision actually frames two different sub-requirements by using the term "patent in force": first, the product must be protected by the basic patent; second, such a patent must still be in force at the filing date of the SPC application. We start with the latter requirement.

10.2.2 The requirement of the patent being in force

The requirement of a "basic patent in force" has given cause for interpretative controversy concerning situations in which either the MA or the patent is granted after the patent's expiration date. Both possibilities were addressed at the Second meeting

[514] What is said in this Chapter with respect to Art. 3 Reg. 469/2009 is also valid, *mutatis mutandis*, for Art. 3 Reg. 1610/96. Specific issues surrounding Reg. 1610/96 are addressed in Chapter 19 of this Study.

[515] See references for a preliminary ruling from the High Court of Justice (Chancery Division) (United Kingdom) made on 8 March 2017 Case C-121/17 *Teva UK and Others* (Pending Case); C-443/17 *Abraxis Bioscience* (Pending Case); Request for a preliminary ruling from the German Federal Patent Court of 17 October 2017 BPatG, *Sitagliptin*, 14 W (pat) 12/17 [2017] GRUR Int. 1048; Request for a preliminary ruling of the German Federal Patent Court of 18 July 2017 (C-527/17).

[516] C-121/17 *Teva UK and Others* (Pending Case); C-443/17 *Abraxis Bioscience* (Pending Case); and the referral of the German Federal Patent Court BPatG, *Sitagliptin*, 14 W (pat) 12/17 [2017] GRUR Int. 1048.

of national "Supplementary Protection Certificate" (SPC) experts held on 9 October 2006 in Brussels.[517] We will examine the two situations separately.

10.2.2.1 A patent has expired or will expire before the MA is granted

(a) *The problem*

In order to receive SPC protection, a patent must be in force and an authorisation must be valid in the country in which the application for an SPC is filed. These two requirements must both be met at least at the time the patent holder files the SPC application. It may happen that the patent is about to expire before the MA is issued. Such a situation may trigger two reactions[518] of the patent holders:

- they could file an SPC application while the patent is still in force, but the MA still has to be granted, or
- they could file an SPC application soon after the MA is granted, although the patent has already expired.

In the first case, the SPC application would not meet the requirement of Art. 3(b) Reg. 469/2009. This is because, at the filing date, a valid MA had not yet been issued. In the second scenario, the application would not be consistent with Art. 3(a) Reg. 469/2009. This is because, at the filing date, the product was not protected by a patent in force.[519] The patent had in fact expired.[520]

In both cases, there are no procedural remedies for the patent holder. Indeed, if the patent holder files an SPC application after the MA is granted and the basic patent has expired, it cannot successfully invoke the *restitutio in integrum* provided under domestic law. Art. 3(a) Reg. 469/2009 lays down a substantive requirement and not a time limit.[521]

Conversely, if the patent holder files the SPC application while the patent is still in force, but the MA has not yet been issued, it cannot then invoke Art. 10(3) Reg. 469/2009 in order to rectify the lack of an MA at the date of SPC filing. This provision only allows for correcting formal deficiencies. For instance, if the MA was granted while the patent was in force and before the SPC application was filed, but the patent holder omitted for whatever reason to include a copy of the MA in the SPC application, such irregularity can be rectified under Art. 10(3) Reg. 469/2009.

The requirement that the patent must be in force at the SPC filing date exists in the majority of non-European jurisdictions that contemplate patent extensions. Some of them, however, provide the applicant with some procedural relief if obtaining the MA takes more time than the term of the patent. In the USA[522] the applicant can file a

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517 See Records of the Second meeting of national "Supplementary Protection Certificate" (SPC) experts held on 9 October 2006 in Brussels, p. 6.

518 See also Andrew Hutchinson et al, 'The Return of SPC Referrals' [2017] Simmons & Simmons LLP, p. 2, available at http://www.elexica.com/-/media/files/articles/2017/intellectual%20property/elexica%20article%20the%20return%20of%20spc%20referrals.pdf (last accessed 7 September 2017).

519 Marco Stief, Dirk Bühler (eds), *Supplementary Protection Certificates* (C.H. Beck, Hart, Nomos 2016) p. 14.

520 This was also the conclusion of all the patent offices that took part in the MPI Questionnaire for the NPOs, Annex VI of this Study.

521 See BPatG, *Abamectin,* 15 W (pat) 71/97 [2000] GRUR 398.

522 John Thomas, *the USA* in Annex II of this Study, Chapter 8, Section 8.5.2.1.

request for an *interim* extension if the patent is about to expire. In Europe, this remedy does not exist. The MPI has therefore posed the question whether this represents a lacuna, and if so, whether there is some practical need for creating similar procedural relief in the SPC legislation.[523]

In national case law, the German Federal Patent Court already took a position on this question in 1999. In the *Abamectin* case,[524] the court expressly suggested amending the Regulations to create the possibility of an interim request along the lines of US law. According to the German court, it was not justified to deny the grant of an SPC merely because the MA was granted after the expiration of the patent. Further, the court observed that these cases may not be exceptional. It quoted the study of *Suchy*, published in 1992, according to which in 23 out of 252 cases the MA procedures ended after the expiry of the relevant patent.[525] The German Federal Patent Court was also of the opinion that denying the option to obtain an SPC in these cases was in conflict with the purposes of the Regulations. On the one hand, SPCs were introduced because the MA procedures reduced, in an unacceptable manner, the effective protection term provided by a patent; on the other hand, the SPC was unavailable in the cases where the MA procedure was so long that the patent expired before the grant of the MA. However, the court came to the conclusion that such apparent contradiction within the Regulations could not be corrected by the courts by applying the provisions concerning *restitutio in integrum*. It is the task of the EU legislature to intervene to fill the lacuna.

(b) *The CJEU case law*

As mentioned before, the risk that the MA is granted after the expiration date of the patent can lead to two reactions of the patentee and two factual scenarios. The first scenario is based on the German judgment in the case *Abamectin*,[526] and exists when the patentee files the SPC application after the MA has been granted and asks for a *restitutio in integrum*. The second factual scenario exists when the patentee files the SPC application before the expiration date of the patent and submits the MA later. The CJEU still has to deal with the first factual scenario. The second one, by contrast, is at the basis of the Referral C-567/16.[527] In that case the applicant has tried to argue that an End of Procedure Notice issued by the reference Member State under Art. 28(4) of Dir. 2001/83 was equivalent to the granted MA for the purposes of Art. 3(b). The End of Procedure Notice was issued before the expiration date of the patent. In that factual scenario the existence of procedural relief, such as that discussed in this section, would have made the question whether or not an End of Notice Procedure Notice is equivalent to an MA irrelevant.

(c) *The options*

Should the European Commission consider appropriate legislative action in this regard, two options are available.

The first option is to grant the applicant the right to file a request for an SPC before the expiration of the patent with the obligation to submit the MA in the course of the

523 See MPI Questionnaire for the NPOs, Q27, Q28, Annex VI of this Study and Allensbach Survey, Annex III of this Study, Q56, Q57.
524 See BPatG, *Abamectin,* 15 W (pat) 71/97 [2000] GRUR 398.
525 See Herbert Suchy, `Patentrestlaufzeit neuer pharmazeutischer Wirkstoffe´ [1992] GRUR 7, 8-11.
526 See BPatG, *Abamectin,* 15 W (pat) 71/97 [2000] GRUR 398.
527 See *Merck Sharp & Dohme v Comptroller-General of Patents* [2016] EWHC 1896.

procedure.[528] In this case the legislature should adopt some precautions in order to reduce the uncertainty for third parties. We would advise at least the following measures:

- The application should be filed before the expiration date of the patent and published immediately, so that the third parties are put on notice that certificate could be granted despite the forthcoming expiration of the patent.
- If the condition for the application are met, the patentee shall be granted a non-extendable period of time (six months) within which it should submit the MA.
- The non-extendable period of time should be calculated from the expiry of the basic patent.

The second option for the EU legislature is to provide the applicant with the right to request *restitutio in integrum* after obtaining the MA. Such option would, in analogy to Art. 122 EPC, require some safeguards for third parties.[529] The legal framework would become more complex.

In Table 10.1 below we sum up the two possible models to address the issue in this section:

	Interim request model	Re-establishment of right model
Deadline for filing the request	Request must be filed before the patent expires	Request must be filed after the MA has been granted
Publication of the request	Yes	Yes
Rights granted	No rights granted for the period after the expiration of the patent and before the filing of the MA or the grant of the SPC	No rights granted before the grant of the SPC
Third party	No prior user right	Prior user rights for third parties that in good faith start to exploit the subject matter of the SPC after the expiration of the patent

Table 10.1: Interim request model and re-establishment of right model

In both models, the duration of the SPC starts from the expiration date of the patent.

(d) *Opinions of the NPOs and stakeholders*

Both the MPI Questionnaire for the NPOs and the Allensbach Survey included questions concerning the opportunity of creating procedural relief for the patentee in cases where the MA has yet to be granted at the expiration date of the patent.

[528] See also for a similar proposal concerning the introduction of an interim application Marco Stief, Dirk Bühler, *Das ergänzende Schutzzertifikat* in Maximilian Haedicke, Henrik Timmann, HANDBUCH DES PATENTRECHTS (C.H. BECK 2012) § 14, marginal note 53 et seqq.

[529] Such as for instance prior user rights.

The reactions of the NPOs were ambivalent. Most NPOs consider this case to be exceptional and very rare.[530] For this reason, they would consider legislative action to be inopportune. Such reform would in their view create legal uncertainty for third parties; the benefit for SPC applicants would likely be negligible.

Other NPOs, by contrast, would consider such a procedural tool useful, considering that the patentee lacks full control over the time necessary for completing the clinical trials and receiving the MA. Still other NPOs are of the opinion that only the users of the system should address the question of whether or not a practical need for such a reform exists.

As for the Allensbach Survey, a majority of all participants (54 per cent) do not perceive a practical need for amending the SPC Regulations in this regard (Q56). Only 29 per cent of the representatives of potential beneficiaries of a possible amendment – the originator companies – are of the opinion that a need for such procedural relief exists.

Several stakeholders are of the opinion that amendment would create legal uncertainty, and that 20 years should be sufficient to obtain an MA. Further, the following comments were made:

> "It would not appear necessary to question the judgement of the original legislators in setting patent expiry as a "hard" deadline for SPC filing. This is not least because in those situations where an SPC application is filed very close to patent expiry, it is likely that other, "regulatory" exclusivities (e.g. data protection of up to 10 years from MA issuance) will both: (a) serve as an absolute barrier to generic market entry; and (b) outlast any SPC protection that might be granted."
>
> "That would mean the approval was given twenty years after the substance was first identified to have a medical use. Currently there is no need for this due to the evergreening patents that are filed. This could be discussed as a feasible option, if the basic patent would be defined to be substance patent only, and given that the Interim Extension would be publicly viewable."
>
> "There should be clarity for third parties, the interim extension should be published. However,
>
> considering that SPC last for 5 years and the data exclusivity periods are 8 years it is not clear which will be the benefit of granting SPCs in such situations. In the event that the MA would be for a new indication for an old product, the SPC should be clearly limited to the indication covered by such new MA and should not affect the products already on the market."
>
> "But there should be exceptional circumstances that have determined a very long period of trials and the MA applicant should prove this."
>
> "This situation becomes only relevant when the development of a new medicinal or plant protection product takes a very long time or is started very late during the regular patent term, which is a rare situation; 3rd parties need certainty regarding the length of protection to be expected; balancing the very rare situations with the uncertainty that could be expected, we come to the conclusion that an interim extension, although useful in a few special situations, would not justify the disadvantages to introduce the uncertainty of predictability of protection term (this uncertainty could be limited by providing a minimum term, e.g. 6 months before regular patent expiry when at latest such an interim extension can be validly filed)."
>
> "Wasn't aware of US provision. EU Reg is already favourable compared to US and does not require diligence in getting product into development in timely manner. You have to draw a line somewhere."[531]

The argument that when it has taken more than 20 years to obtain an MA, data protection will be longer than the SPC is well thought out and can be found also in the literature.[532] It is also convincing as regards cases when the patentee or its licensee is

[530] MPI Questionnaire for the NPOs, Q26.
[531] Annex III of this Study, comments to Q56, pp. 370-371.
[532] See for example Robert Wenzel, *Analoge Anwendung der Verordnung über das ergänzende Schutzzertifikat für Arzneimittel auf Medizinprodukte?* (Nomos 2017) p. 133.

the holder of the MA and the product may benefit from a regulatory exclusivity. However, following *Biogen* it is possible to obtain an SPC based on the MA of an unrelated entity even if the latter disagrees. Following *Neurim*, it became possible to obtain an SPC for old active ingredients. In such factual scenarios data exclusivity is limited or not available. Therefore, in these situations, the argument that the patentee can already benefit from data exclusivity is less convincing.

(e) *Recommendation*

The MPI cannot answer the question *whether* there is a practical need for amending the SPC Regulations in order to address the factual scenario where the patent is about to expire but the MA has yet to be granted. No conclusive evidence can be collected on the basis of interviews or questionnaires. The MPI can provide a recommendation on *how* to implement such a procedural tool in the case that the European Commission considers an amendment of the legislation appropriate. The preferable solution in this respect is the option of admitting *interim* requests in line with US law. Such a model would ensure sufficient legal certainty for third parties. The latter would receive notice of the existence of a pending SPC application before the expiration of the patent. The situation would not be different from an SPC application in which the applicant includes a copy of an MA already granted. In both cases the third parties are informed of the chance that after the expiration of the patent subject matter covered by said patent could still be subject to the *jus excludendi* of the patentee. The SPC Regulations allow the grant of an SPC even if the patent has expired, provided that the deadline of Art. 7 Reg. 469/2009 was respected by the applicant.

(f) *Summary*

The problem identified in this section occurs when the patent is about to expire and no MA has been granted. In this case in Europe the patent owner cannot file an *interim* request and cannot obtain a *restitutio in integrum*. No conclusive evidence is available to the MPI that this factual scenario occurs often or that it cannot be avoided by pursuing diligently the MA procedure.

In the case that the European Commission intends to formulate a proposal in this respect based on its own data or assessment, the MPI suggests adopting an *interim* request model based on the following elements:

- the application must be filed before the expiration of the patent;
- the NPOs must be obliged to publish expediently the application together with the information that an MA has yet to be filed;
- the MA must be submitted within a specific deadline (e.g. six months);
- the term of the SPC should start from the expiration date of the patent.

10.2.2.2 Patent granted after its expiry date

(a) *The problem*

The other constellation that tends to be problematic under Art. 3(a) Reg. 469/2009 occurs when the patent has already expired at its granting date.[533] In this case as well, according to the prevailing interpretation, the grant of an SPC is not possible.[534] Indeed, if the patent applicant files for an SPC while the patent application is still pending, the office cannot grant the SPC. At the filing date, the product is not protected by an issued patent, but only claimed in a pending application. If the patent holder files the SPC application after the patent is granted, the patent office must likewise reject the SPC application. Again, at the SPC filing date, the product is protected by a patent that has been issued, but has already expired and therefore is no longer in force.

(b) *The options*

In analogy to the situation discussed above (10.2.3.1), in which the MA is not granted before the patent's expiration date, one could advocate creating some procedural relief for the SPC applicant in situations in which the patent is granted after its expiration date.

Here there are also two options:

- creating the opportunity to file an SPC application on the basis of a pending patent application and a granted MA. The SPC application could then be examined after the grant of the patent;
- allowing the filing of an SPC after the grant of the patent even if the latter has already expired at that date.

(c) *Recommendation*

The MPI does not recommend legislative action to address the factual scenario in which the patent is granted after its expiration date.

First, a practical need for amending SPC provisions in this respect is not evident. The cases in which a patent has been granted after the date of expiration are exceptional. According to the data collected by the MPI, since the EPC's entry into force in 1978, only 43 European patents have been granted after their expiration date.

Second, under European law, the applicant has the right to speed up the granting procedure. Under PACE,[535] the patent applicant can file a request for a speedy

[533] See Records of the Second meeting of national "Supplementary Protection Certificate" (SPC) experts held on 9 October 2006 in Brussels, p. 6.

[534] See Answers to the MPI Questionnaire for NPOs, Q29.

[535] PACE is the acronym for the "Programme for accelerated prosecution of European patent applications" introduced by the EPO in 1997. By filing a request with the EPO to issue the search report together with the opinion under Rule 62(1) EPC and the first examination report, the applicant can significantly shorten the examination time; see Notice from the European Patent Office dated 4 May 2010 concerning the Programme for accelerated prosecution of European patent applications – "PACE" [2010] OJ EPO 352.

examination without additional costs at any time. If an applicant fails to do so, it must bear the consequences of the omission.[536]

Third, if the increase in European patent applications should lead to a situation where the granting proceedings – specifically in the case that the application was originally rejected and a successful appeal followed – frequently take more than 20 years, this problem should be addressed by reforming patent regulations rather than SPC legislation. One NPO in this regard has observed:

> "More generally, we are aware that patents in some offices are being granted more than 20 years from filing. However, this is not something resulting from a failure of the SPC legislation, rather, it relates to the manner by which the process for granting patents is resourced and managed at national or regional level. The response should be to tackle the problem at its source so that all the patent applications can be granted before 20 years."

We agree with these considerations.

10.2.3 "Product protected by the basic patent"

10.2.3.1 Introduction

The requirement that the product must be protected by the patent has been the subject of several requests for a preliminary ruling by the CJEU. Still today, however, according to several opinions the CJEU has failed to provide clear guidance in applying Art. 3(a) Reg. 469/2009. In 2017 the High Court of Justice (Chancery Division, the UK) has again asked the CJEU to answer the question "what protected by the patent" means pursuant to Art. 3(a) Reg. 469/2009.[537] Nonetheless, it is not necessarily true that such case law has been static. The jurisprudence of the CJEU has undergone an evolution. One may identify at least three distinct phases:

- *Farmitalia*
- *Medeva*
- *Actavis I* and *Actavis II*

In the next sections the analysis will proceed as follows. First, we explain the development of the case law (10.2.3.2). Then we address the question of how such case law is implemented by the NPOs (10.2.3.3) and what the critical issues are (10.2.3.4). Finally we analyse the possible options for lawmakers to address these critical issues (10.2.3.5).

Before proceeding with this exposition, one introductory remark seems to be appropriate. In applying Art. 3(a) Reg. 469/2009, a national authority is confronted with a question that must be answered before addressing the issue of what *protected* really means. This preliminary question is whether the word *protected* is to be understood as a concept of the SPC legislation or as a reference to the law governing the basic patent. The two options imply two different approaches. They have also significant institutional consequences.

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536 One could object that the PACE programme applies to EPO applications and not national applications. However, the MPI Questionnaire for the NPOs confirms that for the NPOs, the situation in which a national patent has been granted after its expiration date is absolutely exceptional. In most offices, it has never occurred.

537 Case C-121/17: Reference for a preliminary ruling from the High Court of Justice (Chancery Division) (United Kingdom) made on 8 March 2017 - *Teva UK Ltd, Accord Healthcare Ltd, Lupin Ltd, Lupin (Europe) Ltd, Generics (UK) trading as 'Mylan' v Gilead Sciences Inc.*

If the expression is a reference to the law governing the basic patent, then the CJEU has a limited say in it because the provisions governing the extent of protection of a European or national patent – unlike the provisions determining the rights conferred by such a patent[538] – are not a part of the EU's legal order. It is the task of the national courts – or of the future UPC – to interpret these provisions.

If the expression represents an autonomous concept of the SPC legislation, then mainly the CJEU is responsible for its interpretation. Of course, the CJEU cannot apply the rule and the test to a concrete set of facts. The application of EU regulation remains the prerogative of the national courts. But the principles governing the application case by case will be coined by the CJEU.

The first judgment in which the CJEU answered the question of what *protected* under Art. 3(a) Reg. 469/2009 means seemed to adopt the first approach. It considered the term *protected* as a reference to the law governing the basic patent. In subsequent decisions, the CJEU seemed to adopt an approach that was at least *not only* based on national law.

10.2.3.2 The case law of the Court of Justice

(a) *The first phase of the case law: Farmitalia*

(i) The referral of the BGH and the judgment of the CJEU

The first CJEU judgment that dealt with the interpretation of Art. 3(a) Reg. 1768/92 was *Farmitalia*.[539] The facts of the case have already been described in Section 9.2.3.8 (b) of this Study. As explained there, the Court referred two questions to the CJEU: one concerned Art. 3(b) Reg. 469/2009 and is not directly relevant here; the other question in the English translation reads as follows:

> "According to which criteria is it to be determined whether the product is protected by a basic patent within the meaning of Article 3(a), where the grant of a protection certificate is sought for the free base of an active ingredient including any of its salts, but the basic patent in its patent claims mentions only the free base of this substance and, moreover, mentions only a single salt of this free base? Is the wording of the claim for the basic patent or the latter's scope of protection the determining criterion?"[540]

The CJEU answers this question as follows:

> "23. By its second question, the Bundesgerichtshof is, in substance, asking what are the criteria, according to Regulation No 1768/92 and in particular Article 3(a) thereof for determining whether or not a product is protected by a basic patent. [24] In that connection, it should be noted that one of the conditions for obtaining a certificate is that the product should be protected by a basic patent in force. [25] As indicated in the seventh recital in the preamble to Regulation No 1768/92, the patent concerned may be either national or European. [26] As Community law now stands, the provisions concerning patents have not yet been made the subject of harmonisation at Community level or of an approximation of laws. [27] Accordingly, in the absence of Community harmonisation of patent law, the extent of patent protection can be determined only in the light of the non-Community rules which govern patents. [28] As is clear in particular from paragraph 21 of this judgment, the protection conferred by the certificate cannot exceed the scope of the protection conferred by the basic patent. [29] The answer to be given to the second question must therefore be that, in order to determine, in connection with the application of Regulation No 1768/92 and, in particular, Article 3(a) thereof, whether a product is protected by a basic patent, reference must be made to the rules which govern that patent. In order to

538 Art. 28 TRIPS is part of the union legal order.
539 C-392/97 *Farmitalia* [1999] ECR I-5553.
540 *Ibid*., para. 16.

> determine, in connection with the application of Regulation No. 1768/92 and, in particular, Article 3 (a) thereof, whether a product is protected by a basic patent, reference must be made to the rules which govern the patent."[541]

According to Justice Arnold the answer provided by the CJEU presented two deficiencies.[542] It did not explain which national provisions of patent law should be applied. It did not address the question of how the purpose of the SPC Regulation to ensure uniform conditions for granting SPCs could be achieved when the main criterion for selecting what is SPC-eligible and what is not is based only on the non-harmonised rules of national patent law. The provisions governing the extent of protection of national and European patents are uniform in Europe,[543] but the implementation of *Farmitalia* by national courts led to different approaches.

(ii) The implementation of *Farmitalia*: infringement test in Germany

The German courts inferred from *Farmitalia* that national judges should apply national provisions governing the extent of protection of a patent. As a consequence, the question whether the product is protected was transmuted into the question whether or not the product falls under the scope of the claims of the patent.[544]

This approach presented two differences from the approach of the German Federal Patent Court in the first decision adopted in the case *Farmitalia*.[545] On the one hand, the SPC could be granted for a product even when all or some of the embodiments of this product fall under the scope of protection of the basic patent only by the equivalence doctrine. On the other hand, such SPC could be granted for a product if the latter was not mentioned at all in the disclosure of the patent, so that the patent could not be limited to such a product without violating Art. 123(2) EPC or the corresponding provisions of the domestic patent act.[546]

To the knowledge of the authors, however, German courts' decisions following *Farmitalia* have never dealt with a case where the patent claimed just one single compound (*Compound X*), and did not include any other patent claim for that compound in combination with another pharmaceutical agent (for instance, *pharmaceutical composition comprising compound X and at least another pharmaceutical agent*). It is possible that the German courts would have considered such a combination as protected by a basic patent claiming compound X as such. However, this conclusion is only a speculation. Exactly this set of facts, however, was the subject of *Takeda*, the decision that according to some observers rejected the infringement test and developed an alternative approach to Art. 3(a) Reg. 469/2009.

(iii) …and the *Takeda* decision in the UK

In the proceedings that led to the decision *Takeda,*[547] two basic patents were designated for six SPC applications. The basic patents concerned a pyridine derivative and the use of this pyridine derivative for manufacturing a pharmaceutical product. No claim of either patent was directed to a pyridine derivative combined with another

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541 *Ibid.*, paras. 23-29.
542 *MedImmune v Novartis* [2012] EWHC 181 (Pat).
543 See Chapter 5, Section 5.7.1; see also Annex I, Section 1 of each national Report.
544 BGH, *Idarubicin II*, X ZB 13/95 (BPatG) [2000] GRUR 683.
545 BPatG, *Decision of 15 May 1995*, 15 W (pat) 122/93 [1995] BPaTGE 35, 145.
546 BGH, *Sumatriptan,* X ZB 12/01 [2002] GRUR 2002, 415.
547 *Takeda Chemical Industries Ltd's SPC Applications (No. 1)* [2004] R.P.C. 1.

pharmaceutical agent. No claim was directed to the use of a pyridine derivative for manufacturing a pharmaceutical product including that compound and at least another active ingredient.[548]

The SPC was requested for a pyridine derivative – the anti-ulcer agent lansoprazole – combined with two antibiotics. The Patent Office rejected the request, *inter alia*, because it did not comply with the conditions of Art. 3(a) Reg. 469/2009. In the decision, it was observed first:

> "Although the designated patents claim a certain type of pyridine derivative, such as lansoprazole, either in its own right or in the context of a Swiss-type claim, neither patent claims or discloses the use of the pyridine derivative in combination with any other active ingredient. More particularly, there is no hint whatsoever in these patents that a derivative, such as lansoprazole, could be used in combination with two antibiotics chosen from clarithromycin, amoxycillin and metronidazole. It is the absence of any such disclosure or any such hint that lay at the heart of the examiner's preliminary view that the product identified in each of the requests was not protected by either of the designated basic patents."[549]

The Hearing Officer acting for the Comptroller General of Patents, Mr. Walker, referred then to the answer given to the second question by the CJEU in *Farmitalia*. Accordingly, he proceeded with the analysis of the national law governing the basic patent in examining whether the requirement under Art. 3(a) Reg. 469/2009 was satisfied. Like the German courts, for this examination he considered first the domestic provisions corresponding to Art. 69 EPC[550] relevant. He did not contest the argument of the SPC applicant that *protected* under Art. 3(a) should be equated with "falling within the scope of the claim". However, he disagreed with the conclusion that such an approach implies that a combination is protected only because one of the two things of which the combination consists falls under the scope of the claim. Referring to Section 60 Patent Act 1977 – the provision corresponding to Art. 28 TRIPS which uses the expression *patent for an invention* – he came to the conclusion that "a patent protects no more and no less than the invention as construed by reference to the claims in accordance with Section 125". Consequently, he observed further:

> "The references in this provision [Section 69] to 'a patent for an invention' and 'any of the following things [..] in relation to the invention' indicate, in my view, that the patent protects no more and no less than the invention as construed by reference to the claims in accordance with s.125. Thus, where there is a combination of things and only one of those things is identifiable with the invention of a patent, unauthorised use of the combination will result in the one thing infringing the patent. However, the patent protects just this one thing. The other things making up the combination have no bearing whatsoever on the question of infringement because they are not identifiable with the invention and so are not protected by the patent."

With respect to the case, the Hearing Officer concluded that lansoprazole as an active ingredient of a medicine was protected by the basic patent, but the use of lansoprazole in combination with an antibiotic was not. Therefore, the SPC for lansoprazole was correctly granted, but an SPC for lansoprazole in combination with two or more antibiotics was to be refused.

In confirming the decision on appeal[551] Justice Jacob observed:

> "7. Mr Alexander, for Takeda, submits that the combination of lansoprazole with an antibiotic, if sold, would infringe the patent (and for this purpose it matters not which). So, the combination is protected by a basic patent which is in force. So, Takeda comply with

548 *Ibid.*
549 *Ibid.*
550 See Section 125 Patent Act 1977.
551 *Takeda Chemical Industries Ltd's SPC Applications (No.3)* [2004] R.P.C. 1 [2003] EWHC 649 (Pat).

> condition 3(a). Moreover, he submits, definition (b) specifically contemplates that 'product' may be a combination of active ingredients. So it is clear that condition 3(a) contemplates protection of a combination.
>
> (…)
>
> 10. Mr Birss, for the Comptroller, submits Mr Alexander's argument is flawed. I agree. The so-called 'combination' of lansoprazole and an antibiotic would only infringe because of the presence of the lansoprazole. In truth, the combination is not as such 'protected by a basic patent in force'. What is protected is only the lansoprazole element of that combination. It is sleight-of-hand to say that the combination is protected by the patent. The sleight-of-hand is exposed when one realises that any patent in Mr Alexander's sense protects the product of the patent with anything else in the world. But the patent is not of course for any such 'combination'."

The *Takeda* test can thus be summed up in the following terms:

- If the SPC is requested for a combination of two products, and this combination falls under the scope of the patent only because one of the two active ingredients falls under the scope of the patent, the combination is not protected.
- If the SPC is requested for a combination of two ingredients and this combination is claimed as such by the patent, then such combination is protected by the patent.

In other words, the *Takeda* test asked why the product was infringing the patent. If the reason was because of one component and not because of the product as such, then the product was not protected. Three points must be made.

Firstly, this test does not seem to imply any difference to the infringement test when the certificate is requested for a single active ingredient and such active ingredient falls under the scope of the basic patent.

Secondly, the *Takeda* test has been given many definitions, one of which is that of *disclosure test*. This definition is however over-reading the decisions. In them there is nothing that suggests that the combination of two active ingredients, in order to be eligible for an SPC, must be unambiguously disclosed in the application for the basic patent (Art. 123(2) EPC standard disclosure). So if by the term *disclosure* one means that the combination must have been *individually* disclosed in the patent specification and claimed, this inference does not find any basis either in the decision of the Hearing Officer acting for the Comptroller General of Patents or in the appeal judgment.

Third, the *Takeda* decisions did not address how to decide cases where the patent includes – alongside the product claim for the single product – further claims for the combination of that product with other active ingredients. Such additional independent or dependent claims may have a different degree of specification, as the following examples may show:

Example No. 1	Pharmaceutical composition comprising compound Y
Example No. 2	Pharmaceutical composition comprising compound Y together with a pharmaceutically acceptable carrier and optionally other therapeutic ingredients
Example No. 3	Pharmaceutical composition comprising compound Y and at least a second therapeutic agent in a therapeutically effective amount
Example No. 4	Pharmaceutical composition comprising compound Y and at least a second therapeutic agent, for instance an antibiotic
Example No. 5	Pharmaceutical composition comprising Compound Y, alone or in combination with at least another therapeutic agent in the presence of a pharmaceutically acceptable carrier for the prevention or treatment of the disease X

Table 10.2: Examples of claims in patent applications for a new class of compounds

The decision did not address these factual scenarios because there was no reason for doing so. The basic patents designated for the SPC procedure did not include such types of claims. However, no fundamental hurdles exist for an applicant to obtain a patent with such claims in prosecuting a European patent application before the EPO when the single compound disclosed by said application is new and inventive.

(b) *The second phase of the case law: Medeva and the "specified in the claims"-requirement*

(i) The referral

The two different approaches to Art. 3(a) Reg. 469/2009 made a further referral to the CJEU likely. The occasion for it was given by SPC applications directed to vaccines, a technical field where, *inter alia* for health policy reasons, the medicinal products placed on the market regularly include more than one active ingredient. In the case concerned, the basic patent designated for the procedure before the UK IPO disclosed a method for obtaining a vaccine against *Bordetella pertussis*.[552] The resulting product was the combination of pertactin and filamentous haemagglutinin in amounts that could produce a synergistic effect.

The applicant filed five SPC requests based on this patent. Several MAs were granted for a combination of several ingredients including pertactin and haemagglutinin. The factual scenario for some of the SPC applications filed by *Medeva* reads as follows:

[552] The first independent claim of the basic patent reads as follows: "A method for the preparation of an acellular vaccine, which method comprises preparing the 69kDa antigen of Bordetella pertussis as an individual component, preparing the filamentous haemagglutinin antigen of Bordetella pertussis as an individual component, and mixing the 69kDa antigen and the filamentous haemagglutinin antigen in amounts that provide the 69kDa antigen and the filamentous haemagglutinin antigen in a weight ratio of between 1:10 and 1:1, so as to produce a synergistic effect in vaccine potency".

Product protected by the method claim	A-B
Product definition in the SPC application	A-B-C
Product for which the MA was obtained	A-B-C-D-E-F

Table 10.3: Simplification of the factual scenario in *Medeva*

There were two mismatches in the concrete case:

- between the product obtained by the process claimed by the patent and the product definition of the SPC application;
- between the subject of the MA and the product definition of the SPC application

The Hearing Officer at the UK IPO, Dr. Lawrence Cullen, denied the compliance of the SPC applications with Art. 3(a) Reg. 469/2009. The claims of the patent protected – as a product of the process – only a combination consisting of A and B. In the patent specification there was no reference or claim to a combination including A-B with other active ingredients.[553] By contrast, further active ingredients were mentioned in the specification of the basic patent only to show the differences with the invention. While the UK IPO, applying the *Takeda* test, rejected the SPC applications[554] and Mr. Justice Kitchin dismissed the appeal,[555] the Court of Appeal (England and Wales) referred several questions to the CJEU.[556]

The question directly relevant for the analysis of this section was what is meant in Art. 3(a) by "the product is protected by a basic patent in force" and "what are the criteria for deciding this".

(ii) The judgment of the CJEU

The Advocate General *Trstenjak* had suggested in very elaborate conclusions rejecting the infringement test advocated by *Medeva*.[557]

The CJEU in turn did not explain whether it intended to depart from *Farmitalia*. The Court just mentioned the principle formulated in *Farmitalia* according to which the question whether or not a product is protected by the patent must be answered on the basis of the un-harmonised provisions of national patent law.[558] After doing that – and without a "but" or a "however" – the Court noted the Regulations' aim to create a uniform system for granting SPC in order to prevent a heterogeneous development of the national legislations, and observed that pursuant to Art. 5 of the Regulations the SPC confers the same rights as conferred by patent. From the latter provision the Court inferred that Art. 3(a) Reg. 469/2009 "must be interpreted as precluding the

553 See UK IPO, BL O/357/09 *Medeva BV*, Decision of 19 November 2009 ("I can find no reference in the specification of the basic patent nor in its claims to teach that the invention consists of anything other than the method of producing the combination of the Filamentous Haemagglutinin and Pertactin active ingredients defined in claim 1").
554 *Ibid.*
555 *Medeva BV v The Comptroller General of Patents* [2010] EWHC 68 (Pat).
556 *Medeva BV v Comptroller General of Patents, Designs and Trade Marks* [2010] EWCA Civ 700 [2010] RPC 27.
557 Case C-322/10 *Medeva BV v Comptroller General of Patents, Designs and Trade Marks* [2011] ECR I-12051, Opinion of AGl Trstenjak.
558 Case C-322/10 *Medeva* [2011] ECR I-12051, para. 22.

competent industrial property office of a Member State from granting an SPC relating to active ingredients which are not specified in the wording of the claims of the basic patent relied on in support of the application for such a certificate". According to the CJEU, these conclusions are confirmed by paragraph 20 of the Explanatory Memorandum, which in the context of what is protected by the patent refers exclusively to the claims of the patent, and by Recital 14 Reg. 1610/96.[559]

Now, *prima facie*, it is not clear whether *Medeva* is correcting *Farmitalia*. Some authors and judges have seen no contradiction between the two opinions.[560] Such an interpretation is not without merit.

On the one hand, *Medeva* and *Farmitalia* related to very different factual situations and legal issues. In *Farmitalia*, the application for a certificate concerned a single compound. The question was whether the certificate could be granted with terms covering all variants of the free base, even if the patent mentioned only one salt and the MA was granted for a medicinal product including one specific salt as active. *Medeva* concerned the case where the certificate is requested for a combination of *different* active ingredients (A-B) and the certificate is requested for a combination including further active ingredients than those claimed and disclosed by the patent (A-B-C).

On the other side, if one considers the provisions of the Medicinal Products Regulation and the passage of the Explanatory Memorandum quoted by the CJEU in reasoning the conclusion that only those products that are specified in the wording of the claim of the basic patent are SPC-eligible, it is possible to argue that the main purpose of *Medeva* is only to ensure that no SPC is granted for a product that is not covered by the patent. Since the protection conferred by basic patent is defined by the claims, *Medeva* could have only the purpose of avoiding a grant of an SPC for a product described, but not claimed by the patent or for a product that is indicated in the claim, but in combination with other elements, so that it would not fall as such under the scope of the basic patent. From this intention follows the emphasis on the patent claims, which define the protection conferred by a patent. Having ensured this, one could legitimately assume that the Court of Justice did not intend to depart from *Farmitalia*. However, if only this was intended, the Court could have simply stated that the product must fall under the scope of the basic patent in order to be eligible for protection.[561] It did not do so. It pointed out that the need for the system to grant SPCs must be uniform and prevent a heterogeneous development of the law of the EU Members. Only after this statement does the Court introduce a new formula – "specified" in the wording of the claim – as a criterion for granting an SPC.

This criterion was confirmed in another set of orders delivered by the CJEU following further references of national courts for a preliminary ruling under Art. 267 TFEU.[562] In the headings and in the text of these decisions the CJEU used instead of or alongside

559 *Ibid.*, para. 27.

560 See for instance the essay of Dr. Peter Meier-Beck, Presiding Judge of the 10th Civil Senate (Patent Division) of the German Federal Supreme Court, entitled *Richard Arnold, Joachim Bornkamm and die Curie – ein europäisches ABC* in Wolfgang Büscher et al, FESTSCHRIFT FÜR JOACHIM BORNKAMM ZUM 65. GEBURTSTAG (C.H. Beck 2014) p. 699 et seqq.

561 Adding an additional element of unclarity, the CJEU does not explain whether it is following or contradicting the Opinion of the Advocate General.

562 Case C-518/10 *Yeda Research and Development Company and Aventis Holdings* [2011] ECR I-12209; Case C-630/10 *University of Queensland and CSL* [2011] ECR I-12231; Case C-6/11 *Daiichi Sankyo* [2011] ECR I-12255.

the formula "*specified in the wording of the claims*" also the expression "*identified in the wording of the claim*". According to the prevailing opinion, the two expressions are equivalent.[563] We report in the table below the questions formulated by the referring national court, the reformulation of said questions by the CJEU and the Court's answers to them.

	First referred Question	Reformulation by the CJEU/ECJ	Answer
Yeda (C-518/10)	"'If the criteria for deciding whether a product is "protected by a basic patent in force" under Article 3(a) of … Regulation [No 469/2009] include or consist of an assessment of whether the supply of the product would infringe the basic patent, does it make any difference to the analysis if infringement is by way of indirect or contributory infringement based on Article 26 of the [European] Patent Convention, enacted as Section 60(2) of the [UK] Patents Act 1977 in the United Kingdom, and the corresponding provisions in the laws of other Member States of the Community?'"	"By its question, the Court of Appeal asks, in essence, whether Article 3(a) of Regulation No 469/2009 must be interpreted as precluding the competent industrial property office of a Member State from granting an SPC where the active ingredient specified in the application, even though identified in the wording of the claims of the basic patent as an active ingredient forming part of a combination in conjunction with another active ingredient, is not the subject of any claim relating to that active ingredient alone."	"the answer to the question referred is that Article 3(a) of Regulation No 469/2009 must be interpreted as precluding the competent industrial property office of a Member State from granting an SPC where the active ingredient specified in the application, even though identified in the wording of the claims of the basic patent as an active ingredient forming part of a combination in conjunction with another active ingredient, is not the subject of any claim relating to that active ingredient alone."
Queensland (C-630/10)	„ Regulation No 469/2009 … recognises amongst the other purposes identified in the recitals, the need for the grant of an SPC by each of the Member States of the Community to holders of national or European patents to be under the same conditions, as indicated in recitals 7 and 8 [of the Regulation]. In the absence of Community harmonisation of patent	"The questions referred in the present case are, for all essential purposes, similar to those referred by the Court of Appeal (England and Wales) (Civil Division) and by the referring court in the cases which gave rise to the judgments of 24 November 2011 in Case C-322/10 *Medeva* [2011] ECR I-0000 and Case C-422/10 *Georgetown University*	"The answer to the first five questions is, therefore, that Article 3(a) of Regulation No 469/2009 must be interpreted as precluding the competent industrial property office of a Member State from granting an SPC relating to active ingredients which are not identified in the wording of the claims of the basic patent relied on in support of the SPC

[563] This conclusion is also supported by other versions of the decisions, in which the past tense "specified" and "identified" are translated with same word.

	law, what is meant in Article 3(a) of the Regulation by "the product is protected by a basic patent in force" and what are the criteria for deciding this?	*and Others* [2011] ECR I-0000."	application."
Daiichi Sankyo (C-6/11)	In the absence of Community harmonisation of patent law, what is meant in Article 3(a) of the Regulation by "the product is protected by a basic patent in force" and what are the criteria for deciding this?	"By its questions, which it is appropriate to consider together, the referring court asks, in essence, whether Article 3(a) of Regulation No 469/2009 must be interpreted as precluding the competent industrial property office of a Member State from granting an SPC where the active ingredients specified in the SPC application include active ingredients not identified in the wording of the claims of the basic patent relied on in support of that application."	"In view of the foregoing, the answer to the questions referred is that Article 3(a) of Regulation No 469/2009 must be interpreted as precluding the competent industrial property office of a Member State from granting an SPC relating to active ingredients which are not identified in the wording of the claims of the basic patent relied on in support of the SPC application."

Table 10.4: Questions formulated by the referring national Court concerning Art. 3(a) Reg. 469/2009, the reformulation of said questions by the CJEU and CJEU's answers

In none of the judgments mentioned in Table 10.4 has the CJEU explained further the meaning of the formulas "*specified in the wording of the claims*" or "*identified in the wording of the claims*". Some more explanations were given in the *Eli Lilly* case.[564] This case – unlike *Medeva* – concerned a single product and not a combination.

(iii) The further development of *Medeva*: *Eli Lilly* and referral of the German Patent Federal Court of 17 October 2017 (14 W (pat) 12/17

The patent in suit in the proceedings that lead to the *Eli Lilly* judgment discloses a new polypeptide, the Neutrokine-α protein.[565] The patent includes some claims directed to antibodies that may specifically bind the Neutrokine-α polypeptides claimed by the patent. The patent claim (no. 13) that matters for the procedure for granting the certificate read as follows:

"13. An isolated antibody or portion thereof that binds specifically to:
(a) the full length Neutrokine-α polypeptide (amino acid sequence of residues 1 to 285 of SEQ ID No: 2); or

564 Case C-493/12 *Eli Lilly and Company* [2013] EU:C:2013:835.
565 EP 0939804.

(b) the extracellular domain of the Neutrokine-α polypeptide (amino acid sequence of residues 73 to 285 of SEQ ID No: 2)."

The patent specification stated that such antibodies could be effective against autoimmune diseases. It did not disclose the structure of any antibody that falls under claim 13, but mentioned standard procedures for their preparation.[566]

The plaintiff of the proceedings in which the referral was made wanted the judge to ascertain that an SPC for a specific antibody binding to the protein as LY2127399 (tabalumab) could not be granted in view of the CJEU case law, since such antibody did fall under the scope of protection of claim 13 of the patent, but was not specified in such claim and was not protected within the meaning of Art. 3(a) Reg. 469/2009. The High Court of Justice referred the following questions to the CJEU:

"(1) What are the criteria for deciding whether "the product is protected by a basic patent in force" in Article 3(a) of Regulation [No 469/2009]?
(2) Are the criteria different where the product is not a combination product, and if so, what are the criteria?
(3) In the case of a claim to an antibody or a class of antibodies, is it sufficient that the antibody or antibodies are defined in terms of their binding characteristics to a target protein, or is it necessary to provide a structural definition for the antibody or antibodies, and if so, how much?"

In essence, the question to be decided was whether a product can be considered specified or identified in the wording of a claim even if such claim does not mention such product by its structure or otherwise either in the patent claims or in the patent specification. The answer to the questions given by the Court reads as follows:

"Article 3(a) of Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products must be interpreted as meaning that, in order for an active ingredient to be regarded as 'protected by a basic patent in force' within the meaning of that provision, it is not necessary for the active ingredient to be identified in the claims of the patent by a structural formula. Where the active ingredient is covered by a functional formula in the claims of a patent issued by the European Patents Office, Article 3(a) of that regulation does not, in principle, preclude the grant of a supplementary protection certificate for that active ingredient, on condition that it is possible to reach the conclusion on the basis of those claims, interpreted *inter alia* in the light of the description of the invention, as required by Article 69 of the Convention on the Grant of European Patents and the Protocol on the interpretation of that provision, that the claims relate, implicitly but necessarily and specifically, to the active ingredient in question, which is a matter to be determined by the referring court."

The judgment has given some additional indication on how to apply the *Medeva*-requirement. In order to satisfy this requirement it is not necessary for a patent claim to indicate the structure of the product. However, the *Medeva*-requirement is met only when the claim interpreted on the basis of the description pursuant to Art. 69 EPC *relates implicitly but necessarily and specifically* to the active ingredient in question. This caveat is a new formulation coined by the CJEU and was not used before. It is ambiguous because it is open to at least two interpretations:

- The expression could suggest that the Court intends to draw a distinction between products that fall under the scope of the patent claim with functional features, but are not specifically disclosed in such patent, and products that fall under the scope of the claim with functional features and are specifically disclosed. By this interpretation of the judgment, it would not be sufficient that

[566] The assumption of the patent was therefore that once the proteins were disclosed, those skilled in the art could have prepared without undue burden the isolated antibodies and use them for a medical purpose that was made plausible by the patent specification.

a product is claimed as such by the patent to consider it eligible for SPC. Something more would be required. This more could be an individualised disclosure of the compound in the patent specification, but it is not stated expressly.[567]

- The second reading is that for *Eli Lilly* it is sufficient that the claim, interpreted on the basis of the description, cover the product as such.

The judgment of the High Court delivered on the basis of the *Eli Lilly* opinion followed according to our understanding the second reading of the CJEU ruling. Justice Warren considered the antibodies protected by the patent because they fall under the scope of the patent according to the extension of protection rules. It considers *Medeva* relevant only for claims containing a wording that extends the claim beyond its principle scope ("pharmaceutical composition comprising").[568] According to some opinions, this interpretation does not explain why the court should have added the caveat that the claim must relate "*implicitly but necessarily and specifically*" to the active ingredient if it was sufficient for the product to fall under the scope of the patent in order to be SPC-eligible pursuant to Art. 3(a) Reg. 469/2009.[569]

In a subsequent decision concerning the referral C-121/17 (*Teva UK and Others*, 8 Mar 2017), the High Court observed that in *Eli Lilly* the CJEU failed to give a clear indication to the national offices of how to apply Art. 3(a). It did not explain how to assess whether the claim relates implicitly but necessarily and specifically to the product for which an SPC is requested.

The German Federal Patent Court arrived at the same conclusion in a factual situation similar, but not identical to that discussed in *Eli Lilly*, and has referred again to the CJEU questions concerning Art. 3(a) Reg. 469/2009. The question is whether a product is protected within the meaning of Art. 3(a) only when the patent includes an individual disclosure as embodiment of the invention of that product or whether it is sufficient that the functional claim covers that product.

We report the wording of the question in the translation published in the SPC Blog[570]:

> "1. Is a product protected by a basic patent in force according to Article 3 (a) of Regulation (EC) No 469/2009 only if it belongs to the protected subject-matter as defined by the claims and is thus provided to the person skilled in the art as a specific embodiment?
> 2. Is it therefore not sufficient for the requirements of Article 3 (a) of Regulation (EC) No 469/2009 that the product in question meets the general functional definition of an active substance class as mentioned in the claims, but apart from that is not individualized as a specific embodiment of the teaching protected by the basic patent?
> 3. Is a product not protected according by Article 3 (a) of Regulation (EC) No 469/2009 by a basic patent in force if it is covered by the functional definition contained in the claims, but was developed only after the filing date of the basic patent based on independent inventive activity?"

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567 The formulation itself might recall however some formulations coined by the EPO with respect to Art. 123(2) EPC, for instance with respect to implicit disclosures. This hypothesis would not be completely out of place since the European Commission recommended, in defining the criteria for the application of Art. 3(a) Reg. 469/2009, referring to the case law concerning the amendments of the patent application pursuant to Art. 123(1) EPC.

568 *Eli Lilly v Human Genome Sciences Ltd* [2014] EWHC 2404 (Pat).

569 See the review by Justice Rian Kalden, Discussion of recent CJEU case law on SPCs: 'The three 12 December 2013 cases', Supplementary publication [2015] OJ EPO 123-124.

570 Translation available at http://thespcblog.blogspot.de/2017/11/a-new-cjeu-referral-on-claims-with.html (last accessed 24 May 2018).

(c) *The third phase of the case law: Actavis I and Actavis II*

(i) Premise

We have identified a third phase in the case law of the CJEU. This phase follows the judgment *Actavis et al. v Sanofi et al*, C-443/2012 (*Actavis I*) and *Actavis Group PCT EHF and Actavis UK Ltd v Boehringer Ingelheim Pharma GmbH & Co. KG, C-557/13* (*Actavis II*).[571]

(ii) *Actavis I* and *Actavis II*

The factual scenario in *Actavis I* and *Actavis II* was similar for the purposes of the SPC law analysis. In *Actavis I* the patent[572] in suit claimed a class of compounds of a specific formula. Further patent claims were directed to a compound according to the first independent claim in combination with other active ingredients. Claim 20 reads as follows:

> "A pharmaceutical composition containing a compound according to any one of claims 1 to 7 in association with a diuretic".

An SPC was granted for the compound irbesartan on the basis of a first MA for this product. Irbesartan fell under the scope of the claim 1 of the Patent. On the basis of a second MA for the compound irbesartan in combination with the diuretic hydrochlorothiazide, the patentee requested and obtained a second SPC. The product definition of this second SPC reads as "Irbesartan optionally in the form of one of its salts and hydrochlorothiazide". Hydrochlorothiazide is a diuretic well known since 1958 and has already been used in combination with other active ingredients.

In *Actavis II* the patent in suit claimed a class of compounds that constitutes all benzimidazole derivatives. On the basis of this patent the patent owner obtained an SPC for telmisartan, which falls under the scope of the first independent claim of the patent and was the specific subject of claim 5 of the patent. On the basis of a second MA for telmisartan in combination with hydrochlorothiazide, Boehringer requested an SPC for the combination of telmisartan and hydrochlorothiazide.

The table below sums up the factual scenario of the two cases:

First MA	A
First SPC	A
Second MA	A-B
Second SPC	A-B

Table 10.5: *Actavis I* and *Actavis II* factual scenarios

A difference in the factual scenarios of the two cases lies in the wording of the claims of the basic patents concerned. In *Actavis I* the patent in suit includes a claim directed

[571] Case C-577/13 *Actavis Group PTC and Actavis UK* [2015] EU:C:2015:165.
[572] European Patent (UK) No 0 454 511 with the title "N-substituted heterocycle derivatives, their preparation, compositions containing them".

to the combination of irbesartan with a diuretic. A similar combination claim was omitted in the European patent covering telmisartan. In the view of the UK IPO this does not seem to be due to an insufficiency of the specification of the patent application as filed. Indeed the patent owner filed before the UK IPO a request for limiting one of the dependent claims to such a combination. Such amendment was held to be consistent with the requirements of the UK Patent Act.[573]

In *Actavis I* Justice Arnold referred the question "what are the criteria for deciding whether 'the product is protected by a basic patent in force' in Art. 3(a) Reg. 469/2009?".

This question was based on two premises. First, according to Justice Arnold the CJEU has correctly held that one of the purposes of the SPC Regulation is to establish a uniform law for granting SPC and prevent a heterogeneous development of the national systems. As a consequence, Art. 3(a) "must be interpreted as involving a question of European, not national, law".

Second, according to the referring Court the CJEU holds that the requirement that the product infringes the patent is necessary, but still not sufficient in order for the product to be considered as protected by the patent. Something more is required. However, the CJEU has still to clarify the question "what more is required". Justice Arnold suggested an answer to the question: the product shall be considered protected as such when it embodies the "inventive advance" of the basic patent. According to the referring Court this criterion would have led to a straight result in the case examined:

> "(…) in a case such as the present, where the inventive advance of the Patent consists generally of the compounds of formula I, including specifically irbesartan, a medicinal product whose active ingredient is irbesartan is protected by the Patent within the meaning of Article 3(a) because it embodies the inventive advance of the Patent. A medicinal product whose active ingredients are irbesartan and a diuretic such as HCT in combination is not protected by the Patent within the meaning of Article 3(a) because the combination, as distinct from irbesartan, does not embody the inventive advance of the Patent. This is not a question of the wording of the claims of the basic patent, which as discussed above can be manipulated by the patent attorney who drafts it, but of its substance."

Justice Arnold formulates a second question, and more precisely whether Art. 3(c) Reg. 469/2009 would prevent the NPOs from granting an SPC for a combination, when one of the ingredients of this combination was already the subject of an SPC granted to the same applicant.

In the national proceeding that led to the referral to the CJEU in *Actavis II* Justice Birss was already aware of the referred questions summed up above. The second question takes up the idea that at least for combination products the question whether such combination embodies the inventive advance of the patent on which the application relies could matter if the application for SPCs is based on the same patent and there is already an SPC for one of the two ingredients. Justice Birss refers on this question generally to Art. 3 Reg. 469/2009, but he made clear that he considers this

[573] The amended patent claim on which the SPC applied for the combination was based at "pharmaceutical compositions as claimed in claim 8 containing one or more inert carriers and/or diluents and a further active substance selected from bendroflumethiazide, chlorothiazide, hydrochlorothiazide, spironolactone, benzothiazide, cyclothiazide, ethacrinic acid, furosemide, metoprolol, prazosine, atenolol, propranolol (di)hydralazine-hydrochloride, diltiazem, felodipin, nicardipin, nifedipin, nisoldipin and nitrendipin".

question relevant only for the case in which an SPC for one of the ingredients was already granted.[574]

In *Actavis I* the CJEU came to the conclusion that Art. 3(c) precludes the grant of a second SPC for the combination of Irbesartan and hydrochlorothiazide. Therefore, it was not necessary for the Court to answer the first question. The heading of the judgment read as follows:

> "In circumstances such as those in the main proceedings, where, on the basis of a patent protecting an innovative active ingredient and a marketing authorisation for a medicinal product containing that ingredient as the single active ingredient, the holder of that patent has already obtained a supplementary protection certificate for that active ingredient entitling him to oppose the use of that active ingredient, either alone or in combination with other active ingredients, Article 3(c) of Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products must be interpreted as precluding that patent holder from obtaining – on the basis of that same patent but a subsequent marketing authorisation for a different medicinal product containing that active ingredient in conjunction with another active ingredient which is not protected as such by the patent – a second supplementary protection certificate relating to that combination of active ingredients."

Since Art. 3(c) Reg. 469/2009 applies when an SPC is requested for the same product as a previous SPC, the Court considered that product A and combination A-B are the same product, unless the combination is a separate innovation and is protected as such by the patent.

In *Actavis II* the Court answers Question 2 coming to the same results as in *Actavis I*. However, instead of core inventive advance it introduces the concept of the "sole subject matter of the invention":

> "Article 3(a) and (c) of Regulation (EC) No 469/2009 of the European Parliament and of the Council of 16 May 2009 concerning the supplementary protection certificate for medicinal products must be interpreted as meaning that, where a basic patent includes a claim to a product comprising an active ingredient which constitutes the sole subject-matter of the invention, for which the holder of that patent has already obtained a supplementary protection certificate, as well as a subsequent claim to a product comprising a combination of that active ingredient and another substance, that provision precludes the holder from obtaining a second supplementary protection certificate for that combination."

In the text of the judgment the CJEU referred, however, to paragraph 31 of the *Actavis I* judgment. The majority of the NPOs consulted by the MPI are of the opinion that no different standard is meant despite the different expression used by the CJEU.

The purpose of this case law is explained in paragraph 36 of the *Actavis II* judgment.

> "36. In the light of the need, referred to, *inter alia*, in recital 10 in the preamble to Regulation No 469/2009, to take into account all the interests at stake, including those of public health, if it were accepted that all subsequent marketing of an active ingredient in conjunction with an unlimited number of other active ingredients which do not constitute the subject-matter of the invention covered by the basic patent would confer entitlement to multiple SPCs, that would be contrary to the requirement to balance the interests of the pharmaceutical industry and those of public health as regards the encouragement of research within the European Union by the use of SPCs (see, to that effect, judgment in *Actavis Group PTC and Actavis UK*, EU:C:2013:833, paragraph 41).

[574] The question reads as follows: "For the purposes of determining whether the conditions in Article 3 are made out at the date of the application for an SPC for a product comprised of the combination of active ingredients A and B, where (i) the basic patent in force includes a claim to a product comprising active ingredient A and a further claim to a product comprising the combination of active ingredients A and B and (ii) there is already an SPC for a product comprising active ingredient A ("Product X") is it necessary to consider whether the combination of active ingredients A and B is a distinct and separate invention from that of A alone?".

> 37. Accordingly, in view of the interests referred to in recitals 4, 5, 9 and 10 in the preamble to Directive 469/2009, it cannot be accepted that the holder of a basic patent in force may obtain a new SPC, potentially for a longer period of protection, each time he places on the market in a Member State a medicinal product containing, on the one hand, an active ingredient, protected as such by the holder's basic patent and constituting the subject-matter of the invention covered by that patent, and, on the other, another substance which does not constitute the subject-matter of the invention covered by the basic patent (see, to that effect, judgment in *Actavis Group PTC and Actavis UK*, EU:C:2013:833, paragraph 30)."

The CJEU considered it possible that the grant of an SPC for Irbesartan could have prolonged *de facto* the monopoly for the single ingredient. From a legal perspective this is not possible. The SPC for A-B does not prevent any competitor from marketing A, and the marketing of A as such can never amount to a contributory or direct infringement of a claim for A-B. However this does not mean that such multiple SPCs could not have the effect of delaying generic competition. This is however the result of a series of factors and not of the mere existence of an SPC or a patent for a combination including the active ingredient.

In reaching this conclusion in *Actavis I*, the Court seemed to adopt a test for applying Art. 3(c) Reg. 469/2009 that resembled the test suggested by Justice Arnold to question concerning Art. 3(a) Reg. 469/2009. According to many observers – including the NPOs – the CJEU has adopted the answer suggested by the referring Court. However, it based this test in *Actavis I* on Art. 3(c) Reg. 469/2009. In *Actavis II*, by contrast, the CJEU mentioned both Art. 3(a) and (c) Reg. 469/2009.

Whether such test is based on Art. 3(a) or Art. 3(c) Reg. 469/2009 has practical implications. At the moment, this question – like other issues concerning the reach of *Actavis I* and *II* – is unclear.

(d) *Summary of CJEU case law on Art. 3(a) Reg. 469/2009*

The case law on Art. 3(a) CJEU is still in development. It is possible that the answer to the referral *Teva* 2017 EWHC 13 (Pat) will provide for some more clarity. At the moment two ways of understanding the case law remain possible.

According to the first possible understanding, a product is protected under the CJEU case law when it is *specified in the wording of the claim.* This is the only requirement that the product must satisfy to comply with Art. 3(a) Reg. 469/2009. The core inventive advance is not relevant in the context of Art. 3(a) Reg. 469/2009. The legal basis for such limitation to the SPC eligibility is Art. 3(c) Reg. 469/2009.

According to the second possible understanding, a product is protected within the meaning of Art. 3(a) Reg. 469/2009 when two requirements are cumulatively satisfied:

- It is specified in the wording of the claim and
- It embodies the core inventive advance of the patent.

In this view, the inventive-advance requirement elaborated in *Actavis I* and *II* constitutes an interpretation of Art. 3(a) Reg. 469/2009. As a consequence, it applies to all SPC applications whether or not the applicant has obtained an SPC on the basis of the same patent. The core inventive advance does not replace the *Medeva*-requirement, but it just supplements it.

In *Teva* 2017 EWHC 13 (Pat) Justice Arnold has referred again the question what *protected by the patent* means. He suggested an answer in line with that formulated in the referral that led to the *Actavis I* judgment and endorsed the core inventive test. In this view, the requirement that the product must embody the core inventive advance of the basic patent replaces the requirement "*specified in the wording of the claim*" and does not supplement it.

For the sake of clarity in all the possible readings of the CJEU case law mentioned above, the product must fall under the scope of protection of one patent claim in order to be considered protected. This is a common feature to all understandings of the case law on Art. 3(a) Reg. 469/2009. This is true at least when a product claim is the subject matter of the basic patent, while the situation is somewhat more complicated in the case of a process claim.

We illustrate the differences and the common elements of the three possible understandings of the case law on Art. 3(a) Reg. 469/2009 summed up in this section in the table below:

I. Understanding of the CJEU case law on Art. 3(a)	**II. Understanding of the CJEU case law on Art. 3(a)**	**III. Understanding of Art. 3(a) proposed by High Court in *Teva* [2017] EWHC 13 (Pat)**
The product is protected by the basic patent when • it falls under the scope of protection of the basic patent • it is specified in the wording of the claims of the basic patent	The product is protected by the basic patent when • it falls under the scope of protection of the basic patent • it is specified in the wording of the claims of the basic patent, and • it embodies the core inventive advance of the basic patent	The product is protected by the basic patent when • it falls under the scope of protection of the basic patent • it embodies the core inventive advance of the basic patent

Table 10.6: The three possible understandings on the case law on Art. 3(a) Reg. 469/2009

10.2.3.3 The CJEU case law: implementation by NPOs and courts

(a) *Introduction*

The MPI has reviewed how NPOs and national courts have implemented the case law of the CJEU on Art. 3(a) Reg. 469/2009. We distinguish between the requirement that the product must be specified in the claim (*Medeva*-requirement) and the requirement that it must embody the core inventive advance of the patent (*Actavis-r*equirement).

(b) *Medeva-requirement*

(i) The practice of NPOs: general considerations

In the MPI Questionnaire for the NPOs several questions were directed to the *Medeva* case law and its implementation.

The first question was whether such case law provides the NPOs with a clear guidance in deciding over pending SPC applications. The majority of the offices answered this question in the negative.[575] This statement does not mean, however, that the CJEU has not contributed to harmonising some aspects of the granting practice.

First, the majority of the NPOs agree that the fact that the product falls under the scope of protection of the patent is necessary for the compliance of the SPC application with Art. 3(a) Reg. 469/2009, but it is not sufficient for that purpose according to the CJEU case law. Something more is required.

Second, the majority of the NPOs agree that if the claim indicates and discloses structurally the compound for which the SPC is requested, then the SPC can be granted.

Third, the majority of the NPOs agree that even if the claim reads on the product, without indicating or mentioning it, but the product is individually and specifically disclosed in the patent specification, so that the patent could be limited to such compound without violating Art. 123(2) EPC or corresponding provision of national law, this is sufficient to satisfy Art. 3(a) Reg. 469/2009. Some NPOs in this case require the applicant to amend the patent and include in it a dependent claim for the specific compound. In some jurisdictions, such amendment is not possible. But as long as such amendment is possible under national law, the NPO can issue an SPC for the product concerned.

Against this background, it is a common element of the practice of the NPOs that every time the SPC is requested for a product specifically disclosed by the patent by their chemical name or structure, this will be sufficient for sastifying *Medeva*.

Divergences exist with respect to products that are not individually disclosed in the patent, particularly when they are covered by a functional claim.[576] The evidence that we have collected confirms that there is some uncertainty in this regard.

(ii) The practice of some selected NPOs

The Swedish Patent Office seems to follow an interpretation of Art. 3(a) Reg. 469/2009 that is in line with the approach taken by Justice Arnold in *Sandoz Limited and G.D. Searle LLC* [2017] EWHC 987 (Pat). Markush claims or claims with functional term reading on the product are sufficient for the product in order to be considered protected by the patent for the purpose of the SPC procedure. In the same time,

[575] See MPI Questionnaire for the NPOs, Q18: "In your practice or case law, does a medicinal product need to be specified or identified in the claims of the basic patent to meet the requirements of Art. 3(a) Reg. 469/2009/EC?"

[576] For products that are not individually disclosed in the patent the MPI refers to products to which the patent cannot be limited without violating Art. 123(2) EPC or corresponding provision of the national patent acts.

however, the product must embody the core inventive advance of the basic patent in order to be eligible for a certificate.

With respect to the requirement of the expression "specified in the wording of the claim", the German Patent and Trade Mark Office (DPMA) follow the *Ranibizumab*[577] decision of the German Federal Patent Court (BPatG).[578] For this decision it is not sufficient that the product falls under the scope of the patent for the product to be considered protected by the patent within the meaning of Art. 3(a) Reg. 469/2009. The claims of the basic patent must at least indicate the structure and/or the properties of the specific active ingredient. Since this decision has been indicated as representing the current practice of the DPMA, we have translated the relevant passages of this decision:

> "(…) according to the most recent decisions handed down in English by the CJEU, Medeva of 24 November 2011 [Case No. C-322/10] (GRUR 2012, 257 with comment by Seitz; cf. also Brückner, GRUR Int 2012, 300) and Queensland of 25 November 2011 [Case No. C-630/10] (BeckRS 2011, 81931 = GRUR-RR 2012, 57 L), under Article 3 lit. a of Regulation (EC) No. 469/2009, a supplementary protection certificate may only be granted for active ingredients that fulfil the condition set out in operative part 1 of Medeva of being "specified in the wording of the claims of the basic patent" (German translation: "die in den Ansprüchen des Grundpatents, auf das die betreffende Anmeldung gestützt wird, genannt sind"; all language versions accessible at http://curia.europa.eu). According to operative part 3 of Queensland, moreover, Article 3 lit. a of this Regulation is to be interpreted to the effect that a supplementary protection certificate may only be granted for such products that are "identified in the wording of the claims of that patent as the product deriving from the process in question" (German translation: "das in den Ansprüchen dieses Patents als das durch das fragliche Herstellungsverfahren gewonnene Erzeugnis bezeichnet ist"; cf. also e.g. CJEU [Case No. C-574/11], EuZW 2012, 431 = BeckRS 2012, 80616 – Daiichi Sankyo [Novartis/Actavis] ...).
>
> This raises the question whether and to what extent the CJEU is now, in a departure from previous case-law, establishing a new, restrictive criterion to the effect that the relevant product and/or its composition and/or its properties must be explicitly named in the claims of the basic patent (references omitted).
>
> 3.1. The wording of the decisions and the use of the expressions "identified in the wording of the claims" and "specified in the wording of the claims" shows, in the view of this Court, that the relevant ingredient must be "specified, described, individually named, precisely named, exactly described" ["spezifiziert, beschrieben, einzeln genannt, genau benannt, genau beschrieben"], or "identified, determined, stipulated" ["identifiziert, genau bestimmt, festgelegt"] in the claims of the basic patent (cf. LEO German-English online dictionary dict.leo.org; Collins English Dictionary, 2010, key words "specify" and "identify").
>
> (….)
>
> 3.3. In the estimation of this Court, this argumentation, founded on the wording, spirit, purpose, origin and classification of the relevant provisions and based on established case-law, as well as the unambiguous wording of the decisions, support the conclusion that the CJEU, in order to achieve the objective of the Regulation to ensure uniform conditions in every Member State, establishes with its recent case-law a further Community-law criterion to delimit and further specify the Farmitalia decision (GRUR Int 2000, 69 = NJWE-WettbR 2000, 13). Thus, in contrast to the previous national case-law, it does not look exclusively at the extent of protection of the basic patent, that is, not solely at the possible prohibitive rights in the basic patent, but sets narrower requirements for the grant of a supplementary protection certificate. (….)

In accordance with this approach, the German NPO has for instance declined to grant an SPC for a combination of efavirenz, emtricitabine and tenofovir disoproxil fumarate, because the claims of the basic patent did not mention efavirenz in combination with emtricitabine or tenofovir disoproxil, but included only the generic indication that emtricitabine is combined with "a nucleoside analog having biological activity against HIV reverse transcriptase". Neither the claims nor the description of the patent

577 BPatG, *Ranibizumab*, Decision of 2 Mai 2012, 3 Ni 28/11 [2013] GRUR 58.
578 Anwers to Q18 of the MPI Questionnaire for the NPOs.

mention as combination partners for efavirenz the compounds for which the SPC was requested. The Office therefore denies that the SPC can be granted in such a case. The same approach was taken with an SPC requested for efavirenz with emtricitabine. In both cases, the Office pointed out that the old case law, according to which a generic definition of the product was sufficient in order to consider it protected, was not valid anymore. Such case law is considered by the German Patent and Trade Mark Office not consistent with the *Medeva* judgment.[579]

The Latvian Patent Office seems to apply a similarly strict approach. The compounds, for which the SPC is requested, must be "defined precisely in claims" or "mentioned as an example in the description" of the patent.[580] The Latvian Patent Office has rejected applications where the product was covered by a Markush formula but the name of the product was not mentioned anywhere in the claims or in the description. However, these decisions are under appeal.[581]

According to the Hungarian Patent Office, the claim must relate implicitly and necessarily and specifically to the active ingredient or combination of active ingredients for which the SPC is requested. The question whether this requirement is complied with by the SPC application must be assessed if the "ingredient is disclosed in the description in a way that the skilled person will necessarily select it". The approach seems to require an individual disclosure, that is, that the compound is individually mentioned in the patent specification. Only in this case, by reading a claim covering such compound, can the compound itself come immediately to the mind of those skilled in the art. This approach is based on the Budapest Regional Court Decision 3 Pk. 22.474/2015/10.

The NPO of the Netherlands considers the product protected by the patent when it falls under the scope of that patent according to Art. 69 EPC (if the patent is a European patent) or Art. 53(2) Dutch Patents Act (if the patent is a national patent) and further "the average skilled person, taking into account the description and his common general knowledge at the priority date of the patent, should be able to identify the product". Such standard does not likely require that the active ingredient or the combination for which the certificate is applied for be individually disclosed in the patent specification, but rules out that any product that read on the features of the Markush claim or of product claim with functional term will be considered automatically protected for the purposes of the SPC legislation. Something more is required: it is necessary that the product come to the mind of the skilled of the art because either the prior art or the specification leads to such product.

In the practice of the Industrial Property Office of the Slovak Republic the product

> does not necessarily need to be specified or identified in the claims in a strict sense of the word, but on the basis of the claims, interpreted in light of the description and/or optionally having regard to common general knowledge at the date of filing the patent application (e. g. when there is a reference in the basic patent to the pharmaceutically acceptable salts of an active compound without individually listing them, based on the common general knowledge it is clear that this term covers hydrochloride, mesylate, tosylate, … and any other salt which, at the time of filing the patent application, has generally been known to be pharmaceutically acceptable), it should be clear that the claims relate necessarily and specifically also to the product for which an SPC is

[579] The NPO came to a similar conclusion as Justice Arnold in *Teva* [2017] EWHC 539 (Pat).
[580] MPI Questionnaire for the NPOs, Annex VI of this Study, Answer to Q17.
[581] *Ibid.*

requested (the product should by covered by claims and at the same time be clearly identifiable in the description).[582]

The practice of the French National Patent Office considers the product protected by the basic patent when the patent specification indicates the chemical structure by its name. However, if a functional or a Markush claim covers the product, the SPC can be granted when the product is exemplified in the description of the patent. The situation is more complex when the product is not exemplified in the patent claims or in the specification. In this case the French Patent Office has developed some secondary indicia, which are positive or negative. A positive indicium is that the applicant is the owner of the MA. A negative indicium is that the product was then disclosed by a later granted patent. Another negative indicium is that the patent discloses specifically other products falling under the scope of the functional claim.[583]

The Austrian Patent Office has dealt with a claim including a generic definition (for instance, anti-inflammatory agents) for one of the products of the combination for which the SPC was sought in the *Nepafenac* case. The patent claim on which the SPC application relied was directed to nepenafac in combination with one or more anti-inflammatory agents. The Patent Office held that such generic terms – such as anti-inflammatory agent – are not sufficient for considering a product as specified in the claim if such product is not described or mentioned in the patent specification. In the decision – confirmed by the court of appeal[584] – it was considered that the concept of anti-inflammatory agent includes three categories of products (e.g. steroidal, non-steroidal) that comprise very different structures.

The UK IPO practice usually admitts the grant of an SPC for a substance that falls under the scope of a Markush claim when there was an individual disclosure in the patent specification. For cases in which an individualized disclosure is missing, the practice seems to be still in development. The case law dealt with this matter in a decision of 2017 concerning the active ingredient Darunavir.[585] Here the High Court considered that a product covered by a Markush claim is protected by the patent within the meaning of Art. 3(a) Reg. 469/2009 as long as it falls under the product claim of the basic patent and embodies the core inventive advance of said patent. The High Court did not consider as relevant whether or not the compound was individually disclosed in the basic patent. If this approach is taken, all products falling under the Markush claim are eligible for a certificate of protection under Art. 3(a) Reg. 469/2009.

Some NPOs stated that whether the *Medeva*-requirement is met is decided case by case.

582 *Ibid.,* Answer to Q18.
583 Presentations of Representatives of the French Patent Office, MPI Workshop, 21 March 2017.
584 Higher Regional Court of Vienna (OLG), Decision of 10 February 2016, Case 34 R 138/15m – *Nepafenac* – ÖBl 2017/13, 45.
585 *Sandoz Limited and G.D. Searle LLC* [2017] EWHC 987 (Pat).

(iii) National case law

In the case law of the national courts we identified three main lines of interpretation of *Medeva*:

- The first approach considers *Medeva* relevant only in the factual situation that the patent claims A and the SPC is requested for A-B. As a consequence, a product is protected when it is claimed as such by the patent. If the patent claims A-B, the SPC may be granted for a product consisting of two ingredients that fall respectively as species under A and B. If the patent claims only A and does not include any claim directed to A in combination with another active ingredient, the SPC can be granted only for A. If the patent includes a Markush formula and the SPC is requested for a product falling under this formula, the SPC can be granted, whether or not the compound is mentioned in the claim or in the specification. Such understanding has been followed by Italian, English and Spanish judgments. These courts have ruled that *Medeva* in no way mandate a specific disclosure of the product in order for the product to be protected by the patent.
- According to the second approach, it is not sufficient for the product to be claimed by the patent in order for the SPC application to comply with Art. 3(a) Reg. 469/2009. In cases of combination products it is not sufficient that the claim present features that read on all ingredients of which the combination consists. Something more is required. However, there is no clarity or consistency over the *quid pluris* that is required.[586]
- According to a third line of interpretation the core inventive advance must be based on Art. 3(a) Reg. 469/2009 and is applied as interpretation of said provision.[587]

(c) *Actavis requirement*

The core inventive advance is at the moment recognised as a part of the examination practice by the majority of the NPOs. Further, it has been applied by Italian,[588] German,[589] English[590], French[591] courts. However, the published case law is still too limited to allow a comprehensive analysis.

[586] The Dutch case law requires that the product be identifiable on the basis of the specification of the patent and the common general knowledge of those skilled in the art. In the judgment concerning Irbesartan, the Hague Court came to the conclusion that the combination was protected, even if Hzd was not mentioned either in the claim nor in the specification. The reason for that was that Hzd would have come immediately to mind to those skilled in the art on the basis of their common general knowledge and the specification of the patent. By this approach, an individualised disclosure is not necessary for the product to be protected. The German court seems to apply a stricter disclosure requirement. Whether, as in previous case law, it is necessary to have an individual disclosure that – if earlier – would anticipate that compound is still to be decided. The Budapest Court also seems to follow a stricter approach.

[587] For this position see *Teva UK Ltd & Ors v Gilead Sciences Inc* [2017] EWHC 13 (Pat).

[588] Court of Milan, Decision of 29 December 2012 - *Sanofi v EG*; Order of the Court of Milan of 22 December 2012 - *Sanofi v Teva*; Order of the Court of Milan of 22 December 2012 - *Sanofi v Mylan*; Order of the Court of Milan of 20 April 2013 - *Sanofi v Sandoz*; appeal order of the Court of Milan of 6 March 2013 - *Teva v Sanofi*; Court of Milan appeal PI order in *Mylan v Sanofi* of 29 December 2012 in *Doc Generici v Sanofi*.

[589] BPatG, *Telmisartan*, 3 Ni 5/13 [2014] GRUR 1073.

[590] *Teva UK Ltd & Ors v Merck Sharp & Dohme Corporation* [2017] EWHC 539 (Pat).

[591] High Court of Paris, Interim Proceedings Order, 5 Septemer 2017, available at http://thespcblog.blogspot.de/2017/09/tenofovir-high-court-decision-in-france.html (last accessed 13 November 2017).

In order to assess the practice of the NPOs, the MPI has included some questions in the MPI Questionnaire for the NPOs. The information collected suggests that there is some common understanding of the significance of the core inventive advance. This is true at least for the examination of combination products.

The MPI Questionnaire for the NPOs includes the following question:

> In the case of combination products we understand the "core inventive advance test" in the following terms: if the basic patent discloses and claims the compound Y, and this patent includes claims directed to a combination of Y with another compound X, the combination involving Y and X should be regarded as eligible for SPC protection only when the claim directed to such a combination is "independently valid" over the claim to the single active ingredient Y. Do you agree with this understanding?

In a footnote the MPI explained the meaning of "independently valid" in the following terms:

> Under the expression "independently valid" we understand that the combination of the active ingredient Y with another active ingredient is novel and inventive against a prior art (fictionally) including the single active ingredient Y.

Our understanding of the core-inventive-advance test is therefore such that the examination is similar to those practiced under US patent law with respect to non-statutory double patenting under the pre-ACTA Patent Act.[592] The question is whether a claim to a combination would be valid over a fictional prior art including the claim for the single ingredient (and the part of the patent application supporting such claim).

Almost all NPOs agrees with this understanding. The fact that almost all the NPOs agreed with this understanding does not imply that uniformity exists.

The second question (Q23) of the MPI Questionnaire for the NPOs was whether such approach would make a difference in the case of a claim to a single compound with respect to an infringement test and what the difference would be. Here the answers were divided. Some NPOs consider that in the case of a monotherapy product no difference exists between an infringement test and the technical advance test. However, the UK office observed in this regard:

> "In our view, the core inventive advance and the infringement test would not lead to identical outcomes for the following reasons:
> - The infringement test would not require that the compound covered by the Markush formula is disclosed or exemplified in the description – it would be sufficient that the compound of interest fell within the Markush formula.
> - The core inventive advance test would require an SPC examiner to assess the product protected by the claim(s) in light of the description, and make an assessment as to whether that product for which SPC protection is sought forms the core invention of the patent. It would involve a consideration of matters such as what was the problem or objective that the patent set out to solve, and how does the compound of interest answer that problem or objective, is the compound of interest listed as an example, is it listed as one that meets the functional definition given in the patent? In IPO Decision BL O/117/16 (see here) the SPC applicant provided evidence to explain what the state of the art was at the priority date of the application and why the invention in the application represented a new therapeutic approach, the Hearing Officer found that this was relevant to understanding that the

[592] See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re White*, 405 F.2d 904, 160 USPQ 417 (CCPA 1969); *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968); *In re Sarett*, 327 F.2d 1005, 140 USPQ 474 (CCPA 1964)804. See also for a possible similar understanding of *Actavis*, Mike Snodin, 'Three CJEU decisions that answer some questions but pose many more' [2014] 9(7) Journal of Intellectual Property Law & Practice 599.

> combination product X-Y and the mono-product Y both formed part of the core inventive advance."

Further, if we consider the decisions known to the MPI made by the Netherlands Patent Office and the UK IPO in which the inventive advance test was considered and applied, open questions and potential differences emerge.

(i) The practice of the Netherlands Patent Office: decision of 28 April 2017 on application No. 300689

In the decision of 28 April 2017 the Netherlands Patent Office (*Octrooicentrum Nederland*)[593] examined an appeal filed against the decision of the examiner to reject SPC application No. 300689. The application was directed to a combination of ezetimibe and atorvastatin based on an MA covering a fixed combination product including the two actives mentioned. Ezetimibe had already been the subject of a certificate granted to the same applicant on the basis of the same patent and an earlier MA. The examiner made the grant of a certificate dependent on whether the combination of ezetimibe with atorvastatin represented the subject matter or the core inventive advance of the invention or a separate innovation according to the judgements *Actavis I* (C 443/12) and *Actavis II* (C-577/13). In assessing this question, the examiner applied the inventive advance test as elaborated by Justice Arnold.

In the second instance the Patent Office confirmed this approach and established some criteria of general relevance for examining combinations.

For the Netherlands Patent Office the question to be answered in the case of a combination is whether or not it was obvious to the person skilled in the art to combine the mono-product at issue – ezetimibe – with the other substance(s) of the combination for which the certificate is requested. This examination is based on establishing a "fictional prior art", that is a prior art that includes not only the prior art quotable under Art. 54(2) and (3) EPC against the basic patent, but also a member of the class of compounds disclosed by the basic patent that is a component of the combination for which the certificate is requested.

In answering the question whether the combination is inventive *vis-à-vis* the active ingredient that is already the subject of a certificate, the NPO considered applicable the 'problem solution approach'. This is the method for examining the inventive step developed by the EPO and adopted by several continental jurisdictions, including the Dutch courts.[594] If this approach is taken, case law concerning plausibility, admissibility and relevance of post-published evidence, secondary indicia for inventive step, developed with respect to patents, would apply to SPCs.[595]

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593 See Decision of the Octrooicentrum Nederland on SPC application No 300689 OCNL with reference ORE/300689/L073 upholding the decision to reject certificate application No. 300689. We are thankful to Mr. K.A.J. Bisschop for providing us at our request an unofficial translation of the decision and of the appeal filed, both available in the original language on the website of the Dutch NPO.

594 For the Netherlands, see AIPPI Netherlands, *The Patentability Criterion of Inventive Step/Non-Obviousness*, Resolution Question Q217 (May 26, 2011) at 12 with references to the case law.

595 In accordance with this premise, the Netherlands Patent Office resorts to the case law concerning patents also for the question whether and to what extent the applicant can rely on evidence not mentioned in the patent application as filed to support the inventive nature of the combination. This shall be possible only when statements about efficacy or advantages were already included in the application as filed, and such statements were plausible.

The approach of the Netherlands Patent Office seems to be in line with the following statements of Justice Arnold concerning the validity of an SPC granted by the UK IPO for "a combination of efavirenz, emtricitabine or a pharmaceutically acceptable salt or ester thereof, and tenofovir or a pharmaceutically acceptable prodrug, salt or ester thereof, particularly tenofovir disoproxil, especially tenofovir disoproxil fumarate"[596]:

> "170. Counsel for the Claimants submitted that it should be assumed for this purpose that the skilled person had efavirenz and its activity against HIV reverse transcriptase disclosed to them at the priority date. Although counsel for MSD took issue with this, I consider that it is correct. The question to be considered is not the conventional one of whether a claim is invalid over a particular item of prior art read in the light of the common general knowledge, but whether, given the invention of efavirenz, claim 16 represents a distinct invention such that it could in principle form the subject-matter of a separate patent.
> 171. Considered in that way, I consider that claim 16 is not independently valid over the claims which protect efavirenz and does not represent a distinct invention. There is nothing in the Patent to suggest that claim 16 represents a distinct invention. Given the need for a simple and transparent system for the grant of SPCs, it seems to me that that should ordinarily be the end of the matter and that it should not be necessary to adduce expert evidence on this question."[597]

(ii) The practice of the UK IPO: decision BL 0/117/16 of 12 January 2016

In deciding over the UK parallel application for a certificate[598] for ezetimibe and atorvastatin based on EP 599[599], the Hearing Officer, Dr. Lawrence Cullen, considered extensively the case law of the CJEU, and in particular *Actavis I* and *Actavis II*, and inferred from both judgements – correctly in our view – that in principle a patent can be the basis for a certificate covering a single active ingredient as well as a combination including that active under that case law. Both products within the meaning of Art. 1 (b) can represent the subject matter or the core inventive advance of that patent. This opinion does not diverge from the interpretation of the CJEU case law followed by the Netherlands Patent Office.

In assessing whether the combination was eligible for protection, the Hearing Officer considered relevant the question whether or not the combination of an azetidinone (such as ezetimibe) and a statin (such as atorvastatin) was novel and inventive at the priority date of the patent, and whether the patent offered a basis for considering the use of the compound included in the monoproduct with a certain other ingredient as part of the inventive contribution of the patent. The UK IPO in this assessment also relied on post-published evidence produced by the applicant and aimed at showing that the combination provided an equivalent therapeutic result to ezetimibe but with lesser side effects. The following considerations referring to the combination of ezetimibe (the subject of a previous certificate) and statin seem to be significant in this regard:

> "124 I find the test in Boehringer is not substantively different from that in Sanofi, the subject matter of the invention is a different way of stating the core inventive advance, the test in Boehringer is merely developed from Sanofi with the benefit of clarifying what may constitute a product "as such". I find support that the CJEU intended the tests to have the same meaning from the fact that in Boehringer paragraph 37 (see above), it refers directly to para 30 of Sanofi. I consider that Boehringer advances the situation from Sanofi to require that the product which is the subject of the SPC application is 'protected as such'.
> 125 To determine if the combination is protected as such by the basic patent, I will turn to what was known at the time of the priority date of the basic patent in the art of drug

596 SPC/GB08/022.
597 Teva v MSD [2017] EWHC 539.
598 SPC/GB14/062.
599 See O/117/16, decision of 12 January 2016.

> combinations to treat hypercholesterolaemia, and what the patent teaches. I have been addressed on this in a witness statement by Professor Gerd Assman which (in his own words) "addresses the treatment of coronary heart disease with lipid lowering agents in the early 1990's in addition to the relative efficacy and clinical benefits of ezetimibe monotherapies and ezetimibe/statin combination therapies." He points out that "To achieve the desirable low target values of LDL cholesterol not infrequently requires the highest approved dose of a statin at which unwanted side effects are more common." At the priority date, the existing combinations (as indicated in paragraph [0008] of the basic patent were limited to treating patients with severe hypercholesterolemia for whom nothing else worked, they suffered from the combined side effects and contraindications of each of the individual drugs in the combination and there was no suggestion that the combination of the present SPC (i.e., an azetidinone – ezetimibe – and a statin – atorvastatin) would be useful. At the priority date of the combination (which I have checked is 9 June 1994), Professor Assman did not find the combination of the SPC application was known and found that the combination represented a significant technical advance "The introduction of ezetimibe in combination with statins was a notable further improvement to the known available treatments of [sic] therapies. Particularly where (i) the ezetimibe plus statin combination therapy contained a statin in a low dosage (producing comparable cholesterol lowering but with reduced side effects); or (ii) the combination therapy contained a statin in an equivalent dosage to monotherapy and achieved greater cholesterol lowering and fewer cardiovascular events. Although combination therapy is something that had been desired to achieve maximum lowering of LDL cholesterol, it was not possible before the advent of ezetimibe" (see para 42 of witness statement)."

Two points are relevant for our analysis. First, in the specific case, the Hearing Officer did not address the question whether the combination of ezetimibe and atorvastatin was inventive *vis-à-vis* a fictional prior art including ezetimibe. Further, he did not refer expressly to an inventive-step analysis, for instance to the *Windsurfing* approach, which is the British equivalent to the problem-solution approach.

Second, the UK did not refer to the criteria governing the conditions under which post-filed evidence can be considered in assessing the inventive step of a patent. This could suggest that the approach to examining the technical advance would be SPC-specific, and not be based on an automatic transposition of the principles governing the examination of patents.

10.2.3.4 Assessment of the CJEU case law: critical issues

The next sections sum up the critical issues in our view of the CJEU case law with respect to Art. 3(a) Reg. 469/2009.

(a) *Medeva-requirement*

We are of the opinion that the CJEU has failed so far in delivering a clear test for applying Art. 3 (a) Reg. 469/2009. We identify two reasons why this is the case.

Firstly, the Court has ruled out that the mere fact that a product falls under the scope of the patent can be sufficient in order for the product to be protected within the meaning of Art. 3(a). It has required that the product be specified in the wording of the claim. In *Eli Lilly* the Court maintained that it is not necessary for the claim to mention the product by its name or chemical structure in order to satisfy Art. 3(a) Reg. 469/2009. However, it has differentiated between products to which the claims relate, implicitly but necessarily and specifically, and products to which the claims do relate necessarily and specifically. Whether a product falls under the first or second group must be assessed on the basis of national patent law. This law consists of the provisions that govern the extent of protection of the patent (that is: Art. 69 EPC and corresponding provisions of national law).

Now, the fundamental problem with this approach is that on the basis of the law governing the basic patent one can discern the following distinctions:

- Products that fall under the scope of the patent versus products that do not fall under the scope of the patent;
- Products that fall under the scope of the patent and are individually disclosed so that the patent could be limited specifically to them without violating Art. 123(2) EPC versus products that fall under the scope of the patent but are not individually disclosed in that patent, so that the patent cannot be limited to them without infringing Art. 123(2) EPC;
- Products that fall under the literal scope of the patent *versus* products that fall under the scope of the patent only because of the equivalence doctrine.[600]

The distinction between a product that is specified in the wording of the claims and a product that is not specified in the wording of the claims can be based on the law governing the basic patent only if one of the former concepts is intended. If something else is meant, the law governing the basic patent cannot be invoked as a basis for this distinction.

The second problem of the case law is that the CJEU, according to our understanding, has not explained the purpose of the *Medeva*-requirement. A number of goals come to mind:

- Ensuring that the SPC is granted only for a product that falls under the scope of the basic patent, that is that the scope of the certificate does not go beyond the scope of the basic patent;
- Ensuring that the question whether the product for which the certificate is requested is protected by the basic patent is uniformly answered on the basis of European criteria and not criteria derived from national patent law, since the latter is not harmonised by union law and is not subject to the jurisdiction of the CJEU;
- Ensuring that the SPC is granted only for the specific product claimed by the patent and not any other combination including such product, unless the latter is claimed as such by the patent, in order to limit the grant of multiple SPCs covering the same product (alone or in combination with other products).
- Ensuring that the SPC is granted only for a product that has been developed and disclosed by the patentee at the priority date.

In the conclusions of the Advocate General and in the reasoning of the judgments of the CJEU one could find arguments for one or all of these purposes, but not a clear indication of the true purpose.

(b) *Actavis requirement*

The requirement that the product must represent the core inventive advance of the patent and that a combination including that product must represent a separate

[600] Protocol on the Interpretation of Article 69 EPC of 5 October 1973 as revised by the Act revising the EPC of 29 November 2000. According to Art. 2 "for the purpose of determining the extent of protection conferred by a European patent, due account shall be taken of any element which is equivalent to an element specified in the claims". The Protocol indeed distinguishes between elements "specified" in the claim and an element not specified in the claim, but equivalent to an element specified in the claim. It is the only source of law that adopts a terminology that is somewhat close to *Medeva*.

innovation in order to be eligible for protection poses several challenges. It is clear in its function, but many issues surround its concrete operation:

- It is unclear whether this requirement is based on Art. 3(c) or Art. 3(a) Reg. 469/2009. This has practical implications. On the one hand, Art. 3(c) can be easily circumvented.[601] On the other hand, if the time for obtaining the first MA for the monotherapy product or the combination covered by the patent is less than 5 year since the patent filing, and the patentee decides to request the SPC directly for a follow-up combination on the basis of a later MA, Art. 3(c) is not applicable, because no previous certificate has been granted.
- It is unclear what the criteria are for deciding whether or not a separate innovation exists, whether this test shall consist in an inventive step-like analysis on the basis of a fictional prior art or another test(s) shall be applied. In accordance with a specific understanding of Recital 14 Reg. 1610/96 one could consider the existence of a patent necessary and sufficient. But the existence of a separate patent does not imply that the product for which the SPC is requested is a separate innovation,[602] and the absence of such patent does not imply the opposite.
- It is unclear whether by answering the question of the core inventive advance or of the existence of a separate innovation only the patent specification is to be considered or further, possibly post-published evidence shall be admitted.
- It is unclear whether this test is relevant only for combination products.

10.2.3.5 The options

(a) *Introduction*

The case law of the CJEU has for the moment failed to deliver clear criteria for applying Art. 3(a) Reg. 469/2009. *Medeva* is unclear in its content and in its function. *Actavis* is clear in its function, but it is unclear in its legal basis, scope and operation. This section will review the possible approaches that the EU legislature could adopt with respect to these issues.

(b) *Reasons against and for an amendment of the SPC Regulations*

A possible first approach for EU lawmakers would be of course to leave the law as it stands. One could find several arguments for such a conservative approach.

First, the European case law has evolved and developed over the last 20 years. This development was made possible by a dialogue with the national courts and by an analysis of concrete cases. It may be true that the "specified in the claim" test is still unclear. But it may be expected that with further references such case law could evolve further and mature. If the law maker changed the requirements under Art. 3(a) Reg. 469/2009 and Art. 3(a) Reg. 1610/96, this case law would be lost. Further, the amendments of the provision could create reasons for new interpretative issues.

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601 Chapter 12, Section 12.1.3.

602 The patent claiming the combination could be based on a divisional application that shares the same priority of the patent application filed for the single active ingredient. It could be based on a patent application filed within the deadline of 18 months from the filing date of the first patent application for the single active ingredient. In both cases, the combination could be obvious vis-à-vis the single active ingredient, but still inventive, since the latter would not be quotable prior art.

Second, even if the expressions "*specified in the claims*" or "*identified in the claims*" were not clear, many of the stakeholders consulted are of the opinion that in most of the cases patent holders, examiners and competitors may easily assess whether or not a specific product is eligible for protection under Art. 3(a) Reg. 469/2009. There are relatively few situations where the lack of clarity in the CJEU test results in a corresponding lack of certainty on how to assess a specific SPC application. Published judgments or orders deal mostly with borderline cases, pathological situations. These borderline cases are not the rule, but the exception. They are limited to combination products or purely functionally drafted patent claim for class of biological products.

Third, the UPCA will have a significant impact on the SPC system.[603] A single unified court, indeed, will decide in Europe on the validity and infringement of SPCs granted by national offices. The UPC will be in a position to develop a uniform approach in interpreting SPC Regulations and implementing the CJEU case law. Such a uniform approach will influence the practice of the NPOs and of the national courts. This will reduce the occasions for references to the CJEU. So the clarification und unification of the practice that would be the intended goal of amending the law could more easily result from the UPCA entering into force and the UPC becoming operational.

Lastly, a change of Art. 3(a) Reg. 469/2009 could result in additional practical problems. For instance, the amendment would raise issues of intertemporal law and make transitional rules necessary.

However, one can also find reasons for a legislative action.

First, the requirements laid down in Art. 3 Reg. 469/2009 are interrelated with each other. A strict interpretation of Art. 3 Reg. 469/2009 could lead to severe results if not compensated by a more generous handling of Art. 3(b) Reg. 469/2009. In turn, a generous interpretation of Art. 3(a) Reg. 469/2009 could lead to problematic results if the use of third-party authorisation were allowed without any limitation. By contrast, a patent-holder-friendly interpretation of Art. 3(a) Reg. 469/2009 could hardly be balanced by a broad understanding of the concept of product for the purposes of Art. 3(c) Reg. 469/2009. The latter provision can be easily circumvented.[604] Again, the whole system of SPCs should be viewed in the broader context of incentives for pharmaceutical innovation (data exclusivity, trade secret protection). The case law has only few occasions to offer a review of the different requirements and to draw a balance of them in a structured and rational way. It is concerned with the concrete case and a concrete provision.

Second, the different interpretations advocated in the literature or case law imply different policy choices. So it would be justified to leave it to the lawmakers to make this choice. One could reasonably argue that it is up to the lawmakers, and not the courts, to decide whether patents granted for the immediate results of basic research may be also the basis of a supplementary period of protection. Lawmakers, and not the courts, should decide whether second medical indication or new formulation should benefit from SPC protection, and likewise on whether and to what extent to allow the use of third-party authorisation. In other jurisdictions these decisions, indeed, were taken by the parliaments and not by the judges.

603 See Chapter 20, Section 20.1 et seq.

604 For instance, by filing several applications and transferring some of them before grant or by transferring the right to the patent before filing an application or by transferring only the priority right to an independent entity. See Chapter 12, Section 12.1.3.

An intermediate approach between the two discussed above could consist in leaving the law as it stands, but supplementing it with soft-law provisions, such as for instance a notice for the interpretation of the substantive provisions of the Regulations. The notice could include guidelines for the application of Art. 3 Reg. 469/2009. Such guidelines would not bind the courts and NPOs. A problem for this approach would be the fact that such guidelines would require that the drafters of the guidelines and the NPOs agree on how to understand and implement the case law of the CJEU. By contrast, if an amendment of the law were to be adopted, then such soft law of the European Commission could be more easily agreed upon with the participation of the NPOs. The guidelines would relate formally to a new provision for which no CJEU ruling would be binding.

(c) *The options for amending Art. 3(a) Reg. 469/2009 and soft law instruments*

The next section identifies three options for possible amendments to Art. 3(a) Reg. 469/2009. These three options have one element in common: they are all based on notions taken from European and national patent law. As a consequence, the discrimination between products eligible and products not eligible for SPC protection can be based on criteria that have their basis in concepts and notions that are not alien to patent law.

(i) Infringement test

The first option for lawmakers would be to adopt what – for the sake of simplicity and at the cost of accuracy – we may call an infringement test. Under this option, the product is protected by the basic patent if it falls under the scope of protection of said patent pursuant to Art. 69 EPC and corresponding domestic provisions. The implications of such an approach become obvious if we consider the following examples:

- If the basic patent describes and claims a genetic sequence coding for a polypeptide that the patent application identifies as a receptor, and includes also a claim for all agonists that may bind on the receptor in question, under the infringement test such agonists will be protected by the basic patent for the purposes of Art. 3 Reg. 469/2009.
- If the basic patent includes a Markush claim for a class of compounds, each of the compounds claimed will be eligible for SPC under Art. 3(a) Reg. 469/2009.
- If the basic patent includes a claim for compound A and a claim for any therapeutic composition comprising the compound A together with another active ingredient, it will be possible to get an SPC for A-B, even if B is neither claimed nor mentioned in the patent.

Such approach is therefore relatively generous towards the patent holder. The latter could get an SPC for products that are not individually disclosed in the patent. It is an approach that allows entities involved in basic research – for instance, research or university institutions that disclose for the first time a new class of receptors – to get SPCs even for agonists whose identification at the priority date of the patent would have required further research efforts and even lead to patentable inventions.

The infringement test has two significant advantages. It is clear, and it is likely the test suggested by the wording of Art. 3(a) Reg. 469/2009.

Three objections against its adoption are also conceivable, however.

The first one is that only at first glance is it simple for the NPOs to handle such a test. In reality the test could cause difficulties for the examiners. The question whether a product falls under the scope of protection is not a question that the NPOs have to examine daily in their granting practice.[605]

Second, the provision could display some deterring effects on subsequent research. The overcompensation of the applicant for a new class of receptors could result in an undercompensation of the subsequent applicants that would obtain a patent for the agonist that could not be exploited without infringing the older patent. Indeed, if these competitors obtain MAs for subject matter that falls under the scope of the mentioned broad functional claim, they would also allow the holder of the dominant patent to prolong the protection and obtain an SPC.

Third, the provision could favour an "evergreening" strategy. A company could indeed apply for and receive several MAs for compound A, then the combination A-B, then A-B-C. Of course, the SPC granted for A-B would not prevent the competitor from marketing A, and the SPC granted for A-B-C would not prevent the competitor from marketing A-B. Delays in generic competition are not the mere result of secondary patents or secondary SPCs.

Now all these arguments may have some political and logical weight. Each of them is, however, open to counterarguments.

First, it is true that the NPOs do not examine whether a specific product falls under the scope of protection of a patent claim. However, they have to apply Art. 69 EPC or corresponding provisions of the national patent law for other purposes. They have to interpret a claim, and sometimes they have to determine the scope of a specific patent claim.[606] In any event the lawmaker could provide that for the purposes of Art. 3(a) Reg. 469/2009 only such products shall be considered as protected that fall under the literal scope of the patent pursuant to Art. 69 EPC. In assessing this the NPOs may not take account of equivalents to the elements specified in the patent claim. This would simplify the task of the NPOs.

The second criticism carries weight. But the assessment would be different if lawmakers in facilitating the grant of SPCs under Art. 3(a) Reg. 469/2009 were to prevent unjustified dependencies. It is also possible to adopt the infringement test and at the same time prohibit the use of a third-party MA. The connection between the requirements under Art. 3(a) Reg. 469/2009 and the question of third-party MAs has been pointed out by a patent office that in answer to Q23 of the MPI Questionnaire for the NPOs in the context of the option of adopting an infringement test observed:

> "the number of patents which would qualify as a basic patent for an SPC would be significantly higher, including also patents which did not or only marginally contribute to the development of a

[605] MPI Workshop of 21 March, observation of the representative of an NPO.

[606] This is the case, for instance, when the patent is amended during an opposition procedure. In this case it will be necessary to determine whether the scope of protection is extended or not. But this is so in general when assessing the admissibility of a claim. Indeed the claim must first be interpreted. And such interpretation occurs on the basis of Art. 69 EPC. Furthermore, some offices in assessing novelty applied a so called "reverse" or "post-infringement" test. This test is not adopted by the EPO, and with good reason. But it shows that the determination of the scope of the claims is not a task completely foreign to the examining offices as it is not foreign to the tasks of the judge who assesses the validity of a claim.

> specific medicinal product (e.g. general formulation patents, general screening or modification methods, extension of principal claim scope by using "comprising" etc.). Nevertheless, this option together with the compulsory requirement that the patent owner himself has to obtain an MA for a medical product protected by the basic patent in the sense of b would be most favourable."

As for the question of evergreening, it is accurate that a simple infringement test would allow the patentee to obtain several SPCs for a combination including the products. Whether this strategy can lead to a delay of generic competition is unclear. Art. 3(c) Reg. 469/2009 could in this case limit the number of multiple patents covering the same products.[607] It is true, however, that as the law stands Art. 3(c) Reg. 469/2009 can be circumvented in several ways. However, one could provide that an SPC granted for a combination including a product that has already been the subject of an SPC granted on the basis of the same patent shall have the same expiration date as the SPC granted for the single active ingredient. Only by adopting something similar to a terminal disclaimer the applicant could get further SPCs.

(ii) Art. 123(2) EPC standard-disclosure test

The second option for lawmakers would be to adopt a disclosure test. Two clarifications are necessary.

This test would not be an alternative, but an additional requirement to the principle that the product must be covered by the basic patent. The product must first fall under the scope of protection of the patent in order for it to be SPC-eligible.

Second, the disclosure standard referred to here is the standard that applies to Art. 54 EPC, Art. 123 EPC and Art. 87 EPC, and not Art. 83 EPC.[608] If one indeed applied a standard consistent with Art. 83 EPC, this approach would hardly differ from an infringement test. In accordance with these premises, Art. 3(a) could be redrafted in the following terms:

> The product is protected by a basic patent in force when:
> It falls under the extent of protection of the basic patent pursuant to applicable provisions of the EPC and national patent acts and is, be it explicitly or implicitly, directly and unambiguously disclosed to the skilled person in said basic patent and in the patent application as filed.

The Enlarged Board of Appeal of the EPO has emphasised that "the European Patent System must be consistent and the concept of disclosure must be the same for the purposes of Articles 54, 87 and 123 EPC".[609] This option would extend the uniform concept of disclosure to the question whether the SPC may or may not be granted for a product claimed by the patent. If the patentee could not limit the patent to a product without violating Art. 123 EPC, then it would be equally prevented from getting an SPC.

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607 According to the antitrust literature, secondary patents and secondary SPCs are not as such able to delay competition, but are instruments that, if combined with other elements, can lead to such a result. These other instruments are the withdrawal of the original version of the brand product, even the withdrawal of the MA, and the introduction of a new version of the drug covered by a more recent patent or SPC, forced switches of the patient to the new versions. In this perspective, the existence of an SPC for the combination is an instrument of the strategy. By preventing the grant of such SPC, one could argue that the Regulation would also prevent such strategic uses of these secondary SPCs. At the same time, limitations of the SPC eligibility as a limitation of patentability may have an ambivalent effect on competition. Though they may improve generic competition, they can have a deterring effect on the competition among originators. Indeed the so-called secondary patents are very often obtained by different companies than the holders of the original patent for the compound.

608 See on this standard of disclosure Chapter 5, Section 5.6 of this Study.

609 EPO, Case G 0002/10 *Disclaimer/SCRIPPS* [2011] ECLI:EP:BA:2011:G000210.20110830.

A recital or a notice could clarify that the standard in question is the same as the one that applies to Art. 123 EPC. Of course, this would not imply that the case law of the EPO is binding.

Such an option has two advantages in our view. First, it introduces a standard that already applies to several institutions and provisions of the patent system (Art. 54 EPC; Art. 87 EPC, Art. 123(2)). To all patent lawyers, such standard is familiar and understandable.

Second, such standard is consistent with a view of the SPC as a limitation of the patent to a specific product. If the patentee intended to include a claim directed to the specific compound in the patent application or in the granted patent, it would need an individual disclosure of such compound. This standard ensures that the same criterion applies to the product definition of the SPC.

Third the criterion ensures that the SPC is granted only for a compound that the patent application has disclosed, so that it would be justified to allow an extension of the patent protection even if the MA has been finally obtained by an unrelated entity.

Such criterion may also have some shortcomings. According to the reactions of the NPOs to our Question 23a (MPI Questionnaire for the NPOs) this test would be very strict and reduce the number of SPCs. Thus the comment of one NPO reads as follows:

> "The test *per se* would be clear, since it is used for a long time by the EPO and patent practitioners. It might be a proper test for "small molecules", but it is likely that this standard would lead to a markedly reduced number of SPC grants. In particular, if a basic patent contains broad claims (e.g. Markush-formulae or broad functional claims in the field of biotechnology), it may be difficult or sometimes impossible for a patent proprietor to either limit a patent (for Art. 123(2) EPC reasons) or to obtain a more specific follow-up patent (for Art. 56 EPC inventive step reasons). So even if a patentee obtained an MA based on his (broadly) patented research, he might be unable to get an SPC. Furthermore this test does not seem to solve the problem as to how specific a biological molecule (e.g. an antibody) has to be described in a patent to be protected for the purposes of Art. 3(a) of Reg. 469/2009/EC. Must the full primary sequence be provided in the basic patent?"

The comments of another NPO on our Question 23 are in line with the previous ones:

> "This would apply more certainty and leans in the right direction but the term "disclosed" has a very narrow meaning in patent law jurisprudence. A true disclosure test would be extremely strict, because it would rule out both generic functional descriptions as well as Markush claims. This would put an enormous burden on the industry and could possibly result in very long patent applications which list each and every possible embodiment. It may also result in not applying for the patent until the specific compound is found, which is not good for the early dissemination of information (one of the prime purposes of patents).
> But this problem can simply be avoided by using the words "identifiable by" instead of "disclosed to". Such wording would be fully in line with the current practice of our office (see answer under 19):
> The average skilled person, taking into account the description and his common general knowledge at the priority date of the patent, should be able to identify the product."

We found these considerations well thought out. However, patent law does not prevent the innovator from getting a further patent for subject matter that already falls under the scope of a granted and valid patent claim. A claim for the genus does not prevent a patent for a species. The disclosure content of a prior patent is not coextensive with its scope of protection. Patents for selection inventions could be a sufficient incentive for the patentee, and they could then be selected as the basic patent for the purpose of an SPC procedure.

Another shortcoming mentioned by the stakeholders is that this criterion is new and would not find a basis in the case law of the CJEU. However, one could argue that a claim can relate "necessarily and specifically to the product" as required in *Eli Lilly* only when such compound is disclosed in the patent specification. The reasons of the judgment do not leave such reading entirely without support. However, it would be over-reading the decision to assume that such standard was endorsed by the CJEU.

(iii) Core-inventive-advance test

The third possible approach is to require that the product embodies the inventive advance of the basic patent. The core-inventive-advance test is already a part of the system. *Actavis I* based this test on Art. 3(c) Reg. 469/2009. If such a standard is based on Art. 3(a) Reg. 469/2009, for all applications the examiner must check whether or not the product definition relates to the core inventive advance of the basic patent.

There are two shortcomings with the core-inventive-advance test. First, it would oblige the patent offices to deal with an inventive-step or anyway a technical analysis. This is likely in conflict with the intention of the historical lawmakers to design a simple system for granting SPCs.[610] Second, there is little guidance in the case law on how to apply the test to patents granted for formulations, uses or any other subject matter that does not consist in a combination product, in the use of a combination product or in a process for obtaining a combination product.

Furthermore, it has been argued that one does not need an advance test to limit the number of certificates for combinations including the same active ingredient.[611] *Medeva* requires indeed that the product be specified in the wording of the claims of the patent. This requirement limits the options for a patentee for obtaining a certificate for the active ingredient that is the subject matter of the invention "in conjunction with an unlimited number of other active ingredients".[612] However, if the patentee has included in the patent application as filed a list of known substances (for instance, a standard list of known diuretics) that can be in principle combined with the single active ingredient that represents the subject matter of the patent, we believe that the requirements formulated by the CJEU in *Medeva* and *Eli Lilly* would be satisfied, and the applicant could obtain an SPC for each combination disclosed by the patent.[613]

10.2.3.6 The opinions of the stakeholders and of the NPOs

(a) *NPOs*

The MPI addressed several questions to the patent offices with respect to Art. 3(a). The first one was whether the *Medeva*-requirement is a clear test to apply:

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610 European Commission, Explanatory Memorandum to the Proposal for a Council Regulation (EEC), of 11 April 1990, concerning the creation of a supplementary protection certificate for medicinal products (COM(90) 101 final – SYN255), para. 16.

611 Tony Rollins et al, `From Takeda to Teva v Merck: Are we treading the right path on combination product SPCs? (Part 2)´ [2017] EIPR 697, 703.

612 *Ibid.*

613 If the combination(s) was individually disclosed in the patent application as filed, the patentee can also limit a generic claim (A + a diuretics) to that combination(s) under Art. 123(2) EPC.

> According to the CJEU, a product is protected by the basic patent within the meaning of Art. 3(a) Reg. 469/2009/EC when it is specified in the wording of the claims of the basic patents (see for instance decision C-6/11). Does this case law provide a clear test in your view?[614]

The question is of course the result of an oversimplification, because a test may be unclear in its meaning, but still allow an easy decision in the majority of cases, or it may be clear in the sense of when and how to apply it, but still not allow a straightforward decision in several cases. One example of the latter is the problem-solution approach in examining Art. 56 EPC: the way to proceed with the examination is clear and established in our view; however, in several cases one could not predict whether the invention will be found obvious or not.

Despite the epistemic limitations of our question, the answers of the NPOs showed a tendency. Four of the 24 NPOs that participated in the MPI Questionnaire for the NPOs found the *Medeva* test to be a clear test, and one NPO did not answer the question. A NPO answered that the test was clear in most of the cases but with some limitations; another NPO answered the question with "not in all cases", which actually indicates that the examiners of this NPO also found the test in principle sufficient to decide about most of the applications. However, 17 NPOs did not find this test as clear. Some NPOs also provided brief comments:[615]

> "CJEU´s decisions C-6/11 + C630/10 + C-493/12 clarify the mentioned issue in most cases, but there are some limitations. Many of [the] products are not chemical individuals describable by [a] chemical formula and therefore there may be doubts about identity of the product mentioned in the MA with respect to the Article 3 (a) and S (b) Reg. 460/2009/EC."

> "No, as there would be constantly a dispute about the question if "specified in the wording" also includes "implicitly"."

> "Starting with C-322/10 Medeva, the CJEU has used several different wordings ("specified in the wording of the claims", "identified in the wording of the claims", "protected as such", "sole subject-matter of the invention", "the claims relate, implicitly but necessarily and specifically, to the active ingredient", "core inventive advance" etc.) without indicating clearly which criteria have to be fulfilled for a product to be protected by a basic patent in the sense of Art. 3(a) of Reg. 469/2009/EC.
> Despite numerous referrals asking for such criteria, no clarity has been achieved as yet."

> "Not without interpretation and further development into patent law compliant terminology."

> "This definition of the product "protected" by the basic patent, brought by the CJEU case law was of the utmost importance and enabled it to remove considerable legal uncertainty, while at the same time excluding the "infringement test", which was at odds with the objectives of the SPC system.
> But it does not allow to resolve all cases, and is not enough when the product is not the core inventive of the patent, or when it is covered by a functional formula."

> "Maybe not, as a further definition of specified is not provided. Does specified mean chemical name, structure, functional term etc.?"

> "The decision CJEU C-6/11 does not seem to be clear or reliably applicable as such, because, as we understand Art. 3 (a), it is necessary but also sufficient that the product is covered by its structural or functional characteristics defined in patent claims, and not to be qualified by any new conditions (like "identified in the wording")."

> "It is not sufficiently clear. The wording 'specified' or 'identified' leaves open the question to what extent exactly the product needs to be incorporated in the claims."

> "No, since the meaning of the word "specified" may be interpreted quite narrowly but, on the other hand, also quite broadly. The term "specified" is vague in this regard. Moreover, this approach has been applied by the CJEU in case of combination products. This test would not be appropriate in case of products comprised of only a single active ingredient (patent claims are not drafted so as to explicitly list or identify every single compound (element) which they are intended to cover, they rather define the scope (limits) of the protected subject matter."

[614] Q16 of the MPI Questionnaire for the NPOs, Annex VI of this Study.
[615] The given citations are in anonymous form since they do not relate to the implementation of the CJEU case law, but to an evaluation of this case law.

"No because it can also be provided by a functional definition (more usual in the biotech products)."

"We do not consider that this is a clear test in our view. The CJEU decisions in Medeva (C-322/10), Georgetown (C-422/10), Daiichi-Sankyo (C-6/11), Queensland (C-630/10) and Yeda (C518/10) in which the CJEU developed and confirmed that the test for Art 3(a) is that the active ingredient must be "identified" or "specified" in the wording of the claims, did not provide any general indication of how this test or requirement could be applied to such claims.

This prompted further referrals seeking legal clarity on what was meant by these terms, including Eli Lilly (C-493/12). When this case returned to the national courts (Eli Lilly v Human Genome Sciences, [2014] EWHC 2404 (Pat)), the judge commented on the lack of general guidance from the CJEU on how the limit "specified" and "identified" in the claims should be assessed (in this case in relation to a functional description and functional definition) – as to how to assess the limit of "specified in the wording of the claims" or "identified in the wording of the claims". In this case, the claims of the patent related to a functional description/functional definition of the invention. The need for further referrals results in legal uncertainty for an extended period.

It should be noted, however, that in Eli Lilly, the CJEU did at least provide some general guidance on how to work out if the functionalised formula in the patent claims provided a sufficient basis to meet the requirement of Art 3(a) of the SPC Regulation (see paras. 34-40 and 45 of the CJEU judgment) – in so far as it is able given that the EPC is not an EU legislative provision falling within the competence of the Court. This is important because such functional definitions are often found in patent claims in the life science and pharma field which serve as the basic patent for SPC applications.

A question that is generating wide discussion in the (…) office in relation to Markush formulae is whether all variations encompassed by a Markush formula can be considered to be "specified" or "identified" in the wording of the claim, or whether it is restricted to hose structures which are that are named or exemplified in the description. This is relevant to the situation where the MA relates to a medicinal product which includes an active ingredient that falls within the scope of the Markush formula but is not named as an example in the patent. (…).

We would also draw to your attention that case C-121/17 Teva v Gilead has very recently been referred to the CJEU, once again asking the Court to clarify what is meant by Article 3(a) of the SPC Regulation. This underlines the current lack of clarity and legal certainty in relation to this provision."

The second question (Q23) posed by the MPI regards the three possible amendments of Art. 3 considered above. In this respect, the majority of NPOs are of the opinion that an infringement test would provide clearer results than the *Medeva*-requirement. Nevertheless, the majority of the NPOs rejected this option. Among the reasons for this attitude was the argument that an infringement test would create a huge burden on NPOs. Some NPOs consider themselves ill-equipped to determine the scope of the patent. This is a task for the judges dealing with infringement.

The NPOs that expressed a preference among the three options considered by the MPI were equally divided between a disclosure test and a core-inventive-advance test.

Regarding the core-inventive-advance test some NPOs make the point that it is not consistent with the original purpose of designing a simple system for granting SPCs. One NPO has argued that the test would require detailed guidance for its application in order to ensure uniformity.

Some NPOs have also pointed out that this test would be suitable for combinations, but not for monotherapy products. One NPO pointed out that the best solution could be to apply both the disclosure test and the core-inventive-advance test.

With respect to the disclosure test some offices observed that such a standard would significantly reduce the number of SPCs. The standard of Art. 123(2) EPC is very strict and could even require information relating to the amino acid sequence in the case of antibodies. The majority of the NPOs recognise that an Art. 123(2) EPC-like disclosure test would be clear. One NPO argues however that incorporating language that reproduces not Art. 123 EPC but the interpretation of this provision adopted by the

Enlarged Board of Appeal could lead to problems if the EPO case law changes or if the CJEU adopts an understanding of this formula that diverges from the understanding of the EPO.

In general, the majority of the NPOs agree that the *Medeva*-requirement is not clear. However, there is no evident preference for any of the options mentioned in our analysis.

(b) *Stakeholders: survey and interviews*

A significant portion of the stakeholders does not consider a change of Art. 3(a) as necessary or opportune. However, a slight majority of 51 per cent would welcome a change according to the responses on Q48:

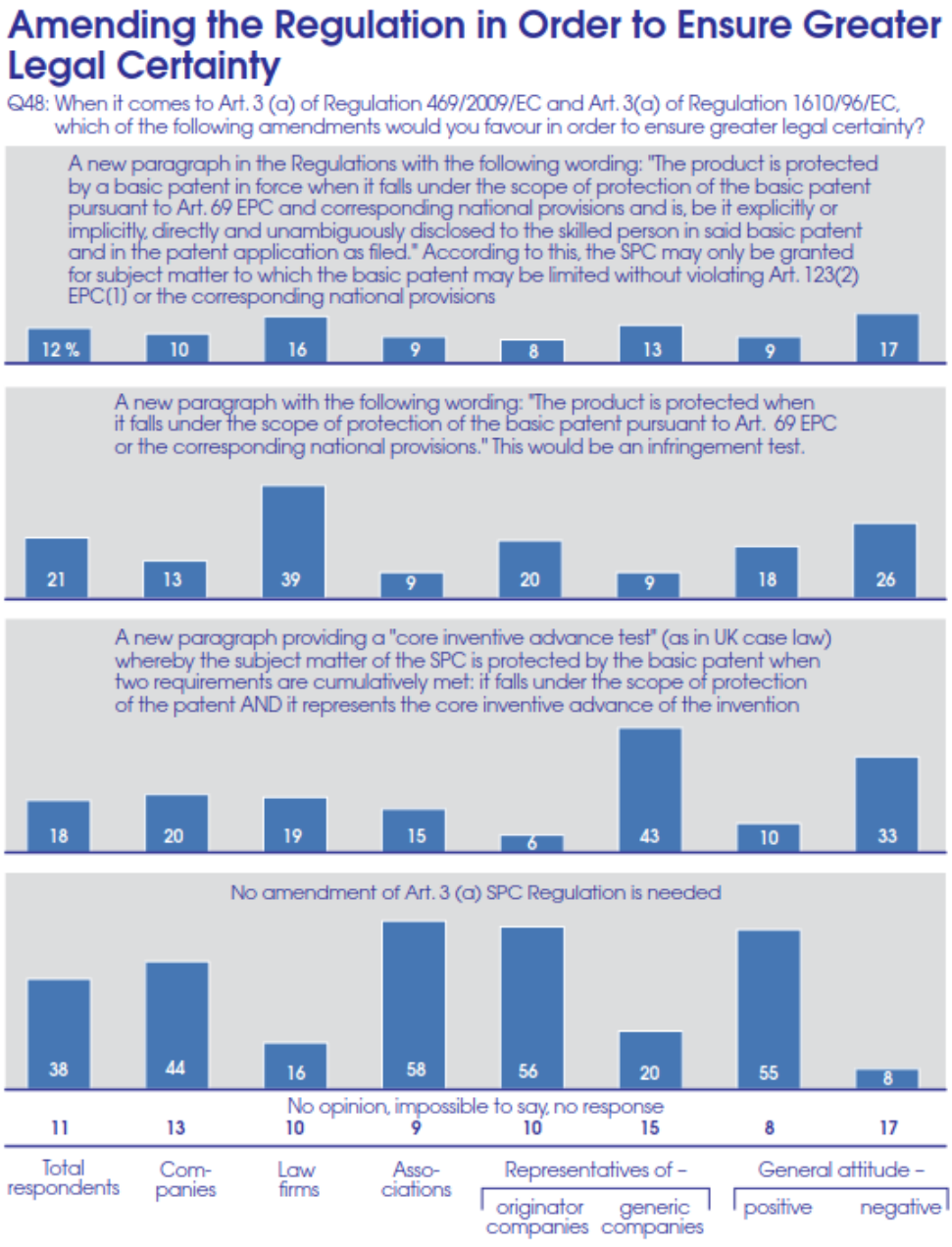

Figure 10.1: Q48 of the Allensbach Survey

While a very slight majority would favour a legislative action, no clear preference for one of the options considered in the Allensbach Survey emerged from the responses given. The "core inventive advance test" receives approval by 18 per cent of all respondents (among companies and law firms 20 and 19 per cent, respectively). However, the adoption of an inventive advance test would be applauded by the relative majority of the representatives of generic companies (43 percent), An "infringement test" would be welcomed by 21 per cent of the total respondents, and in particular 39 per cent of the law firms. 12 per cent of all respondents are in favour of a disclosure test.

Several comments were provided by the stakeholders. We report three different views:

First, according to several stakeholders, Art. 3(a) is drafted clearly and does not need to be amended. Any lack of clarity is due to the case law and not to the wording of the provision. Therefore, it is the task of the case law and pending referalls to remove such unclarity. An amendment would give rise to further case law and uncertainty.

Second, some commentators observed that no amendment could ensure uniformity, because the lack of uniformity is a consequence of divergences in substantive patent law to which Art. 3(a) refers. No amendment of Art. 3(a) can cure these divergences. We disagree however with the view that there are any divergences in the substantive patent law applicable to the basic patent that could be relevant for Art. 3(a). The scope of protection and rights conferred by the patent are indeed subject to uniform rules in Europe.

Third, an observer has argued that the only consequence the case law has is that SPCs for combinations were not acceptable when one of the active ingredients was already protected by an SPC. This observer suggests adopting measures other than an amendment of Art. 3(a), such as a terminal disclaimer:

> "The whole problem behind the Article 3a questions has arisen from the fact that there is a certain type of combination products that the CJEU seems not to like. To this extent this has created too much unclarity. This could perhaps be solved, e.g. by amending Art. 13 and adding terminal disclaimer-like provisions so that only a second SPC could be granted with longer duration based on the same MA and basic patent if the product was patentably distinct. New patent, same MA, different situation. Just a thought on a more manageable solution. Then the applicant could argue why it was patentably distinct."[616]

Finally some comments point out that the core-inventive-advance test would not be clear, or would make a difference compared to an infringement test only in the case of combinations, but not monotherapy products covered by Markush claims.

10.2.3.7 Conclusion

(a) *Recommendation*

Several stakeholders have maintained that the case law concerning Art. 3(a) Reg. 469/2009 does not lead to any significant problems in practice. The Regulations work efficiently in most cases. A reasonable prediction of whether or not an SPC can be granted or is valid is possible in most cases.

[616] Annex III of this Study, p. 413.

However, we are of the opinion that the CJEU case law has not provided the NPOs and the national courts with a clear answer to the question of what are criteria for deciding whether or not a product is protected by the basic patent. We have mentioned the reasons why this is the case. The CJEU has introduced a distinction between products specified and products not specified in the claims of the basic patent that do not exist in national and European patent law. At the same time, it has asked the courts to apply this distinction on the basis of the law applicable to the basic patent.

Against this background, the MPI proposes two measures. First, the lawmakers should define what "protected" means. We have identified three approaches, all of which would in our view be clear for EU patent lawyers, because they are based on well-known concepts of European patent law.

Second, the lawmaker should adopt soft-law measures consisting of guidelines for substantive examination. With the support of soft law, the NPOs would be assisted by examples and explanations of how to approach the criteria enshrined in Art. 3(a) Reg. 469/2009.

Which criteria should be preferred is a matter of policy. But this question is closely interrelated with other provisions of the SPC system. For instance, if an SPC can only be granted if the patentee itself has made the necessary investment to obtain the MA or if the owner of the MA is at least a licensee of the patentee, this could justify adopting the infringement test. This test would ensure that the patent provides the patentee and its licensees with a solid foundation for making further investments in seeking a suitable therapeutic candidate. If such a candidate is identified, then the product could benefit from SPC protection whether or not this product was already identified in the patent application as filed.

If, by contrast, stricter requirements apply under Art. 3(a) Reg. 469/2009, then as compensation it might be conceivable to allow, without any limitation, the use of third-party MAs (see Chapter 13).

In considering which solution would be less disruptive and more consistent with the CJEU case law, the core inventive advance would seem an obvious option. It is already part of the CJEU case law, albeit based on Art. 3(c). It could avoid multiple SPCs for the same ingredient unless a separate innovation exists. It would provide a uniform European criterion that could prevent a division of the common market.

Adopting a core-inventive-advance test also has its shortcomings. NPOs would be burdened with an inventive-step-like examination. This was clearly not the intention of the EU lawmakers. However, such an issue could be addressed by making the examination of Art. 3(a) optional or by providing the possibility for non-examining offices to cooperate with examining offices or with the Unitary SPC Office that is to be established to grant unitary SPCs.[617] Furthermore, the burden on the NPOs should not be overestimated. It is unlikely that the inventive-advance test will require a specific examination that goes beyond the application of the extension of protection-rules when an SPC is requested for a monotherapy product. The inventive-advance test will require a specific examination for combinations, but not in every case. The test is only relevant when the prior art considered in examining the inventive step of the designated basic patent under Art. 56 EPC or corresponding national provisions does

[617] See Chapter 20, Section 20.3.1.

not include all active ingredients of the combination for which the certificate is requested.[618] However, the recommendation formulated in this section is subject to a qualification.

(b) *Caveat: the issue of fixed combination products*

A significant part of the case law analysed in this chapter, starting with *Takeda*, has dealt with combinations. In the relevant cases, the patentee had obtained a certificate for a product (for instance, A or A-B) or could have obtained such a certificate, but with a limited or even negative term, and then tried to obtain a certificate for a combination including that product (for instance: A-B-C). Before the lawmakers decide what approach to take with respect to Art. 3(a) Reg. 469/2009, a preliminary policy question must be adressed first, namely whether or not combinations including active ingredients already authorised in the past should be eligible for a certificate. Posing this question is legitimate for several reasons.

First, US-law does not admit protection for combinations including active ingredients already authorised. A patent claiming a combination of A and B is only "eligible for term extension if either A or B had not been previously marketed".[619] The reason for this limitation is that the US-legislation is designed to foster the development of new chemical entities. The different approach to combinations adopted in European law requires some justification.

Second, the purpose of the SPC legislation was to address the assumed decline in the development of new active ingredients or new active substances. The Medicinal Products Regulation admittedly draws a distinction between active ingredient and combinations of active ingredients in Art. 1(b) Reg. 469/2009. Yet there is no evidence in the literature that preceded the Explanatory Memorandum or in the Explanatory Memorandum itself that the assumed lack of sufficient incentives for developing new chemical entities also pertains to combinations including old active ingredients. The study of *Suchy* refers only to the erosion of the patent term for new active substances.[620]

Whether or not an inventive advance is opportune depends on the preliminary question of the purpose of the SPC legislation. If the lawmakers only intend to foster and reward research in new active ingredients, they could adopt the US-approach. In

[618] This can be the case if the SPC is requested on the basis of the same patent that claims and discloses one of the components of the combination. Yet the situation mentioned in the main text can also occur when the basic patent is a separate patent specifically covering the combination, but is based on a divisional application that shares the same priority as the patent application filed for the single active ingredient or an application filed before the publication of the patent application filed for the single active ingredient (see Art. 56 EPC).

[619] John Thomas, *the USA* in Annex II of this Study, Chapter 8, Section 8.5.1.3; Arnold P'ship v. Dudas, 362 F.3d 1338 (Fed. Cir. 2004).

[620] Admittedly, recent studies pointed out that also for combinations the time between the priority date of the patent and the grant of the MA can be significant. Rollins et al. observe that "for chemical combination SPCs filed between 2009 to 2011 (with the exception of two SPCs) far more than half the patent term had expired before a marketing authorisation was obtained, hence why the average time from marketing authorisation to SPC expiry was 10.6 years (which is far less than the 15 years envisaged by Recital 9 of the SPC Regulation)", see From Takeda to Teva v Merck: Are we treading the right path on combination product SPCs? (Part 2), E.I.P.R. 2017, 39(11), 697, 702. However, the time requested for obtaining an MA is influenced by endogenous factors, which may be relevant particularly in the case of combinations including products already been placed on the market. So it would be necessary to consider also when the pre-clinical studies and clinical trials were started and when the MA application was filed in assessing the average erosion of the patent term for combinations. See Chapter 16, Section 16.2.

this case a core inventive advance is not needed. If the lawmakers intend to create an incentive for companies to bring to market improved combination products including the single active that is the subject matter of the patent, then the core inventive advance should be rejected. But if the lawmakers intends to allow certificates for combinations of old active ingredients only when a company has developed a new combination that is the subject matter of the basic patent, then the inventive-advance test is the only approach developed by the case law that is effective in implementing such a policy choice.

10.2.3.8 Summary

- The CJEU case law has failed to provide clear guidance for applying Art. 3(a). The MPI has identified three possible criteria for determining the SPC eligibility of a product under Art. 3(a) that are borrowed from the law applicable to the basic patent and are understandable for the NPOs: an Art. 123(2) EPC-based disclosure-test, an infringement-test and a core-inventive-advance test.
- The core-inventive-advance test could provide some advantages *vis-à-vis* the other two options. It is already part of the system. The CJEU adopted such approach in *Actavis I*, but based it on Art. 3(c) Reg. 469/2009. It could avoid multiple SPCs for the same ingredient in combination with other actives unless a separate innovation exists. The test would provide the NPOs with a uniform criterion that could prevent a division of the common market. It is likely that some if not all of these policy goals were at the basis of the CJEU case law.
- However, the core-inventive-advance test would require common guidelines for the examination. Furthermore, lawmakers would have to provide institutional instruments to assist NPOs that do not perform a full examination of patents.

11 CONDITIONS FOR GRANTING AN SPC: ART. 3(B) AND (D) REG. 469/2009

11.1 ART. 3(B) AND (D) REG. 469/2009

Article 3(b) and (d) provide for the second and fourth condition for obtaining an SPC. Both conditions are interrelated since they refer to the authorisation to place the product on the market.

The provisions read as follows:

> "A certificate shall be granted if, in the Member State in which the application referred to in Article 7 is submitted and at the date of that application
> (….)
> b) a valid authorisation to place the product on the market as a medicinal product has been granted in accordance with Directive 2001/83/EC or Directive 2001/82/EC, as appropriate;
> (….)
> d) the authorisation referred to in point (b) is the first authorisation to place the product on the market as a medicinal product."

From the combined reading of both provisions, it can be inferred that the MA on which the application for a certificate relies not only must have been granted at the filing date of the SPC, but also must be the first relevant authorisation for the product. As the first sentence of the Art. 3 makes clear, both provisions are referring to MAs granted with effect for the Member State in which the application for a certificate is filed.[621]

In the following we will first address the issues concerning Art. 3(b) and in a second step the issues concerning Art. 3(d) Reg. 469/2009.

11.2 ISSUES CONCERNING ART. 3(B) REG. 469/2009

11.2.1 Mismatch between MA and SPC product definition

A highly relevant issue from a practical point of view concerned the cases of a mismatch between the MA and the SPC product definition. Before the CJEU's *Medeva* decision,[622] most NPOs[623] considered an SPC application as complying with Art. 3(b) Reg. 469/2009 only when the subject of the MA and the product subject to the respective SPC application was identical. This requirement was significant in the case of combinations. If the patentee decided to bring to market the subject matter claimed by the patent, e.g. active ingredient A, together with at least one other active ingredient, for instance active ingredient B, and the MA was requested and granted for a medicinal product containing such combination (A-B), then such MA could not support an SPC requested for A. Indeed, if the MA was granted for the active ingredients "A and B", but the SPC was requested only for "A", the MA and the SPC

621 Christopher Brückner, *Supplementary Protection Certificates with Paediatric Extension of Duration*, (2nd edn, Heymanns 2015) Art. 3, marginal note 569; see also BPatG, *Clarythromycin,* 15 W (pat) 106/96 [1999] BPatGE 41, 56.
622 Case C-322/10 *Medeva* [2011] ECR I-12051.
623 This was for instance the opinion of UK IPO, BL O/357/09 *Medeva BV*, Decision of 19 November 2009.

application referred to two different products pursuant to Art. 1(b) and Art. 3(b) Reg. 469/2009.

The CJEU rejected this approach in the *Medeva*[624] *and Georgetown I*[625] judgments, however; the second headings of *Medeva* reads as follow

> "Article 3(b) of Regulation No 469/2009 must be interpreted as meaning that, provided the other requirements laid down in Article 3 are also met, that provision does not preclude the competent industrial property office of a Member State from granting a supplementary protection certificate for a combination of two active ingredients, corresponding to that specified in the wording of the claims of the basic patent relied on, where the medicinal product for which the marketing authorisation is submitted in support of the application for a supplementary protection certificate contains not only that combination of the two active ingredients but also other active ingredients."[626]

In *Medeva,* the requirement of an MA for the relevant product was considered to be satisfied by an authorisation granted *inter alia* for the product for which the SPC application is filed, even though a combination of two active ingredients pursuant to Art. 1(b) Reg. 469/2009 is a different product for the purposes of the Regulation than the single active ingredient alone and although the authorisation to bring a combination of A-B-C to the market does not imply the authorisation to bring only A or only A-B or only A-C to the market. For the latter, further authorisations would be needed.

In *Georgetown I*, the same principle was considered applicable to monotherapy products[627]: an MA granted for A-B was considered a valid MA for the purposes of Art. 3(b) to support an application for a certificate for the product A. These principles shall apply equally to Art. 3(d), Art. 13 and Art. 7. Therefore, if an MA is granted for A-B, and a patent has been granted before such date for A, this MA will trigger the deadline for filing an application for a certificate for A under Art. 7 Reg. 469/2009. Furthermore, such MA will be the relevant MA for calculating the duration of the certificate under Art. 13 Reg. 469/2009. The same principles apply to the corresponding provisions of the Plant Protection Products Regulation.

The principle that an SPC can be granted even if the MA supplied in support of the application covers the active ingredient(s) concerned in combination with one or further active ingredients can be considered settled in the practice of the NPOs. Almost all NPOs have confirmed that a redrafting of Art. 3(b), according to which the valid authorisation to place the product on the market has been granted for the product alone or in combination with other active ingredients, would reflect their practice and be consistent with the CJEU case law.[628] However, this does not apply without qualification to national case law.

The Swedish Court of Patent Appeals in case 13-099 of 18 March 2016[629] considered *Medeva* not applicable in situations where an older MA has been granted for A-B, and a certificate is requested only for A on the basis of a more recent MA granted for that

624 Case C-322/10 *Medeva* [2011] ECR I-12051.
625 Case C 422/10 *Georgetown University and Others* [2011] ECR I-0000.
626 Case C-322/10 *Medeva* [2011] ECR I-12051.
627 Case C 422/10 *Georgetown University and Others* [2011] ECR I-0000, para 33: However, it should be added that, in such a situation, first, only the authorisation in respect of the first medicinal product placed on the European Union market comprising, among its active ingredients, the active ingredient which is the subject of the application may be regarded as the first MA for that 'product' as a medicinal product within the meaning of Article 3(d) of Regulation No 469/2009 (Medeva, paragraph 40).
628 Answers to Q33 of the MPI Questionnaire for the NPOs, Annex VI of this Study.
629 Answer of the Swedish NPO to Q33 of the MPI Questionnaire for the NPOs, Annex VI of this Study.

active ingredient A. The judgement followed from an appeal against the decision of the Swedish NPO to refuse an application filed for the active A. The refusal was based on Art. 3(d), since an earlier MA was granted for a combination including A together with other active ingredient. However, the Court of Patent Appeals stated that the product in the earlier MA was a combination product according to Art. 1(b) Reg. 469/2009 and thus the product of the later MA only containing A had a different composition and could not be considered to be the same product. As consequence, the earlier MA containing A+B was not considered as the first MA for the single ingredient A under Art. 3(d) Reg. 469/2009. In commenting *Medeva*, the Court considered the second headings of the latter judgement applicable only to the specific situation of combinations including different active ingredients having different therapeutic indication, as for instance a multivaccine comprising several antigens each of them with different therapeutic purpose.

Also the District Court of Düsseldorf adopted a qualification to *Medeva* and *Georgetown I* principles, considering the latter relevant for combinations, but not for monotherapy products.[630] The District Court referred to Art. 1(b) Reg. 469/2009, by virtue of which a single active ingredient and a combination including such ingredient are two different products. As consequence, if a senior MA was granted for A-B, and the SPC is requested for A on the basis of a more recent MA issued only for A, the more recent MA covering A and not the senior MA covering A-B is the one that matters for the purposes of Art. 7 Reg. 469/2009, Art. 13 469/2009 and Art. 3(d) Reg. 469/2009. In the specific case the District Court considered valid – in the context of a preliminary infringement proceedings – a certificate granted for Desogestrel on the basis of an MA for a medicinal product including as only active substance Desogestrel, although an older MA had been invoked by the defendant as invalidity ground, older MA that had been granted for a combination of active ingredients consisting of Desogestrel und Ethinylestradiol.[631] In justifying this approach, the District Court seems to believe that both *Medeva* and *Georgetown I* judgements concerned combinations, what is true for *Medeva*, but not for *Georgetown I*.

One NPO pointed out that there is a balance and an interaction between Art. 3(a) and Art. 3(b). If Art. 3(a) is to be "construed widely, then Art. 3(b) should be construed narrowly; and if Art. 3(a) is broadly applied, Art. 3(b) should be narrow". We agree with this statement. This NPO confirmed also that a generous approach to Art. 3(b) can imply some disadvantages for the applicant under Art. 13 Reg. 469/2009. If Art. 3(a) is amended in the sense that an infringement test applies, the approach to Art. 3(b) developed in *Medeva* is likely not necessary anymore, and should be replaced by an interpretation more consistent with the regulatory framework. If by contrast the *Medeva* principles are to stay, their codification or explanation in form of soft law is opportune. Such guidelines would be of assistance for the national Courts in drawing all necessary implications from a case law that has specified the notion of product subject of the MA for the purposes of Art. 3(b) in a manner that does not comply with meaning of the same term applicable to other provisions of the SPC legislation nor with the regulatory framework applicable to the MAs supplied in support of the application for a certificate.

630 District Court of Düsseldorf, *Decision of 15 November 2012*, 4b O 123/12 [2012] openJur 2013, 3044; *Ibid*., 3259.

631 *Ibid.*

11.2.2 Must the authorisation be in force at the filing date?

A further issue relating to Art. 3(b) Reg. 469/2009 is whether the MA must be in force at the date the SPC is requested. The opinions of the NPOs diverge in this regard. For instance, for an SPC to be granted in the UK[632] is sufficient that the MA has been granted. Whether or not it is valid at the SPC filing date, does not matter. Of course, the MA must be in force when the SPC is granted, otherwise the latter would expire under Art. 15 Reg. 469/2009. In the practice of the German[633] and Swedish[634] NPOs, by contrast, the MA must be in force at the date on which the SPC is requested.

These diverging views are due in part to the fact that the wording of the Regulation is not uniform in the different language versions. For instance, the Italian, French and Spanish version seems to require expressly that the MA must still be valid at the filing date, while the English wording allows for a different interpretation:

> **English:**
> a valid authorisation to place the product on the market as a medicinal product has been granted in accordance with Directive 2001/83/EC or Directive 2001/82/EC, as appropriate;
>
> **German:**
> für das Erzeugnis als Arzneimittel eine gültige Genehmigung für das Inverkehrbringen gemäß der Richtlinie 2001/83/EG bzw. der Richtlinie 2001/82/EG erteilt wurde;
>
> **French :**
> le produit, en tant que médicament, a obtenu une autorisation de mise sur le marché en cours de validité conformément à la directive 2001/83/CE ou à la directive 2001/82/CE suivant les cas.
>
> **Italian :**
> per il prodotto in quanto medicinale è stata rilasciata un'autorizzazione in corso di validità di immissione in commercio a norma, secondo il caso, della direttiva 2001/83/CE o della direttiva 2001/82/CE;
>
> **Spanish:**
> el producto, como medicamento, ha obtenido una autorización de comercialización vigente conforme a la Directiva 2001/83/CE o a la Directiva 2001/82/CE, según los casos;

From a policy perspective, it has been argued "that a certificate has no legal effect whatsoever until it takes effect at the end of the lawful term of the basic patent and it should only be decisive whether from that time onwards the first MA for the product in the country concerned is valid, regardless what turbulent history that MA may have undergone in the past".[635] One could contend, however, that in the interest of legal certainty the third parties must be able to assess at the filing date whether or not the requirements for granting a (valid) certificate are met.

It is likely that the question at issue here is of limited practical importance. Usually, it is the grant of the MA that triggers the six-month deadline under Art. 7 Reg. 469/2009. It is unlikely that in that period of time – that is, the period of time between the grant of the MA and the filing of the application for a certificate – the MA will be revoked or withdrawn. If the grant of the patent triggers the six-month deadline and the first MA granted in the State concerned at that time is not valid anymore, this may have several reasons: but these are reasons that may make the issue in practical or legal terms not relevant for granting the SPC. Indeed the MA can be no longer valid because the product was not profitable and therefore withdrawn

632 Fiona Warner et al, *United Kingdom* in Annex I of this Study, Chapter 13, Section 13.3.
633 Oliver Werner, *Germany* in Annex I of this Study, Chapter 4, Section 4.5.2.
634 Joakim Sånglöf et al, *Sweden* in Annex I of this Study, Chapter 11, Section 11.5.
635 See Herwig von Morze, Peter Hanna, 'Critical and Practical Observations Regarding Pharmaceutical Patent Term Restoration in the European Communities (Part I)' [1995] 77(7) Journal of the Patent and Trademark Office Society 479, 490.

from the market, so that the MA was also withdrawn. In this case the question of whether an application for a certificate complies with Art. 3(b) Reg. 469/2009 is likely theoretical, because the patent holder might not have an interest in filing such an application. It is possible that the originally granted MA is not valid anymore because another MA was requested and granted for an improved version of the product, for instance a combination. In this case, it would not be justified in our view to exclude the grant of the SPC or its validity after grant or to consider it lapsed only because the first MA issued in the State concerned is not in force anymore and another MA has taken its place. Finally, the MA could no longer be valid because it was suspended. This would likely be an obstacle to the grant of the SPC, but it is not frequent that an MA is suspended and it is even less frequent that such suspension is revoked between the filing of the application for a certificate and the date on which the NPO has to decide whether or not to grant the certificate.

In any event, the issue of whether the MA must be still in force at the date the application is filed or whether it is sufficient that has been granted before that date for the grant of the SPC can be clarified by adopting soft law. The wording of the SPC Regulations in the different languages can accommodate both interpretations mentioned above.

11.3 ISSUES SURROUNDING ART. 3(D) REG. 469/2009

11.3.1 SPCs for new medical uses of an active ingredient already authorised as a medicinal product

11.3.1.1 Introduction

All patents that protect either the process for obtaining an active ingredient or the active ingredient as such or the use of this active ingredient can, in principle, be the basis for an SPC. This principle applies also to patents granted for the first, second or further medical uses of a known substance. However, if the compound concerned has been already authorised as active substance of a medicinal or veterinary product, Art. 3(d) Reg. 469/2009 will be an obstacle. According to this provision, the MA must be the first authorisation granted to place the product on the market as a medicinal product. The same is true for plant protection products (Art. 3(d) Reg. 1610/96). The wording of the provision does not place any relevance on the medical indication or use for which the active ingredient was authorised.

The practical implications of this wording are obvious if we consider the following scenarios:

	First MA	Second MA
Scenario I	Veterinary/Indication A	Human/Indication A
Scenario II	Human/Indication A	Human/Indication B
Scenario III	Veterinary/Indication A	Human/Indication B

Table 11.1: Factual scenarios relevant under Art. 3(d) SPC Regulations

In the first scenario, the more recent MA concerns the use of the active ingredient on a different species, but for the same indication as the first MA. Such scenario was the subject of the CJEU's decision in *Pharmacia Italia*.[636]

In the second scenario the second MA concerns the use of the active ingredient on the same species as the first MA, but for a different indication. It was the subject of the CJEU's *Yissum* decision.[637]

In the third scenario, the MA concerns the use of the active ingredient on a different species and for a different indication. The CJEU decided on this scenario in *Neurim*.[638]

In *Pharmacia Italia*, the CJEU maintained that "that the decisive factor for the grant of the certificate is not the intended use of the medicinal product", and "that the purpose of the protection conferred by the certificate relates to any use of the product as a medicinal product without any distinction between human use or veterinary use".[639] *Yissum* confirmed the principles stating that:

> "Article 1(b) of Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products, in the version resulting from the Act concerning the conditions of accession of the Republic of Austria, the Republic of Finland and the Kingdom of Sweden and the adjustments to the Treaties on which the European Union is founded, is to be interpreted as meaning that in a case where a basic patent protects a second medical use of an active ingredient, that use does not form an integral part of the definition of the product."[640]

These decisions concerned Art. 19 and Art. 1(b) Reg. 1768/92. However, they had a direct impact on Art. 3(d) Reg. 469/2009, because the concepts of active ingredient and marketing authorisation must have the same meaning within the Regulations. As a consequence of this uniform understanding, if the first MA is granted for a veterinary medicinal product, such MA is the first MA within the meaning of Art. 3(d) Reg. 469/2009 for that active ingredient for any SPC applications concerning that active substance. The fact that the patent designated for the procedure for granting the SPC concerns the use of that substance for a different indication and/or species than the first MA does not matter and cannot matter: Art. 3(d) refers to the active ingredient and not to its use.[641] This case law was clear and consistent. It called for the NPOs to examine only whether the active ingredient for the use of which an SPC was requested was the subject of an MA in the State concerned that was older than the MA submitted by the applicant. If this was the case, and if the deadline of Art. 7 Reg. 469/2009 taking into account the first MA was not respected, the application was rejected. In *Neurim* the CJEU changed this case law.

636 Case C-31/03 *Pharmacia Italia* [2004] ECR I-10001.
637 Case C-202/05 *Yissum* [2007] ECR I-2839.
638 Case C-130/11 *Neurim Pharmaceuticals* [2012] EU:C:2012:489.
639 See Case C-31/03 *Pharmacia Italia* [2004] ECR I-10001, para. 20.
640 Case C-202/05 *Yissum* [2007] ECR I-2839.
641 If the first MA is for human use for indication B, this MA is the first MA for all SPC applications concerning that active ingredient, whether or not the patent on which the application relies concerns indication B or another indication.

11.3.1.2 The CJEU's Neurim judgment

(a) *The granting procedure and the High Court decision*

Neurim Pharmaceuticals on 26 September 2007 filed an application for a certificate for the product melatonin before the UK IPO. The MA on which the application relied was issued for the use of melatonin for insomnia, and was issued by the EMA on 29 June 2007. The basic patent designated for the purpose of the procedure was the European Patent 0518468 B1 (EP ´468). The first independent claim of EP ´468 reads as follows:

> "a process for preparing a pharmaceutical formulation, for use in correcting a melatonin deficiency or distortion in the plasma melatonin level and profile in a human subject, which comprised melatonin in combination with at least one pharmaceutical carrier, diluent or coating, wherein the melatonin was present in the formulation in controlled-release form adapted to release melatonin following administration to a human patient".

In a technical sense, therefore, the patent concerned a process for preparing a formulation of the active ingredient. The patent itself included a second medical use claim based directed to the use of the formulation manufactured by the claimed process.

The UK examiner considered the application as not complying with Art. 3(d) Reg. 469/2009. The MA supplied in support of the application was not the first granted in the UK for marketing melatonin as a medicinal product. A previous MA had been granted for a veterinary product called Regulin that comprised melatonin (Regulin MA). In the following hearing the Hearing Officer entrusted with the case confirmed the assessment of the examiner that the application did not comply with Art. 3(d), basing its decision on *Pharmacia Italia Spa*, *MIT* and *Yissum*.[642]

In the appeal proceedings Justice Arnold rejected *Neurim*'s argument that the case should be distinguished from *Yissum* and *Pharmacia Italia* since the former concerned a different indication for the same species and the latter case the same indication for different species, while the *Neurim* case concerned a different species and a different indication. Indeed, Justice Arnold inferred from the case law existing at that time that a difference neither in the indication nor in the species matters for the question of which of several MAs granted for the same active ingredient is the earliest one under Art. 3(d) Reg. 469/2009. Therefore, as a matter of logic, "a difference in both" – that is, species and indication – "cannot be material either". As a consequence, the High Court of Justice considered the decision by the Comptroller-General of Patents and appealed by *Neurim* as consistent both with the Reg. 469/2009 and with the case law of the CJEU.[643] The appeal was dismissed.

(b) *The referral decision*

Neurim filed an appeal against the judgment and advanced the following arguments before the Court of Appeal to justify the grant of the SPC or to obtain a referral to the CJEU:

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642 Case C-202/05 *Yissum* [2007] ECR I-2839.
643 *Neurim Pharmaceuticals (1991) Ltd v Comptroller-General of Patents* [2010] EWHC 976 (Pat).

- The Medicinal Products Regulation must be interpreted teleologically. Its fundamental objective is to ensure protection for pharmaceutical research; Recitals 3 and 4 make clear that the loss of time caused by the need for an MA affects such research.
- Each patent can have its own SPC, and the relevant MA is the MA that falls within the scope of the patent.
- The same product would not be subject to several certificates, since the medicinal product would not be the same.
- Minor changes to a medicinal product may not be grounds for an SPC, but changes that warrant the grant of a patent are relevant and sufficient for obtaining a certificate.

The Court of Appeal (Civil Division) seemed to agree with all the above-mentioned statements. The pithy reasoning of the court reads as follows:

> "28. We consider that Neurim's arguments are not only tenable: in our view they are right. Many kinds of valuable pharmaceutical research will not get the encouragement or reward they deserve if they are not. Pharmaceutical research is not confined to looking for new active compounds. New formulations of old active substances are often sought. Most are unpatentable but from time to time a real invention is made and patented.
>
> 29. Moreover there is much endeavour to find new uses for known active ingredients. The European Patent Convention 2000 has indeed made the patenting of inventions in this area clearer. Its effect is that a patent for a known substance or composition for use in a method of treatment is not to be regarded as old (and hence unpatentable) unless use for that method is known.
>
> 30. In short, if Neurim are wrong, then the Regulation will not have achieved its key objects for large areas of pharmaceutical research: it will not be fit for purpose. Whether that is so or not is clearly a matter for the EU's highest court."[644]

(c) *The judgment of the CJEU*

Advocate General Trstenjak concluded that a literal interpretation of the Regulation requires that any MA for any medical use of an active ingredient matters for Art. 3(d) Reg. 469/2009. However, she ultimately turned to and relied upon a teleological approach.

The guiding principle behind what she calls a "schematic-teleological" interpretation was

> "the idea that any basic patent should, in principle, be open to an extension of its term of protection under the conditions laid down in Article 3 of Regulation No 1768/92 where the subject-matter of that patent is the result of work which is worthy of protection in the light of the objectives of that regulation."[645]

In her view, the development of a new use of a known substance was such an invention. In this respect, she referred to the EPC 2000 that has recognised the patentability of second and further medical uses of substances. [646]

As a consequence, Advocate General Trstenjak suggested adopting *Neurim's* argument that only the first MA that falls under the scope of protection conferred by the patent is relevant for the purposes of Art. 3(d) and Art. 13(d) Reg. 469/2009.

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644 *Neurim Pharmaceuticals (1991) Ltd v Comptroller-General of Patents* [2011] EWCA Civ 228, paras. 28-30.
645 Case C-130/11 *Neurim Pharmaceuticals* [2012] EU:C:2012:489, Opinion of AG Trstenjak, para. 58.
646 *Ibid.*

The CJEU followed the advice of the Advocate General. The first two headings of the judgment read as follows:

> "1. Articles 3 and 4 of Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products must be interpreted as meaning that, in a case such as that in the main proceedings, the mere existence of an earlier marketing authorisation obtained for a veterinary medicinal product does not preclude the grant of a supplementary protection certificate for a different application of the same product for which a marketing authorisation has been granted, provided that the application is within the limits of the protection conferred by the basic patent relied upon for the purposes of the application for the supplementary protection certificate.
>
> 2. Article 13(1) of Regulation (EC) No 469/2009 must be interpreted as meaning that it refers to the marketing authorisation of a product which comes within the limits of the protection conferred by the basic patent relied upon for the purposes of the application for the supplementary protection certificate."[647]

11.3.1.3 Open issues

The *Neurim* judgment led to some unresolved follow-up issues. It is not clear, indeed:

- whether the Court intended to overrule completely *Pharmacia Italia* and *Yissum*, or to make an exception to the principles laid down in these decisions for the case where the earlier MA was granted for a veterinary medicinal product and the later MA for a medicinal product for human use;
- whether the SPC should be available only for any new medical indication for which a patent has been granted, provided that the MA submitted in support of the application is the first that falls under the scope of the basic patent;
- which MA qualifies for granting the SPC, and whether the variation of an existing MA can qualify as first MA that falls within the scope of the basic patent;
- whether Art. 3(c) continues to apply to the active ingredient as such, or whether the holder of an SPC can obtain a second SPC, provided that the requirements of *Neurim* are met.

11.3.1.4 Practice of the NPOs

In the practice of the NPOs two approaches can be identified. Some NPOs (NL[648]; PT) apply *Neurim* only to the specific factual scenario considered in the referral proceedings, that is, first MA for a veterinary use and second MA for a human use. This approach is supported by the fact that *Neurim* does not state expressly that *Yissum* is overruled and that the headings of the decision refer expressly to "a case such as that in the main proceedings".

The overwhelming majority of NPOs applies *Neurim* also when the first MA was granted for a use of the active ingredient for the same species as the first MA. This approach is able to invoke some paragraphs[649] of the reasoning of the decision, which seems to refer also to scenarios where the first MA authorises a different use for the same species.

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647 Case C-130/11 *Neurim Pharmaceuticals* [2012] EU:C:2012:489.

648 The District Court of the Hague in the judgment of 1 February 2017, Case number No. SGR 15/8480, has rejected the interpretation of *Neurim* adopted by the Netherlands Patent Office. An appeal filed by the Netherlands NPO against this decision is still pending. We thank Advocaat Ms. Machteld Hiemstra for providing the MPI with a translation of the judgment.

649 Case C-130/11 *Neurim Pharmaceuticals* [2012] EU:C:2012:489, paras. 25-27.

Within the latter group, some NPOs do not grant SPCs any time the SPC application can rely on a second-medical-indication patent and a new MA. Instead, they require a new medical indication. New medical indications exist in this approach when the active ingredient is to be applied for a new population of patients not treated before, that is, when the active ingredient is instead to treat a new disease.

As regards the MA, some NPOs (e.g. in Austria and the UK) also grant SPCs for type-II variations of an existing MA. In contrast, other offices (e.g. in Spain) do not consider variations as relevant and sufficient for granting a certificate for the reason that the office cannot examine whether or not such variation concerns a new indication.

11.3.1.5 Opinion of the NPOs and stakeholders

Some NPOs considered *Neurim* to be a significant change of the CJEU case law; some of them have expressed reservations towards the approach taken in *Neurim*. The decision is considered to be neither consistent with the previous case law nor with the wording of the SPC Regulations. Further, it has been observed that the *Neurim* decision does not conform with general principles of patent law and the principle of "one SPC for one product", since "every time you get a new patent for a new product, [with a] new formulation, it would automatically never cover an earlier authorisation because it's prior art".[650] It is therefore questionable whether the balance as drawn by the lawmaker has been taken into account appropriately. It is also in contradiction with other rulings, and even with rulings quoted by the CJEU in its own decisions.

Some NPOs also pointed out that there is uncertainty on:

a) when the *Neurim* principle should apply,
b) what a new MA is for the purposes of *Neurim*, and
c) whether and when the concept of variation can fulfil this requirement.

Some of the law firms which the MPI addressed in the course of the fact-finding process for this Study have expressed support for *Neurim*. Others have pointed out that the decision is flawed on the grounds of inconsistency with Art. 3(d) Reg. 469/2009. We refer to Annex III for more detailed comments in this regard.

11.3.1.6 Opinion of the MPI

(a) *Neurim is in conflict with the wording of Art. 3(d) Reg. 469/2009 and with the legislative intent*

The MPI agrees with Advocate General Trstenjak that an interpretation pursuant to which Art. 3(d) refers to the first MA within the scope of the patent *is not consistent* with the wording of Art. 3(d).[651]

The MPI further agrees with the Advocate General that a purely literal interpretation of Art. 3(d) implies that

> "a supplementary protection certificate for a product and thus for an active ingredient or for a combination of active ingredients may be applied for only on the basis of the first authorisation to

[650] MPI Workshop for the NPOs of 21 March 2017. The records are with the authors of the Study.
[651] Case C-130/11 *Neurim Pharmaceuticals* [2012] EU:C:2012:489, Opinion of AG Trstenjak, para. 23.

> place that active ingredient or that combination of active ingredients on the market as a medicinal product for human use or as a veterinary medicinal product"

and that

> "it follows directly that any further authorisation to place that active ingredient or that combination of active ingredients on the market as a medicinal product is to be regarded as a later authorisation."[652]

The MPI, however, disagrees with the assessment of the Advocate General and the CJEU that teleological or systematic arguments justify the departure from the wording of Art. 3(d). Our different assessment is based on the following reasons.

First, the Advocate General and the CJEU have inferred from paragraph 12 of the Explanatory Memorandum that "all research, whatever the strategy or final result, must be given sufficient protection" and that "the proposal for a regulation was not confined to new products only"; indeed "a new process for obtaining the product or a new application of the product could also be protected by a certificate".[653] As a consequence, if a patent protects a new application, such patent shall enable the patentee to obtain an SPC. In this situation only the first MA for the medicinal product that uses that indication may be considered the first MA.

This reference to the Explanatory Memorandum is problematic because it does not seem to take into account other paragraphs of the Explanatory Memorandum that are more and directly relevant for the interpretation of Art. 3(d) Reg. 469/2009 and for answering the questions that the Advocate General examined.

Paragraph 29 of the Explanatory Memorandum, with respect to Art. 1, repeats and specifies the principle stated in Paragraph 11 in the following terms:

> "the proposal does not provide for any exclusions. In other words, all pharmaceutical research, provided that it leads to a new invention that can be patented, whether it concerns a new product, a new process for obtaining a new or known product or a new combination of substances containing a new known product, must be encouraged, without any discrimination, and must be able to be given a supplementary certificate of protection **provided that all of the conditions governing the application of the proposal for a Regulation are fulfilled**.[654]

The paragraph does not suggest that the aim of the SPC Regulations to foster pharmaceutical research justifies a deviation from the "conditions governing the application of the Proposal for a Regulation". We understand this statement as referring among other things and above all to the conditions provided under Art. 3 of the Proposal (Art. 3 Reg. 469/2009).[655] Paragraph 29 does not say – or implicitly suggest – that the purpose of the Regulation is to reward any patented pharmaceutical inventions with a certificate. Only applications that comply with the conditions as set out in Art. 3 Reg. 469/2009, and that therefore are based on the first MA for the active ingredient, can lead to the grant of a valid SPC. This conclusion finds confirmation in Paragraph 35 of the Explanatory Memorandum, which deals directly with Art. 3:

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652 *Ibid.*, para. 23.
653 *Ibid.*, para. 50.
654 European Commission, Explanatory Memorandum to the Proposal for a Council Regulation (EEC), of 11 April 1990, concerning the creation of a supplementary protection certificate for medicinal products (COM(90) 101 final – SYN255), para. 11. Emphasis added.
655 *Ibid.* See for a similar understanding UK IPO, BL 0/138/05 *Knoll AG,* Decision of 19 May 2005, paras. 35-39.

> "It occurs very often that one and the same product is successfully granted several authorisations to be placed on the market, namely each time a modification is made affecting the pharmaceutical form, dose, composition, **indications, etc**.[656] In such a case, only the first authorisation for the product to be placed on the market in the Member State in which the application is presented is taken into account for the purposes of the proposal for a Regulation. In particular for calculating the period of six months which the holder of the basic patent has to submit an application for a certificate. Furthermore, if the first authorisation given is also the first authorisation to place the product on the market in the community it serves as the only reference for all of the Member States for the purposes of calculating the duration of each of the certificates granted in each of the Member States for the same product (see Article 8)."

Furthermore, Paragraph 11, under the heading "a balanced system", explains:

> "The proposal for a Regulation therefore concerns only new medicinal products. It does not involve granting a certificate for all medicinal products that are authorised to be placed on the market. Only one certificate may be granted for any one product, a product being understood to mean an active substance in the strict sense. Minor changes to the medicinal product such as a new dose, the use of a different salt or ester or a different pharmaceutical form will not lead to the issue of a new certificate."

These considerations were confirmed by the Explanatory Memorandum to the Plant Protection Products Regulation in 1994:

> "It is frequently the case that one and the same product is successively granted several authorisations to be placed on the market, in particular every time a modification is made affecting dose, composition or use, and **every time a new use for the product is developed**. In such a case, only the first authorisation to place the product on the market in the Member State in which the application is lodged is taken into account for the purposes of the Regulation, in particular for calculating the period of six months available to the holder of the basic patent to submit an application for a certificate. Furthermore, if the first authorisation given is also the first authorisation to place the product on the market in the Union, it serves as the sole reference for all of the Member States for calculating the duration of each of the certificates they grant for the same product (see Article 13)."[657]

It follows from these passages of the Explanatory Memorandum that when a patentee obtains *instead of* or *along with* a patent for the product a patent for the first medical indication or the second medical indication, it can designate such a patent in the application for a certificate. However, the grant of the SPC will be possible only if the MA on which the SPC application relies is the first granted for the active ingredient and the other requirements are met. *Schennen*, commenting on Art. 3(d), came to the conclusion that second-medical-indication patents will practically be excluded from SPC protection if the active ingredient to which they refer has already been authorised for any medicinal use.[658] The EU lawmaker was therefore well aware that more patents and more MAs may be granted for different uses and formulations of the same products.[659] Despite that, they decided that Art. 3(d) must be met in order for the certificate to be granted, and that this provision refers to the first chronologically given authorisation for the product.

There is another argument that calls into question the soundness of the teleological argument used in *Neurim*. One of the purposes of Art. 13 is to ensure that the duration of an SPC for a product is not more than 15 years from the first application to place it on the market as a medicinal product. This purpose of Art. 13 has been

656 Emphasis added.

657 Explanatory Memorandum to the Proposal for a European Parliament and Council Regulation (EC), of 9 December 1994, concerning the creation of a supplementary protection certificate for plant protection products (COM(94) 579 final), para. 68. Emphasis added.

658 Detlef Schennen, *Die Verlängerung der Patentlaufzeit für Arzneimittel im Gemeinsamen Markt* (Bundesanzeiger 1993) p. 52. This contribution is quoted by the AG in footnote 29 of the conclusions.

659 This was pointed out also by a representative of the NPOs on the second day of the MPI Workshop in Munich, 21 March 2017.

emphasised in *Pharmacia Italia*[660] and *AHP*[661]. This principle has however been undermined by *Neurim*.

Finally, let us recall that the Proposal for a Regulation was based on the US legislation. In US law a new drug intended as an active ingredient can be extended only if "the permission for the commercial marketing or use of the product after such regulatory review period is the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred".[662] As a consequence of this provision, the new use or new formulation of an active ingredient that has been already authorised once cannot be the basis for a patent extension on the basis of a commercial MA for that formulation or that use. This principle was confirmed in *Fisons*, where the patentee makes policy arguments similar to those that the Court of Appeal found so persuasive. The Federal Circuit observed in this regard:

> "Fisons makes what can only be characterized as a "policy argument" pointing to statements of lofty goals indicating that Congress broadly sought to encourage pharmaceutical innovation by enacting the 1984 Act. Fisons urges that it makes little sense, in view of such goals, to restrict patent term extensions so as to encourage development only of new chemical entities (NCEs), and not of new uses and doses for such drugs. Per Fisons, developments of new uses and doses for known compounds are as important as NCE developments. It is irrelevant, however, that we might agree with Fisons that, as a matter of policy, Congress might better achieve its goals through a more liberal grant of patent term extension benefits. Matters of policy are for Congress, not the courts, to decide. See, e.g., Hudson Distribs., Inc. v. Eli Lilly & Co., 377 U.S. 386, 395, 84 S. Ct. 1273, 1279-80, 12 L. Ed. 2d 394 (1964); Baltimore & Ohio Ry. Co. v. Jackson, 353 U.S. 325, 331, 77 S. Ct. 842, 846, 1 L. Ed. 2d 862 (1957). Accordingly, Fisons' policy arguments are unhelpful in our interpretation of the complex statutory provision at issue."[663]

The MPI finds that similar considerations would have been perfectly appropriate in *Neurim*, as well.

(b) *Neurim is not justified by any technical or legal development not considered by lawmakers*

The CJEU has recognised several times that it is not entitled "to assume the role of the Community legislature and interpret a provision in a manner contrary to its express wording".[664] It is the responsibility and the task of the legislative organs of the EU to submit proposals for appropriate legislative amendments. This basic principle does not mean that the CJEU is prevented from going beyond the plain letter of a provision. Like any court – and particularly courts with a constitutional rank – the CJEU has the power to further develop secondary law and adapt it to new technological circumstances. However, the departure from the wording and the meaning of a provision of a secondary act or an analogous application of such provision requires a justification. Possible justifications are:

- the need to close a gap that otherwise would imply an unequal treatment,
- the need to avoid a conflict with primary law or
- the need to take into account new legal or technical developments.

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660 Case C-31/03 *Pharmacia Italia* [2004] ECR I-10001, para. 21.
661 Case C 482/07 *AHP Manufacturing* [2009] ECR I 7295, para. 40-41.
662 35 U.S.C. § 156(a)(5)(A) U.S.C. See also the analysis of John Thomas, the *USA* in Annex II of this Study, Chapter 8, Section 8.5.2.6.
663 876 F2d 99 *Fisons Plc v J Quigg*; see the analysis of John Thomas, *USA* in Annex II of this Study, Chapter 8, pp. 86-91.
664 Joined Cases C-310/98 and C-406/98 *Hauptzollamt Neubrandenburg v Leszek Labis and Sagpol SC Transport Miedzynarodowy i Spedycja* [2000] ECR I-1797, para. 32.

However, neither the conclusions submitted by the Advocate General nor the CJEU's *Neurim* judgment itself mention any relevant circumstance in this regard. If at all, one could only consider the argument brought forward by Advocate General Trstenjak in relation to the reform of the EPC, precisely Art. 54(5) EPC 2000, which deals with the second medical indication of a known active ingredient.[665] The CJEU, in contrast, has omitted any reference to these provisions.

Still, in our opinion, Art. 54(5) EPC 2000 also does not support *Neurim* for the simple reason that this provision does not make possible a patent protection which was previously excluded under EPC 1973. Patents have been granted for the first medical indication of a known product since the inception of the EPC. Patents for second medical indications have been expressly recognised since the EPO Enlarged Board of Appeal decision in G 5/83.[666] Accordingly, these categories of patents were expressly taken into account in the Explanatory Memorandum. By referring to a patent for the application of the product,[667] it already takes into account patents for the first and second medical indications of the active ingredient in contrast to a patent for the active ingredient as such. EPC 2000, therefore, did not introduce a legal novelty not previously considered by the drafters of Reg. 1768/92 or Reg. 1610/96.

(c) *Neurim has practical implications for NPOs' examination*

Neurim has considerable practical implications as to how NPOs have to examine Art. 3(d) SPC Regulation. While previously the NPO just had to check whether or not the active ingredient was the subject of an MA that was older than the MA supplied in support of the application, the NPOs, after *Neurim*, have to assess not only whether a prior MA concerns the same active ingredient, but also whether it falls under the scope of the patent designated for the purposes of the procedure.

We found nothing in the Explanatory Memorandum or in the Regulations that suggests that the scope of the basic patent is of any bearing in applying Art. 3(d). Equally, there is no indication that the subsequent grant of a patent for a new indication affects the issue of what is in chronological terms the first MA granted for a specific active ingredient.

(d) *Conclusion*

The teleological arguments of the Advocate General and the conclusion of the CJEU are persuasive only if the purpose of Reg. 469/2009 was to reward with an SPC any pharmaceutical invention that has been the subject of both a patent and an MA. However, in our view this is not the purpose pursued by the lawmakers. Reg. 1768/92 did not intend to allow the grant of SPCs in all cases where a medicinal product protected by a patent has been the subject of an authorisation.[668] Only products that

665 Justice Jacob referred to the EPC 2000 as well; see *Neurim Pharmaceuticals (1991) Ltd v Comptroller-General of Patents* [2011] EWCA Civ 228, paras. 28-30.

666 EPO, Case G 5/83 *EISAI/Second medical indication* [1984] ECLI:EP:BA:1984:G000583.19841205.

667 Art. 1(b) Proposal for a Council Regulation (EEC) concerning the creation of a supplementary protection certificate for medicinal products, COM (90) 101 final [1990] OJ C 114, para.

668 European Commission, Explanatory Memorandum to the Proposal for a Council Regulation (EEC), of 11 April 1990, concerning the creation of a supplementary protection certificate for medicinal products (COM(90) 101 final – SYN255), para. 24 ("The system established by the proposal does not apply to all patented medicinal products placed on the market, but only to those which consist in new medicinal products. A large proportion of the medicinal products sold on the market have only few innovative features, or none at all. There are not covered by the scope of the proposal. Each year, only about 50

met the requirements under Art. 3 should be SPC-eligible. One of these requirements is that the MA submitted in support of the application is the first MA granted for the active ingredient in the Member State. Notably, the same is true under 35 U.S.C. § 156(a)(5)(A).[669] The duration of the certificate shall be calculated on the basis of the first MA for the active ingredient in the EU/EEA.

This requirement under Art. 3(d) is based on the assumption that only the first MA has required those extensive clinical trials and has entailed that delay that the Regulations intend to compensate. Indeed, the SPC Regulations are based on the assumption of a vertical integration of the research that from the invention leads to the marketable product; it is based on the assumption that the holder of the patent is also the holder of the MA.[670] The regulation under Art. 13 Reg. 469/2009 has the purpose to ensure that the exclusivity conferred upon the patent owner by the grant of an SPC is limited to a time period of a total of 15 years starting from the grant of the first MA in the EU.

Neurim has undermined the function of these provisions. On the basis of *Neurim*, a company having obtained a hybrid authorisation under Art. 10 Dir. 2001/83 for an active ingredient already authorised or a variation on an existing MA for a new indication could be entitled to an SPC. Under *Neurim*, certificates granted for the active ingredient, even if covering a specific indication, could have a duration that extends beyond the limit of 15 years from the granting of the first MA for the active concerned.

However, the real impact of the decision ultimately depends on the interpretation relied upon by the NPOs. If they limit the scope of *Neurim* to the specific and exceptional situation where the first MA is issued for a veterinary medicinal product and the second for a medicinal product for human use such an impact would be limited. That factual scenario is exceptional according to the information collected by the MPI. The same may be true if they adopt the approach that *Neurim* applies only to new indications. But to the extent that the NPOs apply the *Neurim* principle also in the case where a previous MA for use of the active ingredient on the same species exists, and any time the MA concerned is the first that falls under the scope of the basic patent, then this would potentially lead to the grant of an SPC any time a new MA and patent for a second medical indication are granted. It would result in the grant and existence of a number of SPCs with an expiration date beyond the 15-year term after the first MA for the active ingredient.

In this scenario, economic analysis is needed in order to assess whether the *Neurim* decision and the respective SPC-granting practice have altered the balance between different interests that the Regulation intended to achieve with the requirement laid down in Art. 3(d) Reg. 469/2009 and the regulation under Art. 13(1) Reg. 469/2009

11.3.1.7 Options

If the lawmaker intends to address the question whether and under what condition new uses of an active ingredient already authorised before for a medicinal use shall be SPC-eligible, the following options could be taken into consideration:

new medicinal products are authorized worldwide. It is these that are covered by the proposal for a Directive").

669 35 U.S.C. § 156(a)(5)(A).

670 See Chapter 13, Section 13.1 et seq.

- In accordance with the US regime and with what we consider to be the original intention of the SPC Regulations, lawmakers could confirm that a second-medical-indication patent can be eligible for an SPC only if the requirement under Art. 3(d) Reg. 469/2009 is met and the MA on which the application for a certificate relies is the first MA granted for the active ingredient in the Member State, whether or not the use authorised falls under the scope of the basic patent or not. The same principle should apply to the MA identified for the purposes of Art. 13 Reg. 469/2009. However, the EU lawmakers should and could allow the grant of a certificate when the earlier MA was for a veterinary medicinal product, since the existence of such MA does not imply that the burden for getting the MA for a medicinal product for human use is significantly reduced.
- Lawmakers could allow the grant of SPCs for any new pharmaceutical use provided that the MA is the first within the scope of the patent, while confirming that Art. 3(c) continues to apply and prevent that the same entity can get two SPCs of different scope for the same product. *Neurim*-style SPCs would benefit only originators other than the entity that has developed the substance and already obtained an SPC for it.
- Finally, the lawmakers could allow the grant of an SPCs for any new pharmaceutical use whether or not the applicant has already obtained a certificate for that product. In this case, a new notion of product, that includes the medical indication, shall apply to both Art. 3(c) and Art. 3(d).

11.3.1.8 Recommendation

In 1992 the lawmakers decided to limit the SPC protection to "new medicinal products".[671] By this term the drafters of the Explanatory Memorandum meant medicinal products that include an active substance or a combination of active substances not authorised before as a medicinal product.[672] New medical uses of "old active ingredients", therefore, were not eligible for protection on the basis of later MAs granted for a specific indication. The task of Art. 3(d) was to implement this policy choice that was in line with the US-American model that inspired the European legislature.

In the US the United States Court of Appeals for the Federal Circuit has refrained from questioning the decision made by Congress in limiting the subject matter that is eligible for a PTE to therapeutic moieties not authorised before. In the EU, the Court of the European Justice, on the basis of similar policy arguments as those made in the US before the Federal Circuit, decided to develop the law. It is not clear to what extent this happened. The prevailing view is that *Neurim* is not limited to the specific and absolutely exceptional situation at the basis of the referral, where the older MA was granted for a veterinary medicinal product and the more recent MA submitted in support of the application for a certificate was issued for uses as human drug. If this interpretation is accurate, the CJEU has extended SPC protection beyond what was intended by the lawmakers.

The decision whether and to what extent second medical use of an old active ingredient should benefit from longer patent protection is a question of policy. As

671 See analysis Chapter 2, Section 2.1.3.
672 *Ibid.*

such, the decision must be taken by the lawmakers. Therefore, we suggest closing the gap between the wording of Art. 3(d) and the interpretation adopted by the CJEU. *Neurim* was not based on or mandated by primary Union law, nor has the Court invoked the prohibition of discrimination under Art. 27 TRIPS to justify the interpretation adopted. The lawmakers are fully free to decide whether to adopt *Neurim* and to extend its logics to any new patented medicine, to adopt *Neurim* but to select the factual situations to which it is to apply, or simply to confirm the legislative choices made in 1992. Three aspects in this regard are relevant in our view.

First, in addressing this question the system of incentives for pharmaceutical innovation and the purpose of the SPC Regulations need to be taken into particular account. It is indeed unclear whether SPCs are intended as a reward for having developed a marketable product and obtained an MA or whether the mere fact of having developed an invention and obtained a patent is sufficient, provided that someone else obtained the MA for the subject matter protected. If the patentee may obtain the SPC only if it is the holder of the MA or the holder of the MA agrees, then the grant of the SPC will be possible only in situations where MA and patent are in the same hands or MA holder and patent holder cooperate and act in mutual agreement. In this case, the SPC will benefit both: the SPC could be considered a reward for the investment made in developing a marketable product. One possible implication of this approach is that the SPC-related legal provisions would need to be more stringently coordinated with the provisions concerning data and market exclusivity. On the relationship between data protection and SPC legislation with respect to variation of an existing MA as a basis for applying for an SPC, one NPO[673] has observed in this regard:

> "Another factor to consider is that (…) the medicines legislation – which implements Directive 2001/83/EC and related provisions – and the Variation Regulation EC 1234/2008 (as amended by Commission Reg 712/2012) incentivises the submission of variations for new indications in the first 8 years of approval of the original MA. The applicant is also at liberty to submit a separate new MA application for the new indication but if it falls within the Global Marketing Authorisation concept (as set down in Art 6 and Art 10(1) of Dir 2001/83/EC), it will not benefit from additional data exclusivity over that of the first approved MA. Thus, in the wider context, it may be necessary to verify if the reward gained by the MA holder if this variation can also serve as the basis for a new SPC application is appropriate. This may be a matter for the Commission to consider.
>
> (b) The clinical research involved in approving a new indication for an approved product can be substantial and this is recognised in medicines legislation through incentives such as extension of data exclusivity periods – as mentioned above. If this can also serve as the basis for an SPC application which can provide up to an additional 5 years' monopoly after the patent has expired, it would be appropriate for the Commission to confirm that the – on the face of it – related rewards in the medicines legislation and under the SPC legislation is justified."

Second, the reasons for introducing SPCs for active ingredients in the EU were and are not the mere fact that medicinal products are subject to an MA. Such requirements also exist in other technical fields. The main reason for creating SPCs was the assumption that because of the significant amount of pre-clinical and clinical work needed to develop the data necessary for obtaining a marketing authorisation for an active ingredient, pharmaceutical research could turn out not to be profitable anymore, because the ordinary duration of patent protection was not sufficient to ensure an adequate return for the companies involved. In the terminology of IP

[673] MPI Questionnaire for the NPOs, Q34. "(a) Reg. 1234/2008/EC describes revised variation details for an MA for medicinal products. In your view, should the variation of an MA be considered a new MA for the purposes of Art. 3(b) and (d) Reg. 469/2009/EC?
(b) Or does the amount of investment necessary for the related clinical research not justify such a qualification?"

theory, the reason for the extended exclusivity was that the 20-year patent protection was deemed not to be sufficient to prevent a market failure. This risk was perceived (and partly documented) at that time only for new active ingredients, products for which evidence of their safety and efficacy must be submitted.[674] The need of additional incentives for developing new uses or new formulations of old active ingredients whose safety and efficacy had already been proved in the past was not thematised at that time.

Now, in assessing whether or not new indications should obtain longer patent protection, one should look mainly and first of all at whether the absence of SPCs implies an analogous risk of market failure as in the case of new active ingredients. The main question is whether or not a 20-year patent protection is long enough to create sufficient incentive for this type of innovation. If the answer is no, one should assess whether there is at least the probability that longer patent protection could correct this deficiency, and lead to innovation in Europe that would otherwise not take place. It is clear that it is a very complex assessment that requires data, specialised economic research and a political debate. Such an assessment cannot be made within the context of a reference for a preliminary ruling.

Thirdly, we are not aware of economic literature or policy contributions suggesting that making a distinction between the investments and work required for developing and bringing to the market for the first time a new active ingredient and the work and investments required for developing and bringing to the market an old active ingredient with a new formulation and/or for a new indication, would be arbitrary. The Australian Productivity Commission Inquiry Report, published in December 2016, with respect to the extensions of the pharmaceutical patent term (EoTs) provided under Australian law, observes in this respect:

> "A further policy consideration is whether EoTs should only apply to select products. Ideally, EoTs would apply to those drugs where the standard patent has not provided a pharmaceutical company with sufficient opportunity to recoup their investment. This depends on the costs of research and development, and the returns the pharmaceutical company is able to appropriate due to a period of market exclusivity. Allowing EoTs on a drug-by-drug cost basis would make the system more adaptable. However, as the failings of the previous EoT scheme highlight, utilising a case-by-case approach can be cumbersome and expensive. A simpler approach could be to use easily identifiable proxies, such as whether the patent is over an active pharmaceutical ingredient (API).
> New APIs are generally the most expensive form of drug to develop. They generally involve a higher risk and intensive development process than is required for follow-on products (section 10.5). New APIs also tend to be associated with step changes in innovation, rather than incremental improvements in the effectiveness of existing treatments.
> Restricting EoTs to new APIs would realign the scheme with its original objectives. While the inclusion of *per se* in s. 70(2) of the *Patents Act 1990* (Cth) was originally intended to limit EoTs to new APIs, the boundaries of the definition have become blurred by developments in case law. The 2013 judgment in *Spirit v Mundipharma* held that OxyContin, a controlled release formulation of the opioid oxycodone (which itself was first patented in Germany in 1916) was a different pharmaceutical substance to oxycodone itself, and that it was a pharmaceutical substance *per se* within the meaning of s. 70(2). This example highlights the potential for future cases to further expand the definition, allowing EoTs for progressively smaller advances. With this in mind, the Commission considers there is value in realigning the definition to restrict EoTs to APIs (as is the approach in Singapore)."[675]

[674] Chapter 2, Section 2.1.3.

[675] Australian Government, Productivity Commission, Intellectual Property Arrangements, Productivity Commission Inquiry Report No 78, 23 September 2016, p. 307.

11.3.1.9 Summary

- The decision made in *Neurim* departs from the wording of Art. 3(d). The teleological interpretation adopted by the CJEU is not supported by the recitals and the *travaux* of the SPC Regulations. It is likewise not justified by EPC 2000.
- Whether or not a patent for the new use of an active ingredient already authorised for medicinal purposes deserves SPC protection is a decision that must be made by the lawmakers. Therefore, we recommend closing the gap between the wording of Art. 3(d) and the case law. In deciding whether and to what extent to adopt or reject the logic of *Neurim* no limitation to the legislative discretion of the lawmakers can be inferred from the case law of the CJEU.

11.3.2 New formulation of old active ingredients

11.3.2.1 The issue

Based on the CJEU's *Neurim* decision, Art. 3(d) must be interpreted as allowing the grant of an SPC where the MA for a specific medical indication is the first authorisation within the scope of the basic patent designated for the SPC procedure. This raises the question of whether the same principle applies when:

- the basic patent covers a new formulation of an active ingredient already authorised as active substance of a medicinal product in the EU (old active ingredient);
- the MA supplied in support of the application for the SPC is the first MA within the scope of the patent claiming the new formulation.

This question is the subject of a referral made in the *Abraxis* case, which is addressed below.

11.3.2.2 Abraxis: the proceedings before the UK Patent Office and the referral to the CJEU

The facts of the case were as follows: the basic patent concerned "protein stabilized pharmacologically active agents and their use". Claim 33 of the basic patent is directed to "a composition according to claim 32, wherein said antineoplastic is paclitaxel and said protein is albumin." The product of the MA to which the application for certificate referred – E/1/07/428/001 – was nab-paclitaxel. The indication for the product in the MA is the treatment of metastatic breast cancer and other cancers. Paclitaxel was already the subject of an earlier MA for the same indication. For this reason, the examiner did not grant an SPC on the grounds that MA E/1/07/428/001 was not the first MA within the meaning of Art. 3(d). In the appeal proceedings, *Abraxis* presented the following arguments:

- Nab-paclitaxel is a combination of an active ingredient with an excipient or adjuvant; this combination is a different product to paclitaxel within the meaning of Art. 3(d). Since E/1/07/428/001 was the first authorisation for such product, the application for the certificate complies with Art. 3(d).
- As was the case in *Neurim*, E/1/07/428/001 was the first MA within the scope of the basic patent, and accordingly the same policy consideration applies to

the SPC application even if the latter relates to a new formulation of an old active ingredient and not to a new indication.

According to the Hearing Officer, neither contention was convincing: on the one hand nab-paclitaxel was the combination of an active substance with a substance that is only a carrier and does not have a pharmaceutical effect on its own; on the other hand the *Neurim* decision was limited to cases where the basic patent claims a new therapeutic use of an old active ingredient. Sir Justice Arnold agreed with the Comptroller that nab-paclitaxel is not the active ingredient of Abraxane because albumin is only a carrier.[676] Furthermore, he agreed that the case law of the CJEU is clear in stating that the combination of an excipient, an adjuvant or a carrier with an active substance does not represent a combination of active ingredients within the meaning of Art. 1(b). For this reason, he saw no need to refer any question to the CJEU with respect to Art. 1(b). However, he was of the opinion that it was unclear whether the reasoning of *Neurim* should apply only to new medical uses. Therefore, he referred the following question to the CJEU:

> "Is Article 3 (d) of the SPC Regulation to be interpreted as permitting the grant of an SPC where the marketing authorisation referred to in Article 3 (b) is the first authorisation within the scope of the basic patent to place the product on the market as a medicinal product and where the product is a new formulation of an old active ingredient?"

11.3.2.3 Opinion of the MPI

The Explanatory Memorandum and the wording of the Medicinal Products Regulation make clear that the concept of active ingredient must be interpreted strictly. Therefore, neither the patenting of a new use nor the patenting of a new formulation of the same active ingredient can have any bearing for the question of what the first MA issued for that active ingredient. We refer in this regard again to the paragraphs of the two Explanatory Memoranda quoted in the previous section of this Study.[677] However, despite the wording and the clear intention of the lawmakers, the CJEU in *Neurim* has considered the scope of the basic patent as a controlling factor in the question of whether an active ingredient was already the subject of an MA. One could argue that the same principle must apply in the case of a new formulation. If the first MA granted for a a product does not fall under the scope of a basic patent designated for the procedure and granted for a new formulation of that product, that MA could be disregarded. As a consequence, one can conclude that two formulations of the same product are two different products for the purposes of Art. 3(d). This raises the issue of whether the principle must apply also for assessing the scope of the SPC, with the consequence that the MA on which the SPC relies will limit the scope to the specific formulation even if the basic patent is not limited to that formulation.

Considering the systematic impact that such an answer would have for the SPC Regulations, and considering on the other hand that reasons for distinguishing the new formulation of an old active ingredient from a new medical indication are not so obvious as is generally assumed, the *Abraxis* case could be considered as further evidence that *Neurim* is not just an interpretation, but a development of the SPC legislation. Indeed, its rationale raises issues that had already been answered by the

[676] The High Court of Justice, Chancery Division, Patents Court, *Abraxis v Comptroller General of Patents* [2017] EWHC 14 (Pat).
[677] Section 11.3.1.6 (a) of this Chapter.

wording of the Regulations, the Explanatory Memoranda and the subsequent case law[678].

11.3.2.4 Recommendation

The decision whether the new formulation of an old active ingredient should be protected by a certificate is a question of policy. As such, it requires a systematic review of the incentive system. The intention of the EU legislature in 1992 was that the SPC should reward the development of new medicinal products, meaning active ingredients put on the market for the first time. The MPI is of the opinion that an interpretation of Art. 3(d) Reg. 469/2009 according to which only the first MA for a formulation within the basic patent is considered as the first MA is in conflict with the purpose of the Regulations as historically defined by the lawmakers and with their wording. But the same conclusion was true for the second medical use of an active ingredient already authorised for other medicinal use. Despite this fact, the CJEU in *Neurim* decided that the first authorisation that is relevant under Art. 3(d) is the first authorisation within the scope of the patent designated in the procedure for granting a certificate.

It is up to the lawmakers to decide whether the original scheme of the Regulations is still valid or not, and whether new formulations of old ingredients should be eligible for protection. This issue is relevant for technical fields that are still in development but that could acquire strategic relevance for the European industry in future, such as nanomedicine (see Chapter 18.4). If the lawmakers decide to adopt the *Neurim*-logics, a distinction between a new formulation and a new indication of an old active ingredient is *prima facie* not justified, because:

- from a regulatory perspective, the distinction is arbitrary: the time and the investments that may be needed to bring a new formulation on the market for an old indication are not necessarily less than the time and the investments needed to bring an old formulation on the market for a new indication;
- the distinction could be difficult to implement for the NPOs: a patent for a new formulation can include a claim for a second medical use; it is sufficient to this purpose that the patent claim include a new technical feature. Such technical feature may also consist in a new formulation;
- from the point of view of primary and international law, a differentiation between new formulations and new indications could turn out to be problematic if the prohibition of discrimination under Art. 27 TRIPS or the principle of equal treatment applies to SPCs.

[678] See for instance *Draco AB's SPC Application* [1996] R.P.C. 417.

12 CONDITIONS FOR GRANTING AN SPC: ART. 3(C) REG. 469/2009

12.1.1 The original wording and purpose of Art. 3(c) Reg. 469/2009

Article 3(c) Reg. 469/2009 lays down the third requirement for granting an SPC. The provision reads as follows:

> "A certificate shall be granted if, in the Member State in which the application referred to in Article 7 is submitted and at the date of that application:
> (….)
> (c) the product has not already been the subject of a certificate."

This provision reproduces the wording of Art. 3(c) Reg. 1768/92, whose purpose is illustrated in paragraph 36 of the Explanatory Memorandum as follows:

> "Lastly, the product must not have been the subject of a certificate in the Member State concerned. The certificate is designed to encourage research into new medicinal products so that the duration of protection it affords, together with the effective duration of protection by patent, is sufficient to enable the investments made in the research to be recovered. However, it would not be acceptable, in view of the balance required between the interests concerned, for this total duration of protection for one and the same medicinal product to be exceeded. This might nevertheless be the case if one and the same product were able to be the subject of several successive certificates.
> This calls for a strict definition of the product within the meaning of Article 2. If a certificate has already been granted for the active ingredient itself, a new certificate may not be granted for one and the same active ingredient whatever minor changes may have been made regarding other features of the medicinal product (use of a different salt, different excipients, different pharmaceutical presentation, etc).
> In conclusion, it should be noted that, although one and the same product may be the subject of several patents and several authorizations to be placed on the market in one and the same Member State, the supplementary protection certificate will only be granted for that product on the basis of a single patent and a single authorization to be placed on the market, namely the first chronologically given in the State concerned (the first authorization in the Community being taken only to calculate a uniform duration of different certificates for one and the same product)."[679]

As the quoted passage confirms, the European Commission was well aware that the same product can be covered by multiple patents and several MAs. However, it stipulated that only one SPC could be granted for one and the same product on the basis of the first MA granted in the country concerned. Art. 3(c) together with Art. 3 (d) Reg. 1768/92 was the instrument for implementing this goal. In the absence of such requirement several certificates were possible on the basis of different patents covering the same product.[680] This would have extended the protection granted for the same product beyond the five-year maximum laid down in Art. 13 Reg. 469/2009 with respect to the single certificate. Even if the various SPC applications relied on the same MA, this would not be sufficient to ensure a uniform expiration date of the certificates granted in the Community and in the Member States concerned. Indeed the different filing date of the basic patents may trigger different expiration dates of the corresponding SPCs.

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679 European Commission, Explanatory Memorandum to the Proposal for a Council Regulation (EEC), of 11 April 1990, concerning the creation of a supplementary protection certificate for medicinal products (COM(90) 101 final – SYN255), para. 36.

680 For instance: a patent for a class of compounds that have the property to bind to a specific receptor; a patent that identifies and discloses such compounds; a patent for use of this compound for a specific medical purpose; a patent for a specific form of this compound; a patent for a specific formulation of the compound. All these patents could potentially protect the product within the meaning of Art. 3(a) Reg. 469/2009.

If one considers the plain wording of Art. 3(c) Reg. 1768/92 and Reg. 469/2009, the prohibition applies whether or not the subsequent application for the product was filed by the same or a different applicant. There is no reference to the person to whom the first certificate is granted, and no reference to the patent designated for that procedure. However, Art. 3(c) Reg. 69/2009 prevents the NPO from granting a second SPC for the same product only when a certificate has already been issued at the filing date of the SPC application. If two applications are co-pending, Art. 3(c) does not preclude the grant of two SPCs. Further, the provision concerns only SPCs applied for with respect to the same product. Pursuant to Art. 1(b) Reg. 469/2009 the product means the active ingredient or a combination of two active ingredients, so that one could argue that an active ingredient Y and a combination of active ingredients including the active ingredient Y are not the same product for the purposes of Art. 3(c) Reg. 469/2009.

Legislative developments and case law have altered this literal understanding of the provision.

12.1.2 The legislative amendment and the judicial development of the prohibition

12.1.2.1 Art. 3(2) Reg. 1610/96

Reg. 1610/96 reproduced for plant protection products the prohibition of Art. 3(c) Reg. 1768/92, but it supplemented it with a further rule – Art. 3(2) Reg. 1610/96 – which reads as follows:

> "the holder of more than one patent for the same product shall not be granted more than one certificate for that product. However, where two or more applications concerning the same product and emanating from two or more holders of different patents are pending, one certificate for this product may be issued to each of these holders."

In commenting the proposal for this paragraph in the Explanatory Memorandum to the Amended proposal for a European Parliament and Council Regulation (EC) concerning the creation of a supplementary protection certificate for plant protection products, the European Commission stated:

> "This new paragraph states that, as a rule, the holder of a number of patents for the same plant protection product may not be granted a number of certificates for that product, and sets out the specific circumstances (where two or more applications are pending) in which two or more certificates may be issued for the same product."[681]

According to this explanation, the first part of Art. 3(2) Reg. 1610/96 confirms the principle that only one SPC may be granted for the same product. The second part of the provision states an exception to this principle, an exception that is subject to two cumulative conditions: two applications are pending, and they originate from two different entities.

Pursuant to Recital 17 Reg. 1610/96 this provision shall apply, *mutatis mutandis*, to the interpretation of Art. 3(c) Reg. 1768/92. As already explained in Chapter 3, Section 3.3.2.3, it is questionable that the lawmaker can affect the interpretation of

[681] European Commission, Explanatory Memorandum to the Amended Proposal for a European Parliament and Council Regulation (EC) of 5 October 1995 concerning the creation of a supplementary protection certificate for plant protection products COM(95) 456 final, 94/0285 (COD), para. 3

previous legislation through the (non-binding) recitals of a later piece of legislation. In any event, the Plant Protection Products Regulation cannot amend Reg. 1768/96. Since Reg. 469/2009 has not incorporated the wording of Art. 3(2) Reg. 1610/96 in the binding part of the Regulation, but it has only stated that reference to the repealed Reg. 1768/92 shall be construed as a references to Reg. 469/2009 (Art. 22 Reg. 469/2009), national courts can take into account Art. 3(2) Reg. 1610/96 in interpreting Reg. 469/2009. However, Art. 3(2) Reg. 1610/1996 is not a *lex specialis* that can derogate to Art. 3(c) Reg. 469/2009. Indeed, a recital cannot justify an interpretation that departs from the wording of a binding provision.[682] This principle applies also to Recital 17 Reg. 1610/96, which is the basis for the relevance of Art. 3(2) Reg. 1610/96. The latter provision, indeed, does not mandate its application to medicinal products, but it concerns only plant protection products.

In proceedings before national courts it has been maintained that Art. 3(2) Reg. 1610/96 has not just clarified, but amended Art. 3(c) Reg. 469/2009.[683] On the one hand the wording of Art. 3(c) Reg. 1768/92 rules out the grant of two SPCs irrespective of the identity of the applicant. On the other hand, the wording of the provision did not rule out *a priori* that the same or other applicant can be issued two SPCs for the same product, when two applications are co-pending since the requirements of Art. 3 Reg. 469/2009 are examined with reference to the filing date and not the granting date. Following this view, if two applications of the same applicant are co-pending, both can lead to the grant of an SPC, even if they relate to the same product.

12.1.2.2 The case law

The case law of the CJEU has had a significant impact on the scope of Art. 3(c). A first line of decisions has limited the scope of the prohibition. Three judgments are relevant in this context: *Biogen*[684], *AHP Manufacturing*[685] and *Georgetown II*[686]. A second line of decisions has expanded the applicability of Art. 3(c) in a specific situation where the SPC is requested for a combination including an active ingredient that has already been the subject of a certificate. We have already analysed this case law in Chapter 10, Section 10.2.3(c).

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682 See Case C 345/13 *Karen Millen Fashions* [2014] EU:C:2014:2013, para 31, where the CJEU observed: "Thus, regarding, first, the arguments based on recitals 14 and 19 in the preamble to Regulation No 6/2002, which use the expressions 'the existing design corpus' and 'in comparison with other designs', it should be borne in mind that the preamble to a Community act has no binding legal force and cannot be relied on either as a ground for derogating from the actual provisions of the act in question or for interpreting those provisions in a manner clearly contrary to their wording (Deutsches Milch-Kontor, C 136/04, EU:C:2005:716, paragraph 32 and the case law cited)." See also Case C-136/04 Deutsches Milchkontor [2005] EU:C:2005:716, para 32, where the Court stated: "As regards the ninth recital in the preamble to Regulation No 1706/89, it is sufficient to recall that the preamble to a Community act has no binding legal force and cannot be relied on either as a ground for derogating from the actual provisions of the act in question or for interpreting those provisions in a manner clearly contrary to their wording". 54, and Case C-308/97 Manfredi [1998] ECR I-7685, paragraph 30)." [Case C-136/04 *Deutsches Milchkontor* [2005] EU:C:2005:716, para. 32]

683 See UK IPO, BL 0/138/05 *Knoll AG, Decision* of 19 May 2005; UK IPO, *Chiron Corp's And Novo Nordisk A/S's SPC Application* [2005] R.P.C. 24, 587; see also the analysis in Katarzyna Zbierska, *Application and Importance of Supplementary Protection Certificates for Medicinal Products in the European Union* (Shaker 2012) pp. 168-169.

684 Case C-181/95 *Biogen v Smithkline Beecham Biologicals* [1997] ECR I-357.

685 Case C-482/07 *AHP Manufacturing* [2009] ECR I-7295.

686 Case C-484/12 *Georgetown University* [2013] EU:C:2013:828.

(a) *Biogen*

Biogen is a judgment from 1995 that is directly relevant for the question of whether or not certificates based on a third-party MA are possible. Therefore, the set of facts that lead to the referral and the content of the judgment are explained in detail in the pertinent Chapter.[687] In this context it is sufficient, but necessary, to point out that *Biogen* stated for the first time that two holders of two different patents may be issued an SPC for the same product. Accordingly, the prohibition laid down in Art. 3(c) Reg. 469/2009 shall apply only when the application for a certificate originates from an applicant that has already obtained a certificate for that product. According to the CJEU indeed

> "where a product is protected by a number of basic patents in force, which may belong to a number of patent holders, each of those patents may be designated for the purpose of the procedure for the grant of a certificate."[688]

This principle shall apply with a significant caveat: "under Article 3(c) of the Regulation, however, only one certificate may be granted for each basic patent". These conclusions are based on following arguments:

> "Article 6 of the Regulation confirms that the certificate is to be granted to the holder of the basic patent or his successor in title. Article 1(c) mentions the basic patents which may be designated for the purpose of the procedure for the grant of a certificate, namely those which protect a product as such, a process to obtain a product or an application of a product. The Regulation thus seeks to confer supplementary protection on the holders of such patents, without instituting any preferential ranking amongst them."[689]

Both the conclusions and the arguments supporting the first answer of the Court to the referred question deserve some critical thoughts.

First, the plain wording of Art. 3(c) Reg. 469/2009 prohibits the grant of a second SPC for the same product without attributing any relevance to who has applied for it. This is not the result of bad legislation drafting. The lawmakers consciously intended to allow only one certificate per active ingredient.

Second, the prohibition does not refer at all to the patent, but concerns only the product. Consequently, if two patents cover the same product, Art. 3(c) Reg. 469/2009 allows only one SPC to be granted. If the same patent covers two different products, Art. 3(c) Reg. 469/2009 does not prevent the NPO from granting two SPCs. The practice of some NPOs[690] in allowing more than one SPC for the same basic patent for different products was in line with the wording of the Regulation.

Third, the statement that SPC legislation does not institute any preferential ranking among the applicants remains an assumption in the judgment – indeed it does find support in Art. 3(c) Reg. 1768/92 and Art. 3(2) Reg. 1610/96. If Art. 3(c) allows the grant of a certificate only when no certificate has been already granted it establishes a distinction between two categories of applicants and patent holders: those that have filed the application before and those that have filed the application after the event to

687 See Chapter 13, Section 13.2.1.
688 Case C-181/95 *Biogen v Smithkline Beecham Biologicals* [1997] ECR I-357, para. 28.
689 *Ibid.,* para. 27.
690 See the data and information provided by Martijn De Lange, Examiner of the Netherlands Patent Office, concerning the practice of the NPOs, in '"Just one SPC per patent": time for some number-crunching', SPC Blog, 19 January 2012, available at http://thespcblog.blogspot.de/2012/01/just-one-spc-per-patent-time-for-some.html (last accessed 12 January 2018).

which Art. 3(c) Reg. 469/2009 refers – that is, the grant of a certificate – has occurred. Since the Regulation was drafted assuming that patent and MA were in the same hands, and since the time for prosecuting the applications filed for a certificate can be assumed to be the same in one and the same Member State, the provision creates an incentive to obtain an MA and file the application for a certificate as soon as possible – at least in the case that other companies have filed or obtained patents on overlapping subject matter. As such, the rule is not more unfair than general principles that apply to other IP rights.[691]

A last remark on the meaning of *Biogen* for the further development of the SPC case law is needed in this respect. As explained in Chapters 2 and 13, the Regulations were drafted on the assumption that MA and patent were in the same hands, and the patentee had the faculty to choose one of the possible patents protecting the product covered by the MA in order to obtain a certificate, but not the MA. As a consequence, the number of SPCs would have matched in the expectation of the European Commission the number of new active ingredients authorised each year (circa 50). *Biogen* has admitted the grant of an SPC on the basis of third-party MAs. As a result, two different applicants could obtain two SPCs for the same product on the basis of the same MA, which could have been issued to one of the two competing applicants or even to an unrelated third party.

(b) *AHP Manufacturing v Bureau voor de Industriele Eigendom (C 482/07)*

In *AHP Manufacturing* the Court of Justice had to deal with a set of facts that was not expressly considered in *Biogen.* In the national proceedings the Dutch Industrial Property Office (BIE) had rejected the application for the product *etanercept* filed by Hoffmann-La Roche, because two other SPCs on the basis of different patents had already been granted to other companies at the date of the application. Between the grant of the last SPC and the application filed by Hoffmann-La Roche more than two years had passed.[692] The national court before which the appeal was lodged referred several questions to the CJEU, the first of which reads as follows:

> "1. Does [Regulation No 1768/92], and more specifically Article 3(c) thereof, preclude the grant of [an SPC] to the holder of a basic patent for a product for which, at the time of the submission of the application for [an SPC], one or more [SPCs] have already been granted to one or more holders of one or more other basic patents?"[693]

The CJEU examined the questions all together and decided that also in that situation examined by the referring court the grant of a (further) certificate for the same product was possible. The headings of the judgment (delivered without opinion of the Advocate General) reads as follows:

> "Article 3(c) of Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products, considered in the light of the second sentence of Article 3(2) of Regulation (EC) No 1610/96 of the European Parliament and of the

691 While the reasoning of the Court may not be completely convincing, this does not mean *Biogen* was not rightly decided. Art. 3(c) Reg. 469/2009 prohibits the grant of the SPC when a certificate has already been granted at the filing date. Whether the certificate was granted in Belgium to the Institute Pasteur – the other patent holder mentioned in the judgment – before or after the filing of the application of *Biogen,* is not stated in the judgment.

692 The patent designated for the procedure was granted after the MA, and the six-month deadline started from the granting date of the patent; see Art. 7(2) Reg. 1768/92.

693 Reference for a preliminary ruling from the Rechtbank's-Gravenhage (Netherlands) lodged on 2 November 2007 - *AHP Manufacturing BV v Bureau voor de Industriële Eigendom*, also operating under the name *Octrooicentrum Nederland*.

> Council of 23 July 1996 concerning the creation of a supplementary protection certificate for plant protection products, must be interpreted as not precluding the grant of a supplementary protection certificate to the holder of a basic patent for a product for which, at the time the certificate application is submitted, one or more certificates have already been granted to one or more holders of one or more other basic patents."[694]

The CJEU has motivated this result with various arguments. First the CJEU has based the conclusion on Art. 3(2) Reg. 1610/96. The CJEU recognised in para. 24 that "the second sentence of Article 3(2) Reg. 1610/96 refers expressly to such a grant only where the SPC applications emanating from the patent holders are pending"[695]. However, it did not consider this wording as precluding the grant of an SPC for a product for which an SPC was already granted at the time the application is filed. The reasons for this opinion are laid down in paras. 25 and 26 of the judgment, which read as follows:

> "25. In that respect, it should be pointed out that the first sentence of Article 3(2) precludes the grant, to the holder of more than one patent for the same product, of more than one SPC for that product. However, the second sentence of Article 3(2) allows such a grant to two or more holders of different patents for the same product. It is thus apparent that the special condition for the grant of two or more SPCs for the same product is that the relevant applications emanate from different holders of basic patents. The second sentence of Article 3(2) does not require, on the other hand, that the applications be pending at the same time. Moreover, the word 'pending' does not feature in the Italian language version of Regulation No 1610/96, according to which those applications must merely have been submitted ('[t]uttavia, se sono state introdotte due o più domande …').[696]
> 26. It is apparent from the findings in the preceding paragraph that the simultaneity of the applications in question cannot be considered an essential condition for the grant referred to in the second sentence of Article 3(2) of Regulation No 1610/96."[697]

Second, the Court observed that the second sentence of Art. 3(2) Reg. 1610/96 "must be interpreted not solely on the basis of its wording, but also in the light of the overall scheme and objectives of the system of which it is a part"[698]. In this respect, the Court considered relevant Art. 7 Reg. 1768/92, according to which the application must be submitted within six months of the date on which the MA or the patent was granted, whichever is later. The argument made by the Court was that if the application submitted within this period were refused, because a certificate was already granted, then the applicant would be deprived of the benefit of this six-month period for filing the application.

Third, the Court recalled the fundamental objective of the Regulation to encourage pharmaceutical research. By referring to *Biogen*, the Court stated that the Regulation aims to confer protection on the holders of national European patents, without instituting any preferential ranking among them. As consequence:

> "31 If there are two or more holders of patents for the same product, who all make an SPC application to the competent industrial property office of the Member State in question within the periods laid down in Article 7 of Regulation No 1768/92, making the grant of an SPC subject to the condition that those applications be pending would risk denying to one or more of those holders the benefit of the supplementary protection allowing them better to cover the investment which they have put into the research, with the result that preferential ranking would be instituted amongst the holders.[699]
> 32 If such a condition existed, the grant of an SPC could depend on an event which was uncertain and, as a rule, outside the control of the applicant, namely the date of the office's decision on the grant of one or more SPCs. Accordingly, once a positive decision had been

694 Case C-482/07 *AHP Manufacturing* [2009] ECR I-7295.
695 *Ibid*., para. 24.
696 *Ibid.,* para. 25.
697 *Ibid.,* para. 26.
698 *Ibid.,* para. 27.
699 *Ibid*., para. 31.

> taken with regard to one or more SPC applications for the same product, those applications would no longer be pending, so that another SPC application, whether it had been lodged before or after that decision or even prior to the lodging of the applications which are the subject of the decision, would have to be refused.[700]
>
> 33 Such a solution would thus risk considerably reducing the possibility, provided for in Article 3(2) of Regulation No 1610/96, for two or more holders of different patents for the same product to obtain an SPC for that product."[701]

Fourth, since the Regulation does not provide for any time limit within which the NPOs of the Member States have to make a decision on the application, the lengths of the procedure for granting SPCs vary in Europe. According to the Court, this would lead to a situation where the same certificate can be granted in one country because the time to make a decision on an earlier application is longer, but also in another country, because there the time to make a decision is shorter or the first application was filed earlier. A fragmentation of the common market would follow as a consequence.

Finally, the CJEU was aware that Art. 3(c) had the function of avoiding that "the same product being the subject of a number of successive SPCs, so that the overall duration of protection for one and the same medicinal product could be exceeded"[702]. Art. 3(c) together with Art. 3(d) was indeed the main instrument for ensuring the balance of interests that the Regulation intended to achieve. However, according to the CJEU "it is not at all necessary, in order to achieve the balance between the different interests envisaged by that regulation, to refuse such a grant on the ground that one or more SPCs have already been granted to other holders of basic patents for the same product"[703], because this result is already ensured by the rules on the duration of the SPCs, that is Art. 13 Reg. 1768/92, according to which the SPC cannot be granted for a period exceeding five years, and by the provisions that limit the duration of the patent to 20 years. The following comments of the CJEU are significant in this regard:

> "[…] point 36 of the Explanatory Memorandum to the Proposal for a Regulation, cited at paragraph 28 of the present judgment, states that the purpose of Article 3(c) of Regulation No 1768/92 is to avoid the same product being the subject of a number of successive SPCs, so that the overall duration of protection for one and the same medicinal product could be exceeded. For the reasons set out in the previous two paragraphs, a number of SPC applications emanating from different holders of basic patents for the product concerned, whether they are pending at the same time or not, cannot lead to a period of exclusive rights exceeding 15 years from the grant of the first authorisation to place that product on the market in the Community."[704]

The reasoning of the CJEU has been criticised in a part of the literature. This criticism is not unjustified. Indeed the statement of the courts according to which Art. 3(2) Reg. 1610/96 does not require that the two applications be co-pending cannot be agreed with, because it is exactly what the provision requires. This is confirmed by the comments of the European Commission itself in explaining the amended proposal for the Plant Protection Products Regulation[705].

Second, the Court seems to be aware that the wording of Art. 3(2) Reg. 1610/96 refers expressly to a grant of second certificate only when the two applications are co-

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700 *Ibid*., para. 32.
701 *Ibid.,* para. 33.
702 *Ibid*., para. 42.
703 *Ibid*., para. 40.
704 *Ibid*., paras. 41-42.
705 See again the comments of the European Commission reported above in Section 12.1.2.1 of this Chapter contained in the Explanatory Memorandum to the Amended Proposal for a European Parliament and Council Regulation (EC) of 5 October 1995 concerning the creation of a supplementary protection certificate for plant protection products COM(95) 456 final, 94/0285 (COD), para. 3 ("this new paragraph ... sets out the specific circumstances (where two or more applications are pending) in which two or more certificates may be issued for the same product").

pending. For this reason the CJEU resorts to a systematic and teleological interpretation of Art. 3(2) Reg. 1610/96, and transposed the result of this interpretation to Art. 3(c) Reg. 469/2009. The intrinsic problem of this approach is that the provision that applies to medicinal products is Art. 3(c) Reg. 1768/92 and not Art. 3(2). Reg. 1610/96. The latter is only one element to be taken into account in the interpretation of Art. 3(c).[706] Since it is not possible on the basis of a recital to adopt an interpretation that is in conflict with the wording of a binding provision of Union law, it is questionable whether on the basis of Recital 17 Reg. 1610/96 the CJEU may adopt an interpretation that is in conflict with the clear wording of Art. 3(c) Reg. 469/2009. This is true even if the latter interpretation would be a teleologically justified development of Art. 3(2) Reg. 1610/96.

Third, the argument that the SPC Regulation does not intend to establish a preferential ranking among the applicants, and that therefore Art. 3(c) Reg. 469/2009 must be intended in a way that such ranking is not established – even the wording of the latter suggests the opposite – is circular reasoning. Indeed, the statement that the Regulation does not provide for such ranking is based on *Biogen*, and not on the Regulation itself.

Fourth, as correctly pointed out in the literature[707], Art. 7 Reg. 469/2009 is only a procedural provision. It is at the very least questionable that such procedural provision shall mandate a specific interpretation of Art. 3(c) Reg. 469/2009.[708]

Finally, the argument that the function Art. 3(c) is intended to serve can be already achieved by the provisions that limit the duration of the patent to 20 years and the provisions that limit the duration of the SPC to five years and to 15 years since the issue of the first MA is surprising. The lawmakers were well aware of the existence of Art. 13 and of the 20-year limited term of patents. Despite that, they decided to adopt Art. 3(c) Reg. 1768/96.[709] The reasons are well explained in the Explanatory Memorandum. Further, one shall nowadays take into account also the interaction between *AHP* and *Neurim*. The principle that all the SPCs granted for the same product would expires 15 years after the issue of the first MA in the EU/EEA for that active ingredient is not true (anymore).[710]

For all these reasons, we agree with the opinion[711] that the CJEU has adopted a *contra legem* interpretation of the SPC legislation, ruling against the wording of the provision applied. It is not apparent that for such approach superior principles of the Union legal order and provision of primary law could have been invoked.

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706 Katarzyna Zbierska, *Application and Importance of Supplementary Protection Certificates for Medicinal Products in the European Union* (Shaker 2012) p. 168.

707 Robert Wenzel, *Analoge Anwendung der Verordnung über das ergänzende Schutzzertifikat für Arzneimittel auf Medizinprodukte?* (Nomos 2017) pp. 144-145.

708 *Ibid.* Also the assumption that all applicants shall benefit from a 6-month period to file the application, and that only the advocated interpretation of Art. 3(c) could ensure that this is the case, is questionable. Indeed, if the MA is granted less than 6 months before the expiration of the patent, the applicant will not benefit from the whole period laid down in Art. 7 for filing the application. Nevertheless, nobody would assume that Art. 3(a) shall be interpreted so that the applicant can file the application after the expiration date of the patent in order to enjoy the full period provided after Art. 7 Reg. 469/2009.

709 Robert Wenzel, *Analoge Anwendung der Verordnung über das ergänzende Schutzzertifikat für Arzneimittel auf Medizinprodukte?* (Nomos 2017), pp 146.

710 See Chapter 11, Section 11.3.1.6 (a).

711 *Ibid.*

(c) *Georgetown II*

In *Georgetown II*[712] the questions referred to the Court concerned the following factual scenario: the patent in question protected a combination including a specific active ingredient and the single active ingredient included in the combination. The applicant had already obtained a certificate for a combination on the basis of the patent and had filed a second application directed to one of the active ingredients covered by the patent. Therefore, the factual scenario was the opposite of *Actavis I* and *Actavis II*, where first a certificate for the monotherapy product and then a certificate for the combination was applied for.

The Court decided that

> "[..] [i]n circumstances such as those in the main proceedings, where, on the basis of a basic patent and a marketing authorisation for a medicinal product consisting of a combination of several active ingredients, the patent holder has already obtained a supplementary protection certificate for that combination of active ingredients, protected by that patent within the meaning of Article 3(a) of Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products, Article 3(c) of that regulation must be interpreted as not precluding the proprietor from also obtaining a supplementary protection certificate for one of those active ingredients which, individually, is also protected as such by that patent."[713]

This conclusion is in apparent conflict with the statement made in *Biogen* that only one certificate for each basic patent can be granted. However, we are of the opinion that the latter principle does not have a backing in Art. 3(c) Reg. 469/2009.

(d) *Result*

As a result of this case law, the prohibition of Art. 3(c) Reg. 469/2009 applies only in the case that the same patentee has already obtained an SPC for the same product. If other entities than the applicant have obtained an SPC for the same product, Art. 3(c) Reg. 469/2009 does not apply. The same holds true if the same patentee requests on the basis of the same patent two SPCs for two different products. This does not imply that the prohibition of multiple SPCs has lost any relevance. While the line of decisions discussed in the previous section has benefited the applicants, another development concerning the concept of product pursuant to Art. 3(c) Reg. 469/2009 has reduced the SPC eligibility of combinations. Indeed after *Actavis I* and *Actavis II* if a patentee has already obtained an SPC for compound Y, Art. 3(c) prevents the grant of a further SPC to the same patentee for any combination including such compound, unless such combination represents a separate innovation. Following *Actavis I* and *Actavis II* single compound and any combination of active ingredients including such compound are considered to be the same product under Art. 3(c) Reg. 469/2009 unless the combination is inventive *vis-à-vis* the single compound.

There is another reason why Art. 3(c) is still relevant. In *Neurim* the CJEU allowed the grant of an SPC on the basis of an MA that is not the first MA for the product concerned, provided that such MA is the first that falls under the scope of the patent designated for the SPC procedure. With respect to Art. 3(d), therefore, the examination of whether the product covered by an earlier MA than the MA supplied in support of the application for a certificate must take account of the medical indication for which the MA was granted. As a consequence of *Neurim*, a product for indication A

712 Case C-484/12 *Georgetown University* [2013] EU:C:2013:828.
713 *Ibid.*

and a product for indication B are not the same product under Art. 3(d), and the MA covering the product for indication A is not the first MA with respect to an SPC requested on the basis of a patent for product Y for indication B. However, *Neurim* does not address the question of whether this concept of product formulated for Art. 3(d) applies also to Art. 3(c). If this is not the case, Art. 3(c) would limit the applicability of *Neurim* to situations where on the basis of the first MA for the active ingredient either no SPC was granted or such SPC was granted to an unrelated entity.

12.1.3 The issues arising from the CJEU case law

Since the CJEU based this core inventive test on Art. 3(c) Reg. 469/2009 and since this test plays an important role in the view of the CJEU in ensuring the balance between the interests involved, and since Art. 3 (c) could grow in importance following *Neurim*, the question arises whether Art. 3(c) can fulfil the function, after the case law applies the prohibition only when the two applications are filed by the same applicant.

The following factual scenarios can help to understand the issues resulting from the developments discussed in the previous section:

> **Scenario I**: Applicant A files a patent application and a divisional application. The latter is directed to a combination including the active ingredient Y and is transferred to a parent company B.
> **Scenario II**: Applicant A files a national application and transfers the priority right to a third company for the purposes of a European application.
> **Scenario III**: Applicant A files a first application and the parent company B files another application within the 18-months from the filing date or priority date of the first application. The older application will be relevant only for examining novelty but not inventive step with respect to the later application, see Art. 56 and Art. 54(3) EPC.
> **Scenario IV**: Applicant A files several applications, and transfers some of the granted patents to a licensee.

In all these situations two (or more) patents are granted that can cover identical products within the meaning of Art. 1 and Art. 3(c) Reg. 469/2009. If these patents are in the same hands, the patentee has *the right and the obligation* to choose one of these patents as basic patent for the purpose of the SPC granting procedure. If the patents are in different hands the situation is unclear.

A part of the literature has maintained that a substantive and not a formal approach must apply to Art. 3(c) Reg. 469/2009 and Art. 3(2) Reg. 1610/96. Where a relation between the patent holders exists, one of the SPCs must be refused or declared void.[714] By contrast, some NPOs seem to consider, at least in some of the above-mentioned scenarios, the grant of several SPCs as possible. Indeed the question was posed to the NPOs in the MPI Questionnaire whether it is possible in their practice for the applicant to circumvent Art. 3(c) Reg. 469/2209 by filing several divisional applications and transferring some of these applications to a third company.[715] The majority of the NPOs maintained that in such a case Art. 3(c) Reg. 469/2009 is not offended. As a consequence, both the owner of the parent patent and the owner of the divisional patent can obtain an SPC. Of course, we can infer from this answer that the same applies when the patents are independent of each other, and one covers generically the product and the other specifically the active ingredient, or one covers

[714] See for instance Franz Hacker in Rudolf Busse, Alfred Keukenschrijver, *Patentgesetz* (Walter de Gruyter 2017) Anhang § 16a, marginal note 68, according to which Art. 3(c) Reg. 469/2009 shall apply when two applications for the same product are filed by two companies belonging the same group.

[715] MPI Questionnaire for the NPOs, Q41.

the class of compounds and the other a process for their manufacture. As long as the applicants are formally two different entities, related or not, the prohibition under Art. 3(c) does not apply in several jurisdictions. The answers of the NPOs are summed up in the table below:

NPO	Q41: Under your jurisdiction is it possible to circumvent the requirement based on Art. 3(c) Reg. 469/2009/EC by filing several patent applications on the same date or within the 18 months before the publication of the first application, or by filing several divisional applications and then transferring some of them before or after grant to a third company?	Q42: Applicant A files a first SPC application directed to substance X based on Patent No. 1 owned by Applicant A. Applicants A and B file a second SPC application directed to the same substance X based on Patent No. 2 owned by Applicant A and B. How does your Office proceed in this case?
Austria	Yes	The Office will grant both SPCs.
Croatia	Yes	The Office would not grant the second SPC.
Czech Republic	No	One SPC will be granted (e.g. owners A+B). After that there will be an objection that the conditions mentioned in Art. 3(2) of the Reg. 1610/96 are not met in the case of the other SPC application. One holder (A) cannot obtain two SPCs for product X.
Denmark	Yes	Our understanding of Art. 3(2) is that the same applicant cannot be granted two SPCs for the same product. In this case the question is whether or not A and A+B are the same applicant. If we have doubts on whether the applicants are identical or not, we ask the applicant to provide us with information that documents that the applicant of the first and second SPC are two different legal entities, for instance by submitting a trade register excerpt. If they are not able to provide us with convincing documentation we would probably reject the application if no other evidence could substantiate the claim. Each case will however always be based on an individual assessment.
Finland	Yes	Two certificates may be granted as B is also entitled to a certificate.

France	It is possible to file several patent applications within the 18 months before the publication of the first application but not if their claims are identical to the first's ones, as this would result in a double patenting. In any case, it would not be possible to circumvent the requirement based on art 3(c) by filing several applications. The grant of a first SPC would preclude the grant to the same owner of another SPC on the same product, regardless of the basic patent. It is possible to file several divisional applications and then transfer some of them before or after grant to a third company. In such a case, SPCs on a product X may be granted both to the owner of the "parent" patent and to the third company that owns the divisional patent, provided they both protect the product X.	The Office would refuse to grant the second SPC filed by applicant A and B because A has already taken advantage of the first SPC.
Germany	Filing of several patent applications by the same applicant in any chronological order does not provide an instrument to circumvent Art. 3(c). On the contrary, by transfer to an independent third party the provision could be circumvented.	Since ownership of an SPC by A and B in the given case could be used to circumvent Art. 3(c) Reg. 469/2009/EC and A would be the (co-) owner of two SPCs for the same product, the Office is critical towards the grant of a second SPC.
Greece	The Office does not examine the requirement of Art. 3(c) and (d).	If the conditions of Art. 3(a) and (b) are met, the Office will grant both SPCs.
Hungary	Yes	The second SPC would not be granted, since applicant A already has a valid SPC for substance X. If the second application is transferred to applicant B, he may be granted the SPC for substance X.
Ireland	Yes	Irish NPO has granted an SPC to A and to A and B in cases such as this, after having raised an issue under Art. 3(2).
Italy	Yes	The Office grants the SPC

Latvia	No answer. This situation has not occurred in the Office's practice.	Probably the second SPC will be granted, but the Office does not have a clear answer. It would be good if this situation could be more precisely regulated.
Lithuania	No answer.	Such case would most probably result in Art. 3(c) refusal.
Luxembourg	The Office does not verify whether Art. 3(c)'s condition is met.	The Office does not verify if there are two conflicting SPC applications.
The Netherlands	No answer. This situation has not occurred in the Office's practice.	A and A+B are considered to be different patent holders. Two SPCs can be issued for the same product.
Poland	No	The SPC for Applicant A is granted based on Patent No. 1. The SPC for Applicant B is granted based on Patent No. 2.
Portugal	No	In this case our office grants the SPC since we believe that B should not be prejudiced because of A.
Romania	No answer. This situation has not occurred in the Office's practice.	No answer.
Serbia	Please see the answer to Q40. Also, it is not necessary to transfer divisional applications to a third company because, to our understanding, a new compound and its combination(s) with other known compound(s) are independent products in accordance with Art. 1 Reg. 469/2009.	We did not have the case. Per our current understanding the holder of more than one patent for the same product shall not be granted more than one certificate for the product, so applicant A can be granted only one SPC.
Slovak Republic	So far the Office has not had any case law or provision dealing with this. Thus, it seems to be possible.	The Office has not had such case so far, but we assume that the second SPC based on the second SPC application should be granted at least (or exclusively) to Applicant B.
Spain	Yes	For the grant of two or more SPCs for the same product, the relevant applications must emanate from different holders of basic patents. Therefore, applicant A cannot obtain a second SPC based on Patent No. 2.
Sweden	Yes, different legal entities are seen as different applicants in view of the SPC Regulation. This makes it possible to circumvent the requirement of Art 3(c) by transferring patents to other legal entities within for example the same	We grant the second SPC, since applicant B is eligible to his right. The case is different if A+B has been granted the first SPC. In that case, both the applicants have already been afforded compensation.

	company group. In the last couple of years this has been more common.	
Switzerland	Under the current practice this circumvention would not occur. However, it is under discussion in Switzerland.	A and A+B are considered different applicants
United Kingdom	Yes	The Office would not consider Article 3(2) 1610/96 to be offended.

Table 12.1: Scope of Art. 3(c) Reg. 469/2009 (Q41-42 MPI Questionnaire for the NPOs)

12.1.3.1 Options

The case law has radically transformed the scope of Art. 3(c) Reg. 1768/92. Originally intended to allow only one certificate per product, the provision as interpreted by the CJEU now prohibits the grant of a second SPC only in case of identity of the applicants. Multiple certificates for the same product based on the same MA became possible. This is true even in cases of applications that were not co-pending.

If one agrees with our interpretation that Art. 3(c) Reg. 1768/92 should apply in the view of the historical lawmakers to any application directed to a product for which a certificate was granted, irrespective of the identity of the applicant, with the only exception of co-pending applications, then a discrepancy between written law[716] and case law would exist.

In this case, the lawmakers have two options. If they agree with the reasons that led the case law to erode the prohibition of multiple certificates for the same product, then they may codify this case law. If they consider the reasons that induced the lawmakers in 1992 to limit the number of SPCs to the number of active ingredients authorised for the first time (c. 50), then the lawmakers shall incorporate the wording of Art. 3(2) Reg. 1610/96 in Art. 3 Reg. 469/2009 and confirm by a recital that only a literal and narrow interpretation of the exception laid down in Art. 3(2) Reg. 1610/96 (co-pending applications) is allowed.

The decision between the two options is a question of policy. The arguments that have led the CJEU to develop teleologically Art. 3(c) are explained in *Biogen* and *AHP*. The reasons that led to the adoption of Art. 3(c) are explained in paras. 34-38 of the Explanatory Memorandum to the Medicinal Product Regulation. It is clear that the choice between the two options is interrelated with the other questions: whether or not the patentee may obtain the certificate on the basis of a third-party MA, and if the consent of the latter is required, whether or not the holder of the MA can entitle two different applicants to obtain a certificate on the basis of the same MA for the same product.

If the European Commission came to the conclusion that when two independent entities on the basis of two separate courses of research develop two patentable inventions, and the patents granted for these inventions cover overlapping subject

[716] Now Art. 3(c) Reg. 469/2009.

matter, it may be justified that two certificates are issued for the same product incorporating both inventions, even if the application for the certificate is based on the same MA, and that therefore the case law of the CJEU deserves to be supported and codified, then it shall amend Art. 3(c) Reg. 469/2009 and redraft Art. 3(2) Reg. 1610/96 as well in line with *AHP*. In this case the prohibition shall apply only to situations where the same entity is applying for a second certificate or has filed two applications for a certificate concerning the same product. In doing so, the lawmakers shall address the resulting weakness of a provision whose applicability depends on the identity of the applicants. Indeed such subjective requirement includes a problematic aspect already addressed: even if the patents are the result of activities within the same company, the applicant could be able to obtain several SPCs by filing multiple applications and transferring the resulting patents (or patent applications or priority rights) to different entities. This outcome would frustrate even the residual function that Art. 3(c) was intended to fulfil under the case law of the CJEU. There are three possible approaches to address this issue.

First, one could provide that for the purpose of Art. 3(c) Reg. 469/2009 the same applicant exists any time the patent designated for the purpose of the procedure shares at least one inventor with the previous patent for which an SPC has been granted (**overlapping inventorship**). An example of this approach exists in the draft bill implementing the unitary patent package into German patent law. The prohibition of enforcing a national patent covering the same subject matter as a European patent with unitary effect pursuant to Art. II § 18 IntPatÜbkG will apply even if the applicants filing for the two patents are different entities, but only under the condition that the patents share the same inventors.[717] A further example of this approach is found in US case law. The obviousness-type double patenting prohibition applies so far as the patent applications share even only partly the same inventorship.[718]

Since under European and national law the applicant has a legal duty to indicate all inventors,[719] and since the inventors have an interest in being indicated in the patent application and have an enforceable right to be mentioned, such an approach could increase the effectiveness of Art. 3(c) Reg. 469/2009.

A possible wording implementing such suggestions could read as follows:

> A certificate shall be granted if, in the Member State in which the application referred to in Article 7 is submitted and at the date of that application:
> (….)
> c) the product has not already been the subject of a certificate granted to the same applicant or a group of applicants including the same applicant;
> (…)
> (2) The holder of more than one patent for the same product shall not be granted more than one certificate for that product. However, where two or more applications concerning the same product emanate from two or more holders of different patents, one certificate for this product may be issued to each of these holders, unless the patents concerned were granted to successors in title of the same inventor or inventors.

[717] The prohibition applies to patents that belong to successors in title of the same inventor(s). Even if the rights on the invention follow automatically from the existence of an employement contract and the application for a patent is filed by the employees, the latter are still successors in title of the inventor. See for an unofficial translation of Art. II § 18 IntPatÜbkG Peter Höcherl et al, 'Double protection and forum shopping under Germany's draft UPC legislation', available at https://www.bristowsupc.com/commentary/double-protection-and-forum-shopping/ (last accessed 12 January 2018).

[718] *In re Hubbell* (Fed. Cir. 2013).

[719] See Art. 60 EPC.

A second approach could be to consider different applicants as the same applicant for the purpose of Art. 3(c) Reg. 469/2009, when they represent **related entities**. An example of such an approach exists in European regulatory soft law. In the case of global marketing authorisation, different entities are treated as the same applicant or marketing authorisation holder when (i) they are part of the same group, or (ii) a control relationship exists between them, or again (iii) a licensee agreement or another contractual agreement for the development or marketing of the product exists.[720]

A third approach could combine and cumulate both abovementioned solutions.

Against these proposals one could argue that the MPI has no evidence whatsoever that the practices that the proposed rules would address occur at all. In fact, the MPI has not collected evidence that Art. 3(c) Reg. 469/2009 is circumvented by applicants by resorting to veiled company-based filing strategies. That this happens was highlighted in some interviews by some stakeholders (generics companies). But this information constitutes of course only anecdotal evidence. However, this does not appear to be decisive for an action of the lawmakers in this respect. If the above scenarios are exceptional, the implementing rules discussed would not really affect the system users. If the opposite is true, the supplementary rules proposed here could provide Art. 3(c) more relevance.

A second objection could be that for an NPO it is very difficult to check whether a relationship between two companies exists.[721] However, overlapping inventorship can be considered by the granting office. The existence of a connection between the companies can be examined in the case that the third party files observations or starts a revocation action[722]. The NPO itself in dubious cases could ask the applicant for a statement about the relationship with the owner of a granted certificate or pending application for the same product. Such statement could then be included in the file of the application. False statements of the applicants in granting proceedings could trigger liability under antitrust rules.[723]

12.1.3.2 Legislative aspects

Not all options discussed in the previous section necessarily call for an amendment of Art. 3(c). More precisely, if the lawmakers consider satisfactory the development of the case law, but intend to ensure that related entity cannot circumvent the prohibition under Art. 3(c) by transferring the patent application, the patent or the priority right, then it could be possible to ensure this result by adopting implementing rules or soft law. Indeed, the concept of the holder of the patent is not defined by the SPC Regulations. Article 3(2) Reg. 1610/96 does not mandate a narrow and formal understanding of this notion. Further, the term "holder" can also be intended to cover an assignee of the same inventor or inventors, or group of inventors including the same inventor, even in the case that under national law an employer automatically acquires the right to an invention made by the employee(s). Further the concept of

720 See European Commission, 'Notice to the Applicants, Vol. 2A Procedures for marketing authorisation, Chapter 1, Marketing Authorisation', July 2015, para. 28.

721 See Jürgen Schrell in Rainer Schulte (ed.), PATENTGESETZ MIT EPÜ (10th edn, Carl Heymanns Verlag 2017) §16a, marginal note 47.

722 See Franz Hacker in Rudolf Busse, Alfred Keukenschrijver, *Patentgesetz* (Walter de Gruyter 2017) Anhang § 16a, marginal note 68.

723 Case T-321/05 *Astra Zeneca v Commission* [2010] ECLI:EU:T:2010:266.

the holder of the basic patent can be equally extensively interpreted in the sense that related companies can be considered to be the same holder.

However, a legislative amendment is to be preferred to a clarification by interpretative means, because only the CJEU has the final word over the question whether or not a clarification is just interpreting or amending a primary provision. It is not possible to change Reg. 469/2009 by implementing rules or soft law.

12.1.4 The effect of surrender and revocation of the SPC on the operation of Art. 3(c) Reg. 469/2009

Article 3(c) Reg. 469/2009 refers to an SPC that has been granted. Based on the wording of the provision it does not matter what the subsequent fate of the SPC is – how long the right exists and whether or how it has ceased to exist. As a consequence, it is not possible to obtain a further SPC for the same product even after the earlier SPC has been surrendered or revoked. It remains a fact that the surrendered or revoked SPC was "granted" within the meaning of Art. 3(c) Reg. 469/2009. This is necessary, but also sufficient, to apply the prohibition.

This interpretation is however not unanimous. According to the German Federal Patent Court, the revocation of a certificate has the effect that Art. 3(c) Reg. 469/2009 does not prevent the NPO from granting an SPC for the same product to the same applicant.[724] This reasoning is based on the retroactive effect of the revocation. Such an interpretation of Art. 3(c) Reg. 469/2009 would oblige a company that is clearing the way for its product to reach the market to initiate further actions against subsequent SPCs.

This result is not consistent with the function of the provision. Irrespective of whether the revocation or the surrender has retroactive effect, they should not interfere with the operation of Art. 3(c) Reg. 469/2009.[725]

Admittedly, this principle, if applied to revocation of the SPC, is open to some objections. It may have harsh results when the certificate is invalid because the designated patent is void, and another patent would cover the product. The same holds true when in consequence of a development of the case law the MA supplied in support of the application turns out not to be a valid MA within the meaning of Art. 3(b). This was indeed the situation of *iodosulfuron*[726]: the certificate was granted on the basis of an emergency authorisation. However, situations where uncertainty about the status of an MA for the purposes of the SPC legislation leads the applicant to file earlier the application for a certificate on the basis of an MA that turned out later to be not a relevant MA for the purposes of Art. 3(b) are almost exceptional. As for the

[724] BPatG, *Iodosulfuron,* 3 Ni 16/08 [2010] GRUR 132; see Christopher Brückner, *Supplementary protection certificates with paediatric extension of duration* (2nd edn, Heymanns 2015) Art. 3, marginal note 545 *et seqq*.

[725] An analogy can be drawn with the provision concerning the prohibition of double protection that exists in the national law of some EPC contracting parties. On the one hand, according to the national provisions the revocation or the surrender of a European patent does not imply a resurrection of the national patent covering the same subject matter that has become ineffective as a consequence of the coexistence with the European patent concerned. On the other hand, patent law does not allow the grant of a new patent with a later priority date for subject matter disclosed by an earlier European patent.

[726] BPatG, *Iodosulfuron*, 3 Ni 16/08 [2010] GRUR 132; see Christopher Brückner, *Supplementary protection certificates with paediatric extension of duration* (2nd edn, Heymanns 2015) Art. 3, marginal note 545 et seqq.

invalidity of the designated patent, the patentee has the freedom to choose which patent is designated for the purpose of the procedure. He/she must also bear the responsibility for this choice.

We are therefore of the opinion that Art. 3(c) Reg. 469/20009 must remain applicable as long as an SPC has been granted for the product, no matter how long the SPCs remain effective and what effect – *ex nunc* or *ex tunc* – the surrender or the revocation of the first SPC may have. An example for such regulation is provided under the Canadian legislation on CSP. A corresponding proposal is discussed in Chapter 20, Sections 20.3.2.7 and 20.3.2.8.

12.1.5 Summary

- In the intention of the lawmakers, Art. 3(c) Reg. 469/2009 had the function of ensuring that only one certificate is issued for the same product. The case law has strongly limited the scope of the provision, by allowing multiple certificates for the same product, provided that the corresponding applications originated from different applicants. While the provision shall implement the principle of one certificate per product, the CJEU has adopted a rule of one certificate for the same product per patentee.
- At the same time, the case law has expanded the scope of the provision in cases where the same applicant has filed an application for a product and for a combination including such product. Also, Art. 3(c) Reg. 469/2009 could acquire further relevance in consequence of *Neurim*, since *Neurim*-style applications that no longer fail under Art. 3(d) Reg. 469/2009 could still be rejected under Art. 3 (c) Reg. 469/2009.
- As a consequence of this development, the lawmakers have several options. If the lawmakers agree with the reasons that have induced the CJEU to allow multiple certificates for the same product, it could codify this case law and amend Art. 3(2) Reg. 1610/96 and Art. 3(c) Reg. 469/2009 accordingly.
- In this case, however, in order to ensure the effectiveness of Art. 3(c) Reg. 469/2009, the lawmakers could provide that the prohibition applies in situations where (i) the applicants are formally distinct, but substantially related entities and/or (ii) the patents share even partly the same inventorship. If the lawmaker considers by contrast the original reasons for adopting Art. 3(c) Reg. 469/2009 still valid, then it should re-establish the principle that only one certificate per product is possible by amending the Regulation accordingly.
- Surrender of the SPC shall not have any effect on the application of Art. 3(c) Reg. 469/2009.

13 SPCs BASED ON THIRD-PARTY MARKETING AUTHORISATION

13.1 THE ISSUE

In *Biogen Inc. v SmithKline Beecham Biologicals S.A.* (C-181/95)[727] Advocate General Neil Fennelly maintained that Reg. 1768/92 was drafted with a business model in mind in which research, development and marketing are "vertically integrated"[728] and consequently the applicant for an SPC is both proprietor of the patent and holder of the MA. The situation in which the patent and MA are in different hands was in contrast – in the opinion of the Advocate General – not considered by the legislators.[729] In practice, however, ownership of the basic patent and holdership of the MA are not necessarily in the same hands.

At least, following different scenarios can be identified in this regard:

Scenario I: siblings companies relationship	An entity develops the invention and obtains the patent; another entity within the same group develops the product
Scenario 2: licensor-licensee relationship	An entity develops the invention and licenses the patent; the licensee invests in the clinical trials and obtains the MA
Scenario 3: joint development contract	An entity develops an invention, and another entity working on similar subject matter agrees to a common development of the product and involves for this purpose a third entity or creates a joint venture to which the patents of both entities are licensed or assigned
Scenario 4: unrelated entities	An entity develops and patents an invention; an unrelated entity obtains an MA for subject matter falling under one of the claims of the patent

Table 13.1: Scenarios for SPCs based on third-party MAs

The first three scenarios – parent company, licensor-licensee, joint development situations – are not problematic.[730] The entity that holds the MA will usually agree to the grant of the SPC. In most cases, it will also be obliged to do so under applicable contractual agreements. In all three scenarios the patentee is involved indirectly in the MA procedure, either as a member of the same group of companies or as a licensor of the patent, or as a partner in the product and development agreement. In all jurisdictions reviewed,[731] the grant and the validity of the SPC or a PTE would not be an issue in these cases.

The last scenario – unrelated entities (No. 4) – is by contrast more difficult to assess. In the US[732], Japan[733], Korea[734] and Taiwan[735], the patentee must be the entity that

727 Case C-181/95 *Biogen v Smithkline Beecham Biologicals* [1997] ECR I-357, Opinion of AG Fennelly.
728 *Ibid*., para. 29.
729 *Ibid*., para. 1 et seq.
730 See also Jens Schovsbo et al, 'Reap what you sow! – But what about SPC squatting?', forthcoming [2018] Journal of Intellectual Property Law & Practice.
731 See Annex II of this Study.
732 See John *Thomas*, *the USA* in Annex II of this Study, Chapter 8, Section 8.6.
733 See Yoshiyuki Tamura et al, *Japan* in Annex II of this Study, Chapter 4, Section 4.5.1.

participates in the product approval process or must have the consent of the holder of the MA or a principal-agent relationship with him. The legal situation in the EU is less clear.

13.2 CASE LAW OF THE CJEU

13.2.1 *Biogen*

The CJEU *Biogen* judgment is considered by some authors as the turning point in relation to the reference to third-party MAs in SPC application proceedings in some parts of the literature.[736] The judgment is interpreted as indeed expressly allowing for the grant of an SPC despite the opposition of the relevant MA holder. However, while the decision was the first one to deal with the use of third-party MAs, the question whether the patentee needs the consent of the MA holder in order to obtain a valid SPC was not expressly referred to the CJEU.

In the main proceedings before the Belgian court (*Tribunal de Commerce of Nivelles*), the parties involved were on the one side Biogen as the holder of two patents for antigens of the hepatitis B virus which were manufactured, according to the invention, through recombinant DNA technology, and on the other side SKB as the holder of several MAs for a vaccine against the hepatitis B virus. Such vaccine included as an active ingredient an antigen that falls under the scope of both patents granted to Biogen.

SKB had obtained a licence for both of Biogen's patents. The product concerned, the antigen Engerix B, was also protected by a further patent granted to the Institut Pasteur. On the assumption that an SPC could only be granted for the product Engerix B, SKB provided the Institut Pasteur with a copy of the MA for that product in order to let Institut Pasteur include this copy in the application for a certificate. However, SKB refused to provide Biogen with a corresponding copy of the MA to apply for an SPC in Belgium.

Biogen requested the Belgian Ministry of Public Health to provide a copy of the MA. This request was, however, rejected on the grounds that SKB had not granted permission. Biogen therefore filed a lawsuit with the court in Nivelles against SKB alleging a violation of fair competition rules and requesting an injunction to prevent SKB from continuing its alleged discriminatory behaviour by providing a copy of the MA that would have enabled Biogen to apply for and obtain an SPC in Belgium. The court took the view that the interpretation of some provisions of Reg. 1768/92 was relevant for deciding the case. Accordingly, it referred the following questions to the CJEU:

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734 See Jun-seok Park, *Korea* in Annex II of this Study, Chapter 5, Section 5.5.

735 See Kung-Chung Liu, *Taiwan* in Annex II of this Study, Chapter 9, Section 9.6.

736 According to Christopher Brückner*, Supplementary protection certificates with paediatric extension of duration* (2nd edn, Heymanns 2015) Art. 6, marginal note 41, before *Biogen* it was not possible to obtain an SPC based on a third-party MA. The author quotes Detlef Schennen, *Die Verlängerung der Patentlaufzeit für Arzneimittel im Gemeinsamen Markt* (Bundesanzeiger 1993) p. 61 in support of this statement. However, the quoted passage does not support his conclusion. There Schennen in interpreting the Regulation simply states that the consent of the holder of the MA is required, and not that the filing of an application for a certificate on the basis of a third-party MA is excluded. Furthermore, before *Biogen* the literature reported cases of the Netherlands Patent Office granting SPCs on the basis of third-party MAs.

"1. In the event that the holder of the basic patent or his successor in title is a person other than the holder of the authorisation to place the medicinal product concerned on the market, is the latter obliged to provide to the patent holder on request, or, where appropriate, several patent holders when they so request, the "copy" of that authorisation which is referred to in Article 8(l)(b) of Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products?
2. Where one and the same product is covered by several basic patents belonging to different holders, does Regulation No 1768/92 preclude the grant of a supplementary protection certificate to each holder of a basic patent?
3. Regard being had to the wording of Article 6 of Regulation No 1768/92, may the holder of the authorisation to place the medicinal product on the market refuse to give a holder of a basic patent or his successor in title the copy of that authorisation referred to in Article 8(1)(b) of the Regulation and thereby deprive him of the possibility of completing his application for a supplementary protection certificate?
4. May the relevant administrative and/or government authority which granted the authorisation to place the product on the market or is the depositary of an original or a copy of the said authorisation refuse to supply a copy to the holder of the basic patent or patents concerned or to his successor in title or may it decide, arbitrarily or subject to certain conditions, whether it is advisable to provide or communicate such copy with a view to its being used to support an application for a supplementary protection certificate under the provisions of Council Regulation No 1768/92 of 18 June 1992 (OJ 1992 L 182, p. 1)?"

The second question was relevant for the case because SKB's refusal to provide Biogen with a copy of the MA was, *inter alia*, motivated by the assumption that only *one SPC* could be granted for the same product. The first and the third questions concern the issue of whether or not a substantive right to obtain the copy of the MA was laid down in the Regulations. The last question concerned the duties or discretionary powers of the authority that could provide such a copy.

The answer of the Court is as follows:

"2. Regulation No 1768/92 does not require the holder of the marketing authorisation to provide the patent holder with a copy of that authorisation, referred to in Article 8(l)(b) of the Regulation.
3. Where the basic patent and the authorisation to place the product on the market as a medicinal product are held by different persons and the patent holder is unable to provide a copy of that authorisation in accordance with Article 8(l)(b) of Regulation No 1768/92, an application for a certificate must not be refused on that ground alone."

These guiding principles of the judgment, however, do not allow for a clear answer to the question whether or not the opposition of the holder of the MA is immaterial for the grant of a valid certificate. According to the third guiding principle of *Biogen*, NPOs cannot reject the SPC application *only* for the reason that the patentee is unable to include a copy of the MA in the application for the SPC. The Court has not stated expressly that SPCs can be granted whether or not the holder of the MA agrees. Such a conclusion is, however, drawn in the literature and this with good reason.

Indeed, SKB argued before the CJEU that if the administration provided the patentee with a copy of the MA then "the holder of the authorisation would be definitively and wrongfully deprived, without consideration or justification, of income which he is entitled to expect in return for the effort and cost incurred with a view to obtaining the authorisation". The Court observed in this regard that if the NPO could not ask for a copy of the MA, then "the entitlement to the certificate conferred by Article 6 of the Regulation on the basic patent holder would be rendered nugatory". SKB's argument – that in this way the position of the holder of the MA was deprived of a part of the income that it expected in investing in the development of the product – was not considered relevant by the CJEU. In commenting on the case, the 18th edition of Terrell on Patents, edited *inter alia* by Justice Colin Birss, observes:

> "Inherent in the circumstances facing the Court of Justice in the *Biogen* case was the fact that the holder of the marketing authorisation (SKB) did not want the patent holder (Biogen) to obtain a certificate prolonging the lifetime of Biogen's patent and the court's decision permitting Biogen to obtain a certificate in any event necessarily shows that a patent holder does not need the consent of the holder of the relevant marketing authorisation to obtain a certificate."[737]

We agree with this analysis.[738]

13.2.2 *Eli Lilly*

According to several opinions, while *Biogen* allowed for the grant of SPCs irrespective of the MA holder's consent, the CJEU in its *Eli Lilly* decision[739] seems to have questioned this principle and practice.[740]

The main question of the case was whether or not the antibody *tabalumab* was protected by the patent pursuant to Art. 3(a) Reg. 469/2009 even if the patent specification did not mention such an antibody and did not even disclose any other antibody falling under the broad functional claim 13 of the patent.[741] In considering this issue, the Court stated the following:[742]

> "the refusal of an SPC application for an active ingredient which is not specifically referred to by a patent issued by the EPO relied on in support of such an application may be justified […] where the holder of the patent in question has failed to take any steps to carry out more in-depth research and identify his invention specifically, making it possible to ascertain clearly the active ingredient which may be commercially exploited in a medicinal product corresponding to the needs of certain patients. In such a situation, if an SPC were granted to the patent holder, even though – since he was not the holder of the MA granted for the medicinal product developed from the specifications of the source patent – that patent holder had not made any investment in research relating to that aspect of his original invention, that would undermine the objective of [the Regulation], as referred to in recital 4 in the preamble thereto."

These statements seem to suggest that if the patent discloses the compound specifically, then the holder of that patent may base the application for a certificate on a third-party MA whether or not the holder of the latter agrees. By contrast, if the patent does not disclose the compound specifically, then an SPC will only be available provided that the patentee has made investments in the research needed for specifying the product after the filing date. For instance, evidence of such investment could be the existence of another patent application filed by the same entity that specifically discloses the compound generically covered by the first patent. Further evidence could be the grant of an MA to the patent owner itself for that antibody.

It is clear that these considerations do not answer the question of whether or not the patentee can rely on a third-party MA without that MA holder's consent. These considerations rather seem to introduce a further requirement for granting the SPC. Such a requirement would apply with respect to situations where the designated basic patent does not satisfy the requirement "specified in the claim" that the CJEU introduced with its *Medeva* decision.[743] Such patents do not necessarily fail to support

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737 Colin Birss et al, *Terrell on the Law of Patents* (18th edn, Sweet & Maxwell 2016) marginal note 6-59.
738 See also Jens Schovsbo et al, 'Reap what you sow! – But what about SPC squatting?', forthcoming [2018] Journal of Intellectual Property Law & Practice.
739 Case C-493/12 *Eli Lilly and Company* [2013] EU:C:2013:835. See Chapter 10, Section 10.2.4 (b) (iii) of this Study.
740 See Chapter 10, Section 10.2.3.2 (b) (iii).
741 See *ibid.*
742 *Ibid.*, para. 43.
743 Case C-322/10 *Medeva* [2011] ECR I-12051. See above, Chapter 10, Section 10.2.3.2 (b).

an SPC application if the holder has taken further steps, after the priority date of such patents, to carry out more in-depth research to identify the product for which the SPC is requested.

If this reading of *Eli Lilly* were correct, this would imply that the CJEU has the following understanding of the SPC system: SPCs shall be granted as a reward and an incentive for carrying out the research leading to a marketable product. If the patentee has already done this research at the filing date of the patent and has already at that date identified the product of the future MA on which the SPC application relies, the SPC can be granted. Who the holder of the MA concerned is would not matter in that case. But if the patent application does not include this information as filed, then the question of who obtained the MA matters.

This question can be decisive in relation to the SPC eligibility of the product on the basis of the patent concerned. If this view is correct, then the examination in this regard would need to be conducted as follows:

1. Does the patent "relate, implicitly but necessarily and specifically" to the product for which the SPC is requested?
2.a. If the answer is yes, the product is protected by Art. 3(a) Reg. 469/2009.
2.b. If the answer is no, has the patentee taken further steps after the filing date to specify the product? Evidence for these further steps or investments could be the MA, but not the MA alone.
2.b.aa. If the answer is yes, the SPC can be granted.
2.b.bb. If the answer is no, the SPC application is to be rejected.

Assuming our interpretation as set out above is correct, the following two problems arise from the *Eli Lilly* approach.

First, if the patent owner is not the holder of the MA, the NPO can request evidence for the existence of an agreement between the patent holder and the MA holder. While such assessment is rather easily conducted by the NPOs, it is in our view very difficult for them to assess whether the patent owner made investments in developing a therapeutic product after the patent was filed. This assessment has been confirmed by several NPOs.

Second, it is questionable whether the ownership of the MA or the investments made by the patentee after the filing date would have a bearing on the application of Art. 3(a) Reg. 469/2009. Article 3(a) refers to the patent as granted. We do not see how Art. 3(a) Reg. 469/2009 can provide the basis for an inquiry into the question of ownership of the MA or what kind of investments the patentee has made to identify the product. Justice Warren observes in this regard:

> "an approach to Article 3(a) which produces different results depending on who carries out the later research – the original patentee or a third party – cannot be right in principle. Either a basic patent does, or does not, protect a product and I can see no ground at all for saying that the answer to that question depends on who produces the product."[744]

We agree with this consideration.

[744] *Eli Lilly and Company v Human Genome Sciences Inc* [2014] EWHC 2404 (Pat), para. 48.

13.3 NATIONAL CASE LAW AND PRACTICE

13.3.1 Practice of the NPOs

13.3.1.1 General considerations

According to the information collected by the MPI, the NPOs grant SPCs even if the applicant is not the owner of the authorisation to place the product on the market on which the application for a certificate relies.

If the applicant is not able to provide a copy of the MA, as requested pursuant to Art. 8(1)(b) Reg. 469/2009, the majority of the NPOs ask for a copy from the competent granting authority. This practice is deemed to be in line with the CJEU's *Biogen* decision. However, some patent offices (e.g. Greece, Latvia, Czech Republic and Lithuania) do not grant an SPC in that situation. The following table summarises the answers obtained in relation to Question 5 of the MPI Questionnaire for the NPOs:

NPO	Must the SPC applicant also be the holder of the MA to which the application refers pursuant to Art. 8(1)(a)(iv)?	May the applicant refer to a third-party authorisation even if no contractual relationship with this third party exists and no evidence for the consent of the said third party to the grant of the SPC is submitted?	If the patentee cannot provide your Office with a copy of the third-party MA pursuant to Art. 8(1)(b) Reg. 469/2009 to which the application refers, how does your Office proceed?
Austria	For the time being, no. So far, no court decision.	Yes. (In the application procedure the applicant is neither requested to prove a contractual relationship nor to file evidence of the consent of the third party.) See CJEU 181/95. Where the basic patent and the authorisation to place the product on the market as a medicinal product are held by different persons and the patent holder is unable to provide a copy of that authorisation in accordance with Art. 8(l)(b) of Reg. 469/2009, an application for a certificate must not be refused on that ground alone.	If the patentee argues in the SPC application procedure that he cannot provide the Austrian Patent Office with a copy of the third-party MA the patentee is asked to submit evidence a) that the owner of the patent and the third party are different persons and b) that the owner had made unsuccessful efforts to get a copy of the MA. In this case the Austrian Patent Office asks the authority that issued the MA to submit a copy.

Croatia	No, it is not necessary that the SPC applicant is also the holder of the MA.	Applicant is not obliged to submit evidence of the consent of the third party to the grant of the SPC.	Although we have not had such a case in our practice, by simple cooperation with the competent national health authority the Office would try to obtain a copy of the marketing authorisation from the national authority that issued it.
Czech Republic	No	Yes	If the MA is not available we will proceed according to Art. 10(3) and 10(4) of the Reg. 469/2009.
Denmark	It is of no importance to whom the authorisation has been granted, e.g. a licensee. The applicant shall however enclose a copy of the marketing authorisation when filing the application for a certificate.	No answer [but see left]	No answer [but see left]
Finland	No	Yes	We accept, in lieu of said copy, any other document identifying the product and containing the number and date of the MA and the summary of product characteristics (e.g. the public assessment report by the EMA).
France	No	In the French practice, directly based on CJEU *Biogen* case law, the applicant may refer to a third party's MA, regard-less if this third party agrees or not, or if a contractual relationship exists between them or not.	No answer
Germany	There are no limits or preconditions for using a third-party MA.	[see left]	In case no copy of the third-party MA can be provided by the applicant, the DPMA is obliged to order a copy from the respective MA granting authority (C-181/95 *Biogen*).

Greece	No	The applicant can refer to a third-party authorisation, without the consent of the licence holder, but he must provide a copy of the third-party MA pursuant to Art. 8(1)(b) Reg. 469/2009 on which the application refers to.	If he [applicant] cannot provide a copy of the MA, the SPC application is rejected.
Hungary	No answer	The SPC applicant may refer to a third party MA even in the absence of a contractual relationship or consent of the third party. However, no such case has arisen before HIPO, thus we cannot share any practical experience.	The same is true for cases where the patentee cannot provide HIPO with a copy of the third-party MA. The Office would probably attempt to obtain it from the regulatory authority in question.
Ireland	No	Yes	If the MA is a centralised EU MA, we would get a copy from the online Community Register of Medicinal Products. For national MAs, we would request a copy from the appropriate body, which in Ireland is the Health Products Regulatory Authority for medicinal products or the Department of Agriculture for plant protection products.
Italy	No	The applicant may refer to a third-party MA.	MA may be public since it is granted by the EMA. SPC may be granted.
Latvia	Holder of the MA may be the third party; the consent of the holder is not required.	[see left]	Most MAs are centralised authorisations, as far as we know they may be downloaded from the EMA website and the relevant EU websites. We have not had problems with centralised MAs and decentralised MAs in this respect. According to Art. 8 of the Regulation, the MA must be a part of the application. So had we received documents without the MA we would not consider them as an application for an SPC. If we have doubts whether the MA filed is the correct one (MA

			under Art. 3(d)) we ask the applicant to confirm this or file the correct one.
Lithuania	No	The relation of the applicant to the third party is not examined by the Office and no proof is required.	It is compulsory to provide a copy of the MA by the applicant; if he cannot provide it, the SPC may not be granted.
Luxembourg	No	Yes	We would accept getting the MA through administrative cooperation with the issuing administration, in application of judgment C-181/95.
The Netherlands	No	Yes	Has never been an issue in practice. Moreover MAs are published online these days.
Poland	In our jurisdiction the SPC applicant does not have to be the holder of the MA.	The applicant may refer to a third-party authorisation without the consent of the third party.	If the patentee cannot provide a copy of the third-party MA we have to turn to the competent national agency.
Portugal	No	Yes	Our office notifies the applicant in order for him to provide us with a copy of the first MA because Art. 8(1)(b) Reg. 469/2009 states that it is necessary to do so.
Romania	No. The holder of the MA could be different from the SPC applicant.	Yes. The applicant may refer to a third-party authorisation even if no contractual relationship with this third party exists and no evidence for the consent of the said third party to the grant of the SPC is submitted.	In case the patentee cannot provide a copy of the third-party MA pursuant to Art. 8(1)(b) Reg. 469/2009 to which the application refers, the RO Office searches online for the MA, in the Official Journal of the European Union and/or in the European Commission Register.
Serbia	We understand that the objective of Recital 4 of the SPC Regulations is undermined by granting an SPC to the patent holder when he was not the holder of the MA granted for the medicinal product developed from the specifications of the	No answer	No answer

	basic patent, BUT there is no provision in SPC Regulations precluding the patent holder from applying for an SPC based upon an MA obtained by another, unconnected party.		
Slovak Republic	No, in our jurisdiction it is not stipulated that the SPC applicant is also the holder of the MA to which the application refers.	The applicant may, in fact, refer to a third-party authorisation even if no contractual relationship with this third party exists and no evidence for the consent of the said third party to the grant of the SPC is submitted.	Our Office has never had to face the problem where the patentee could not provide a copy of the third-party MA.
Spain	No. The SPC applicant and the MA holder could be different.	We do not examine whether the applicant is the MA holder or not.	We shall apply the CJEU's ruling in Case C-181/95 *Biogen v Smithkline Beecham Biologicals SA* (1997), paragraph 3).
Sweden	No	Yes	Where the basic patent and the marketing authorisation are held by different persons and the patent holder is unable to provide the competent national authorities with a copy of that authorisation, granted by the authorities of a Member State, in accordance with Art. 8(1)(b) of the Regulation, the application for a certificate must not be refused on that ground alone. By simple cooperation, the national authority granting the certificate can obtain a copy of the marketing authorisation from the national authority which issued it.
Switzerland	It is not required that the SPC applicant is the holder of the MA.	He may refer to a third-party authorisation even if no contractual relationship exists with this third party and no evidence of consent is submitted.	If no MA copy can be provided, the Swiss IPO will check the data base of the Swiss regulatory agency Swissmedic. Swiss MA data are published in the Swissmedic Journal. If necessary, the Office can

			contact the MA authorities to check the data.
United Kingdom	The SPC applicant need not be the holder of the MA, and may refer to a third-party MA.	[see left]	If the applicant cannot provide a copy of the third-party MA we proceed in accordance with the Biogen judgment. We ask that the applicant provides evidence that they have sought a copy of the MA from the MA holder, for example they may submit a copy of a letter requesting the MA from the holder. They will also be asked to submit the publicly available information regarding the product and the date of the authorisation. Using the publicly available information regarding the third-party MA the Office will then seek a copy from the authority issuing it. If the authority requests it this MA may be kept confidential – for office use only and not made available to the applicant or the public.

Table 13.2: Q5 MPI Questionnaire for the NPOs

13.3.1.2 NPOs' decisions

It seems to follow from the table 13.2 that the CJEU judgment in *Eli Lilly* has not had any impact on the practice of the NPOs. Rather, in line with *Biogen*, the NPOs grant SPCs based on the third-party MAs even if there is no evidence of agreement with the third party or the third party disagrees and this circumstance is known to the office.[745] However, evidence collected by the MPI suggests that the practice of the NPOs was not completely unaffected by *Eli Lilly*.

In the decision of 14 April 2014 concerning SPC Application No. 1220130000716,[746] the German Patent and Trade Mark Office maintained that an SPC application may be rejected when it is based on a third-party MA and the patent did not individually disclose the product for which the application for a certificate was made. In that case, a company belonging to the same group as the MA holder had filed third-party observations against the grant of the SPC. The decision seems to suggest that, in the case that the patentee had specifically disclosed the product, it would be possible to rely on the third-party MA and obtain a certificate. By contrast, if the patent claims

[745] The NPO could be aware of the opposition of the MA holder in the case that the latter files third-party observations.

[746] Decision of Division of Examination of DPMA of 14 April 2014 concerning the SPC Application No. 122013000071.6, https://register.dpma.de/DPMAregister/pat/register?AKZ=122013000071.6 (last accessed 7 August 2017).

cover the product in a general manner, but the latter is not identified by the patent specification, then the third-party issue is relevant. The Office has observed in particular:

> "Die Antragstellerin mag zwar – wie von ihr vorgetragen – die Grundlagen für das genehmigte Erzeugnis geschaffen haben. Die Angaben im Grundpatent waren aber nicht ausreichend, um das konkrete Erzeugnis zur Verfügung stellen zu können. Dazu war weiterer Forschungsaufwand notwendig. Der Patentinhaberin, welche nicht Inhaberin der Genehmigung für das Erzeugnis Lipegfilgrastim ist, ein Schutzzertifikat zu erteilen, obwohl diese nicht die über das Grundpatent hinausgehenden Spezifizierungen betrieben und daher keine weiteren Forschungsinvestitionen getätigt hat, würde bedeuten, den im vierten Erwägungsgrund der AM-VO genannten Zweck der Verordnung zu missachten (vgl. "Eli Lilly", insbes. Rn. 43). Das grundlegende Ziel der AM-VO besteht darin, einen zeitlichen Ausgleich für die aufwändigen Studien und langwierigen Zulassungsverfahren zu gewähren, die vor der Vermarktung des Arzneimittels notwendig sind und somit einen Anreiz für weitere Forschungs- und Entwicklungsleistungen zu schaffen. Die Patentabteilung kommt deshalb zum Ergebnis, dass die Erteilung eines ergänzenden Schutzzertifikats für Lipegfilgrastim nicht gerechtfertigt und damit der entsprechende Antrag zurückzuweisen ist."[747]

The DPMA did not thereby object to the use of a third-party MA in principle. However, since the patent designated for the SPC procedure did not identify the product, the German Patent Office considered relevant whether or not the patentee is the holder of the MA.

In a previous decision, the MA holder had filed a third-party observation opposing the use of the MA.[748] A parent company of the MA holder was a defendant in infringement proceedings initiated by the patentee before a civil court in Germany. The holder of the MA maintained that the applicant had no right to base the SPC on its own MA, and that the applicant had not made any effort to identify the product for which it had applied for the SPC. The German Office nevertheless granted the SPC. Since the decision to grant an SPC does not need to be reasoned, it is not possible to identify how the third-party issue was considered in the specific granting proceedings. It therefore remains unclear for the time being whether the *Lipegfilgrastim* decision is an isolated case in the practice of the Patent and Trade Mark Office.

A similar approach to the *Lipegfilgrastim* decision of the German Patent and Trade Mark Office has been adopted by the French Patent Office (INPI). In cases where the basic patent does not specifically disclose the product, the French examiners consider other aspects such as the grant of further patents or the ownership of the MA. Again, the approach is not to exclude the option of relying on the third-party MA. However, if the disclosure of the patent does not identify the product in a way that the Office deems to be sufficient to satisfy the *Medeva*-requirement, the Office considers the question of what entity has obtained the MA. If the respective entity is an unrelated

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747 *Ibid.* "The applicant, as it stated, may have created the basis for the approved product. The specifications in the basic patent were, however, not sufficient to make the actual product available. For this, further research efforts were necessary. To grant the patent proprietor, who does not hold the marketing authorisation for the product lipegfilgrastim, a protection certificate, even though it has not carried out any specification beyond the basic patent and therefore has not made any additional research investment, would mean to disregard the purpose of the regulation mentioned in recital 4 of Regulation (EC) No 469/2009 (cf. "Eli Lilly", paragraph 43). The essential aim of this Regulation is to grant time compensation for costly surveys and lengthy approval procedures, which are necessary prior to the commercialization of a pharmaceutical product, and thus to create an incentive for further research and development efforts. The patent department therefore has decided that the grant of a supplementary protection certificate for lipegfilgrastim is not justified and the respective request is to be denied" (MPI translation).

748 Decision of Division of Examination of DPMA of 2 May 2012 concerning the SPC Application No. 122010000026.2, https://register.dpma.de/DPMAregister/pat/register?AKZ=1220100000262 (last accessed 7 August 2017).

third party, this affects the examination of the requirement under Art. 3(a) Reg. 469/2009.[749]

INPI's position consequently seems to be consistent with the abovementioned *Lipegfilgrastim* decision of the German Patent Office (Application No. 122013000071.6).

13.3.2 National case law

The question is whether an SPC is valid even if the holder of the MA has never agreed to the filing, and the grant of the SPC has not yet been decided by the German Federal Patent Court.

However, in infringement proceedings before German civil courts, alleged infringers have argued that the enforcement of an SPC against the MA holder represents an abuse of right. The argument made in infringement proceedings is that SPCs were introduced to compensate the patentee for the delay in the commercial exploitation of the invention due to the MA proceedings. Because of this delay the patent term is not sufficient to remunerate investments made in pharmaceutical research. According to the defendant in infringement proceedings before the Düsseldorf District Court, case No. 4a O 143/10, the purpose of the SPC is to extend the right of the patentee to prohibit the marketing of alternative products that can satisfy the same needs as the protected products. This purpose would be turned upside down if the grant of the SPC leads to the consequence that exactly the product that is the subject of the authorisation on which the SPC is based will be withdrawn from the market.

The Düsseldorf District Court has, however, rejected these arguments. The court agreed that the purpose of the SPC legislation is to compensate for the delay following the MA proceedings and the consequential reduction of the effective patent term. But this fact does not imply that the patent owner is prevented from enforcing the SPC against the MA holder. By contrast, according to the court, the SPC and the MA can be in different hands. The holder of the former can prohibit the economic use of the subject matter of the SPC by the holder of the latter.[750] The court based this opinion directly on *Biogen*.

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[749] For INPI's express response see the above table summarising the NPOs' answers to the MPI Questionnaire for the NPOs.

[750] See Düsseldorf District Court (Landgericht Düsseldorf)*, Decision of 10 November 2011* [2012] BeckRS 21620. We report the original version of the judgment: "Soweit die Beklagten insoweit geltend machen, die Klägerin sei an der Geltendmachung von Unterlassungsansprüchen wegen einer widerrechtlichen Benutzung des Gegenstandes gehindert, weil die Klägerin als Patentinhaberin anstrebe, der Beklagten den Vertrieb genau jenes Arzneimittels zu verbieten, das Gegenstand der Genehmigung für das Inverkehrbringen sei, die gerade die Grundlage für das erteilte ergänzende Schutzzertifikat darstelle, rechtfertigt dies keine andere Bewertung. Zwar weisen die Beklagten zurecht darauf hin, dass mit der Einführung des ergänzenden Schutzzertifikats der Tatsache Rechnung getragen werden sollte, dass staatliche Genehmigungsverfahren, die der Zulassung eines Stoffes oder Verfahrens für den Verkehr vorausgehen, zu einer Einschränkung der effektiven Nutzungszeit des auf das Erzeugnis erteilten Patents führen können (vgl. Benkard, Patentgesetz, 10. Auflage, § 16a, Rz. 6). Jedoch bedeutet dies nicht, dass der Inhaber des Grundpatents auf der Grundlage des Schutzzertifikats nicht gegen den Inhaber der arzneimittelrechtlichen Genehmigung vorgehen könnte. Vielmehr kann die Inhaberschaft an dem Schutzzertifikat und an der arzneimittelrechtlichen Genehmigung auseinanderfallen. Demnach ist es möglich, dass der Inhaber des Schutzzertifikats – wie hier – dem personenverschiedenen Inhaber der Genehmigung die Benutzung des Schutzzertifikats untersagen kann (vgl. EuGH GRUR-Int. 1997, 363 – Biogen; Benkard/Grabinski, Patentgesetz, 10. Auflage, § 16a, Rz. 40)".

In the proceedings *Medimmune Limited v Novartis Pharmaceuticals (UK) Limited & another*,[751] Justice Arnold considered the issue of third-party MAs *ex officio*. His considerations on the matter read as follows:

> "As noted above, in the present case the SPC is based upon a product obtained by means of an allegedly infringing process and upon a marketing authorisation obtained by an alleged infringer of the patent. It might be thought that it was not the purpose of the Regulation to enable a patent owner to obtain an SPC in such circumstances, since the owner has not been delayed in getting the product to market by the need to get a marketing authorisation, and therefore no extension to the term of the patent is needed to compensate him for that delay. Counsel for Medimmune accepted that it was not clear from the judgment of the Court of Justice in Case C-181/95 *Biogen Inc v SmithKline Biologicals SA* [1997] ECR I-386 that this was permissible. Nevertheless, counsel for Novartis made it clear that Novartis was not taking this point."

In *Eli Lilly*, Justice Warren considered the question of third-party MAs, but decided not to refer it to the CJEU. It is significant that in these proceedings the two options discussed in this regard were whether or not, in view of the purpose of the Regulation, a connection between the holder of the MA and the owner of the patent must exist in order for the SPC to be granted.[752] The reason for this approach was the attempt of *Eli Lilly* to distinguish the factual scenario of the case from *Biogen*, where a connection between MA holder and patentee existed (licensee-licensor relationship). As will be explained below, the other approach is to ask whether the MA holder agrees (or must agree because of previous contractual commitments) to the grant of the SPC.

The question whether a patentee can obtain an SPC on the basis of an MA granted to the sued infringer was also discussed, but not decided, in proceedings before the Dutch courts.[753]

13.4 THE OPINIONS IN THE LITERATURE

In the literature, three different solutions to the issue of third-party MAs have been expressed.

According to the first opinion, *Biogen* has correctly clarified the law: the patentee shall be entitled to an SPC based on any MA granted for a product protected by the patent whether or not the MA holder agrees.[754]

Along a second line of thought, such a result would clash with the purpose of Reg. 469/2009 and its provisions.[755] Therefore, it should be possible to grant an SPC on the basis of a third-party MA only when the latter is a licensee of the patent and agrees with the grant of the certificate. It is significant that this opinion with respect to Reg. 1768/1992 was taken by *Schennen*, one of the first commentators on the SPC

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751 *Novartis v MedImmune* [2012] EWHC 181 (Pat).

752 *Eli Lilly and Company v Human Genome Sciences Inc.* [2012] EWHC 2290 (Pat).

753 Gertjan Kuipers et al, 'Recent European developments regarding supplementary protection certificates (SPCs)' [2011] 13(5) Bio-Science Law Review 178.

754 In this sense several statements of originator associations at the MPI Stakeholder Seminar, 11 September 2017; see in the literature Thomas Bopp, *Die Schutzbereichsbestimmung bei ergänzenden Schutzzertifikaten* in FESTSCHRIFT 80 JAHRE PATENTGERICHTSBARKEIT IN DÜSSELDORF (Carl Heymanns Verlag 2016) p. 63 et seq.

755 Jens Schovsbo et al, 'Reap what you sow! – But what about SPC squatting?', forthcoming [2018] Journal of Intellectual Property Law & Practice; Robert Wenzel, *Analoge Anwendung der Verordnung über das ergänzende Schutzzertifikat für Arzneimittel auf Medizinprodukte?* (Nomos 2017), pp. 136-141.

Regulation and of the representatives of the German Government in negotiating the draft Regulation.[756]

There is also a third opinion on the issue. According to *Brückner*, the patentee should be prevented from obtaining an SPC on the basis of a third-party MA. An exception to this principle may apply when the patentee has in turn obtained its own MA (of course, after the third party; if the patentee MA is earlier, no legal issue exists).[757]

This third view appears to find an elegant middle way between the two extremes and has a persuasive value. However, we are not convinced that such a solution would have a significant practical impact *vis-à-vis* the approach that prohibits the use of third-party MAs without the agreement of the MA holder. Indeed in considering the issue of third-party MAs, the systematic link between Art. 3 and Art. 7 Reg. 469/2009 must be taken into account. The third-party MA triggers the deadline by which the SPC is to be filed (unless the patent is granted after the MA issue date). Against this background, *Brückner*'s interpretation would make a difference with respect to an approach according to which the use of third-party MAs requires MA-holder consent only in the case that the patentee obtains its own MA within a period of six months from the issue of the first MA. This situation is likely to be exceptional.[758]

13.5 THE INTERPRETATION OF THE SPC REGULATIONS *DE LEGE LATA*

The wording as well as the recitals of the SPC Regulations offer arguments for both the thesis that the certificate may be granted in the case of diverging MA and patent ownership whether or not the MA holder agrees as well as for the thesis that the SPC in this factual scenario can be issued only if a relationship in the form of an agreement between the MA holder and the patentee exists. The Regulations remain ambivalent if one adopts a teleological approach as well as a literal interpretation.

The thesis that the patentee's ownership of the MA or the consent of the third-party MA holder is an implicit, but necessary, requirement for the validity of the SPC, if granted, can be based on the following arguments:

- According to Art. 14(d) Reg. 469/2009, the validity of the SPC is dependent upon the validity of the MA. As a consequence, it must still be possible for the patentee to bring the product to market. From this provision and from Art. 8 (1) Reg. 469/2009, according to which the holder must be able to submit a copy of the MA, *Schennen*[759] infers that patentee cannot refer to a third party MA if it has not obtained the consent of the MA holder or he/she is not in a contractual relationship with the latter. Indeed the power to prevent the grant

[756] Detlef Schennen, *Die Verlängerung der Patentlaufzeit für Arzneimittel im Gemeinsamen Markt* (Bundesanzeiger 1993) p. 61.

[757] Christopher Brückner, *Supplementary protection certificates with paediatric extension of duration* (2nd edn, Heymanns 2015) Art. 6, marginal note 41.

[758] If this view should in contrast be based on the premise that the deadline of Art. 7 Reg. 469/2009 is triggered only by the first MA granted to the patentee or its licensee despite the existence of an earlier third-party MA, this solution would require an amendment of the SPC Regulations and would be also problematic. Art. 7 Reg. 469/2009 fulfills an important function in the interest of legal certainty for third parties.

[759] Detlef Schennen, *Die Verlängerung der Patentlaufzeit für Arzneimittel im Gemeinsamen Markt* (Bundesanzeiger 1993) p. 61.

of the SPC or to determine the lapse of the SPC by withdrawing the MA implicitly suggests that the consent of the MA holder matters.

- European legislation is inspired by US law and intends to fulfil a similar purpose as the US model. Under US law, the intended beneficiary of the patent extension is not any entity that owns a patent, but only the entity that has invested in obtaining a product approval. The patentee can rely on a third-party MA only subject to the latter being the licensee of the patent and therefore agreeing, or being obliged to agree, to the extension. The same should, therefore, be true for EU law.
- If the patentee could refer without any limitation to third-party MA, even a patentee that has not performed any pharmaceutical research could benefit from the SPC. For instance, a patentee could have disclosed a new class of compounds as colorants and claimed then in a Markush formula; if a third party develops a drug including one of these compounds, for which it has identified pharmacological properties, and obtains an MA for such compound, than the patentee could file the application for a certificate, even if it has not conducted any pharmaceutical research.
- SPCs are intended to incentivise a patent holder to invest in bringing specific medicinal products or plant protection products to the market. This follows from Art. 4 SPC Regulations, according to which the subject matter of protection is limited to the product covered by the MA granted to place the corresponding medicinal or plant protection product on the market and only extends the authorised uses.
- The purpose of SPCs is to offer compensation for the time lost in conducting MA proceedings. As a consequence, only the entity that has directly or indirectly (through a licensee) suffered from this delay should benefit from the extension.

For the opposite view, according to which the SPC applicant does not need the consent of the MA holder to rely on its MA in the SPC granting procedure, one could invoke the following arguments:

- Art. 3(b) Reg. 469/2009 refers to any MA and not just the MA granted to the patentee or a related entity.
- Art. 4 Reg. 469/2009 extends the protection to any authorised uses before the expiry of the SPC and does not attach any relevance to who is the holder of the MA for the new use.
- Art. 6 Reg. 469/2009 only states that the right to the certificate belongs to the patent owner, and does not mention the holder of the MA.
- The purpose of SPCs is not or not only to support the research that leads to the marketable, authorised medicinal or plant protection products, after the invention is made. Rather, SPCs are to foster the research in the field of pharmaceuticals or plant protection products that leads to the patented invention including basic research that just leads to the identification of new therapeutic possibilities or a process for selecting or developing them, and leave it to another entity – downstream research – to develop further, on the basis of these insights, patented subject matters. This follows from the Explanatory Memorandum, paragraph 29, according to which all pharmaceutical research, *provided that it leads to a new invention that can be patented*, whether it concerns a new product, a new process or a new application, must be encouraged.

- Also, a patentee that has made no investment after the disclosure of the patentable invention is affected by the existence of an MA procedure. Indeed, a patentee can obtain revenues and compensation in three ways: it exploits the commercial invention personally; it licenses the invention; or it sues third parties that are using the invention and claims the profits that these parties have obtained by violating the patent. The fact that products incorporating the patented invention cannot be brought to the market without first having obtained an MA affects potential revenues in each of the three situations.

It should not come as a surprise that both opposing views may invoke the intent of the SPC Regulations in their support, and no conclusion based on such a teleological approach is possible. Indeed, what the purpose of the SPC Regulations is, and what the activities are that the Regulation intends to incentivise and reward, depend on the answer to the question who is the intended beneficiary of the legislation: any patentee or only a patentee that directly or indirectly (through an agent, licensee or contract partner) has undergone a regulatory approval procedure.

As a consequence, it is not possible to answer the question of the third-party issue simply by examining the purposes of the SPC Regulations, because such purposes are defined exactly by the answer that we seek.

13.6 THE OPTIONS

13.6.1 The options *de lege ferenda*

Since we are of the opinion that the SPC Regulations do not provide clear guidance on the third-party issue and the same conclusion applies to CJEU case law, this section will explore the options for lawmakers.

In *Eli Lilly*, the alternative discussed was whether or not a connection between the MA holder and patentee exists. However, the term "*connection*" is ambiguous. One party could be connected in some way with the patent holder, but still not agree from the beginning that any results of its clinical research should be exploited by the connected patentee. The distinction "connected" or "connected parties" was made by the plaintiff in *Eli Lilly* in an attempt to distinguish its case from the *Biogen* factual scenario.[760] While understandable for the purposes of that litigation, such a distinction is not useful for addressing the third-party issue *de lege ferenda*. Indeed, the MPI is of the opinion – supported by comparative insights – that the controlling criterion shall be the consent of the MA holder. As a consequence, there are two options for lawmakers.

The first one is to allow the use of third-party MAs whether or not the third party agrees. The ownership or the consent of the MA holder should not be a requirement for granting a valid SPC. Furthermore, this issue should not affect the interpretation and application of Art. 3(a) Reg. 469/2009.

[760] In *Biogen,* SKB was indeed a party connected with the patentee, since it got a licence for the patent. Since *Biogen* seems to authorise the grant of the SPC based on a third-party MA, *Eli Lilly* tried to differentiate that situation (patentee-licensee situation) from the situation of an unrelated party (patentee-potential infringer) – a situation in which *Eli Lilly* found itself.

The second option is to allow the grant of the SPC on the basis of a third-party MA only when the third party agrees or is obliged to agree under a prior contractual obligation signed by the patentee. So, for instance, if a university licenses a patent and a contractual obligation is included in the agreement that the licence holder must agree to and support the licensor in obtaining an SPC in Europe, such a clause would be sufficient. Such solution would not be isolated at international level. As already mentioned, in the USA, the patent proprietor in seeking an extension may rely on a third-party authorisation only if the NDA holder may be considered the agent of the patentee, as in the case of a licensee.[761] In Japan[762], Korea[763] and Taiwan[764] the patent holder can obtain an extension by referring to a third-party authorisation only when a licence relationship exists.

13.6.2 Implementing a consent requirement

If the lawmaker decides to allow SPCs based on third-party MAs only if the MA holder agrees, there are two ways to implement the consent requirement.

The first one is to create a prior consent requirement that must be examined by the NPOs in the granting procedure. In this case, if the patent owner is not the holder of the MA, it will be required to file evidence of the consent of the MA owner that it can rely on the MA before the patent office. An example of this model is offered by the US practice. The United States Patent and Trademark Office (USPTO) Guidelines read in this respect:[765]

> "If the applicant for patent term extension was not the marketing applicant before the regulatory agency, then there must be an agency relationship between the patent owner and the marketing applicant during the regulatory review period. To show that such an applicant is authorised to rely upon the activities of the marketing applicant before the Food and Drug Administration or the Department of Agriculture, it is advisable for the applicant for patent term extension to obtain a letter from the marketing applicant specifically authorising such reliance."

A similar requirement has been adopted in the Swiss legislation with respect to paediatric supplementary certificates.[766]

The second solution is to dispense with this formality for the patent owner and create a post-grant opposition or revocation procedure.[767] The MA holder could be entitled within a specific deadline either to start an opposition procedure or revocation proceedings against the granted certificate. Lawmakers might consider whether or not the opposition or revocation ground should be:

- a relative one, which only the owner of the MA shall be entitled to invoke, in analogy to prior user rights in trade mark legislation or to the absence of entitlement to the patent in some legal orders; or

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761 See John Thomas, *the USA* in Annex II of this Study, Chapter 8, Section 8.6.
762 See Yoshiyuki Tamura et al, *Japan* in Annex II of this Study, Chapter 4, Section 4.5.1.
763 See Jun-seok Park, *Korea* in Annex II of this Study, Chapter 5, Section 5.5.
764 See Kung-Chung Liu, *Taiwan* in Annex II of this Study, Chapter 9 Section 9.6.
765 USPTO, '2752 Patent Term Extension Applicant [R-08.2017], 37 CFR 1.730 Applicant for extension of patent term; signature requirements' in MANUAL OF PATENT EXAMINING PROCEDURE (MPEP) (9th edn, last Revised January 2018),available at https://www.uspto.gov/web/offices/pac/mpep/s2752.html (last accessed 2 February 2018).
766 See Chapter 16, Section 16.5.1.
767 See Robert Wenzel, *Analoge Anwendung der Verordnung über das ergänzende Schutzzertifikat für Arzneimittel auf Medizinprodukte?* (Nomos 2017), pp. 140-141.

- an absolute one, which any interested party may invoke in analogy to the other revocation grounds. If a licence exists, this will be a reason to dismiss the action as inadmissible.

13.7 THE OPINIONS OF THE NPOS AND OF THE STAKEHOLDERS

13.7.1 NPOs

The majority of the NPOs agree that *Eli Lilly* and *Biogen* are somewhat contradictory and that the question whether and under what conditions the patentee can obtain an SPC in the case of diverging ownership of the MA and patent are still to be clarified by the CJEU.

De lege ferenda, the MPI has proposed three different alternatives to the NPOs that are spelled out in Question 7 of the MPI Questionnaire for the NPOs:

> 7. *De lege ferenda*, the legislature could regulate this aspect. Different options are possible:
> a. The applicant may refer to a third-party MA whether or not the holder of the MA agrees.
> b. The applicant may refer to the third-party MA only when the third party concerned agrees and evidence for that party's consent is included in the application.
> c. The applicant may refer to the third-party MA only when he himself has obtained a (more recent) MA for the product concerned.
> In your opinion, which of the abovementioned solutions is more consistent with the purposes of both Regulations?

Most of the NPOs seem to prefer a solution where the patentee can obtain an SPC only if the MA holder agrees or it owns a separate MA.

13.7.2 Stakeholders consulted

The stakeholders were asked two questions in this regard. The first is whether the option of the patentee under *Biogen* to obtain an MA has led to practical difficulties for the MA holder in obtaining a licence for the subject matter covered by the patent (Q54). The assumption that this question relies upon is that the *Biogen* decision strengthens the position of the patentee and weakens the position of the MA holder. Further, under specific conditions it could create an incentive for the entity that is about to obtain an MA to postpone the grant of the MA in order to prevent the grant of the SPC.

The second question (Q55) was directed at two options that we consider realistic and in line with the general scheme of the Regulation. This question reads as follows:

> The case law of the CJEU is not clear with respect to third-party marketing authorisation. Which of the following clarifications would you prefer?
> i) The applicant can refer to a third-party marketing authorisation whether or not the holder of the marketing authorisation agrees to it and without any formality.
> ii) The applicant may only refer to the third-party marketing authorisation when the third party is in agreement and evidence for his/her consent is included in the application.

A relative majority of the stakeholders (44 per cent) seem to favour a solution in which the grant of the SPC is possible only when the holder of the MA agrees or has entered into a contractual relationship. However, SMEs and universities were under-represented in the group of questionnaire participants. As already mentioned, we cannot consider

the sample as truly representative. More interesting, therefore, are the various comments which stakeholders made in the course of conducting the Allensbach Survey.

13.7.2.1 Stakeholders´ comments

First, several stakeholders disagree with the statement included in Q55 that the CJEU case law is not clear with respect to third-party MAs. They maintain in contrast that the CJEU case law is clear and allows the grant of an SPC on the basis of a third-party MA.[768]

A further commentary submitted by several stakeholders is that if the case law is really unclear, then it would be the task of the CJEU to clarify it. Legislative action would thus not be needed.

On the merits, the comments provide arguments for both, opposite options. Unsurprisingly, both opinions invoke the intent of the Regulations for their position.

Regarding the option that an agreement with the third-party MA holder should not be necessary, the argument is made that this solution would penalise small companies, research institutions, universities and other players who are predominantly involved in basic research. It has also been argued that the question and the alternative proposed by the MPI ignore the dynamics of the market and the reality of product development agreements. Further, a solution according to which the holder of the MA must agree in order for the SPC to be granted or to be valid would also lead to an increase in litigation. Indeed, entities that invest in product development would have an incentive to go ahead without negotiating a licence with the patentee first. The following comments of a stakeholder can be considered exemplary in this regard:

> "The question is biased. The CJEU case law is clear in that third-party marketing authorisations may serve as a basis for SPCs, and this is also reflected in the office practice throughout the EU. Leaving that aside, the options presented clearly evidence a fundamental lack of understanding of dynamics. The question and the proposed answers take a static view, which is conceptually flawed from the beginning. Taking this through iterations: if the basic patent covers the product, it means that the third party does not have FTO. If the third party develops without a licence, this is development at risk. If the third party places the product on the market, it risks an infringement case, which may or may not be settled by a license – which would include the SPC. Hence, opting for (2) would only trigger (unnecessary) patent litigation with the third party, in order to obtain such agreement with the MAH. More importantly, this would directly go against the interest of a) research institutions and b) small and medium enterprises, in particular biotech companies, which the Commission tries to support in innovative pharmaceutical research. It is typically those stakeholders who have done groundbreaking research, on which pre-clinical and clinical development is built. If they would be forced to obtain an agreement from the MAH (i.e. force the third party to take a license), research institutions and SMEs would be forced into patent litigation under the basic patent (which is a given!), just to get that consent. That would not be efficient, and highly detrimental to research by such stakeholders. Taking this analysis even further, it would be a clear invitation to the third party NOT to take out any license (not even to the basic patent): the money is in the SPC, and if the third party can avoid the SPC by avoiding an agreement, i.e. a license, they will just risk the patent litigation. In other words, changing the regulation would invite third parties to take a free ride on basic patents that clearly cover the product. That would be a completely nonsensical incentivization."[769]

13.7.2.2 Qualitative interviews

In the qualitative interviews two main lines of comments emerged. First, diverging ownership of the MA and the patent occurs rather frequently. However, in most of the

[768] Annex III of this Study, pp. 367-370.
[769] *Ibid.,* pp. 369-370.

cases this does not cause any significant problems because either the parties belong to the same group or there is an agreement in place between the patentee and the MA holder. Second, these stakeholders considered cases where the parties are unrelated or one sues the other for infringement, as in *Eli Lilly*, as exceptional.

Some stakeholders considered reasonable a rule according to which an agreement is necessary in the case of diverging ownership of the patent and the MA. However, the general attitude of the right holders interviewed was that such a rule is not needed. Market-driven forces can lead to a contractual solution in most cases. The rare case where no agreement exists or may be reached will finally be resolved by the case law.

13.8 RECOMMENDATION

A system of patent extension or SPC protection for products subject to regulatory approval can have two alternative functions.

The first one is to reward and encourage research that leads to patentable inventions. It would incentivise the companies to invest in innovation in technical fields where the commercial exploitation of the invention is subject to delays due to the requirement, mandated by public law, of an authorisation. The SPC is the reward for having successfully conducted such basic research and have obtained a patent for its results.

The second possible function is to reward and encourage research that, after a patented invention has been made, is necessary in order to bring to market a product incorporating the patented invention. The SPC is the reward for having completed this product-development process. In this view, the SPC fulfils a function that is partly similar to that of data-protection rules that benefit not the holder of the patent for the new active ingredient, but the holder of the MA for that ingredient.

What function the SPC system fulfils depends on the answer to the question who is the intended and "primary beneficiary" of the SPC legislation: any patent owner, or only the patent owner that obtained the MA or licenced the patent to an entity that obtained the MA. The answer to this question defines the activities that SPCs must reward. As a consequence, the rule on this issue also defines the policy function that this title of protection shall fulfil within the EU legal order.

It is the opinion of the MPI that this question must be answered by lawmakers and not by the courts, as it concerns the fundamental nature and character of SPCs as a *sui generis* intellectual property right. Such a question affects the solutions and impacts the assessment of many other questions of legislation and case law. Some examples may suffice:

- If the patentee can obtain an SPC only if it is the holder of the MA, interim applications are not needed,[770] since in the case that the MA is granted after the expiration date of the patent, the data protection will be longer than the SPC.
- If the patentee can obtain an SPC only if it is the holder of the MA, then case law and law-making in this field must provide for a more consistent coordination of data protection rules and SPC rules;

[770] See on this topic 10, Section 10.2.2.1.

- All the discussions concerning the scope of the SPC in the case of biosimilars (but not only biosimilars) must be considered from a different perspective if the patentee can obtain an SPC under any conditions, even if a third party invested in obtaining the MA for a product falling under the scope of the patent. For instance, if a competitor obtains authorisation for a competing biosimilar of a reference product for which an SPC has already been granted, then there are two options for the patentee: it can file an application for an SPC on the product authorised by the competitor as a biosimilar, if the latter falls under the scope of the patent. If the application is rejected pursuant to Art. 3(c), then this is a strong argument that both products – reference product covered by the SPC and biosimilar covered by the second MA – are the same product within the meaning of Art. 4 Reg. 469/2009. Of course, this strategy only works if the patent has not expired. But one could wonder if it would then be justified to let the SPC be extended automatically to all biosimilars that fall under the scope of the patent and that are granted an MA during the term of the first SPC, as already provided by Art. 4 Reg. 469/2009 for uses of the same product.

As regards the implementation, a rule that requires evidence of consent before grant has the advantage of providing higher certainty, but the disadvantage that it would create a burden on the applicant. A rule that creates a revocation ground would reduce the burden of the applicant, but create some uncertainty for third parties. Finally, a rule that provides the owner of the MA with the right to oppose the grant within a strict time frame could represent a compromise between the two options.

One question that needs to be considered is whether the contractual relationship between the patent holder and the MA holder must be established before the clinical trials are started or before the request for the MA has been filed. It could be even established *ex post*, after the issue of the MA, the filing of the SPC application or the grant of the SPC. If the policy of the provision is that the SPC should reward the patentee for the time lost in developing the product, then it would be consistent to require an involvement of the patentee relatively early, and that such agreement must have been concluded before the clinical trials are started or at least before the MA is granted or the application for a certificate applied for.

13.9 SUMMARY

- The question of whether the SPC should reward each patentee, or only the patentee that has directly or through a licensor obtained an MA for a product falling under the scope of the patent, has not been clearly answered in the case law of the CJEU.
- It is the task of the lawmakers and not of the courts to answer this question, because it has a policy value and because it requires systematic coordination with other legal institutions. The function of the SPC ultimately depends on this question, and not vice versa.
- The legislature has two options. The first is to allow the patentee to obtain an SPC for an authorised product whether or not the holder of the MA agrees. The second is to require the consent of the MA holder. Which option is to be preferred depends on whether the SPC is intended to reward the pharmaceutical research that leads to a patentable invention or the

pharmaceutical research that leads to a marketable product after an invention is made, and in this way to compensate for the time and resources invested in the clinical trials required by public legislation.

14 SUBJECT MATTER OF PROTECTION OF THE SPC (ART. 4 REG. 469/2009)

14.1 INTRODUCTION

Art. 4 Reg. 469/2009 under the heading of "subject matter of protection" (Schutzgegenstand; Objet de la protection; oggetto della protezione) provides that

> "within the limits of the protection conferred by the basic patent, the protection conferred by a certificate shall extend only to the product covered by the authorisation to place the corresponding medicinal product on the market and for any use of the product as a medicinal product that has been authorised before the expiry of the certificate".

While there is a considerable number of decisions by the CJEU on Art. 3 SPC Regulations, only two judgments of the CJEU deal with Art. 4 Reg. 469/2009.

This does not imply that Art. 4 Reg. 469/2009 has not posed interpretative issues in practice. The next sections review the questions surrounding Art. 4 Reg. 469/2009, both those that may be considered settled and those that may be considered still open.[771]

14.2 WHAT IS THE LEGAL STATUS OF THE PRODUCT DESCRIPTION?

14.2.1 Introduction

All registered IP rights in European law define in the title of protection itself the subject matter for which they confer protection. So, for instance, the application for a design must include a representation of the design suitable for reproduction. This representation defines the design for which the IP right is granted, and the scope of the exclusive right conferred. In patent applications the applicant must indicate the subject matter for which protection is sought. Such statements – patent claims – define the extent of protection of the granted patent.[772] Similar principles and rules exist for plant variety rights[773] and trade marks.[774]

SPCs seem to represent an exception. The protection conferred by the SPC is not autonomously defined by the granted title itself, which, unlike a patent, does not need to include a description of the subject matter and does not provide (expressly) for patent claims-like statements.[775] Further, the protection granted is not even defined autonomously by the source of law governing SPCs. Art. 4 Reg. 469/2009 provides indeed:

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771 The question that follows from the limitation of the protection conferred by the certificate to the uses authorised before the expiry of the certificate, and in particular the question whether the production of the active ingredient or of the final drug for the export infringes the certificate, has been addressed in Chapter 5, Section 5.7.2.

772 See Art. 69 EPC.

773 Art. 50 Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights [1994] OJ L 227/1.

774 Art. 26 para. 1 Council Regulation (EC) No 207/2009 of 26 February 2009 on the Community trademark [2009] OJ L 78/1.

775 BPatG, *Decision of 15 Mai 1995*, 15 W (pat) 122/93 [1995] BPaTGE 35, 145.

> "within the limits of the protection conferred by the basic patent" the certificate protects only "the product covered by the authorisation to place the corresponding medicinal product on the market".

Further, pursuant to Art. 8(1)(b) Reg. 469/2009 the applicant must submit:

> "(b) a copy of the authorisation to place the product on the market, as referred to in Article 3(b), in which **the product is identified,** containing in particular the number and date of the authorisation and the summary of the product characteristics listed in Article 11 of Directive 2001/83/EC or Article 14 of Directive 2001/82/EC [..]"[776]

Recital 13 Reg. 1610/96, which pursuant to Art. 22 Reg. 469/2009 and Recital 17 Reg. 1610/96 is available for interpreting Reg. 469/2009, provides as follows:

> "Whereas the certificate confers the same rights as those conferred by the basic patent; whereas, consequently, where the basic patent covers an active substance and its various derivatives (salts and esters) [..]."

Pursuant to Art. 11(1)(d) and Art. 9(2)(d) Reg. 469/2009, the notification of the fact that an application has been filed or a certificate has been granted shall contain, *inter alia*, the following information:

> "the number and date of the authorisation to place the product on the market, referred to in Article 3(b), and the product **identified** in that authorisation." [777]

From the combined reading of the provisions and recitals mentioned above one could infer that:

- the MA has the function of identifying the product for which the SPC confers protection and is granted (Art. 11(1)(d) Reg. 469/2009);
- the protection conferred by the SPC is limited by the scope of the patent;
- as a result, the protection conferred by the SPC is defined by both the scope of the patent and the subject of the MA; no other documents or statements are of any relevance for this inquiry.

Against this legislative background, one could come to the conclusion that declarations concerning the product that the applicant may or must include in the SPC application do not affect – whether in favour or to the detriment of the SPC holder – the protection granted by a certificate. This would be true for assessing both the validity and the infringement of the certificate.[778]

These conclusions found support in some old case law of the German Federal Patent Court,[779] where the Court excluded the admissibility of patent claim-like statements in the application and in the granted certificate, and further excluded any binding effect that such indications, if admitted by the NPO, might have on the scope of the certificate. Such conclusions are also in line with comments submitted to the Allensbach Survey and with opinions expressed in the literature.

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776 Emphasis added.

777 Emphasis added.

778 So for instance, if the product definition is broader than the subject of the MA or even broader than the scope of the patent, this does not mean that the SPC does not comply with Art. 3(a) or Art. 3(b) Reg. 460/2009, because both the NPO examining the application for the certificate and the judge hearing its validity or infringement must consider only the MA supplied in support of the application for an SPC in determining what the product is for which the certificate is requested or for which the granted certificate confers protection. Conversely, if the product definition is limited to the free base, this does not imply that a salt is not protected, provided that the latter is covered by the patent.

779 BPatG, *Decision of 8 February 1999*, 15 W (pat) 106/96, BPatGE 41, 56.

Thus, two stakeholders observed referring to Q58 and Q61 of the Allensbach Survey:

> "The questions 58 and 59 on product definition do not allow comments, so here a comment in detail. The questions are apparently based on a misunderstanding. The product reference (not definition) is for convenience only and has no legal effect. The scope of protection of an SPC is based on a) the basic patent and b) the marketing authorization. The product reference does not come into play at all, it is legally irrelevant, and for convenience only".[780]

> "There should be no definition of the product in the SPC application, because there is no basis for that in the Regulation and there is no need for it. The scope of protection is provided by Article 4, and not by any product definition. Thus, there is no need for a provision for amendment. Also, the practice of national patent offices to allow product definitions, without any legal basis, is a burden for applicants".[781]

In line with these comments, in a recent publication, practitioners have observed:

> "In our experience of defending the validity of SPCs in the UK, one is often confronted with invalidity arguments based on the wording set out in the SPC's Product Description. The basis of these arguments is, in effect, that the Product Description should be treated in the same way as a patent claim and should delineate the scope of the SPC. In other words, what the SPC holder writes in the Product Description box should be used as the definition of the "product" for the purposes of art.1(b) of the SPC Regulation. If the wording of that definition is broader than what is covered by the wording of the claims of the basic patent, then the product is not protected by the basic patent in force and the SPC therefore falls foul of art. 3(a) of the SPC Regulation. It is our view that this cannot be the correct way to approach the Product Description. Applying for an SPC was (and is) supposed to be a relatively simple and straightforward administrative exercise which requires only the filling out of a short form. Indeed, Mr Justice Arnold noted in his recent decision in Sandoz v Searle that the SPC system is supposed to be "a simple and transparent system". The scope of an SPC is determined by art.4 of the SPC Regulation, which limits the scope to the active ingredient that is the subject of the relevant marketing authorisation. Nowhere does the SPC Regulation state that the scope of the SPC is to be determined by construing the Product Description like a patent claim. Opening up SPC holders to an additional invalidity attack based on the wording of the Product Description is therefore unjustified." [782]

This opinion is also confirmed in qualitative interviews. However, the situation in practice is more complex. As reported in Chapter 20 of this Study,[783] all NPOs require a definition of the product for which the certificate is to be granted. We have identified two approaches in practice. Some NPOs request the applicant to indicate the product identified by the MA submitted in support of the application. This suggests a stricter approach. Others ask the applicant to indicate the product that is to be protected.

Independent of the formula included in the form for the application, according to several NPOs,[784] the applicants try when defining the product to generalise the subject of the MA with various wordings, as for instance "compound Y in all acceptable salts and derivatives" or "compound Z in all pharmaceutically acceptable forms protected by the basic patent" in the chemical fields, and less standardised wordings in the biological field.[785] Such definitions are the subject of main and auxiliary requests in granting proceedings. They are scrutinised and often objected to by the NPOs.[786] Administrative litigation takes place before administrative courts reviewing the NPOs' decisions. This practice may suggest that the applicants as well as the NPOs do not consider the product definition included in the application devoid of legal effect for the scope and the validity of the certificate.

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780 Annex III of this Study, p. 422.
781 *Ibid.,* p. 428.
782 Tony Rollins et al, `The definition of product in the SPC Regulation: What´s in a name?´ [2017] EIPR 555, 557.
783 Chapter 20, Section 20.2.5.4.
784 MPI Workshop with the NPOs, 20-21 March Munich 2017; correspondence with the German NPO.
785 See also Trevor Cook, *Pharmaceutical Biotechnology and the Law* (3rd edn, LexisNexis 2016) marginal numbers 15.27-28.
786 *Ibid.*

14.2.2 The case law

The legal relevance of the product definition has been implicitly or expressly addressed in some opinions or judgments dealing with either the SPC eligibility of the product, or the admissibility of the definition requested by the applicant, or the validity of a granted certificate.

14.2.2.1 Farmitalia case

We reported the facts of the case that led to the *Farmitalia*[787] decision in Chapter 9,[788] and we further commented on the CJEU decision in Chapter 10.[789] As explained there, the origin of the case was the attempt by the applicant to obtain with the main request a certificate granted with the definition "Idarubicin and salts thereof, including idarubicin hydrochloride", while the MA supplied in support of the application for the certificate referred to idarubicin hydrochloride only. The patent designated for the procedure mentioned in the claims only the free base idarubicin and in the specification idarubicin hydrochloride as embodiment of the invention.

The German Federal Patent Court stated as a premise that the applicant has to indicate in the application the product for which the patent office is to grant the certificate.[790] This requirement follows from Art. 9(2)(d) Reg. 1768/92 at that time in force, according to which the NPO must publish the notification of the application and such notification must indicate the number and date of the authorisation, but also the product identified in that authorisation. Since, according to the German Federal Patent Court, the same MA can refer to a number of actives, it is necessary for the applicant, pursuant to Art. 8(1) Reg. 1768/92, to specify the active ingredient or the combination of active ingredients for which the certificate is to be granted. This conclusion was found by court to follow also from Art. 11(1) Reg. 1768/92, by virtue of which the NPOs are to publish the notification of the fact that a certificate has been granted.[791] Such publication must indicate the product identified in the MA.[792] According to the BPatG, this implies that already the decision to grant the certificate determines the product that is protected.

On the merits, the German Federal Patent Court upheld the decision by the German NPO to reject the first main request of *Farmitalia* to grant a certificate for "idarubicin and salts thereof including idarubicin hydrochloride", since not all the salts covered by this definition were described by the patent and therefore protected within the meaning of Art. 3(a), and further only hydrochloride was covered by the MA under Art. 3(b). The premise behind the reasoning of the BPatG was in our view not only that a definition or description of the product is a necessary element of the certificate application in order to identify the product that must undergo the examination prescribed by Art. 10 Reg. 1768/92, but also that such definition (or description) has legal effects.

787 Case C-392/97 *Farmitalia* [1999] ECR I-5553.
788 Chapter 9, Section 9.2.3.8(b).
789 Chapter 10, Section 10.2.3.2
790 BPatG, *Decision of 15 Mai 1995*, 15 W (pat) 122/93 [1995] BPaTGE 35, 145, 156.
791 *Ibid.*
792 Art. 11(1)(d) Reg. 1768/92.

This premise was not called in question by the German Federal Court of Justice[793] in the order in which it referred the two questions already addressed in this Study concerning Art. 3(b) and 3(a) Reg. 1768/92. In the Opinion delivered on 3 June 1999, Advocate General Fennelly seems to assume as well that the terms in which the certificate is granted – that is the product definition admitted by the examiner – matters for the rights granted by the certificate.[794] The CJEU in turn stated the principle "where a product in the form referred to in the marketing authorisation is protected by a basic patent in force, the supplementary protection certificate is capable of covering the product, as a medicinal product, in any of the forms enjoying the protection of the basic patent". The German Federal Court of Justice understood this judgment in the sense that the certificate granted on the basis of an MA for the salt of an active ingredient or on the basis of an MA for the free base automatically as a legal effect covers all derivatives of the actives, provided that such derivatives are protected by the basic patent. This effect and extent of protection seem to not be contingent on a specific language of the product description of the certificate granted.[795] However, the Court upheld the decision of the German Federal Patent Court to refuse the request by the applicant to obtain a certificate with a wording including all idarubicin salts for two reasons. On the one hand, the Federal Court of Justice observed that, with the inclusion of all salts in the product description, the applicant tried to obtain a binding clarification of the scope of the certificate. But an exhaustive and generalising determination of the scope of the certificate is not possible in granting proceedings. It is the task of infringement proceedings to determine with respect to a specific embodiment what the scope of the certificate is. On the other hand, the court observed that if a definition of the product extending beyond the wording of the patent claim and including equivalents were to be admitted, there would be a danger that such a definition would extend the protection to "equivalents of equivalents" of the claimed invention. This was in conflict with the decision of the Court of Justice, and in particular paragraphs 21-28 of *Farmitalia*, according to which the scope of the certificate may not extend beyond the scope of the basic patent.

Now, such concerns are understandable only if one attaches legal consequences to the product definition.

14.2.2.2 Sumatriptan decision

The *Sumatriptan* case concerned an application for a certificate filed before the German Patent and Trade Mark Office (DPMA) where the applicant had indicated as the product in the first main request "Sumatriptan, as well as salts and solvates of it, including succinate", and as an auxiliary request "Sumatriptan hydrogensuccinate".[796]

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793 BGH, *Idarubicin*, Order of 17 June 1997, X ZB 13/95, GRUR 1998, 363.

794 Case C-392/97 *Farmitalia* [1999] ECR I-5553, Opinion of AG Fennelly. See, for instance, in paragraph 30 ("[…] the Regulation should not be interpreted in such a fashion that the certificate holder has greater procedural advantages than he enjoyed *qua* patent holder. This could arise, for example, if an SPC were granted in terms much wider than those used in the original patent, thus potentially affecting the relative burdens of evidence and proof borne by the certificate holder and another manufacturer in subsequent infringement proceedings. More generally, the supplementary protection regime should, in the absence of contrary indications, mirror the procedural steps typical to the national and European patent systems on which it is dependent and, to a large extent, modelled. Thus, to the greatest extent possible, the respective roles of the administrative authorities responsible for granting patents and the judicial bodies responsible for enforcing them should be replicated under the SPC Regulation").

795 BGH, *Idarubicin II*, X ZB 13/95 [2000] GRUR 2000, 683.

796 DE file number 193 75 045.7, available at https://register.dpma.de/DPMAregister/pat/einsteiger (last accessed 24 May 2018).

The latter succinate salt was the subject of the MA(s) supplied in support of the application. The definition to which the main request referred was rejected by the DPMA, because the NPO – as in *Farmitalia* – considered only the succinate salt as the substance covered by the MA for which the certificate can be granted.

For the purpose of our analysis it is not relevant to go into details in the case and in the further requests presented with the appeal lodged against the decision of the DPMA. More important are the legal principles stated by the German Federal Patent Court in the first instance decision, and by the German Federal Court of Justice in the final decision.

The German Federal Patent Court, in line with the *Clarithmycin* decision, stated two principles.[797] First, the applicant for a certificate – unlike the applicant for a patent – does not have the right (or the obligation) to formulate "claims" in the application for the certificate, where he/she defines the subject matter of protection. Second, such statements, even if included in the application and in the granted title, would not have legal effect on the certificate´s scope. The German Federal Patent Court based this conclusion on the following arguments:

- The wording of the Medicinal Products Regulation does not provide a basis for allowing a claims-like statement in the certificate;[798]
- According to Art. 15 as contained in the Proposal submitted by the Commission on 3 April 1990 for a Medicinal Products Regulation,[799] if the subject of the certificate is only partially covered by the basic patent, the declaration of nullity shall take the form of a corresponding limitation of the certificate. Such option of limiting the certificate was not provided for in the wording adopted by the lawmakers of Art. 15 Reg. 1768/92. This confirms the thesis, according to the German Court, that the certificate does not include claims that would be available to a limitation.[800]
- The Plant Protection Products Regulation includes two additional recitals addressing salts and esters; further, Reg. 1610/96 does not include the statement, according to which the protection granted by the certificate shall "be strictly confined to the product which obtained authorization to be placed on the market as a plant protection product" that was provided in the original Proposal of the Commission and was taken from Reg. 1768/92. Despite these changes made to the Plant Protection Products Regulation with respect to the Medicinal Products Regulation, lawmakers did not decide to include in Art. 9 and Art. 11 Reg. 1610/96 as a further element of the application a reference to the subject of protection, although the related problems had already emerged in the practice just after the entry into force of the Medicinal Products Regulation and therefore were well known to the lawmakers.

The Federal Court of Justice rejected the position of the Federal Patent Court and came to the diametrically opposite conclusion.[801] According to the Court, indeed, the applicant has the right, and sometimes the duty, to indicate the product for which protection is sought through a statement in the application. On the basis of this

797 BPatG, *Decision of 2 November 2000*, 15 W 40/95 [2001] GRUR Int. 629.
798 *Ibid.*, 633.
799 Proposal for a Council Regulation (EEC) concerning the creation of a supplementary protection certificate for medicinal products (COM(90) 101 final – SYN 255) [1990] OJ C 114/10, Art. 15.
800 BPatG, *Decision of 2 November 2000*, 15 W 40/95 [2001] GRUR Int., 629, 633.
801 BGH, *Sumatriptan,* X ZB 12/01, GRUR 2002, 415 ff.

statement, the NPO has to decide whether or not the requested certificate shall be granted and define in the granting decision the product. In drawing such conclusion, the BGH relied on the following arguments:

- The list of elements of the application and of the notification of the decision laid down in the SPC legislation is not exhaustive: this follows from the expressions "in particular" and "at least", used respectively in Art. 8(1)(a) Reg. 469/2009 and Art. 9(2) Reg. 469/2009.
- Without a definition of the product it would not always be possible to know the subject matter of the certificate. The MA is for this purpose not sufficient.

14.2.2.3 Yeda case

In the *Yeda* case, the matter on which the Court of The Hague and the Council of State had to decide concerned the admissible wording of the product description.

The applicant applied for a certificate before the Netherlands Patent Office on the basis of an MA granted for the medicinal product *Humira adalimumab*. The form provided by the Netherlands Patent Office to apply for a certificate at that time asked (and asks still today) the applicant to indicate the first national MA to bring the product to the market in the Netherlands, the name of such MA and the "chemische aanduiding van het product", that is the chemical designation of the product. The applicant indicated in the application as chemical designation of the product "human monoclonal antibodies against tumor necrosis factor alpha (TNF-alpha)". Such a definition was admitted by the UK IPO with respect to the UK member of the SPC family requested by *Yeda*.[802]

The Netherlands Patent Office granted a certificate for the product adalimumab[803], which was the active ingredient identified by the MA supplied in support of the application for a certificate, but it refused to grant the certificate with the product description proposed by the applicant. As a consequence, the applicant filed an appeal against the decision, proposing new and more limited product definitions[804] as main and auxiliary requests. What was common to three of the product descriptions filed by the applicant was that they (i) were not limited to adalimumab; (ii) were extended to antibodies qualified, *inter alia*, as therapeutic equivalents to adalimumab, and (iii) were protected by the basic patent (EP 0 186 833). A fourth product definition included technical features aimed at delimiting and identifying the group of antibodies that shall be covered together with adalimumab by the certificate. In support of the appeal and of the submitted product definitions the applicant invoked *Farmitalia*, that in his/her view provided arguments against a product description strictly limited to the active ingredient covered by the MA. According to the reading of the *Farmitalia* decision advocated by the applicant, the protection granted by a certificate is not

802 See SPC/GB04/006.

803 See SPC 300142 granted by the Dutch NPO on 13 June 2005. All documents of the case, including the decisions of the Court of The Hague and of the Council of State quoted in the main text, are available under http://mijnoctrooi.rvo.nl/fo-eregister-view/ (last accessed 16 May 2018).

804 We quote them from decision of the Court of the Hague: "adalimumab en humane monoklonale antilichamen tegen TNF-alfa, therapeutisch geliijkwaardig aan adalimumab" or "adalimumab en humane monoklonale antilichamen tegen TNF-alfa van het IgG-type, therapeutisch gelijkwaardig aan adalimumab" and "adalimumab en humane monoklonale antilchamen tegen TNF-alfa van het IgG1-type, therapeutisch gelikwaardig aan adalimumab", "adalimumab en humane monoklonale antilichamen tegen TNF-alfa waarvan de complementariteits-bepalende gebieden (CDRs) geliik zijn aan dievan adalimumab".

limited to the product strictly covered by the MA, but includes derivatives of the free base. Therefore, this decision allows the applicant to include in the product description derivatives of the active ingredient, provided that they are covered by the basic patent.

The Court of The Hague in the judgment of 12 November 2008[805] upheld the decision of the Netherlands Patent Office. According to the Court, the *Farmitalia* decision could not justify granting a certificate with a broader product definition than that admitted by the NPO. The premise of *Farmitalia* indeed was that the active ingredient and its chemical derivatives, such as salt and esters, are therapeutic equivalents. However, in the case of antibodies, it is not possible to assume that a change in the amino acid sequence of the polypeptide does not affect its therapeutic effect. For this reason, the court concluded that the NPO correctly identified as adalimumab the active ingredient for which the certificate shall be issued.

The appeal filed against the decision of the Court of The Hague was rejected by the Council of State with the judgment of 19 August 2009.[806] According to the Council of State, given the molecular complexity of antibodies, it could not be excluded that a minor change to their amino acid structure has no consequence on the safety and efficacy of the medicinal product. The Council of State found a backing for this position in the regulatory legal framework. Chemical derivatives of an active ingredient, such as salt and esters, are considered the same active ingredients under Art. 10(2)(b) Dir. 2001/83. For this reason, a marketing authorisation for a salt of an active ingredient that has been already authorised may be obtained under the abridged procedure laid down in Art. 10 Dir. 2001/83. Such abridged procedure is not available for biological products. The latter, in consequence of their molecular complexity, are subject to the stricter requirements under Art. 10(4) Dir. 2001/83. The Court confirmed the first instance decision not to admit a product definition including further antibodies covered by the patent other than adalimumab.

In our view, the implicit interpretative premise of the whole case was that the product description has a legal impact on the certificate's scope.

14.2.2.4 The EFTA Court decision E-16/14

The decision E-16/14 delivered by the EFTA Court on 9 April 2015 has addressed the question whether a product definition that is broader than the subject of the MA is a reason for invalidating the certificate.[807]

The referral originated from an action for the revocation of the certificate SPC No 2011024 granted by the Norwegian Patent Office lodged before the Oslo District Court (*Oslo Tingrett*). The plaintiff in the revocation proceedings was the company Pharmaq AS and the certificate owner was the company Intervet International BV (hereinafter: Intervet).

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805 Court of The Hague, AWB 07/3560 Oct 95. The decision is available in the database of the Netherlands Patent Office (Octrooicentrum Nederland).

806 Netherlands Council of State, *Yeda Research and Development Company Ltd v the Netherlands Patent Office*, Decision of 19 August 2009, Case 200809060/1/H3. The decision is also published in BJBLAD BIJ DE Industriele Eigendom, Issue No. 10, October 2009, Nr. 80, 265 *et seqq*.

807 See the facts of the proceedings EFTA Court, Case E-16/14 *Pharmaq AS v Intervet International*, Decision of 9 April 2015, BV [2015] EFTA Ct. Rep. 212.

Based on a Norwegian MA No 10-7431, Intervet applied for and obtained an SPC, whose product definition reads as follows:

> "Salmonid pancreatic disease virus that, when injected intraperitoneally at a titre of 103.5 TCID50 into Atlantic salmon post-smolts held in sea water at 14°C causes the fish to develop symptoms of pancreatic disease, wherein
> a) said virus is the virus strain as deposited at ECACC under Deposit number V94090731 or closely related strains which share similar genotypic and/or phenotypic characteristics to said deposited virus strain and
> b) said virus reacts serologically with convalescent anti-FPDV antiserum or antiserum raised against the deposited virus strain V94090731 and
> c) said virus is an inactive form."

The deposited virus strain referred to in the MA is the SAV-1 deposited by Intervet. With this wording Intervet attempted to obtain a certificate to closely related strains with a similar genotypic structure that were covered by the basic patent. The certificate was issued with the requested wording in the product description.

One of the revocation grounds that the plaintiff invoked was that the scope of the certificate as defined by the product description was broader than the MA. The Oslo Tingrett decided to submit a number of questions to the EFTA Court regarding the interpretation of Arts. 2, 3 and 4 Reg. 469/2009. For the legal status of product description, the following question is of interest:

> "If an SPC has been granted with a product definition that is not strictly limited to the specific strain of the virus authorised to be placed on the market as a medicinal product,
> (a) will such an SPC be valid, or
> (b) will the SPC be valid; such, however, that the scope of protection pursuant to Article 4 does not extend beyond the specific virus strain authorised to be placed on the market as a medicinal product?"

The answer to this specific question of the EFTA Court reads as follows:

> "An SPC is invalid to the extent it is granted a wider scope than that set out in the relevant marketing authorisation."

In the prosecution of the national proceedings the Borgarting Court of Appeal [808] came to the conclusion that "closely related strains which have similar genotypic and phenotypic characteristics as said deposited virus strain" goes beyond the allowed scope of protection of Art. 4 Reg. 469/2009 and creates "a delimitation that keeps vaccines that are systematically, consistently and significantly more effective […] from being made available on the market."[809] As a consequence, the court considered that the SPC is invalid under Art. 4 Reg. 469/2009 because it extends beyond the product covered by the MA and also beyond therapeutically equivalent products.

14.2.3 Options

14.2.3.1 Status quo

The review of the case law leads to an ambiguous conclusion. On the one hand, considering the language of the SPC legislation, the product definition is not a necessary requirement of the application for a certificate. Furthermore, even if it is included in the application and reproduced in the decision notified to the applicant, it

[808] Borgarting Court of Appeal, 19 December 2016, *Pharmaq AS v Intervet International BV*, Case No. 15-170539ASD-BORG/01 and 15-204605ASD-BORG/01.
[809] *Ibid.,* p. 33.

does not affect the scope of the certificate. The latter must be determined on the basis of two documents: the MA supplied in support of the application and the basic patent designated for the procedure. Against this legal background, the status of the product description is similar to that of the title of the invention requested by the EPC. It is only of an informational nature.

On the other hand, considering the case law, the product definition seems to be a necessary feature of the application for a certificate. The MA as such is not always sufficient to identify the product for which the certificate is applied for (even if in most cases it is). Furthermore, in practice, applicants and NPOs behave as though such definition would have an impact on the validity and scope of the certificate, once granted.

For this reason the legal status of the product definition or product description of the certificate – that is whether it is only of an informational nature as the title of the invention in a European patent application or it has legal effect as a patent claim or something between – is in our view not clear at the moment.[810] One obvious approach for the legislature would be to remove this uncertainty.

14.2.3.2 Options

The first option is to confirm that a patent and an MA are the only documents that matter for determining the scope of the certificate. This approach seems to be in line with the original intention of the lawmakers. However, unless *Medeva* and *Forsgren* are overruled, the mere submission of the MA is not sufficient to identify the product for which the certificate is sought. A statement by the applicant is necessary to this purpose, at least when the MA includes more than one active. In this case the product description shall have only the function of identifying the substance among the active(s) contained in the MA that must undergo the examination. It shall not define to what extent, and in which form(s), such active ingredient is then protected by the granted certificate. In the decision granting the certificate, the NPO shall just indicate the active ingredient identified by the MA and by the applicant. The court dealing with infringement will then have the task of deciding whether or not a specific variant is covered by the certificate under Art. 4 Reg. 469/2009.

The second option is to draw all necessary implications from creating a separate title of IP protection instead of extending the basic patent as in the US, and to provide that the certificate shall have its own autonomous and self-sufficient definition of the subject matter protected as any other IP right. This definition shall be in the form of binding statements. We may call them in line with the German case law and a part of the literature[811] "Zertifikatsansprüche", "certificate claims". Once this model has been chosen, then lawmakers shall design an overarching legal infrastructure governing such certificate claims.[812]

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[810] Reg. Nr. AWV 07/3560 OCT 95. The Dutch version of the decision is available in the database of the Netherlands Patent Office (Octrooicentrum Nederland).

[811] See Trevor Cook, *Pharmaceutical Biotechnology and the Law* (3rd edn, LexisNexis 2016) marginal numbers 15.27 *et seqq*.

[812] So, for instance, by analogy with Art. 78(1) EPC, lawmakers shall provide in Art. 8 Reg. 469/2009 that the application for a certificate must include a definition of or a claim to the product for which protection is sought. By analogy with Art. 84 EPC and Rule 43 EPC, lawmakers shall define the requirements that such definition or claim must comply with its form and content. By analogy with Art. 69 EPC, lawmakers shall define the effect on the scope of such certificate claims, and by analogy with

We are of the opinion that for the examination such certificate claims would not necessarily imply a higher burden for the NPOs than in the current practice. Lawmakers could allow only claims directed to the substance identified by the MA and then adopt a provision according to which such definition would afford a scope that goes beyond the strict wording of the product definition.

In favour of certificate claims, one could invoke the argument that the reference to the MA as a criterion for determining the certificate´s scope is legally problematic. An MA is not static, but a dynamic document. It can be subject to amendments, variations and extensions. The law provides that variations concerning the uses or indications have an impact on the scope. But it is silent over variations concerning the manufacturing process that can be relevant for defining the product in the field of biological products. It is silent about extension or variations that affect the active substance. The certificate claims could ensure that the subject matter is defined at the granting date of the certificate. It will then be the task of the courts to assess whether a specific product falls under the scope of the claims. Of course, one could argue that also the patent is a dynamic document and can be amended post-grant. However, it is not possible for the patentee to replace an element of the claim with an *aliud* or to delete one element of the claim. A granted patent can only be limited, but never extended.[813]

14.2.3.3 Opinion of the NPOs and stakeholders

In the Allensbach Survey[814] as well in the Questionnaire for the NPO[815], we included questions concerning the opportunity to provide in the SPC legislation for patent-like statements in the application for a certificate.

Some NPOs seem to consider such approach opportune, others reject it. One NPO has observed that this would not imply a difference with the current practice, because the applicants submit anyway a statement indicating the product for which protection is sought, and that such statement is anyway necessary if an MA for combinations can support the certificate for a sub-combination or an individual product. One NPO would admit a statement where the applicant indicates the product identified by the MA.

While the position of the NPOs does not show a clear tendency, a robust majority of stakeholders that answered a similar question (46,21 per cent)[816] was of the opinion that this measure would not improve the examination. Some comments were provided, and we found the following comment exemplary and significant:

> "Requiring product definitions in the form of patent claims would lead to very variable results on the same application in different offices. Further, some offices do not currently examine for

Art. 2 of the Protocol for the interpretation of Art. 69 EPC to what extent it could be possible to go beyond the language of the claim and the criteria for such operation, or specify that the protection should be strictly confined to the product claimed. It is clear that conceiving such legislation would require an in-depth analysis, that cannot be offered here, and an extensive debate with experts from the NPOs and stakeholders.

813 See Art. 138(3) EPC.

814 Q58, Annex III.

815 Q49-51, Annex VI.

816 14.48 per cent expressed no opinion on the issue, 14.48 per cent was of the opinion that it would not make any difference, and only 24 per cent were of the option that it could facilitate the examination.

> inventive step on national patent applications and do not have internal expertise to assess patent claims. Many legal disputes would follow if such a product definition was required."[817]

This criticism is well founded. However, the current practice is not very different from the scenario feared by the stakeholder. As we have seen, some NPOs examine the admissibility of product definitions. Such examination leads to objections, these objections to refusals of main or auxiliary requests, which in turn lead to appeals lodged before the competent national courts.

The argument that requiring product definition would lead to variable results is also correct in our view. However, such differences already exist, even in the field of small molecules. In Germany, a definition including acceptable salts of the same active ingredients is not permitted, at least by some examining divisions of the German NPO; the same definition is admitted in other jurisdictions, such as France and the UK. In the Netherlands, the product definition covering a biological product – following *Yeda* – cannot in principle deviate from the product identified in the MA.

Finally, the argument that certificates with a different scope would result from the granting proceedings is also plausible. But such reservation does not apply to a unitary SPC granted by a single office.[818]

14.2.4 Conclusion

A clarification of the legal status of the product description is in our view opportune for NPOs, applicants and third parties.

The first option is to clarify that a statement of the applicant defining what is the product for which protection is requested, is not required and, if included in the application, not relevant for the scope of the certificate. Such option is, in our view, consistent with the wording of the SPC legislation. It is likely also consistent with the original intention of the lawmakers. However, the case law, in particular *Medeva* and *Forsgren*, made a product definition on the part of the applicant necessary, since the SPC can be requested also for a sub-combination of the product covered by the MA or even a sub-component or a carrier of the active substance identified in the MA. The examiner, on the basis of the mere MA, cannot identify in specific cases what is the product that must undergo the examination and be granted a certificate.

The option of formalising certificate claims as a feature of the application for a certificate with binding effect on the scope does not meet the favour of the stakeholders. It was also rejected in qualitative interviews. The MPI, however, is still of the opinion that this system would not be distant from the current practice. Further, some of the reservations expressed would not apply to a unitary SPC system where a single unitary division grants the right with Union-wide effect. It would not necessarily imply a burden for the NPOs depending on the legal rules adopted. Also, in view of the fact the MA is a dynamic and not a static document, a document that can be changed and extended after filing the application for a certificate or during the term of the certificate, we are of the opinion that such approach is worth being further discussed.

[817] Annex III, p. 428.
[818] See in unitary SPC Part Four of this Study, Chapter 22.

14.3 DOES THE CERTIFICATE COVER ALL FORMS OF THE ACTIVE INGREDIENT PROTECTED BY THE BASIC PATENT?

An issue for a long time discussed in the literature was whether the certificate protects only the specific form of the active ingredient covered by the MA or any other form of the active ingredient concerned.[819] The CJEU dealt with this question in *Farmitalia*.

14.3.1.1 Farmitalia

As already discussed, the first question referred in *Farmitalia* by the German Federal Court of Justice related to Art. 3(b) Reg. 469/2009, that is the requirements for protection, while the answer given by the CJEU concerned the extent of protection, *id est* the question of what is covered by a granted SPC.[820] Such answer reads as follows:

> "On a proper construction of Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products and, in particular, Article 3(b) thereof, where a product in the form referred to in the marketing authorisation is protected by a basic patent in force, the supplementary protection certificate is capable of covering the product, as a medicinal product, in any of the forms enjoying the protection of the basic patent."

The German Federal Court of Justice interpreted this answer in the sense that an SPC may be granted for the product in all its forms and salts even if the MA covers only a specific salt of the product. The CJEU maintained indeed that if the scope of the SPC were limited to

> "the particular salt form of the active ingredient mentioned as the active constituent in the marketing authorisation, whereas the basic patent protects the active ingredient as such as well as salts thereof, including the one which is the subject-matter of the marketing authorisation, any competitor would be able, after the basic patent had expired, to apply for and, in some circumstances, obtain marketing authorisation for a different salt of the same active ingredient, formerly protected by that patent."

If the SPC could not in this case prevent competitors from bringing the products to the market which were, in principle, therapeutically equivalent to those protected by the certificate, this would frustrate "the purpose of Regulation No 1768/92, which is to ensure the holder of the basic patent of exclusivity on the market during a given period extending beyond the period of validity of the basic patent". We believe that these considerations correctly identify the function of the SPC in delaying generic competition with respect to the product for which the SPC is granted in order to ensure that the patent holder can enjoy a longer period where such product is not exposed to generic competition in order to amortise the investments made.[821] This decision means that all salts sharing the same active part are different forms of one and the same product for SPC legislation. This understanding is in not in conflict with Recital 13 Reg. 1610/96, according to which

> "whereas the certificate confers the same rights as those conferred by the basic patent; whereas, consequently, where the basic patent covers an active substance and its various derivatives (salts and esters), the certificate confers the same protection."

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819 See Chapter 10, Section 10.2.4.2 (a).

820 See Thomas Bopp, *Die Schutzbereichsbestimmung bei ergänzenden Schutzzertifikaten* in FESTSCHRIFT 80 JAHRE PATENTGERICHTSBARKEIT IN DÜSSELDORF (Carl Heymanns Verlag 2016) p. 66.

821 Indeed, if a patent for some reason covers only a specific formulation of the active ingredient, the SPC will not be able to protect against generic entry.

Recital 13 refers to the active substance, and suggests that the scope of the certificate extends automatically – i.e. irrespective of the terms of the product description – to all forms of this active substance (forms sharing the same active moiety), provided that they are covered by the basic patent.

It is important to note that, according to the information collected during this Study, after *Farmitalia*, generic companies seem to have invariably come to market with the identical form of the active substance in the MA that was referred to in the SPC after the expiry of the SPC. We found only one case in the case law in which a generic company tried to enter the market with a different pharmaceutical salt and argued before a court that the SPC was not infringed because of this different pharmaceutical form. This case is described in the decision of 12 October 2017 by the Swiss Federal Patent Court concerning SPC no. C00915894/01. The SPC concerned was granted with the following product description: tenofovir disoproxil fumarate + emtricitabine.

The competitor obtained an MA for emtricitabine and tenefovir disoproxil phosphate. In the proceedings for a preliminary injunction requested by the SPC holder, the question was whether or not a product including the tenefovir phosphate falls under the scope of the certificate. The Court found the certificate to be infringed despite the different salt employed by the medicinal product for which the defendant had obtained a MA.[822]

14.3.1.2 Are all derivatives covered by the SPC granted for the parent compound?

In view of the fact that derivatives of the same active ingredient may be eligible for a certificate and be considered a different product under Recital 14 Reg. 1610/96, one might wonder whether the interaction between *Farmitalia*, Recital 13 and Recital 14 Reg. 1610/96 implies that the same derivative may be covered by two SPCs, one granted for the parent compound and one granted for the derivative as such, provided that a patent specifically claiming such derivative was designated for the second granting procedure. This would lead to a specific hypothesis of a "dependent SPC". While an SPC covering a subject matter that cannot be exploited without infringing another patent and an SPC are possible, we believe that the same criteria shall apply to the question whether a salt of an active ingredient is the same product as the active covered by the SPC for the purpose of Art. 4 Reg. 469/2009 and to the question whether a salt or an ester of an active ingredient is the same product as the active covered by an older SPC or an older MA for the purposes of Art. 3(c) or Art. 3(d) Reg. 469/2009 and Reg. 1610/96. If the same criteria apply, it is not possible that a salt is

[822] Similar proceedings were brought in Ireland, in an action for interlocutory relief, [2017]IEHC 666, 7 November 2017, where the plaintiff, Gilead, sought to prevent entry of combination products containing an alternative salt (in this case the maleate) of tenofovir disoproxil fumarate, an active ingredient of the reference medicinal product, which was a combination with emtricitabine. The plaintiffs argued that the sale of the maleate salt would be an infringement of the SPC which was based on fumarate salt, although the relevant SPC, No 2005/021 described the product as tenofovir disproxil and its salts in combination with emtricitabine. A motivation for generic companies to avoid the fumarate salt was that this was claimed in a patent, EP 998 480, expiring (in July 2018) after the expiry date (July 2017) of the basic patent for the SPC, EP 915 894, but before the expiry date of the SPC (in February 2020).
Although the validity of the SPC was challenged by the defendants and was already the subject of a reference to the CJEU from the English court ([2017]EWHC 13 (Pat), the Irish court held that the plaintiffs had an arguable case for infringement, but did not give reasons. From a regulatory perspective, at the EMA, combinations with alternative salts of tenofovir disoproxil (succinate, maleate and phosphate) were all approved as generic versions of the reference medicinal product, having the fumarate salt of tenofovir disproxil as an active ingredient.

found to be a different product under Art. 3(d) and Art. 3(c) and still considered to be covered by the SPC granted for the parent compound or for a further salt of that compound under Art. 4 Reg. 469/2009.

14.4 SPCs FOR AN ACTIVE INGREDIENT AND FIXED COMBINATION PRODUCTS

Under Art. 1(b) Reg. 469/2009 an active ingredient and a combination of two active ingredients are two different products. Further, a patent claiming compound A cannot support the application for a certificate for A-B, unless the latter combination is specified in the wording of the claim of the basic patent. This legal situation and case law raise the question whether the SPC granted for the active A covers a product including as actives the combination of A-B. This was the subject of two referrals for a preliminary ruling made in the UK by the High Court of Justice (England and Wales), Chancery Division (Patents Court) and in Germany by the Düsseldorf District Court.

The certificates litigated in the two proceedings belong to the same family, and the basic patent (EP 0 443 983, hereinafter EP '983) was the same. Also, the products accused of infringing the certificates were identical. The two cases were decided on the same day by orders of 9 February 2012 in Case C-442/11 Case C-574/11.[823] Both decisions are also referred to as *Novartis* decisions. For the sake of simplicity we will therefore consider only the factual scenario as described in the referral from the UK.

Novartis held EP '983, which expired on 12 February 2011 and which in claim 1 included a general chemical formula, while claiming specifically the active ingredient "Valsartan" in claim 26. *Novartis* received an MA for its product Diovan, which had valsartan as the only active ingredient, on 16 October 1996. Based on EP '983 and the MA for Diovan, *Novartis* applied for an SPC, which was granted on 12 November 2011.

On 30 November 2010, *Actavis* indicated that it intended to market a (generic) medicinal product comprising valsartan in combination with hydrochlorothiazide once EP '983 expired. *Novartis* subsequently sued *Actavis*, claiming that this would infringe the SPC for valsartan. The case therefore concerned the question whether an SPC for a single active ingredient is infringed by a medicinal product that includes that active ingredient together with another active ingredient. The defendant put forward two arguments:

- A combination of valtarsan with hydrochlorothiazide is a different product than valtarsan alone; it requires a different MA (as a fixed combination product) than valtarsan alone;
- The scope of protection conferred by the SPC covers only the product identified by the MA.

This line of arguments was rejected by the CJEU. The CJEU ruled

> "that articles 4 and 5 of Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products must be interpreted as meaning that, where a 'product' consisting of an active ingredient was protected by a basic patent and the holder of that patent was able to rely on the protection

[823] Case C-442/11 *Novartis AG v Actavis UK Ltd* [2012] ECLI:EU:C:2012:66 and Case C-574/11 *Novartis AG v Actavis Deutschland GmbH & Co. KG; Actavis Ltd.* [2012] ECLI:EU:C:2012:68.

> conferred by that patent for that 'product' in order to oppose the marketing of a medicinal product containing that active ingredient in combination with one or more other active ingredients, a supplementary protection certificate granted for that 'product' enables its holder, after the basic patent has expired, to oppose the marketing by a third party of a medicinal product containing that product for the use of the 'product', as a medicinal product, which was authorised before that certificate expired."

The effect of the ruling in *Novartis* is that the owner of an SPC for product A can, during the life of that SPC, prevent the sale of medicinal products containing not just A alone, but A in combination with other active ingredients, B or C or D, for example combinations such as A+B, A+B+C, A+D, etc. The result is justified because otherwise generic competitors would be in a position to enter the market by obtaining an abridged authorisation for a combination including the active ingredient covered by the patent and the certificate. At the same time, this has practical implications for the question whether or to what extent combinations including the single active shall be eligible for a certificate based on the same patent or an associated patent. For a liberal practice one cannot invoke the argument that the SPC granted for the single active would not prevent a generic company from bringing to market products consisting of combinations including that active ingredient.

14.5 WHAT ARE THE CRITERIA FOR DETERMINING WHETHER A PRODUCT FALLS UNDER THE SCOPE OF THE CERTIFICATE?

14.5.1 The issue

In assessing whether a product infringes a certificate under Art. 4 Reg. 469/2009, the national courts have to assess whether such product is the same product covered by the certificate. According to Recital 10 Reg. 469/2009, the protection granted by the certificate shall be strictly confined to the product which obtained authorisation to be placed on the market as a medicinal product. Such Recital was not included in the Plant Protection Products Regulation, but was maintained in Reg. 469/2009. It is not in conflict with *Farmitalia*. The recital refers to the active ingredient and not to its specific pharmaceutical form as covered by the MA. However, such recital does not help further in identifying the criteria for assessing whether the product accused of infringement and the product covered by the MA shall be considered the same product for the purpose of the legislation. Two criteria were discussed in the literature and in the practice.

14.5.2 Is the legal basis of an MA granted for the allegedly infringing product a criterion for deciding infringement?

One simple criterion for assessing the identity of the product covered by the SPC and product accused of infringing the SPC under Art. 4 Reg. 469/2009 could be the legal basis of the MA granted for the allegedly infringing product. If the latter was authorised as generics of the product covered by the MA, then the certificate shall be infringed. If the product was authorised on the basis of a stand-alone application, then an infringement shall be denied. Two recent decisions have dealt with this issue.

In the proceedings E-16/14, the Oslo District Court referred the following question to the EFTA Court on 9 April 2015:

> "When the medicinal product is a virus vaccine, can the scope of protection afforded by the SPC cover not only the specific strain of the virus that is contained in the authorised medicinal product and is covered by the basic patent, but also other strains of the virus that are covered by the basic patent and are therapeutically equivalent to the specific strain?
> In answering this question, is it of significance whether
> (a) such other strains have an equivalent therapeutic effect to the virus strain included in the medicinal product or whether the therapeutic effect is not immediately the same?
> (b) a medicinal product based on such other strain will have to be the subject of a separate marketing authorisation with requirements for documentation of safety and effect?"

In answering this question the EFTA Court maintained that

> "an SPC extends to a specific strain of a virus covered by the basic patent, but not referred to in the marketing authorisation for a virus vaccine relied on for the purposes of Article 3(b) of the SPC Regulation, only if the specific strain constitutes the same active ingredient as the authorised medicinal product and has therapeutic effects falling within the therapeutic indications for which the marketing authorisation was granted. It is not relevant whether a medicinal product based on such other strain would require a separate marketing authorisation."

A separate MA in the referral and in the discussion was intended as an MA granted on the basis of a full application that includes safety and efficacy tests. Under this case law, the regulatory route taken by the allegedly infringing product is not relevant for the assessment.

A different approach was taken by the Swiss Federal Patent Court in a decision of 12 October 2017 concerning the SPC No C00915894/01.[824] The SPC concerned was granted with the following product description: tenofovir disoproxil fumarate + emtricitabine.

The competitor obtained an MA for emtricitabine and tenefovir disoproxil phosphate. One of the disputed questions was whether a product including the tenefovir phosphate falls under the scope of the certificate. The Swiss Federal Patent Court considered material and binding not the terms of the product definition, but the fact that the infringing product was authorised as generics of the product covered by the MA submitted in support of the certificate. Since the product including tenefovir fumarate served as "reference medicinal product" for the MA filed for the allegedly infringing product, the Swiss Federal Patent Court found the certificate to be infringed. In this decision the regulatory route of the infringing product seems to be considered relevant by the Court and even to prevail over a product definition worded in narrower terms.

Our opinion is that in the field of small molecules, if a product is authorised on the basis of an application that refers to the medicinal product covered by the MA submitted in support of the application for the certificate as "*reference medicinal product*", such generics must be covered by the certificate as well, provided that it would fall under the scope of the basic patent. The reverse is not true. In the field of the small molecules, the mere fact that the product of the competitor is subject of a stand-alone MA (Art. 8 Dir. 2001/83) cannot exclude as such an infringement of a certificate. The applicant enjoys discretion in taking the appropriate regulatory route for the product that it intends to market.

[824] Federal Patent Court, Case S2017_006, *Gilead Sciences Inc. v Mepha Pharma AG.* An English translation of the decision rendered in preliminary proceedings for infringement is available at http://eplaw.org/wp-content/uploads/2017/12/CH-S2017_006-English.pdf (last accessed 19 April 2018).

14.6 PHARMACOLOGICAL EFFECT AS A CRITERION?

A second possible (and related) criterion is to base the definition of the scope on criteria borrowed from regulatory law. One author has referred to the provision according to which "an isomer, mixture of isomers, a complex or derivative or salt of a chemical substance previously authorised as a medicinal product in the Union but significantly differing in properties with regard to safety and efficacy from that chemical substance previously authorised" as a criterion for assessing the scope of a certificate.[825] Also the German Federal Patent Court, in deciding whether or not paliperidone palmitate is a different product than paliperidone papiledone for the purposes of Art. 3(c) and (d), has referred to the same provision.[826] However, such approach would not help further in the field of biological products.

14.7 SUMMARY

The question of the scope of the certificate has not led to extensive case law. This does not mean that no legal issue exists in this respect. On the basis of the information collected during this Study, however, it does not seem that such legal issues cause significant uncertainty for the stakeholders. The only exception concerns the status of the product definition. We have considered the options in Section 14.2 of this Chapter.

This analysis, however, is focused on small molecules, that were also the subject of the *Farmitalia* decision. Whether the principles stated in *Farmitalia* can apply, and with what implications to biological products, is unclear, since the regulatory framework draws a distinction between generics and biosimilars that could matter for the SPC legislation. Since some stakeholders have concerns as to whether the SPC legislation can adequately accommodate biopharmaceuticals[827], we have dedicated a specific section to biological products in Chapter 18.[828]

[825] Thomas Bopp, *Die Schutzbereichsbestimmung bei ergänzenden Schutzzertifikaten* in FESTSCHRIFT 80 JAHRE PATENTGERICHTSBARKEIT IN DÜSSELDORF (Carl Heymanns Verlag 2016) p. 66.
[826] See Chapter 9, Section 9.2.3.8 (c) (ii) of this Study.
[827] See Annex III of this Study, Q27 and Q28, pp. 157, 306-311.
[828] Section 18.2.

15 THE RIGHTS CONFERRED BY THE SPC AND ITS LIMITATIONS (ART. 5 REG. 469/2009)

15.1 INTRODUCTION

This Chapter first outlines the rights conferred by SPCs (15.2), and then turns to their limitations. The latter analysis focuses mainly on the possibility of introducing a manufacturing waiver for export and/or stockpiling purposes (15.3), and on the *Bolar* exemption (15.4).

15.2 THE RIGHTS CONFERRED BY SPCS

15.2.1 Source of law

According to Art. 5 of the Regulations "subject to the provisions of Article 4, the certificate shall confer the same rights as conferred by the basic patent and shall be subject to the same limitations and the same obligations".

Under national law patents confer the right to prohibit the direct and the indirect use of the invention. The former right is uniform in all EU States, since the corresponding provisions are harmonised with Art. 28(1) TRIPS. The latter reads as follows:

> "A patent shall confer on its owner the following exclusive rights:
> (a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing for these purposes that product;
> (b) where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process."

The right to prohibit indirect infringement is not addressed by TRIPS. Nevertheless almost all EU States provide or are about to introduce provisions in line with Art. 26 UPCA[829] and Art. 30 CPC.

15.2.2 Rights granted by a pending SPC application

Currently, a pending SPC application does not grant the applicant any enforceable rights against third parties.[830] This situation substantially differs from that of a patent applicant, who can already rely on the application against third parties at least to some extent.

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[829] The wording of Art. 26 UPCA under the heading "right to prevent the indirect use of the invention" reads as follows:
"(1) A patent shall confer on its proprietor the right to prevent any third party not having the proprietor's consent from supplying or offering to supply, within the territory of the Contracting Member States in which that patent has effect, any person other than a party entitled to exploit the patented invention, with means, relating to an essential element of that invention, for putting it into effect therein, when the third party knows, or should have known, that those means are suitable and intended for putting that invention into effect.
(2) Paragraph 1 shall not apply when the means are staple commercial products, except where the third party induces the person supplied to perform any of the acts prohibited by Article 25.
(3) Persons performing the acts referred to in Article 27(a) to (e) shall not be considered to be parties entitled to exploit the invention within the meaning of paragraph 1."

[830] See also Chapter 20, Section 20.3.2.1.

The differences between the protection granted by a patent application and an SPC application do not matter in cases where the SPC is granted before the patent lapses. However, it has been confirmed in our qualitative interviews that there are cases where the patent expires before the SPC has been granted. Generic companies claim that they avoid entering the market in such a phase of uncertainty to prevent unnecessary costs and legal consequences once the SPC is granted. This may explain why case law dealing with this question is not available at the moment.

Nevertheless, the situation is unsatisfactory. On the one hand, the SPC applicant still faces the risk of competition in the time gap between the expiration of the patent and the grant of the certificate. On the other hand, pending applications can deter generic competition. Such deterence would be problematic if the SPCs were then denied. We analyse possible options to address these issues in Chapter 20.[831]

15.3 SPC-SPECIFIC LIMITATIONS TO EXCLUSIVE RIGHTS: THE MANUFACTURING WAIVER

15.3.1 Introductory remarks

15.3.1.1 The issue

Patents claiming a substance as such – product patents – confer on their owner under Art. 28 TRIPS an exclusive right to making, using, offering for sale, selling, or importing for these purposes the patented product. If the patent claims the process for manufacturing the substance, the same rights are granted with respect to the product directly obtained by the process. Under that formula, making a patented product is an infringement, irrespective of whether the use or sale of the product occurs after the patent has expired or abroad where the patent is not in force.[832] Therefore, a patent prevents a generic or API manufacturer not only from selling a patented product on the market where the patent is valid, but also from manufacturing it with the intention to export it to patent-free countries or to sell it after the patent has expired.

To what extent the same principle applies to SPCs is unclear. A majority opinion appears to hold that the legal situation with regard to SPCs is exactly the same as for patents. However, our examination of the issue in Chapter 5[833] has shown that SPCs grant only purpose-bound protection. Furthermore, a valid argument could be made that due to the legal structure and the purpose of SPCs the manufacture of an active ingredient covered by an SPC is not infringing if it is done solely for export or stockpiling purposes. Such activities, indeed, do not require an MA in the EU. As already mentioned, the respective legal questions were referred to the CJEU without receiving an answer.[834]

For the purposes of the following analysis it is nevertheless assumed, in line with the majority opinion, that the manufacture of the active ingredient infringes the SPC even if it is done for export and even if the formulation of the medicinal product is only

[831] See Chapter 20, Sections 20.3.2.1 (b) (ii) and 20.3.2.3(e).
[832] Chapter 5, Section 5.7.2.
[833] See *ibid.*
[834] See *ibid.*

completed abroad. Consequently, any such acts would only be permitted if a manufacturing waiver applies. Furthermore, a manufacturing waiver is needed also if the mere manufacture of the active ingredient is considered SPC-free, but the preparation of a final drug including the active ingredient for an indication authorised in the EU, albeit for export, is found infringing.[835]

Patents for new active ingredients can in principle be obtained in all WTO member states. The same holds true for new processes for manufacturing a known compound.[836] Patent protection obtained in multiple countries expires either simultaneously or within a time frame that is limited to the priority period of 12 months granted by Art. 4 Paris Convention between the country of the first application and the remaining WTO member states.

The situation is different with respect to SPCs or patent extensions. Such rights are not mandatory under the Paris Convention or TRIPS.[837] As a consequence, a number of jurisdictions do not contemplate any extension of the patents granted for medicinal products or plant protection products.[838] Even where such extensions are available, their requirements, terms and scope differ. This means that a compound may still be protected in one jurisdiction, but be patent-free in another jurisdiction. It has been stated by representatives of the generic industry in the course of this Study that European legislation and case law, from a comparative perspective, are generous to patentees. Frequently, a specific compound or combination of compounds is patent-free in most jurisdictions, while still under protection in Europe.

15.3.1.2 The claims of the EU generic industry

Representatives of the generic companies have argued in the course of this Study that companies located in countries without SPCs or equivalent protection (in the following called non-PTE countries)[839] have a time advantage to enter the EU market before companies located in the EU. Indeed, they are able to manufacture the product prior to actual expiry of the SPC in the foreign SPC-free jurisdiction. In this way they are able to place the product on the EU market immediately after the expiry of the SPC. Furthermore, while generic companies in non-PTE countries can manufacture and sell the products on their own territory or in other non-PTE jurisdictions, EU-based manufacturers are not allowed to manufacture the SPC-protected active ingredient in Europe.

According to the opinion of some representatives of the generic industry, that situation has forced generic companies to relocate their manufacturing facilities outside the EU. Only in this way are EU-based manufacturers able to provide products to markets outside the EU as well as to enter EU markets with SPC protection on the first day

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835 If the position in Chapter 5, Section 5.7.2 is adopted, namely that SPCs per se do not extend to manufacturing of substances (raw compounds) or even of the formulation solely for export purposes because these activities do not require an MA in Europe, the introduction of a waiver would serve clarification purposes only.

836 The legal landscape is more complex for second medical use or new formulation of known compounds; see Roberto Romandini, 'Flexibilities Under TRIPS: An Analysis of the Proposal for Reforming Brazilian Patent Law' [2016] 15 J. Marshall Rev. Intell. Prop. L. 150.

837 *Supra* Chapter 3, Section 3.2.1.

838 SPCs or PTEs are not granted in Brazil, China, India, Indonesia, Mexico, Saudi Arabia, South Africa, and Turkey. See Miklos Gaszner, Carla Ji-Eun Kim, 'Considerations for Developing a Global Patent Term Extension Strategy', The National Law Review, available at: https://www.natlawreview.com/article/considerations-developing-global-patent-term-extension-strategy (last accessed 24 August 2017).

839 Among them China, Brazil and India.

after the expiry of protection (so-called "day one").[840] The current legislative framework creates incentives for outsourcing the production of drugs or delocalising altogether.

As a remedy – in order to keep the relevant work force within the EU – it is suggested that these obstacles should be mitigated or removed. A way to address this issue is to introduce a manufacturing waiver for export and/or stockpiling purposes.

The **manufacturing waiver** for **export purposes** would allow the generic companies to manufacture the active ingredients and/or the final drugs including the active ingredient (with labelling consistent with a foreign MA) in order to place them on foreign markets where no patent protection exists. The **manufacturing waiver** for **stockpiling purposes** would allow EU-based manufacturing companies to produce the active ingredient and the final drugs in order to place such products on the EU market the day after the SPC expires. In the view of their proponents, such measures would not affect the certificate holders. Indeed, generic competition in SPC-free markets already takes place: it stems from jurisdictions where patent protection is shorter (or absent). The same holds true for the European market: on "day one" after the expiration of the certificate generic products enter the market anyway, being imported from non-PTE jurisdictions or those where protection expired earlier. As a consequence, a manufacturing waiver would not enable competition that is otherwise absent. It would only affect the geographic origin of the products marketed in Europe after the SPC has expired or in foreign markets where no equivalent protection exists: in the opinion of the proponents, the manufacturing waiver would increase the quota of products manufactured in the EU.

Another argument for reform is made by the generic industry: since manufacturers need approval for a specific production facility, generic companies see no advantage in re-transferring manufacturing capacities to the EU once they commence production abroad.[841] Further, contracts with third-party manufacturers usually last longer than the term of protection of the SPC, thus binding resources outside the EU longer than the term of the relevant patents and SPCs.[842]

One particularly concise response from the online survey bundles all of the arguments presented by generic companies and we present it verbatim:

> An SPC manufacturing waiver is extremely needed. The SPC Regulation, as widely recognised, has the unintended consequence of forcing generic and biosimilar medicines production to non-EU countries where no similar protection is in place. This puts the EU industry at disadvantage vis-a-vis non-EU competitors. This situation prejudices competitiveness of EU companies in the key export markets, like for instance the US market, where patents and patent extensions will, in most cases, expire earlier than in the EU due to the more rapid introduction of new medicines. This is the case with major biological products as well as chemical molecule products. In addition, this situation gives an unintended lead time advantage to non-EU based operators as regards entering EU member states' generics market immediately upon the SPC protection expiry. An SPC Manufacturing Waiver would fix these unintended side effects of the SPC by allowing generic and biosimilar medicines developers to produce during the SPC period in order to supply unprotected markets as soon as possible. In no way will it undermine or change the existing IPR equilibrium in the EU. An SPC manufacturing waiver will bring high skill pharmaceutical R&D and manufacturing back into the EU (companies always prefer proximity of research centres to the manufacturing of the product, so it will actually increase R&D in Europe). It will develop and strengthen EU manufacturing science, boost European SMEs, strongly support the European Active pharmaceutical ingredients (API) industry, increase the EU trade balance, create economic growth

[840] This was expressly stated by Sergio Napolitano, the representative of Medicines for Europe, during the workshop organised in the course of this Study on 20 March 2017.
[841] *Ibid.*
[842] *Ibid.*

> in Europe and ultimately boost the opportunity for the European industry to compete for global leadership. There is no risk with a manufacturing waiver that generics and biosimilars enter the market before SPCs expire. The rules in place today to avoid that this happens will not change at all with an SPC MW. EU countries have all the necessary legal tools to block and seize infringing pharmaceuticals before they reach the market (e.g. preliminary injunctions) and this will not change. NB. until very recently, in eastern European countries, where SPCs where not in place yet, there were already on the market generic products that were unprotected in those markets but still protected in Western EU markets. This did not create infringement issues in protected markets, therefore an SPC manufacturing waiver would not create any specific risks. The SPC MW is only about entering the market and creating competition immediately after SPCs expire. European companies today cannot do it. Either they produce abroad, or they enter the EU market over 6 months after SPCs expire. The SPC MW is not about competitiveness between originators vs. generics. It is about competitiveness between European vs. non-European pharmaceutical industries.[843]

Not surprisingly, the originators consulted in the course of the Study do not agree with these arguments. Their position is presented below.[844]

15.3.1.3 The purpose and the scope of our analysis

There is no doubt that different terms of protection for a specific product in different jurisdictions create an asymmetry. In theory, therefore, the arguments presented by the generic industry make sense. However, the actual magnitude of the negative effects on generic manufacturers caused by the current system depends on several economic factors. These factors are, for instance, whether generic industries from non-PTE countries are able to create substantial post-expiry competition within the EU, and whether the markets in non-PTE countries are attractive for EU companies to compete in during the phase between expiration of the patent and that of the SPC. Furthermore, it is unclear to what extent the decision of (large) generic companies to translocate manufacturing plants to other countries is motivated by the lack of a waiver in current EU law. Other factors could be more relevant.

Not being able to rely on relevant data in this regard, this Study cannot and does not embark on an effort to confirm, reject or relativise the claims made by the generic industry. We intend only to address the legal options available to the EU lawmakers if the manufacturing waiver should be introduced. Further, we will answer the question whether a manufacturing waiver would be consistent with the rationale of the SPC legislation.

In accordance with this, the analysis will proceed as follows. Firstly, we will address the question whether the introduction of a manufacturing waiver would be compatible with international law (15.3.2). Secondly, we will assess the possible models for such waiver and the examples are discussed at the national level (15.3.3). Thirdly, we will provide examples and proposals from different jurisdictions (15.3.4). Fourthly, we will sum up the arguments of the stakeholders against such a waiver (15.3.5), and possible precautions that could address these concerns (15.3.6). Finally, we will address the question whether creating manufacturing waivers would be consistent with the rationale of SPC legislation (15.3.7).

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843 See Annex III of this Study, comments to Q68, p. 380.
844 See in this Chapter, Section 15.3.5.

15.3.2 Manufacturing waiver and international law

15.3.2.1 Introduction

Although the current discussion only concerns SPCs, in the next section we also address the admissibility of a manufacturing waiver applying to patents for the sake of completeness and also to test the limitations of such measures.

15.3.2.2 A manufacturing waiver for patents and TRIPS

(a) *Preliminary remarks*

As mentioned above, during the patent term (i.e. without considering SPCs) the manufacture for export or the manufacture for stockpiling are covered by the rights listed in Art. 28 TRIPS. If the lawmakers create an exception, Art. 28 TRIPS is prima facie contravened. As a consequence, a violation of TRIPS could only be excluded under Art. 30 TRIPS, the so-called three-step test.

In this context, account must be taken of the WTO Panel decision in *Canada – Patents*[845] which was presented earlier (Chapter 3, Section 3.2.3.3 (a)). To evaluate the repercussions the Panel report may have for a patent manufacturing waiver, a distinction must be made between waivers for export purposes and for stockpiling. Regarding stockpiling, the message sent by *Canada–Patents* seems to be that during the patent's lifetime such exceptions are precluded, as they are not sufficiently limited.[846] Unlike stockpiling, manufacturing for export was not considered in the WTO Panel report, so that the issue is undecided as yet. However, considering that a manufacturing (export) waiver would introduce an exception from two of the use modalities reserved to the patent owner under Art. 28 TRIPS – manufacturing and selling – a manufacturing (export) waiver would very likely face the same misgivings as were articulated by the WTO Panel vis-à-vis stockpiling.

On the other hand, it cannot be excluded that the arguments proffered by the WTO Panel must be revisited in the light of subsequent developments, in particular the Doha Declaration.[847] Among other things, the Declaration points out that "the Agreement can and should be interpreted and implemented in a manner supportive of WTO member states' right to protect public health and, in particular, to promote access to medicines for all",[848] and that "in applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, *in its objectives and principles*" (emphasis added).[849] It therefore needs to be considered whether a manufacturing waiver could be justified if the objectives and principles of TRIPS are given more weight.

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845 WTO Panel report Canada – Patents Canada – Patent Protection of Pharmaceutical Products – Complaint by the European Communities and their Member States, WT/DS114/R, 17 March 2000.
846 *Ibid.*, see Chapter 3, Section 3.2.3.3 (a).
847 Doha Ministerial Declaration, WT/MIN(01)/DEC/1 and Declaration concerning the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2, both as of 20 November 2001, adopted 14 November 2001.
848 *Ibid.*, para. 4.
849 *Ibid.*, para. 5(a).

(b) *Arguments pro a patent manufacturing waiver: Seuba et al.*

In an article by Seuba, Genovesi and Roffe (in the following: Seuba et al.),[850] it is argued that a manufacturing (export) waiver can indeed be justified. They point out that the stockpiling exemption was only considered as not sufficiently limited because there was no limit to the quantity of products produced during the relevant period.[851] The authors maintain that if the exception had "incorporated limits relating, for example, to authorised quantities *or in relation to targeted markets*, it would have complied with the standard set forth in Art. 30" (emphasis added).[852] That finding is further corroborated in their view by the interpretation of Art. 30 endorsed in the Declaration on Patent Protection promulgated under the aegis of the Max Planck Institute for Innovation and Competition (MPI Patent Declaration) in 2014,[853] where it is argued that the three-step test must be understood as an indivisible entity, with the individual steps informing each other instead of each one being assessed in isolation. On that basis, an exception must be considered as "limited" if its scope is proportionate to its object und purpose.[854] This is said to be the case here: the purpose of the provision to satisfy demand on patent-free markets is claimed to comply with the goal to foster legitimate trade, as set forth in the preamble, and with the promotion of social and economic welfare addressed in Art. 7 TRIPS. Furthermore, emphasis is placed on the fact that, as the commercial position of the patent proprietor is not negatively affected by sales exclusively directed to patent-free markets, the "normal exploitation" of the right is not interfered with,[855] and that there is no "legitimate interest" of right holders in keeping competitors out of patent-free markets.[856] Alternatively, if a legitimate interest in maintaining full exclusivity in the domestic market should be acknowledged, it is argued that it is not "unreasonably prejudiced" by an export waiver, or that a compromise solution might be to offer "equitable compensation" to the right holder.[857]

(c) *Arguments against a patent manufacturing waiver: Solovy and Raju*

The arguments proffered by Seuba et al. are sharply criticised in an article by Solovy and Raju.[858] Their main point of criticism is that, instead of applying the customary rules of international treaty interpretation as set forth in Arts. 31 and 32 VCLT, Seuba et al. rely on "secondary sources", in particular on the MPI Patent Declaration.[859] They further argue that the policy arguments by Seuba et al. are unspecific, thus resulting

850 Xavier Seuba et al, *A Manufacturing for Export Exemption* in Brian Mercurio, Daria Kim (eds), CONTEMPORARY ISSUES IN PHARMACEUTICAL PATENT LAW (Routledge 2017) pp. 161-185.

851 WTO Panel report Canada – Patents Canada – Patent Protection of Pharmaceutical Products – Complaint by the European Communities and their Member States, WT/DS114/R, 17 March 2000, para. 7.34.

852 Xavier Seuba et al, *A Manufacturing for Export Exemption* in Brian Mercurio, Daria Kim (eds), CONTEMPORARY ISSUES IN PHARMACEUTICAL PATENT LAW (Routledge 2017) p. 174 et seqq.

853 Reto M Hilty, Matthias Lamping (eds), 'Declaration on Patent Protection – Regulatory Sovereignty under TRIPS' [2014] IIC 679, available at https://www.mpg.de/8132986/Patent-Declaration.pdf (last accessed 13 March 2018).

854 Xavier Seuba et al, *A Manufacturing for Export Exemption* in Brian Mercurio, Daria Kim (eds), CONTEMPORARY ISSUES IN PHARMACEUTICAL PATENT LAW (Routledge 2017) p. 175.

855 *Ibid.*, 177.

856 *Ibid.*, 182.

857 *Ibid.*, 181.

858 Eric M Solovy, Deepak Raju, 'A Manufacturing for Export Waiver: a Proposal for Exporting Violations of the TRIPS Agreement and Beyond?' [2018] 13(1) Journal of Intellectual Property Law and Practice 68-77.

859 *Ibid.*, 70.

in a potentially very broad kind of waiver.[860] As another counter-argument, they point out that if an export waiver were fully compatible with Art. 30 TRIPS it would not have been necessary to enter into the complex negotiations among WTO member states, leading to the promulgation of Art. 31bis TRIPS[861] (allowing the grant of compulsory licences for export of medicaments under certain precautions to non-manufacturing countries suffering from pandemics – HIV, malaria, and tuberculosis).

(d) *Evaluation of the arguments*

It is true that the interpretation of the three step-test must place weight on the objectives and principles of TRIPS, as pointed out in the Doha Declaration. However, that does not mean that a manufacturing waiver applying to patents, be it for export or for stockpiling, can be considered TRIPS-compliant. The Doha Declaration was primarily concerned with issues of public health. The primary purpose of a manufacturing waiver (if it were actually considered, which is not the case in the EU) would be to support domestic generic manufacturers in their ability to compete with non-EU-based companies. Of course, the objectives enshrined in Art. 7 TRIPS are broader than the protection of health. They refer in a rather general way to Member States' "social and economic welfare". This may also reflect the interest of national legislatures in domestic economic development and job creation.[862] However, such considerations would hardly be limited to one specific industrial sector, thus making the exception either very broad or risking conflict with the non-discrimination clause in Art. 27 TRIPS.

Furthermore, the reference made by Solovy and Raju to Art. 31bis TRIPS indeed provides an argument against a general manufacturing (export) waiver applying to patents. Although it was pointed out in connection with the promulgation of that provision that it does not diminish the flexibilities otherwise available under TRIPS, it appears most unlikely that creating a rather broadly measured exception for export purposes would pass scrutiny under the three-step test, if at the same time compulsory licences for the same purpose can only be granted under strictly limited conditions and subject to substantial precautions.

15.3.2.3 Manufacturing waiver for SPCs and TRIPS

The literature discussed in the previous sections does not address specifically whether the conclusions reached for patents are valid for SPCs as well. For a number of reasons we are of the opinion that a manufacturing waiver would be allowed if limited to SPCs, even though it would offend international obligations if introduced for patents.

(a) *Are SPCs patents within the meaning of Art. 27 TRIPS?*

As pointed out above (Chapter 3, Section 3.2.1), SPCs are intellectual property rights covered by the general obligations laid down in Part I of TRIPS. However, this does

860 Eric M Solovy, Deepak Raju, 'A manufacturing-for-export exception to patent protection: a proposal for exporting violations of the trips agreement and beyond?' [2018] 13(1) Journal of Intellectual Property Law & Practice 68, 69.

861 *Ibid*., 68, 73.

862 As argued by Xavier Seuba et al, *A Manufacturing for Export Exemption* in Brian Mercurio, Daria Kim (eds), CONTEMPORARY ISSUES IN PHARMACEUTICAL PATENT LAW (Routledge 2017) p. 183.

not necessarily mean that they are "patents" within the meaning of Art. 27 TRIPS. Unlike the Paris Convention,[863] in TRIPS the term "patent" is not a general notion covering a broad number of rights dealing with technical subject matter. Article 27 TRIPS provides for specific features that define the subject matter of a patent, and distinguish the latter from other categories of rights covered by the Agreement. Thus it can be argued that because SPCs do not conform to the defining elements of patents under TRIPS, they are not subject to the specific obligations relating to the latter.

Indeed, the two types of rights differ clearly from each other. Under TRIPS, patents are granted for *technical inventions* (Art. 27 TRIPS). Under EU law, SPCs are granted for a *product subject to a marketing authorisation* required under Dir. 2001/83 or Dir. 2001/82. Under Arts. 27 and 29 TRIPS, patents form a *reward for having disclosed an invention* that is novel, inventive and industrially applicable. Pursuant to Arts. 2 and 3 SPC Regulations, SPCs are meant to compensate for the time lost in *obtaining a marketing authorisation* for a product protected by a basic patent. Patents shall encourage research leading to *patentable inventions*; SPCs, according to the CJEU, shall reward (and encourage) investments that lead to a *marketable product*. The existence of a valid patent, and therefore of a patentable invention, is necessary, but not sufficient for obtaining a (valid) SPC. A marketing authorisation, granted before the expiration of the patent, is required. Furthermore, medicinal products authorised after the expiration of the patent do not infringe the SPC, even if they would infringe upon the patent, unless they correspond to the product covered by the MA. For all these reasons, an SPC is *not simply an extension* of the basic patent. Above all, SPCs do not fulfil the same function.

Thus, while SPCs cannot be considered as being completely exempted from the obligations under Art. 27 et seq. TRIPS, those obligations only pertain to the right *in the shape modified and conditioned by the SPC*.

(b) *Evaluation of an SPC manufacturing waiver under Art. 30 TRIPS*

Based on the previous analysis, the specific nature of SPCs is taken into account for examining the compatibility of a manufacturing waiver with the three-step test set forth in Art. 30 TRIPS. For that purpose the three steps shall be considered individually and separately.[864]

Regarding the first step, the WTO Panel in *Canada–Patents* claimed that due to the double qualification – "exception" and "limited" – an exception may not be more than a "small diminution" of the right, which must be assessed under quantitative and qualitative aspects.[865] The Panel expressly abstained from considering the legal objectives on which the exception is based.[866] That approach contradicts the Doha

[863] To suggest that the Paris Convention is completely silent about the subject matter of the rights defined as patents would likely be inaccurate. The French wording of the Convention uses the expression *brevet d´invention*, but only as a form of the different patents covered by the Treaty.

[864] As set forth in the WTO Panel report Canada – Patents Canada – Patent Protection of Pharmaceutical Products – Complaint by the European Communities and their Member States, WT/DS114/R, para. 7.101. An account of that decision is given in Chapter 3, 3.2.3.3 (a). It is submitted that Art. 30 can also be read in the sense that the three "steps" are separate elements to be included in one comprehensive analysis. However, this is not decisive; more important is the fact that even if the test is performed separately, it must be possible at each step to consider policy elements that potentially serve as justification.

[865] *Ibid.,* 7.30 et seqq.

[866] *Ibid.*

Declaration, which confirmed that the principles and objectives of TRIPS must always guide the interpretation of rights and obligations,[867] thus disallowing an assessment which is decidedly policy-blind. Thus, in the case considered here, account must be taken of the policy objective of manufacturing waivers, namely to correct or at least mitigate imbalances resulting from the fact that generic companies in the EU are hindered from competing on a level playing field with companies based in non-PTE countries.[868] If the exception is tailored precisely so as to target the imbalances, the first step must be considered as fulfilled at least in the sense that the exception cannot be discarded for good, but must be submitted to the more substantial tests on the second and third step.[869]

On the second step – conflict with normal exploitation – the WTO Panel in *Canada – Patents* distinguished between the *de facto* post-expiry protection resulting from the prohibition of manufacturing during the patent term and that resulting from the exigencies of regulatory proceedings. Whereas the enjoyment of exclusivity of the former type was considered as "normal exploitation", this was not held to be the case for the latter, as it resulted from external regulations rather than from the patent itself.

In the case of SPCs as well, protection results from *sui generis* legislation rather than being inherent in the basic patent. As pointed out above, this is relevant insofar as the exclusionary effect does not result from the patent itself, but only from a *modified emanation* of the original right. Thus, what constitutes "normal exploitation" is not determined by the patent in its original form, but by the constituent features of the *sui generis* protection granted. Here, the aspect needs to be considered that patents and SPCs do not have the same purposes and *raison d´être*. The fact that without a waiver the SPC holder may be entitled to prohibit activities that do not interfere with the very purpose of the right is a kind of windfall gain rather than a "normal exploitation" of the right.

Concerning the third step, the WTO Panel, after making a brief comparative analysis of patent systems in other WTO member states, concluded that post-expiry protection of patents was not so common that a "legitimate interest" of right holders in such protection had to be assumed.[870] This is, of course, different here; as the legislature deliberately granted such protection in the form of SPCs, there is no doubt that the right holder has a legitimate interest in that protection being respected. However, again, the extent to which those interests must be respected is conditioned on the legal purpose and constitutive features of the right granted. As said before, the right is predicated on the authorisation obtained for the product being used for specific purposes on a given market. Curtailing the exclusionary effects of the right where it extends beyond the ambit demarcated by those features therefore does not result in an unreasonable prejudice to the legal entitlement provided by the legislation.

867 Doha Ministerial Declaration, WT/MIN(01)/DEC/1 and Declaration concerning the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2, both as of 20 November 2001, adopted 14 November 2001.

868 See in this Chapter Section 15.3.1.1 and the reference to the position of the generic industry in Section 15.3.1.2.

869 Otherwise it might happen that exceptions are discarded at the first step which do not unreasonably conflict with normal exploitation, and which do not unreasonably prejudice the legitimate interests of the right holder.

870 WTO Panel report Canada – Patents Canada – Patent Protection of Pharmaceutical Products – Complaint by the European Communities and their Member States, WT/DS114/R.

It is true that this only applies if it can be ensured that use of the waiver is actually confined to non-interfering activities, that is, to manufacturing solely for export purposes or for storing until the date of permitted market entry. Therefore, the introduction of a waiver should be accompanied by legislation safeguarding the interests of the right holder to prevent illicit uses. Such legislation should spell out due diligence obligations for companies making use of the waiver, possibly including an obligation to report and, under certain conditions, allow inspection of premises etc. (see *infra*, 15.3.6).

(c) *Preliminary conclusions*

Manufacturing waivers in the form of export or stockpiling waivers are *not precluded* by TRIPS if *they only apply to SPCs*.

15.3.2.4 Commitments resulting from bilateral agreements (FTAs)

As pointed out in Chapter 3,[871] the EU has concluded a number of bilateral agreements containing a chapter on intellectual property rights. Most of these also address SPCs. This is most frequently done[872] in the fashion found, for example, in Art. 11.31 of the EU-Singapore FTA (**EUSFTA**):

> [t]he Parties recognise that pharmaceutical products protected by a patent in their respective territories may be subject to an administrative marketing approval process before being put on their respective markets. The Parties shall make available an extension of the duration of the rights conferred by the patent protection to compensate the patent owner for the reduction in the effective patent life as a result of the administrative marketing approval process. The extension of the duration of the rights conferred by the patent protection may not exceed five years.

The Comprehensive Economic and Trade Agreement concluded between the EU and Canada (**CETA**) differs from the usual scheme insofar as it regulates SPCs in more detail,[873] and also because it expressly limits the protection granted to use "as a pharmaceutical product that has been authorised". Consequently, Art. 20.27.9 CETA includes the option of introducing a waiver of rights pertaining to the making, using, offering for sale, selling or importing of products for the purpose of export.

Chapter 14, Art. 35 of the EU–Japan FTA (**EUJFTA**) stipulates that

> With respect to the patent which is granted for an invention related to pharmaceutical products or agricultural chemical products, each Party shall, subject to the terms and conditions of its applicable laws and regulations, provide for a compensatory term of protection for a period during which the patented invention cannot be worked due to marketing approval process. As of the date of signing this Agreement, a maximum of such compensatory term is stipulated as being five years by the relevant laws of each Party.

A somewhat unusual clause concerning term extensions is found in the agreement originally concluded with Peru and Colombia, later-on joined by Ecuador (**EUPCFTA**), which sets forth in Art. 230(3) and (4) that

> (3) When the marketing of a pharmaceutical or agricultural chemical product in a Party requires to obtain an authorisation by its competent authorities in such matters, such Party shall make its best efforts to *process the corresponding application expeditiously with a view to avoiding unreasonable delays*. The Parties shall cooperate and provide mutual assistance to achieve this objective (emphasis added).

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871 Chapter 3, Section 3.2.5.
872 For details regarding other FTAs see Chapter 3, Section 3.2.5.3.
873 For details concerning the regulation of SPCs in CETA see Chapter 3, Section 3.2.5.3.

> (4) With respect to any pharmaceutical product that is covered by a patent, each Party may, in accordance with its domestic legislation, make available a mechanism to compensate the patent owner for unreasonable curtailment of the effective patent term resulting from the first marketing approval of that product in that Party. Such mechanism shall confer all of the exclusive rights of a patent, subject to the same limitations and exceptions applicable to the original patent.

The meaning and scope of those commitments must be interpreted "in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its purpose and objectives" (Art. 31 VCLT).

For the issue treated here, **CETA** can be understood as a confirmation that a manufacturing waiver is considered by both trading partners as a valid option under international law. It is true that by only addressing manufacturing waivers for export purposes CETA might raise the question whether the contracting parties have implicitly renounced the option of introducing a stockpiling exception. However, that interpretation would be flawed. First, it is the aim of CETA to point out legislative options, and not to exclude them. Second, by expressly limiting the rights guaranteed to the holder of the SPC to "use as a pharmaceutical product that has been authorised", one could argue that acts of manufacturing preceding such use are not meant to be comprised.

No obstacle against introducing a manufacturing waiver appears to result from the **EUJFTA.** By stipulating in Art. 14 (Chapter 35) that by granting a compensatory term of protection "subject to the terms and conditions of its applicable laws and regulations" the provision respects the freedom of legislatures to modulate that protection as they consider appropriate. The only exception is made in regard to the term of post-expiry protection which shall remain fixed at a maximum of five years.

Less clear is the impact of previous commitments to "make available an extension of the duration of the rights conferred by the patent protection" (Art. 11.31 **EUSFTA**) or similar formulations, such as the obligation "to provide … for the extension of the duration of the rights conferred by the patent protection" (Art. 10.35 **EUKFTA**). Do such general formulations compel full prolongation of the patent rights? Such an interpretation would fail to take account of the fact that the respective FTAs make reference to the purpose of compensation for delays caused by regulatory proceedings necessary to grant *access to the domestic market*. An interpretation in good faith therefore rather leads to the conclusion that the right granted in order to extend the effects of the patent can be tailored so that it ensures exclusivity on the market and for the purposes addressed by the regulatory proceedings causing the delay, without interfering with activities that are not so targeted.

Finally, the commitment made in Art. 230(4) **EUPCFTA** that the exclusive rights conferred in case of term extensions referred to by that provision shall not only be the same as for the patent, but that they shall be "subject to the same limitations and exceptions applicable to the original patent", could be problematic if applied to SPCs, and if interpreted as meaning that SPCs cannot be subject to any other limitations than those applying to patents. However, Art. 230(4) must be read in context with Art. 230(3) EUPCFTA, where it is specified that the provision is meant to target **unreasonable delays** caused by protracted market authorisation proceedings. This is echoed in Art. 230(4), which also refers to "unreasonable delays". Thus, the purpose of the specific kind of time extension addressed by Art. 230(4) is conspicuously different from that of SPCs. Unlike the latter, the aim is not to compensate for the loss

of time regularly resulting from the efforts necessary to develop a product capable of obtaining a market authorisation; the measure only targets delays caused by **unjustifiably slow** operation of the relevant authorities in granting the MA. That this constitutes an *aliud* to SPCs is further corroborated by the fact that in Art. 8.3 of the agreement concluded with Vietnam, SPCs – meant as a compensation for "the reduction in the effective patent life as a result of the marketing authorisation procedure" – are presented as an *alternative* to patent term extensions sanctioning "unreasonable delays" in the granting of such authorisations. It can therefore be concluded that, because only the latter kind of extensions are addressed in Art. 230(4) EUPCFTA, the obligation set forth therein does **not apply** to SPCs.

15.3.2.5 Conclusions

From the above considerations the conclusion can be drawn that the introduction of a manufacturing waiver for SPCs would not lead to problems under international law, whether under TRIPS or in the light of bilateral agreements concluded by the EU.

15.3.3 Possible models for a manufacturing waiver

As already explained, a waiver can either be directed to export (*manufacturing waiver for export*) or, alternatively or cumulatively, it can allow companies to manufacture SPC-protected products prior to expiration of the SPC term in order to put the products on the market immediately after expiry of the SPC (*stockpiling exemption*).[874] Regarding the legal design of such waivers, different models could be envisaged.

15.3.3.1 Manufacturing waiver as compulsory licence

One option would be to construe a manufacturing waiver in the form of a compulsory licence.[875] Such a licence may either be granted free of charge or on payment of a licence fee. In this scenario, the generic company would need to apply for such a licence, which would then be granted by a competent body. The advantage for the right holder is transparency as to the actual names and the number of beneficiaries of such a waiver. Also, in the administrative procedure conducted before the licence is granted, specific requirements could be imposed upon the manufacturer so as to prevent abusive sales strategies. The disadvantage from the perspective of generic companies is that an administrative procedure involves costs and time delays. Further, if the purpose of the manufacturing waiver is to foster investment in Europe, a system based on a case-by-case decision could not offer sufficient certainty for generic or API manufacturers.

15.3.3.2 Manufacturing waiver as a limitation of the right

Alternatively, the manufacture of the protected product could be allowed *ex lege* provided that a set of predefined requirements is met. This would allow generic companies to manufacture and export the compound under certain conditions without

[874] As Gareth Morgan correctly pointed out in his presentation during the workshop organised by the MPI in the course of this Study on 20 March 2017, the terminology regarding different forms of manufacturing waivers is not consistent. For the sake of clarity, we distinguish the manufacturing waiver in preparation for timely market entry as a stockpiling exemption.

[875] Similar to Art. 6 et seqq. Reg. 816/2006.

having to apply for any kind of prior authorisation. The manufacturing waiver would receive the normative structure of an exemption from infringement, like experimental use, activities covered by prior user rights or the *Bolar* exemption. If the activity is covered by the exemption, it is allowed without any further formal requirement.

15.3.3.3 Manufacturing waiver as a permission subject to payment or other formalities

A third alternative would be to design the manufacturing waiver as an exemption, but subject to conditions or formalities with which the third party must comply before starting manufacture or during the production. These conditions may consist in the obligation to inform the patentee of the intention to make use of the waiver. Or they may consist in the obligation to pay compensation and to communicate the quantities produced. The lawmakers could establish that when such conditions are not met, the general law of infringement applies.

One example of this approach is the farmer's privilege set forth in Art. 14(3) of the Plant Variety Regulation.[876] Under that provision a company can reproduce seeds of a protected variety without the prior consent of the right holder, but only against payment of a remuneration. Consequently, if the relevant product should be produced without complying with the compensation rules, such use would be considered as infringing and the respective manufacturer would be exposed to an injunction.[877] This solution would have the advantage vis-à-vis compulsory licences that it does not require lengthy administrative procedures prior to commencing production. On the other hand, its implementation in practice could raise considerable problems. Issues to be resolved would, in particular, relate to the determination of the appropriate amount of the remuneration. Further, it would have to be decided how the remuneration should be collected and whether a generic manufacturer should only be allowed to start production once an appropriate security had been provided to the holder of the SPC. Also it is unclear what the consequences would be if the parties could not agree on an appropriate remuneration. Should a specific dispute resolution mechanism be implemented? Would mandatory ADR be an option? Finally, should the manufacturer be entitled to continue manufacturing the product while eventual dispute resolution proceedings are pending? As illustrated by these considerations a remuneration-based manufacturing waiver would entail complex legal problems.[878] This might increase transaction costs to an extent that risks clashing with the legal objectives on which a manufacturing waiver might be founded.

On the other hand, a regulation based on the same model could also be envisaged which does not require the payment of remuneration but the fulfilment of other formal requirements, such as advance notification of the right holder. In that case, corresponding to what was said above about payment, manufacturing of goods without such notification would remain infringing, even if the purpose of manufacturing would, in principle, fall within the ambit of the waiver. This model would not give rise to the administrative intricacies associated with a payment obligation.

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876 Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights [1994] OJ L 227/1.

877 Case C-509/10 *Geistbeck* [2012] EU:C:2012:416.

878 To some extent, the corresponding legal issues to be decided could be similar to the complex issues that arise in the context of the enforcement of standard essential patents and corresponding FRAND-licensing obligations; in this regard see Case C-170/13 *Huawei* [2015] ECLI:EU:C:2015:477.

15.3.4 Examples and proposals across the jurisdictions

Various forms of manufacturing waivers or licences for export or stockpiling purposes have been discussed, sometimes even legislated, in several countries. The following sections will briefly review some of these examples.

15.3.4.1 Australia

Australia currently has a compulsory licence for export set forth in Part 3 of Chapter 12 of the Australian Patents Act. This instrument requires an application to a federal court for a compulsory licence and is limited to least-developed countries based on the respective UN list. The scope of the waiver is narrow and, in our view, just represents an equivalent to Regulation (EC) 816/2006 of the European Parliament and of the Council of 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems implementing the Doha Declaration. However, Australia has considered introducing a broader manufacturing waiver for export several times, but so far this has not become law. Two possible reasons are worth mentioning. First, it has been argued that the specific definition of patent infringement during the patent extension term already allows such export activities since "only an act of exploitation of a pharmaceutical substance that constitutes an infringement during the extension period is exploitation for the purpose of therapeutic use in Australia".[879] This interpretation is not unanimous; the opposite view is also endorsed.[880] Second, there have been doubts whether or not Australia is precluded from introducing a manufacturing waiver based on FTAs with the USA.[881] In any case, it has been highlighted in Australia that, in contrast to patents, manufacturing waivers can be stipulated with regard to *sui generis* rights without violation of the TRIPS Agreement.[882]

15.3.4.2 Canada

Canada introduced a compulsory licence for export in 2004 for the purpose of exporting medicinal products to least-developed countries.[883] Recently, Canada passed legislation to adapt its patent law to CETA and to introduce a Certificate of Supplementary Protection.[884] The bill received Royal Assent on 16 May 2017. It will introduce, together with the supplementary protection, a manufacturing waiver for export in Sec. 115(2) of the Patents Act, which states:

> (2) Despite subsection (1), it is not an infringement of the certificate of supplementary protection for any person to make, construct, use or sell the medicinal ingredient or combination of medicinal ingredients for the purpose of export from Canada.

This provision covers the manufacturing of the medicinal ingredient or combination of medicinal ingredients for foreign markets. It does not allow, however, the manufacturing for stockpiling purposes in order for the generic companies to be in a

879 Andrew F Christie et al, 'Review of Pharmaceutical Patent Extension and Springboarding Provisions in Various Jurisdictions' [2002] p. 86, available at http://achristie.com/wp-content/uploads/2011/08/IPRIA-Patent-Extension-Review-2.pdf (last accessed 16 January 2018).

880 Australian Government, Productivity Commission, Intellectual Property Arrangements, Productivity Commission Inquiry Report No 78, 23 September 2016, p. 312.

881 *Ibid.*

882 *Ibid.,* p. 311.

883 Cl. 59 §115[2].

884 See Bill C-30, "An Act to implement the Comprehensive Economic and Trade Agreement between Canada and the European Union and its Member States and to provide for certain other measures".

position to sell the product on the day after the expiration of the certificate. The wording of the provision raises two questions. The first question is whether the provision constitutes solely a clarification of the purpose-bound protection granted by the certificate with only declaratory meaning or conversely an exception to the rights that would cover acts that would otherwise infringe the SPC.

The second question is whether the waiver only allows for the manufacture of the medicinal ingredient or also of the whole final drug. Section 115(2) of the Patents Act indeed refers to a waiver regarding the medicinal ingredient or combination of medicinal ingredients. Like in the European Regulation, Canadian law distinguishes between the finished drug product and the medicinal ingredient. The finished drug product is directed to treating a specific indication and is constituted by the medicinal ingredient (or a combination of medicinal ingredients) and other non-medicinal ingredients packaged according to the foreign or domestic MA. Thus a strict textual interpretation of the conditions of Sec. 115(2) of the Patents Act should lead to the conclusion that the manufacturing of the final drug is not covered by the waiver.

15.3.4.3 Spain

On 1 April 2017, a new law on patents came into force in Spain.[885] The new legislation has replaced the previous Patent Act[886] and has modernised the Spanish patent system in several aspects. As explained in Annex I, the law and its implementing rules include specific provisions dealing with applications for certificates.[887]

The reform has not introduced a manufacturing waiver in Spain. The lawmakers have only slightly amended the wording of the *Bolar* exemption laid down in Art. 61 of the previous Patent Act. However, a proposal to create a general exception for export was made during the parliamentary discussion preceding the reform. The proposal was made by the parliamentary group IU, ICV-EUiA, and CHA (La Izquierda Plural) and was actively promoted by the Spanish generic industry.[888]

The aim of the initiative was to create a further exemption from infringement to be inserted in Art. 61 of what was at that time still a proposal for a new Spanish Patent Act. The latter Article lists the limitations to the rights granted by the patent, such as experimental use or the *Bolar* exemption, and corresponds in its content and function to Art. 27 UPCA. The exception for export (Art. 61.4) in the proposal reads as follows:

> 4. Los derechos conferidos por la patente no se extienden a los actos previstos en el artículo 59 respecto a un producto fabricado para su exportación siempre que la invención objeto de la patente se encuentre en el dominio público en el mercado de exportación.

Translated loosely the proposed exception reads as follows:

> 4. The rights conferred by the patent shall not extend to acts provided for in Art. 59 Patent Act with respect to a product manufactured for export, provided that the invention that is the subject of the patent is in the public domain in the destination market.

885 Law 24/2015 of Patents of 24 July 2015, Boletín Oficial del Estado Núm 177, Sec. I, p. 62765.
886 Law No. 11/1986 of March 20, 1986, on Patents.
887 Gabriel González Limas, María Victoria Rivas Llanos, *Spain* in Annex I of this Study, Chapter 10.
888 In particular Asociación Española de Medicamentos Genéricos (Aeseg).

By stipulating the public domain, the proposal intended either that the invention was never under protection in the market concerned or that patent protection had expired. The proposal for amending the bill was supported and explained as follows:

> The proposal for this exception is put forward to promote the competitiveness of Spanish companies and their internationalisation, as well as to enhance the possibility for innovation in these companies with industrial interests in Spain. That way, it would be possible for the products manufactured in Spain to enter other countries under the same conditions as for those countries which currently destroy the competitive capacity of our (i.e. Spanish) manufacturers. On the other hand, one could avoid the industrial relocation of these companies, which, in order to be competitive at the international level, see themselves forced to situate in third countries, and could attract industry from third countries, which will see the quality of our (i.e. the Spanish) industry as an attraction to invest their resources in Spain.
> In sum, we are talking about a clause of exportation, which consists in the incorporation of an exception, permitting the manufacturing of products for the only purpose of exporting them in markets without exclusivity.[889]

We did not find evidence that a vote ever took place on this proposal in the Spanish parliament. The following points are relevant for our analysis.

The provision was, according to its wording, supposed to apply to all patents and to all products. By virtue of Art. 5 Reg. 469/2009 and Reg. 1610/96, such a limitation would also have applied to certificates granted by the Spanish Patent Office. We believe that such a limitation to the rights granted by the patent would have been in conflict with Art. 28 TRIPS. According to the provision, the patent confers the right to prohibit the making of the product. Furthermore, it is at the very least doubtful that the limitation could have been justified under Art. 30 TRIPS.[890] However, the analysis of this provision helps to clarify a point that has not been considered so far in the debate surrounding the manufacturing waiver.

The interaction of the SPC Regulation and TRIPS prevents national legislatures from creating a manufacturing waiver. Indeed, if national lawmakers create a waiver that only applies to SPCs, they would violate Art. 5 Reg. 469/2009. If they introduce a waiver that also applies to patents, they would violate Art. 28 TRIPS. Admittedly, the two violations do not trigger the same consequences. Article 5 SPC Regulations is directly applicable, while Art. 27 TRIPS most likely is not.[891] But they both make the enactment of national binding legislation in this field unrealistic.

To allow the EU Member States to decide whether or not a waiver should be introduced for certificates, there is therefore only one possibility. The EU legislature must introduce an optional exception in line with what is provided in some copyright directives. The EU legislature could define the content and structure of this possible exception but leave to the EU Member States the decision whether or not to implement it. The optional exception could be given the form of a take-it-or-leave-it

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889 Original text: Se propone esta excepción para fomentar la competitividad de las empresas industriales españolas y su internacionalización, así como para aumentar la posibilidad de innovar de las empresas con intereses industriales en España. Así, se permitiría que los productos fabricados en España puedan entrar en otros países en igualdad de condiciones respecto de los de países que actualmente anulan la capacidad competitiva de nuestros fabricantes. Por otra parte, podría evitarse la deslocalización industrial de aquellas empresas que, para ser competitivas a nivel internacional, se ven obligadas a situarse en terceros países, y podría atraerse industria de terceros países que verán la calidad de nuestra industria como un atractivo a la hora de invertir recursos en España. The proposed amendment is available at http://www.congreso.es/portal/page/portal/Congreso/PopUpCGI?CMD=VERLST&BASE=pu10&FMT=PUWTXDTS.fmt&DOCS=1-1&DOCORDER=LIFO&QUERY=%28BOCG_D_10_555_3711.CODI.%29 (last accessed 9 March 2018).

890 See above, Chapter 15, Section 15.3.2.2.

891 The question whether TRIPS can be attributed direct effect under national law was left open by the CJEU in Case C-414/11 *Daiichi Sankyo* [2013] GRUR 1018.

provision. In this way, the Member States would be prevented from implementing the option in an unharmonised manner.

As long as such legislation is not enacted at the European level, manufacturing waivers under domestic law are excluded. However, this does not prevent the Member States from resorting to instruments other than binding law to foster domestic manufacturing. The French experience offers one example of this alternative approach.

15.3.4.4 France

(a) *Introduction*

As already mentioned, France provided for national certificates before the enactment of the Medicinal Products Regulation. However France (unlike Italy[892]) has never introduced exceptions to the rights granted by the certificate for export or stockpiling purposes. Following the extension of the European Union to countries that did not provide for supplementary protection, the French government envisaged a financial mechanism whose purpose presents some similarities to a manufacturing waiver.

(b) *Historical background*

The origin of the mechanism can be traced back to the 2009 meeting of the *Conseil Stratégique des Industries de Santé* (CSIS) – an informal place of exchange between the French Government and representatives of both the pharmaceutical industry and research institutes.

One of the concerns identified by the CSIS for the French pharmaceutical industry was the divergence of national legislation regarding the possibility for generic companies to manufacture and stock drugs before the expiration of the intellectual property rights protecting the originator.[893] Before the expiry of the SPC, these actions indeed constitute an act of counterfeiting according to Arts. L.613-3 and L.613-4 in combination with Art. L611-2 al.2 of the French Code of Intellectual Property (CIP). Similar legislation was also applicable in the older EU Member States following harmonisation of SPC rules by the Regulation of 1992.[894] But, within the framework of the enlargements of the European Union in 2004 and 2007, transitional regimes were envisaged for the newly acceding Member States.[895] These regimes, discussed during the pre-accession negotiations, provided for different dates at which the originator could claim an SPC in those countries.

The French government, therefore, feared that this discrepancy would induce French generic manufacturers, in order to be active from the first day after the termination of the IPR on the French market, to buy from companies producing the generic drugs in

892 See Section 15.3.4.5 of this Chapter.

893 Présidence de la République Française, Dossier de Presse, Conseil stratégique des Industries de Santé, 2009, pp. 7, 24.

894 Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products [1992] OJ L 182/1.

895 See Art. 20 Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products [2009] OJ L 152/1. For a detailed analysis of the different transitional regimes, see Dimitar Batakliev, 'Supplementary Protection Certificates in Europe – Transitional Regime' [2013] IIC 750–764.

those countries.[896] Over time, this supply from third countries could have led to the permanent localisation of the production of generic medicine in these countries.[897]

(c) *Legal framework*

To avoid this phenomenon, the French government put in place a financial mechanism aiming to incentivise IPR owners to grant licences regarding the manufacture and the stockpiling of generic drugs on French territory before the expiration of their rights.[898]

The instrument was introduced in the Framework Agreement (FA) negotiated between the "Comité Économique des Produits de Santé (CEPS)" representing the French government and "Les Entreprises du Médicament (LEEM)" representing the pharmaceutical industry.

(i) The drug pricing system in France and the role of the FA

The pricing system regarding medicinal products in France presents some specificities. Pharmaceutical undertakings can, in principle, first decide to use the free market price. But, in this case, the cost of their medicinal product will not be refunded to the consumer. If the pharmaceutical company wants its product to be refundable to the consumer, it must request registration.[899] The price of the medicament is then fixed in negotiations between the undertaking and the CEPS. If the negotiations fail, the CEPS is entitled to set the price unilaterally.[900] According to the last activity report of the CEPS, in 2016 the global turnover for the refundable drugs market was 26 billion euros.[901]

The Framework Agreements (FA) are contracts negotiated between the CEPS and the LEEM on a four-year basis. The LEEM is a representative association of 98 per cent of the undertakings working in the French pharmaceutical sector. It represents originator and generic pharmaceutical companies as well as manufacturers. Each FA defines common sets of principles for the negotiations mentioned above, which must take place between the CEPS and the respective pharmaceutical company concerning the fixing of the medicinal product's price. During these negotiations, the pharmaceutical companies and the CEPS might agree among other things on the granting of volume discounts.

(ii) The "manufacturing provision" (Art. 35 a) iii FA)

Following the meeting of the CSIS, in 2009 a "manufacturing provision" was introduced in the FA; the instrument was maintained in each of the further agreements in the exact same terms.[902] This provision aimed to create a financial

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896 CEPS, rapport d'activité [2009] p. 45. On the transitional regime for acceding states, see Dimitar Batakliev, 'Supplementary Protection Certificates in Europe – Transitional Regime' [2013] IIC 750-764.

897 Présidence de la République Française, Dossier de Presse, Conseil stratégique des Industries de Santé, 2009, pp. 7, 24.

898 *Ibid.*

899 Art. L. 165-1 French Social Security Code.

900 Regarding these negotiations and the role played by the CEPS, see particularly Arts. L. 162-16-4 to L. 162-16-6, L-162-1-3 and Art. L-162-17-3 French Social Security Code.

901 See CEPS: rapport d'activité 2016, p. 7, available at http://solidarites-sante.gouv.fr/IMG/pdf/rapport_annuel_2016_medicaments.pdf (last accessed 7 March 2018).

902 See Accord cadre du 25 septembre 2008 (modifié le 26 octobre 2009), Art. 3a, available at http://solidarites-sante.gouv.fr/IMG/pdf/CEPS_-_L_accord_cadre_entre_le_CEPS_et_les_entreprises_du_medicament_du_25_septembre_2008.pdf (last accessed 14 February 2018); Accord cadre du 16 décembre 2011, Art. 3a, available at http://solidarites-sante.gouv.fr/IMG/pdf/accord_cadre_

incentive for IPR owners to grant licences for the manufacturing and the stockpiling of generic drugs on French territory before the expiration of the relevant IP right(s). The financial incentive consists in granting clawback credits to the companies that have granted a licence.[903] These clawback credits are deducted from the volume discounts on the price of their medicinal products that the companies have accepted in the convention mentioned above. It should lastly be noted that the use of clawback credits is not specific to the mechanism at stake; it is instead a lever used by the French government to support diverse policy objectives.

Article 35 a) iii) Framework Agreement provides that:[904]

> The owner of the intellectual property rights to a reference proprietary product may, subject to the provisions of the Intellectual Property Code (Code de la propriété intellectuelle), assign the following rights before they have expired to a duly authorised pharmaceutical establishment acting in the capacity of sub-contractor under the terms of Chapter 7 of the Good Manufacturing Practices stipulated in Article L.5121-5 of the Public Health Code (Code de la santé publique):
> - The right to purchase sufficient quantities of raw materials and generally speaking to carry out any activities that are necessary and essential for the manufacturing process described in the following paragraph:
> - To manufacture a generic version, as defined in Article L.5121-1, paragraph 5 of the Public Health Code, of the proprietary product in question, on behalf of a pharmaceutical establishment authorised to use the marketing authorisation for the corresponding generic drug;
> - To release batches of the generic product thus manufactured 48 hours before the expiry of the intellectual property rights, for the sole purpose of preparing stocks of the product and to the exclusion of any other act, carried out alone or jointly with the pharmaceutical establishment marketing the generic product, which might lead to the sale or delivery of the generic drug. These batches released at this time may not be delivered until after the expiry of the intellectual property rights pertaining to the original proprietary product. The sub-contractor shall guarantee to the owner of the intellectual property rights to the original proprietary product that the pharmaceutical establishment marketing the generic product will refrain from any actions pertaining to sale or delivery as stipulated above.
>
> The authorisations granted by the intellectual property right owners pursuant to this article shall give rise to clawback credits, the sum of which shall be set, depending on the scope of the authorisations, by mutual agreement between the company and CEPS.

(iii) The conditions required by the licence agreement

Regarding the scope of the rights to be licensed, the clause is part of a Framework Agreement whose purpose is to incentivise the conclusion of further and more specific agreements between the CEPS and the pharmaceutical companies separately. Therefore, the definition of individual notions of the FA is in principle left open for these further negotiations. However, regarding the "intellectual property rights to a reference proprietary product" that might be licensed, it is clear with regard to its purpose that the agreement necessarily includes both patents and SPCs.

With that in mind, the text of the clause contemplates three different rights that can be licensed.

The first one concerns the purchasing of the raw material needed for the production of the medicinal product. An authorisation of the IPR holder for these acquisitions is indeed required, since, pursuant to Art. L.613-4 §1 CPI, the supply of means of implementation of a protected invention already constitutes a patent infringement by

dispositifs_medicaux.pdf (last accessed 14 February 2018); Accord cadre du 31 décembre 2015, Art. 35 a) iii) available at http://solidarites-sante.gouv.fr/IMG/pdf/accord_cadre_version_definitive_20151231.pdf (last accessed 14 February 2018).

903 "Avoir sur remise" in the French version. The expression is translated alternatively as "clawback credits" or "credits payment" in the official documents of the CEPS in English.

904 The translation is provided in CEPS, rapport d'activité [2009] (version anglaise) p. 49.

"supply of means". The notion of "raw materials" is not defined more specifically by the agreement. However, the purpose of the clause is to enable the production of generic drugs on French territory. Therefore, we believe that this notion should be understood as encompassing the purchase of any substances required for the production of the generic drug, irrespective of its use as an active substance or as an expedient in the preparation of the pharmaceutical product.

The second licence authorises the manufacturing of the generic product on French territory. It is not clear whether such licence will also cover packaging of the medicinal product. In contrast to the European legislation (see for instance Art. 1.1. Dir. 2001/83), which explicitly encompasses the packaging in the definition of a proprietary medicinal product, the French Public Health Code and especially its Art. L.5121-1 §5, to which the provision referred, make no mention of it.

Lastly, the third licence authorises the preparation of stocks. The constitution of these stocks is tightly framed: firstly, it should only take place in the last 48 hours before termination of the SPC; secondly, it excludes any other actions leading to the sale or delivery of the generic drug. Regarding the interaction of this licence with the previous manufacturing one, the LEEM made clear[905] that in its understanding the faculty to stockpile the manufactured products is necessarily included in the faculty to manufacture, but only as long as the exercise of this faculty remains within the manufacturer's premises.

Regarding the terms of the licences, the clause does not provide for any cumulative requirement regarding the granting of three licences. On the contrary, its last paragraph specifies that the amount of the clawback credits will depend on the scope of the authorisations granted. The clause also does not require the licences to be granted in a non-exclusive way: "the owner of the intellectual property rights … may … assign the following rights … to *a* duly authorised pharmaceutical establishment".[906] For the CEPS, it is even imaginable for the originator and the generic company to be part of the same group.[907] Furthermore, the wording of the clause does not prohibit the originator from obtaining financial compensation from the generic company.

Regarding the characteristics of the licensee, the wording of the clause provides that it needs to be a "duly authorised pharmaceutical establishment acting in the capacity of sub-contractor under the terms of Chapter 7 of the Good Manufacturing Practices stipulated in Article L.5121-5 of the Public Health Code". The requirement that the pharmaceutical establishment "be duly" authorised has the consequence that the licence must be granted to a pharmaceutical establishment present on French territory. However, no mention is made regarding an obligation of the pharmaceutical establishment to produce the generic drugs itself on French territory. Nevertheless, this condition is seen at least by the CEPS as implicit, since it constitutes the reason for the creation of the mechanism.[908] According to information provided, the CEPS has never faced this kind of occurrence. But if it did happen, the CEPS, which enjoys

905 Phone interview with Ms Maréchal, Directeur des Affaires Européennes et Relations Extérieures of the LEEM, Ms Bardant, directrice des affaires juridiques et conformité of the LEEM and Ms Kandel, conseiller juridique propriété intellectuelle et contrefaçon of the LEEM.
906 Emphasis added.
907 Phone interview with Mr Sales, vice-president of the CEPS.
908 Interview with Mr Sales (CEPS) previously mentioned.

discretion as to whether or not to accept a proposed licence by an originator as clawback credits, would probably refuse it.[909]

Regarding, lastly, the destination of the medicinal products, no mention is explicitly made concerning the necessity for the produced generic drugs to be manufactured for the French market. Nevertheless, the purpose of the Framework Agreement is only to organise the bilateral negotiations between the CEPS and each pharmaceutical undertaking regarding the price of the medicinal products *which are refunded by French social security*. Therefore, according to both the CEPS and the LEEM, the clause cannot be understood as a general instrument of industrial politics: its scope is necessarily limited by the very purpose of the Framework Agreement.[910] Thus, a licence granted for manufacturing the products in France for export would likely not be eligible for the mechanism.

(iv) Legal consequences: the faculty for the CEPS to attribute clawback credits

The licence-granting scheme, complying with the conditions previously described, allows the CEPS to grant the licensor clawback credits. This remains a discretionary faculty and not an obligation of the CEPS. Regarding the method of calculation, the CEPS explains that the turnover of the concerned pharmaceutical speciality, the size of the market and the loss of income suffered due to the grant of the licence should be taken into account.

(d) *Effectiveness*

The effectiveness of the mechanism is subject to discussion.

According to the information transmitted by the CEPS and the LEEM, the mechanism has been used five times since 2009, all during the first two years following its introduction (twice in 2010 and three times in 2011).[911] According to the CEPS, the amount of the clawback credits awarded was 17.6 million euros in total. These numbers speak for the low effectiveness of the mechanism. The CEPS also shares this conclusion.[912]

Conversely, the LEEM put forward some grounds for satisfaction regarding the instrument.[913] For the LEEM, the mechanism is perceived positively since it is a "win-win" tool on which all stakeholders were able to agree and which does not require any adaptation of the IPR framework. The aims of the mechanism – to incentivise manufacturers to maintain their activities on French territory – is also welcomed.

Regarding the small number of applications, the LEEM first explains that the amount of discount credits available might have been too low (and was frozen in the last three years). Second, it points out that the interest and the benefits of the provision may not have been sufficiently explained by the French affiliates to their headquarters. Lastly, some endogenous reasons are also advanced: the lack of predictability of

909 Interview with Mr Sales (CEPS) previously mentioned.
910 Interviews with Ms Maréchal, Ms Bardant, Ms Kandel (LEEM) previously mentioned.
911 Interviews with Mr Sales (CEPS) and Ms Maréchal, Ms Bardant, Ms Kandel (LEEM) previously mentioned.
912 Interview with Mr Sales (CEPS) previously mentioned.
913 Interviews with Ms Maréchal, Ms Bardant, Ms Kandel (LEEM) previously mentioned.

medicinal product prices in France or the general decrease in price of some molecules, which could from the outset deter generic pharmaceutical companies from investing in the acquisition of licences, were two factors mentioned in the interviews

Due to this difference of opinion between the CEPS and the LEEM, the question of renewal of the instrument in the next Framework Agreement remains open.

(e) *Final considerations*

The differences between a manufacturing waiver and a mechanism such as that conceived by the French authorities are obvious.

The manufacturing waiver for export or stockpiling purposes creates an exception to the rights granted by the SPC; it requires a modification of the legislation in force. Even if it is framed as a compulsory licence, and even if economic compensation for the use of the protected subject matter is provided, it implies a limitation of the rights granted to the patent or SPC owner.

By contrast, the mechanism is only on a voluntary basis. Since the *jus excludendi* already includes the right to grant licences and to define their scope, the French mechanism is fully consistent with the IP legislation in force. It aims only to create incentives for specific behaviour (granting a licence for manufacturing in France).

Despite their different legal nature, the two measures have similar purposes. Both are based on the assumption that longer terms of protection for IPRs than those available in other jurisdictions create a disadvantage for generic companies located in the territory where longer protection is provided. For this reason, both measures try to correct this disadvantage and to put the generic manufacturers based in this territory in a similar position to those located in the territory where shorter IPR protection applies. Their purpose is to reduce incentives for the relocation of manufacturing facilities to jurisdictions where protection is shorter or absent with respect to a specific medicinal product.

The French mechanism can be taken as an example of pursuing the same goal but by creating incentives for (from the perspective of the lawmakers) virtuous behaviour, instead of adopting mandatory rules that limit the rights of the patentee or SPC holder.

15.3.4.5 Italy

(a) *Introduction*

Italy contemplated national certificates before Reg. 1768/92 was enacted.[914] After the EU lawmakers created certificates with a term of protection shorter than the one provided under Italian law,[915] and after the failure of some civil proceedings directed

[914] See Law 19 October 1991, n. 349 and Art. 61 of the Code of Intellectual Property.

[915] Under Italian law, "the effects of the complementary certificate of protection enter into force from the time at which the patent reaches its natural expiration under law and last for a time equal to the period that passed between the date of filing of the patent application and the date of the order by which the first marketing authorization of the medicine is granted". Pursuant to Art. 81(3) CPI, "the duration of the complementary certificate of protection may in no case be greater than eighteen years, starting on the date on which the patent reaches its natural expiration under law".

to clarifying whether such certificates also covered the manufacturing of the SPC-protected active substance for export,[916] the lawmakers introduced a form of manufacturing waiver for export.

The purpose of the legislation was to improve the competitive position of domestic manufacturers, which were confronted with a longer period of exclusivity as a consequence of certificates granted under domestic law. In accordance herewith, the instrument should apply only to products covered by national certificates.[917] The legal basis for such mechanism is now laid down in Art. 81 Italian Code of Industrial Property (It. CPI), which in English translation[918] reads as follows:

> **81. Complementary certificate pursuant to Law No. 349 of 19 October 1991, and voluntary license on active principles mediated by the Minister.**
> 1. Complementary certificates of protection granted pursuant to Law No. 349 of 19 October 1991 shall be subject to the legal system concerning patents, with the same exclusive rights and obligations. The complementary certificate of protection produces the same effects as the patent to which it refers, limited to the part or parts of it covered by the marketing authorization.
> 2. The effects of the complementary certificate of protection enter into force from the time at which the patent reaches its natural expiration under law and last for a time equal to the period that passed between the date of filing of the patent application and the date of the order by which the first marketing authorization of the medicine is granted.
> 3. The duration of the complementary certificate of protection may in no case be greater than eighteen years, starting on the date on which the patent reaches its natural expiration under the law.
> 4. In order to gradually adjust the duration of the complementary and patent coverage to that established by EU regulations, the provisions of Law No. 939 of 19 October 1991, and of Regulation (EEC) No. 1768/1992 of the Council, of 18 June 1992, shall be implemented through a reduction of the complementary protection equal to six months for each calendar year, starting on 1 January 2004, until full alignment with European law.
> 5. Third parties who intend to produce for export active principles covered by complementary certificates of protection pursuant to Law No. 349 of 19 October 1991 shall be allowed to initiate with the holders of those certificates, at the Ministry of Economic Development, a procedure for the issuance of voluntary non-exclusive licenses for compensation, in accordance with applicable legislation on the subject.
> 6. The licenses indicated in paragraph 5 are however valid solely for export towards countries in which patent and complementary certificate protection does not exist, has expired, or in which the export of the active principle does not constitute an infringement of the respective patent in compliance with applicable laws in the destination countries.
> 7. The license ceases its effect as of the expiration of the respective complementary certificate.

The details of the procedure are laid down in Art. 200 It. CPI:[919]

> 200. Procedure for voluntary license on active principles.
> 1. The application for a voluntary license on active principles, accompanied by the certification demonstrating the payment of the fees in the amount established by the decree of the Ministry of Productive Activities as per Article 226, must contain the following information:
> a) the name or company title and domicile or registered office of the applicant for the voluntary license;
> b) the name of the active principle;
> c) the details of protection, patent number and complementary certificate of protection;
> d) an indication of the Italian pharmaceutical laboratory, duly authorized by the Ministry of Health in accordance with law, if the party intends to produce the active principle.
> 2. The applicant must send to the Italian Patent and Trademark Office (UIBM), by registered mail, return receipt requested or other methods that guarantee confirmation of receipt of the communication, a request, with a translation into the English language enclosed, accompanied by the elements provided for by paragraph 1.
> 3. The UIBM shall give prompt notice of the request, by registered mail, return receipt requested, or by other methods that guarantee confirmation of receipt of the communication, to the interested parties and to those who have acquired rights on the

916 See Chapter 5 of this Study.
917 The mechanism was introduced by Art. 3(8)-*bis*-8-*ter* law 15 June 2002, n. 112.
918 English translation available at http://www.wipo.int/wipolex/en/details.jsp?id=13123 (last accessed 15 March 2018).
919 *Ibid.*

patent or on the complementary certificate of protection based on registered or noted legal documents.
4. If within ninety (90) days of receipt of the application, which period may be extended on agreement between the parties, the parties reach an agreement based on a limited royalty, a copy of the same must be transmitted, by analogous methods, to the Ministry of Productive Activities - UIBM. If in the subsequent thirty (30) days the Office does not communicate any findings to the parties, the voluntary license agreement shall be considered to be completed.
5. In the case that the parties communicate to the UIBM that it is not possible to reach an agreement, the Office shall initiate the conciliation proceeding as indicated in paragraph 6 et seq.
6. The Ministry of Productive Activities, by issuing a decree, appoints a commission with the assignment of evaluating the requests for voluntary licenses for which no agreement was reached between the parties.
7. The commission consists of six members and six alternates, including:
a) two representatives of the Ministry of Productive Activities;
b) a representative of the Ministry of Health;
c) a representative of the Italian Medicines Agency;
d) a representative of the owners of CCPs (complementary protection certificates), on proposal from the most representative trade associations;
e) a representative of the producers of pharmaceutical active principles, on proposal from the most representative trade associations.
8. Within thirty (30) days of the date of the communication received from the UIBM concerning the lack of an agreement reached between the parties, the commission identified in paragraphs 6 and 7 shall proceed to convene the parties, in order to identify a potential agreement aimed at reconciling the needs of the parties, while however guaranteeing reasonable remuneration for the party who issues the voluntary license, through the indication of a limited royalty, set with criteria that take account of the needs of international competition of producers of active principles.
9. If, despite the mediation of the Ministry, a license agreement is not concluded, if the Ministry of Productive Activities determines that the legal prerequisites have been met, the Ministry shall order the transmission of the legal documents of the proceeding to the Italian Antitrust Authority.

These provisions are about to lose practical relevance, since they apply only to certificates granted under domestic law.

(b) *Legal details*

From a legal perspective, the following aspects are relevant for this Study.

First, the law did not provide for a limitation to the rights granted by the certificate. Article 81 in conjunction with Art. 200 CPI only created an option for companies interested in manufacturing an active ingredient covered by the certificate for export to start a procedure for the issue of a licence. The request was to be directed to the national Patent Office. If by the deadline provided for in Art. 200 CPI the parties did not agree on the terms of the licence, the Ministry for Productive Activities was to establish a commission. Such commission had the task of convening the parties and facilitating the conclusion of a licence agreement in line with the procedural step set forth in Art. 200 CPI.

Second, the law spoke of a voluntary and not an exclusive licence. However, the term "voluntary" requires clarification. According to the literature,[920] the licence designed by the Italian legislation was neither a compulsory nor a voluntary one, but something in between.

On the one hand, the commission appointed by the Ministry functioned solely to mediate between the parties. The decision whether and on what terms to grant a licence remained at the discretion of the certificate holder. On the other hand, the

[920] See analysis by Floridia-Lamandini, 'Rifiuto di licenza e abuso di posizione dominante: lezioni dall'esperienza dei certificati complementari di protezione', in Il diritto industriale, 2006, 229 et seqq.

certificate holder was not fully free to refuse the licence. Indeed, if no agreement was concluded, the commission could transmit the acts of the proceedings to the Italian Antitrust Authority to let the latter examine whether the refusal was abusive or not. The latter point is the one most discussed in the literature, for the patent provisions did not provide any additional criteria to direct the possible reaction of the Antitrust Authority. In consequence, common competition law was to serve as the only criterion to assess whether or not the behaviour of the certificate holder – that is, the refusal to grant a licence – was allowed or not. Therefore, the only legal basis for initiating prosecution of the certificate holder was the provision prohibiting an abuse of a dominant position. The thresholds to find the refusal unlawful were by this reading relatively high. According to other authors, by contrast, the patent provisions implicitly designed an autonomous hypothesis of abuse of the certificate rights that was not coextensive with the notion of an abuse of a dominant position and did not require the existence of the latter. The refusal was abusive as soon as it was not objectively justified. In the view of some authors, the definition of abuse as the exercise of the right for a purpose that was not intended by the lawmaker was to apply to the question whether the refusal of the licence was abusive or not. In practice, the decisions of the Antitrust Authority that concerned the refusal to grant a licence despite the procedure under Art. 81 CPI required the existence of a dominant position. At the same time, the assessment of the existence of a dominant position was made with reference to a very narrow and specific market. Furthermore, the abuse was ascertained each time an objective justification for refusing the licence was not made plausible.

Third, regarding the scope of the licence, the procedure was designed to facilitate the grant of licences for the manufacturing of active ingredients. Therefore, the beneficiaries of the mechanisms were API manufacturers rather than the generic industry.

(c) *Effectiveness*

According to information provided by the Italian Patent Office,[921] 16 voluntary licences were granted under the procedure laid down in Italian law between July 2003 and December 2005. This could be evidence for the effectiveness of the legislation or at least for the interest of domestic manufacturers in the mechanism. It is questionable, however, whether such information may allow a prognosis for the relevance of a manufacturing waiver in Europe. Indeed, the licences granted under the mechanism provided for in Italian law could also allow the export to other European countries, including all the most relevant markets. In fact, the protection granted by Italian certificates was far longer than that available in France under national law or in other EU States under the SPC legislation. So the licence was needed to manufacture products for generics based in Europe or elsewhere. Such a situation is unlikely to occur in the case of a manufacturing waiver created under the SPC legislation. This is true even though the manufacturing waiver would allow exports to SPC-free EU countries, and not only exports to non-European markets. Indeed, in most cases SPC protection will expire in Europe on the same date in all the relevant markets.

[921] Email from UIBM representatives to the authors of this Study.

15.3.4.6 European Parliament proposal

Discussion over a manufacturing waiver also took place within the European institutions: in 2002, an amendment proposed by the European Parliament during the creation of the Code for Medicinal Products for Human Use was intended to include a provision that neither patents nor SPCs should prevent third parties from exporting a generic product to third countries where no IPR was still in force covering the medicinal product.[922] The proposed provision reads as follows:

> A medicinal product may be manufactured if it is intended for export to a third country that has issued a compulsory licence for that product, or where a patent is not in force and if there is a request to that effect from the competent public health authorities of that third country.[923]

The European Council rejected the proposal for two reasons. The exception was outside the scope of the Medicinal Product Code and might also collide with the TRIPS Agreement:

> In relation to part of amendment 134 and amendment 196 on exemptions from patent protection for products intended for exports, the Council considers such exemptions to fall outside the scope of what should be regulated in a Directive on medicinal products intended to be placed on the market in Member States. As concerns amendment 196 specifically, the Council refers to the Commission's amended proposal stating that it is in conflict with the WTO TRIPS agreement (Agreement on Trade-Related Intellectual Property Rights).[924]

Such a provision would have covered not only the manufacturing of the active ingredient, but also the preparation of the final drug including its packaging in accordance with the relevant foreign MA.

15.3.4.7 Summing up

The review of the models discussed or tested in the EU or elsewhere shows that different approaches are possible to address the concerns expressed by the EU-based generic industry.

A first approach is to adopt a binding regulation limiting the rights granted by the certificate. Canadian law and the proposals from Spain or the European Parliament are examples of this model. A second approach, explored by France, is to create incentives for virtuous behaviour, without altering the substance of the exclusivity rights. A third approach seeks a balance between compulsory licence/exemption models on the one hand and incentive mechanisms for the granting of licences on the other hand. Italian law could be an example of this approach: the decision whether to grant a licence or to "voluntarily license" is, obviously, in the hands of the certificate holder, but refusal to license is not without consequences. Indeed, it leads to the initiation of a control procedure by the antitrust agency.

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922 For a short report on this attempt, see Xavier Seuba et al, *A Manufacturing for Export Exemption*, in Brian Mercurio, Daria Kim (eds), CONTEMPORARY ISSUES IN PHARMACEUTICAL PATENT LAW (Routledge 2017) pp. 169-170.

923 Position of the European Parliament adopted at first reading on 23 October 2002 with a view to the adoption of European Parliament and Council Directive 2002/…./EC amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, Art. 10 No.5.

924 Common Position (EC) No 61/2003 of 29 September 2003 adopted by the Council, acting in accordance with the procedure referred to in Article 251 of the Treaty establishing the European Community, with a view to adopting a directive of the European Parliament and of the Council amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, § 15.

Another distinction concerns the addressee of the waiver. In Canadian law and in the proposal of the European Parliament, the intended beneficiaries are generic companies, while in the Italian model the intended beneficiaries are API manufacturers. The latter model, of course, does not exclude that generic companies may also benefit from the voluntary licence mechanisms. The addressee of the French mechanisms is the IP right holder, while the licenses eligible for the mechanisms can be granted to both generic companies or API manufacturers.

A last distinction can be made with respect to the purpose of the waiver. The above-presented proposals or legislation from Australia, Canada, Spain, Italy and the EU Parliament focus on manufacture for export. By contrast, only the French mechanism is directed to allowing manufacture for stockpiling purposes.

15.3.5 The opinions of the originators: the arguments against a waiver

While we have explained the arguments made by the generic industry for creating a manufacturing waiver, one could find several arguments militating against such a measure. Such arguments were collected by the Allensbach Survey and confirmed by the MPI qualitative interviews. While we refer to the Allensbach Report[925] for more extensive information, the next sections offer a summary of these arguments.

15.3.5.1 Questionable economic impact

First of all, the opponents of the waiver questioned the economic argument made for a waiver. The possible positive impact in terms of increased EU-based manufacturing and creation of jobs is in their view purely speculative and, at the very best, overestimated. According to these opinions, the divergence of duration of the IPR is not the main factor explaining why companies may outsource or delocalise manufacturing. Other factors are more relevant in this regard, such as labour costs or environmental standards.[926] In any case, the opening of new markets for European generic companies through the creation of a waiver will be limited. Indeed, regarding the European market, the generic companies will still face competition from non-EU generic companies.[927] Since the market is not extendable, an increase in demand for generic products (resulting in higher employment in the generic sector) will consequently cause a decrease in demand for originator products (and therefore lower employment).[928] The same is also true regarding foreign markets with no SPC types of protection. Originators are themselves already competing on these markets. Therefore, generic products manufactured in the EU will replace originator products also manufactured in Europe. The creation of employment in the generic branch will be compensated by a loss of jobs on the originator side.[929]

925 Annex III of this Study, pp. 377-395.
926 Annex III of this Study, comments to Q67, pp. 380, 381, 382, 392.
927 Elise Melon, the representative of EFPIA, during the workshop of 20 March 2017 organised in the course of this Study.
928 Annex III of this Study, comments to Q67, pp. 379, 380, 382, 384, 385, 386, 388, 389, 390, 392, 393, 394, 395.
929 Annex III of this Study, comments to Q67, pp. 379, 380, 382, 383, 384, 385, 386, 388, 389, 390, 392, 393, 394, 395.

15.3.5.2 Risk of abuse (diversion, re-importation, stockpiling)

Those arguing against the introduction of a manufacturing waiver point to the fact that allowing the manufacture of products during the term of the SPC creates a risk of abuse,[930] which can occur in three forms.

First, it is possible that products allegedly manufactured only for export are distributed on the domestic market prior to expiry of the SPC, either by the manufacturer itself or by third parties buying the products abroad and reimporting them. Second, if production is only allowed for export, it may still occur that the manufacturer stockpiles products in order to sell them on the domestic market immediately after expiry of the SPC.[931] Third, the products could be exported to markets where an equivalent patent protection is still in force.

On top of these risks, it is also argued that the monitoring and enforcement of their rights will be burdensome for the originators.[932] Several stakeholders have indeed emphasised that controlling and enforcing the rules of the manufacturing waiver may increase costs for originator companies and increase litigation.

15.3.5.3 Policy arguments

Finally, some reservations about the introduction of a manufacturing waiver are of a political nature. It is argued that the introduction of an SPC waiver clashes with the overall goal of the SPC Regulations to promote innovative activities by improving the situation of originator companies in the EU. Furthermore, stakeholders are concerned that the reform could be extended to patent law as such ("slippery slope" argument).[933] Others argue that if SPC protection in Europe is weakened, it will undermine the Commission's position in bilateral and multilateral negotiations seeking to engage trading partners in an effort to provide a strong patent system.

Assessing the political dimensions of legislative decisions is beyond the scope of this Study. However, regarding the "slippery slope" argument, it should be recalled that, as pointed out above (15.3.2.2), a manufacturing waiver for patents would be incompatible with TRIPS. For that reason alone, fears that corresponding exemptions could be introduced into patent law appear unfounded. Furthermore, regarding the position of the EU in international negotiations, it is of interest that within the framework of CETA the EU has already consented to including a manufacturing (export) waiver as a legislative option. On the other hand, it is true that such openings were not addressed in FTAs preceding CETA, and that, in contrast to manufacturing for export purposes, CETA does not – or at least not expressly – extend to stockpiling for post-expiry supply of the domestic market. However, it is submitted that this does not preclude the legislative options for the EU (see *supra*, 15.3.2.4).

930 Annex III of this Study, comments to Q67, pp. 379, 380.
931 Annex III of this Study, comments to Q67, p. 381.
932 Annex III of this Study, comments to Q67, pp. 379, 380, 381, 383, 384, 386, 388, 389, 390, 392, 393.
933 This has been expressed in the online survey as well as in the qualitative interviews. It was also expressed by Gareth Morgan in the presentation during the workshop organised by the MPI on 20 March 2017 in Munich in the course of this Study.

15.3.5.4 Summary of the position of the EU originator industry

One particularly comprehensive response from the online survey was submitted word for word 15 times and also offers an adequate summary of the arguments presented by the originator companies in qualitative interviews. We present it verbatim:

> While the wording of this question refers alternatively to active ingredients and final products and does not define "final products" (these are different), we would strongly oppose proposals to introduce an SPC manufacturing exemption for export. The generic industry claims that the delay induced by SPCs is hampering its competitiveness globally. We question whether this is the main factor as well as whether there are actual opportunities given the existing competition dynamics within key export markets. Further, the potential of such a measure to bring more than 60,000 highly-skilled jobs back to Europe is highly contested. In fact, a recently published counter analysis (Sussell et al., Journal of Generic Medicines 2017) revealed that the model on which the claim by the generic industry is based, contains several limitations, most notably a substantial arithmetic error and the assumption that increased demand of generic products leads to job gains in the generic sector but that simultaneously, reduced demand of originator products does not lead to job losses in the branded sector. Corrected by these limitations, the counter analysis finds that there would be only a few, if at all any taking into account uncertainty as a parameter, benefits from such a measure. Further and contrary to generic industry claims, this proposal to introduce an SPC manufacturing waiver could also have an effect on European originators' exports to these markets, which is the market on which European generics will be competing – substituting the export value of originator products for lower value generics which could cause job losses in the EU's innovative pharmaceutical sector. It will definitely have a significant impact on European originators in terms of monitoring / enforcement as it will be difficult and burdensome, if it is possible at all, to ensure these proposals are limited to their intended purpose. Most importantly, it would be sending a very bad signal about the EU's respect for and seriousness about building a knowledge-based economy which is at odds with its trade policy where the EU has consistently argued against localisation policies and more particularly about using IP tools to favour domestic production. Finally, such a policy encourages the introduction of similar exemptions by other countries, which are mostly more competitive than Europe is from a manufacturing perspective. And when every country has its manufacturing exemption, and potentially during patent term, what will be left for the EU?

15.3.6 The precautions

One way to address the concerns of the stakeholders about the risk of diversion of the products manufactured under the waiver could be to introduce some precautions along with the exception. The next sections mention some of them.

15.3.6.1 Introduction

Among the arguments proffered against the introduction of a manufacturing waiver is the risk that the freedom to produce protected goods may be misused (see supra, 15.3.5.2). In order to make the system balanced and legally secure, it is therefore advisable to implement certain precautionary measures. In particular, it must be ensured that an SPC-protected invention is only used for the very purpose of the waiver, and that exported products are not reimported into the EU. For the latter purpose, Art. 31bis TRIPS and the corresponding provisions as set out in Reg. 816/2006 can be taken into consideration. Additionally or alternatively, the measures addressed below could be put in place,[934] to the extent that they appear justified under the proportionality principle.

[934] Some of these measures are also considered in the literature; see *inter alia* Xavier Seuba et al, *A Manufacturing for Export Exemption* in Brian Mercurio, Daria Kim (eds), CONTEMPORARY ISSUES IN PHARMACEUTICAL PATENT LAW (Routledge 2017) pp. 125, 135.

15.3.6.2 Allocation of the burden of proof for infringement

It follows from general principles governing the distribution of the burden of proof that the claimant – typically the right holder – must establish the elements on which the claim is founded, whereas the defendant – the alleged infringer – must establish the elements giving rise to an exception or limitation. On the basis of the majority view that any manufacturing of goods covered by an SPC constitutes an infringement, it follows that the right holder must only prove the fact that the product protected by the patent and covered by the MA submitted in support of the application for a certificate has been manufactured. It is for the alleged infringer – if a manufacturing waiver were introduced – to prove that this was only done for the purposes that are covered by the limitation.

However, as pointed out before, the situation is not completely clear. Pursuant to the position endorsed in Chapter 5, Section 5.7.2, that SPCs only grant purpose-bound protection, the manufacture of an active ingredient as such does not result in infringement if it is solely done for export purposes[935] and the substance is not manifestly arranged and prepared for the indication authorised in the State that has granted the SPC. On the basis of that concept, it is for the right holder to prove that the defendant not only produced the substance, but also intended to use it on the domestic market for the purposes covered by the MA.[936] In order to rule out such consequences, it could be stipulated expressly that the right holder has already discharged his burden by proving manufacturing of the active ingredient. The defendant must adduce evidence supporting the limitation.

The generic company would thus have to establish:

- in the case of a manufacturing waiver for export, that the products were actually manufactured for export and were exported to non-PTE countries only;
- in the case of a manufacturing waiver for stockpiling purposes, that the manufactured products have not been placed on the SPC-protected EU market prior to expiry of the SPC.

15.3.6.3 Notification

The risk of abuse of a manufacturing waiver could further be reduced by imposing upon the manufacturer an obligation to notify the SPC holder prior to the start of production. The SPC holder would on that basis be able to monitor the market for potentially infringing products.

A corresponding solution was developed in CJEU case law concerning repackaging of branded goods in the context of parallel imports.[937] When the original package in which branded goods were first released on the market in the EU is replaced by a different one on which the protected mark is affixed or otherwise remains visible, giving prior notice to the trade mark holder is one of the conditions that must be

935 Chapter 5, Section 5.7.2. of this Study.

936 See Berhard Geißler, *Der Umfang des Stoffschutzes für chemische Erfindungen* (Carl Heymanns 1972) p. 181, where he points out that in case of purpose-bound protection of a certain substance it is basically the right holder's responsibility to prove that the substance manufactured by the alleged infringer is manufactured for the purpose recited by the product claim.

937 Case C-102/77 *Hoffmann-La Roche v Centrafarm* [1978] ECLI:EU:C:1978:108; Case C-427/93 *Bristol Myers Squibb v Paranova* [1996] ECLI:EU:C:1996:282, para. 78; Case C-348/04 *Boehringer Ingelheim v Swingward et al* [2007] ECLI:EU:C:2007:249, para. 64.

fulfilled in order for such measures to be admissible under Art. 15 of the Trade Mark Directive.[938] If no such notice is given to the proprietor, the parallel importer infringes the trade mark right "on the occasion of any subsequent importation of that product, so long as he has not given the proprietor such notice".[939]

If the same scheme is applied to production of pharmaceuticals under a manufacturing waiver, it would mean that all products manufactured before notification of the right holder would be considered *ipso jure* as infringing even if the other requirements of the manufacturing waiver are met (on this model see also *supra*, 15.3.3.3).

15.3.6.4 Penalty commitment or requirement of an affidavit

As a further safeguard against abuse of a manufacturing waiver, it could be considered to provide for the requirement of a penalty commitment or an affidavit as a mandatory part of the manufacturer's advance notice. Accordingly, the manufacturer could be required to submit an affidavit along with the prior notice or undertake in such notice to pay an adequate penalty if the products should not only be marketed in non-PTE countries or – in case of a stockpiling exemption – if the products were released on the domestic market prior to expiry of the SPC.

15.3.6.5 Labelling

The legislature could also require products manufactured for export under the waiver to be labelled accordingly. More precisely, the respective products could, for instance, be required to clearly identify, through specific labelling or marking, that they were produced under the export manufacture waiver provision for the purpose of export to a specific country.[940] Such a labelling requirement could reduce the risk of such products being reimported into the respective EU Member States.

15.3.6.6 Notification of product characteristics

In addition, the manufacturer could be required to notify the right holder of the details of the products manufactured for export purposes, including the content of the labelling referred to above. This would enable the right holder to inform the competent customs authorities accordingly and make sure that customs seizure procedures under the Customs Enforcement Regulation (Reg. 608/2013)[941] can be used effectively to detect possible reimported products.

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938 Directive (EU) 2015/2436 of the European Parliament and of the Council of 16 December 2015 to approximate the laws of the Member States relating to trade marks [2015] L 336/1. The other requirements are: (1) reliance on trade mark rights by the proprietor in order to oppose that the marketing of repackaged products under that trade mark would contribute to the artificial partitioning of the markets between Member States; (2) the repackaging cannot affect the original condition of the product inside the packaging; (3) the new packaging clearly states who repackaged the product and the name of the manufacturer; (4) the presentation of the repackaged product is not such as to be liable to damage the reputation of the trade mark and of its proprietor; thus, the repackaging must not be defective, of poor quality, or untidy. See Case C-348/04 *Boehringer Ingelheim v Swingward et al* [2007] ECLI:EU:C:2007:249, para. 54.

939 Case C-348/04 *Boehringer Ingelheim v Swingward et al* [2007] ECLI:EU:C:2007:249, para. 64.

940 Similar to Art. 10(5) Reg. 816/2006.

941 Regulation (EU) No 608/2013 of the European Parliament and of the Council of 12 June 2013 concerning customs enforcement of intellectual property rights and repealing Council Regulation (EC) No 1383/2003 [2013] OJ L 181/15.

15.3.6.7 Opinion of the stakeholders

Several representatives of originators are of the opinion that none of the measures discussed can really eliminate the risks associated with the creation of a waiver.[942] If the manufacturing waiver is nevertheless introduced, the majority of the stakeholders consulted in the course of this Study agree on the opportunity to take some precautionary measures. An evident division exists between representatives of generic companies and representatives of originator companies. The majority of the representative of originators support the introduction of all or some of the measures mentioned in the Allensbach Survey,[943] while the majority of the representatives of the generic companies (61 per cent) "do not suggest any such measures".[944]

The figure below provides some more details:

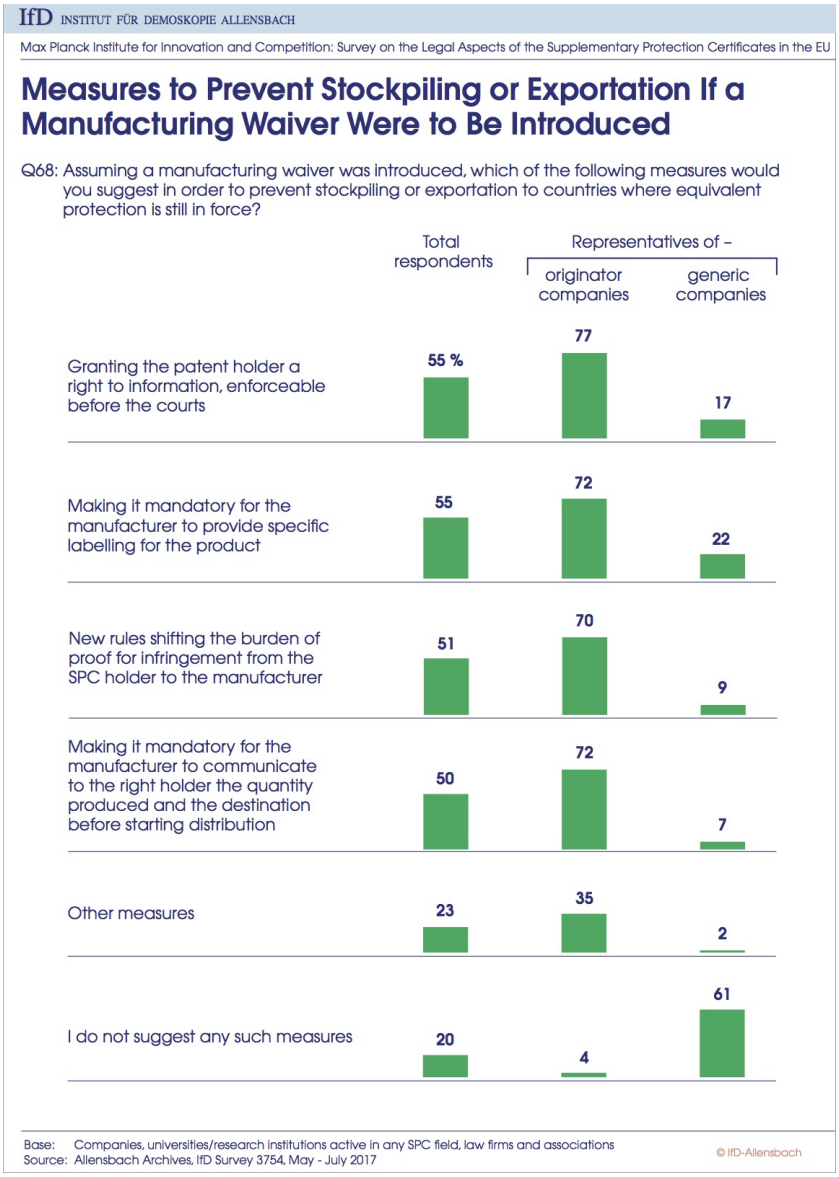

Figure 15.1: Opinion of the stakeholders regarding safeguard measures (Q68 of the Allensbach Survey)

942 Annex III of this Study, Q68, p. 396.
943 Annex III of this Study, comments to Q68, p. 397.
944 Annex III of this Study, Q68, p. 49.

In response to the Allensbach Survey, and in the course of the interviews, some stakeholders have suggested further precautions to prevent abuses or to ensure that the manufacturing waiver is practised in accordance with its purpose. These measures are:

- To address the risk of "repackaging" for solid dosage form, it could be required that the colour of the drug itself should be different from that sold in the EU;[945]
- To allow better control of the SPC holder over the activities of the generic companies, the latter should be obliged to indicate on a website or in a central register the quantity of the drugs being produced for export;[946]
- The installation of some form of "track and trace" system,[947] for instance, traceability requirements on the blister packaging to prevent diversion back to the EU;
- Inspection rights to ensure that stockpiling does not occur (provided of course that the manufacturing waiver is limited to export purposes);
- A requirement that the API or biological product is manufactured in the EU. According to one stakeholder, formulating in the EU or packaging products manufactured elsewhere would not be enough to qualify under the exemption, since the latter is intended to increase jobs in the generic industry in Europe. Of course, this is not a measure that would reduce the risk of diversion.

For more detailed comments, we refer to Q68 in Annex III to this Study, pp. 395–401.

15.3.7 Recommendation

15.3.7.1 Premise

The positions articulated by the generic industries and originator companies both find support in the economics literature, where the opinions endorsed with respect to the benefits of a manufacturing waiver are also divided. According to one view, such a waiver would not undermine the incentives for research and would, by contrast, create new jobs and business opportunities in Europe.[948] According to another view, the benefits of the manufacturing waiver are limited. The measure would even lead to a loss of highly qualified jobs in the innovative industry.[949] A recent study by Charles River Associates for the European Commission – DG Internal Market, Industry, Entrepreneurship and SMEs – concludes that the introduction of a manufacturing waiver would result in net economic benefits for the European Union.[950]

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945 One stakeholder has referred to the letter of IFPMA, Proposal to Include Safeguard Measures for Appropriate Implementation of Article 20.27(9) of CETA, p. 4, where several measures were proposed to prevent diversion of the products manufactured under a waiver and their re-importation to Canada. The letter was directed to the Innovation, Science and Economic Development Canada and is dated 16 September 2016. The letter is with the authors of the Study.

946 *Ibid.,* also Annex III of this Study, comments to Q68, p. 398.

947 Annex III of this Study, comments to Q68, p. 396.

948 Vanda Vincente, Sérgio Simões, 'Manufacturing and export provisions: Impact on the competitiveness of European pharmaceutical manufacturers and on the creation of jobs in Europe' [2014] 11(1/2) Journal of Generic Medicines 35.

949 Jesse A Sussel et al, 'Reconsidering the economic impact of the EU manufacturing and export provisions' [2017] Journal of Generic Medicines 1.

950 Raphael De Conick et al, 'Assessing the economic impact of changing exemption provisions during patent and SPC protection in Europe' [2016] available at http://publications.europa.eu/resource/cellar/6e4ce9f8-aa41-11e7-837e-01aa75ed71a1.0001.01/DOC_1 (last accessed 16 January 2018).

As already explained, the MPI is not in a position to confirm or contradict these opinions. Accordingly, the introduction of a manufacturing waiver is neither suggested nor opposed by us. This is a political decision to be made, *inter alia*, on the basis of further economic studies. However, we can address the question whether the creation of a manufacturing waiver would be consistent with the rationale of SPCs under the SPC Regulations in force. In our opinion, the answer is affirmative, particularly insofar as the waiver for export is concerned. More differentiated opinions are possible with respect to a stockpiling waiver. As a consequence, export waivers are addressed first (15.3.7.2); and stockpiling waivers are considered thereafter (15.3.7.3).

15.3.7.2 Manufacturing waiver for export purposes

The reason for granting SPCs is that a marketing authorisation is needed in order to bring to the market the product incorporating the patented technical teaching. It is basically in line with this goal to limit the protection granted to activities that require such authorisation. For this reason, in our opinion, the protection granted by the SPC already *de lege lata* does not extend to non-pharmaceutical uses of the active ingredient and should not extend to pharmaceutical uses that are authorised abroad but not in the country for which the SPC is granted. As a consequence, the manufacturing of the patented substance for such uses is not covered by the SPC after the expiration of the patent, even if it amounted to an infringement of the patent before that date[951]. However, there is no general agreement on this interpretation. National court decisions are rare[952] and, as long as a ruling by the CJEU is lacking, they would not have authoritative force beyond their own jurisdiction. Nevertheless, whereas the legal status quo remains somewhat uncertain, it is a valid point that in order to satisfy the rationale underpinning the SPC system, it is only necessary to prohibit activities that were actually impeded by the existence of the product approval procedures. Insofar as the introduction of a manufacturing waiver is underpinned by exactly that rationale, its legal basis is sound, irrespective of the economic or political considerations that may also have an impact on the final decision to be made by the legislature.

The following considerations may illustrate this: in order to manufacture a substance and to export it to a foreign country the patentee does not need an MA that would entitle it to an SPC. The patentee can therefore, under Dir. 2001/82 and Dir. 2001/83, begin this activity whether or not an authorisation to place the product on the market within the meaning of Art. 3(b) Reg. 469/2009 exists. To commence production of an active ingredient in the EU, a manufacturer is not required to conduct any studies or trials.[953] Thus, for instance, a company located in Germany could obtain authorisation to place on the market a specific drug in the US; the manufacture of these drugs in Germany does not require an MA under 2001/82/EC. Of course, the company concerned would need an authorisation in the US to place the product on the market, and it would need a production licence in Germany. But neither the FDA authorisation nor the production authorisation would entitle the patent holder to the grant of an SPC, and none of them requires an MA in Europe. The SPC was not created to compensate the patent owner for the time lost in obtaining MAs abroad or any authorisations other than the MA under Dir. 2001/82/EC or Dir. 2001/83.

951 Chapter 5, Section 5.7.2.
952 *Ibid.*
953 See the requirements to obtain permission for manufacturing in Art. 41 Dir. 2001/82/EC.

For the sake of completeness, it must again be pointed out that the hazards potentially resulting from a manufacturing waiver for the interests of right holders can be countered in an appropriate manner by implementing precautionary measures such as those addressed under Section 15.3.6.

15.3.7.3 Manufacturing waiver for stockpiling

Similar to the manufacturing waiver for export purposes, it is also possible to argue with regard to the stockpiling exemption that it is consistent with the rationale of the SPC legislation, given that the production of substances or final products (formulation) does not require an MA, but only a manufacturing licence, which as such does not entitle a manufacturer to an SPC. On the other hand, unlike exports, the products that are stockpiled target the same market for which the MA was acquired (although only after the SPC has ceased to exist) and are prepared for the same use authorised in the country in which the certificate is in force. Further, unlike a manufacturing waiver, a stockpiling waiver may in principle affect the revenues of the originator on the market for which the MA supplied in support of the SPC was granted. Indeed, if production cannot start during the term of the SPC, it can be assumed that competitors based in Europe will not be able to enter the market one day after expiration of the SPC.

Therefore, introducing such a limitation may face higher hurdles from economic and political aspects than the export waiver. One could argue that there are qualitative differences between a manufacturing waiver and a stockpiling waiver, as the position of the innovators holding the SPC are more severely affected by the latter. However, these differences would be less conspicuous if it could actually be established that, as is claimed by generic companies, originators face serious competition from day one after expiry of the SPC anyhow, with the only difference being that it comes from companies based in non-PTE countries. If that is the case, arguably the only effect of prohibiting stockpiling would be to boost the business opportunities of non-EU companies to the disadvantage of generic manufacturers established here. However, that again is a matter of empirical data and analyses which do not form part of this Study.

15.3.8 Implementation

The different models for implementing a manufacturing waiver were already mentioned in Section 15.3.3. Beyond the question of the structure of the waiver, options exist with respect to the nature of the rule creating the exception as well as with respect to the scope of the exception.

As to the nature of a rule creating a waiver, EU lawmakers could decide either

- to introduce the manufacturing waiver as a directly applicable and mandatory rule in the form of a second paragraph to Art. 5 of the SPC legislation (**mandatory manufacturing waiver**);
- or to allow the manufacturing waiver as an option for national lawmakers; in this case a second paragraph to Art. 5 could state simply that in derogation to Art. 5(1) the Member States may provide that the right to prohibit the manufacture of the product covered by the MA submitted in support of the application for the certificate may be limited in specific circumstances. In order to avoid that the EU States exercise this option in an unharmonised manner,

the EU legislature could specifically define the circumstances in which the manufacturing waiver may apply (**optional manufacturing waiver**). In this case, EU Member States would only have the alternative of either implementing the optional exemption literally or of renouncing it.

As to the scope, the EU lawmakers must decide whether to introduce a manufacturing waiver for export only or also for stockpiling purposes. A further question is whether the waiver should only cover the manufacture of the active ingredient or also the formulation and the packaging of a final drug containing that ingredient.

15.3.9 Summary

- Two general concepts for a manufacturing waiver must be distinguished: an export waiver and a stockpiling exemption.
- From a legal perspective, manufacturing waivers in both forms are consistent with the purpose of the SPC Regulations to provide an extended period of time to compensate for the delay in the commercial exploitation of the invention that arises as a consequence of the requirement for an MA under Dir. 2001/82 and Dir. 2001/83. That rationale is satisfied if the exclusive rights granted by the SPC only extend to activities that are delayed by the requirement for such MA. This means that neither the production for export, nor the production for stockpiling purposes run counter to the legal objectives of the SPC system.
- Nevertheless, the stockpiling waiver appears more problematic than the export waiver as it concerns the manufacturing of goods destined for the same market and for the same purposes as those covered by the MA. Therefore, the potential negative effects on the position of the SPC holder are more aggravating, and the hurdles for introducing such a waiver must therefore be higher than for the export waiver.
- Both forms of manufacturing waiver have the purpose of levelling the playing field between EU-based generic companies and generic companies in non-PTE countries. However, in order to assess whether such legislation would have the desired effects or rather produce undesirable side-effects, further economic and political factors must be taken into account that cannot be addressed in this Study.
- As a corollary to the introduction of waivers in one or both forms, precautionary measures could be envisaged in order to ensure that generic manufacturers respect the terms of the limitation, without impeding activities permitted under the waiver in a disproportionate manner.

15.4 LIMITATIONS TO THE SPC RIGHTS ENSHRINED IN PATENT LAW

15.4.1 *Bolar* exemption

15.4.1.1 General observations

One of the tasks of this Study is to examine the *Bolar* exemption as provided under the UPC and national law. The Study cannot offer data to support any conclusion on the question of whether or not a broad *Bolar* exemption can reduce the costs for companies located in Europe or can influence the decisions of companies to conduct

clinical trials in Europe or outside Europe. It is possible that the question whether or not clinical trials can infringe a patent or are exempted *a priori* is a factor that, all else being equal, influences the decisions of a company in this respect. However, we have no empirical data supporting this assumption.[954] Our analysis, as in the rest of the Study, is purely legal.

15.4.1.2 The Bolar exemption in Europe

The *Bolar* exemption was first introduced in the USA following the judgment in *Roche v Bolar.*[955] In that case, Roche filed an action against *Bolar* for conducting clinical trials in preparation for an application for an MA. Roche argued, and the courts confirmed, that any use of the patented compound for commercial purposes outside the scope of the statutory limitations amounts to patent infringement. *Bolar* argued that it would not be able to enter the market immediately after expiry of the patent if it was not allowed to conduct in advance the studies and trials required to apply for an MA.

The US legislature recognised the dilemma reflected in this case and decided to act. With the goal of achieving a fair balance, the Hatch-Waxman Act[956] not only introduced patent extensions but also an exemption directed to clinical studies and trials, since then known as the *Bolar* exemption.[957]

In the EU a provision similar to the US *Bolar* exemption has been introduced in Art. 10(6) Dir. 2001/83 and in Art. 13(6) Dir. 2001/82.

Art. 10(6) Dir. 2001/83 states:

> Conducting the necessary studies and trials with a view to the application of the paragraphs 1, 2, 3 and 4 and the consequential practical requirements shall not be regarded as contrary to patent rights or to supplementary protection certificates for medicinal products.

Both provisions have no direct effect and require implementation by the Member States. To be exempted under the wording of Art. 10(6) Dir. 2001/83, the relevant acts must satisfy three requirements:

- the acts concerned are undertaken for trials and studies to generate data for an MA procedure in an EU or EEA country;
- the MA procedure concerned is directed to the grant of an MA under Art. 10(1) to (3) and 10(4) of Dir. 2001/83/EC, that is, an MA for a generic product;[958]
- the studies and trials concerned are necessary for that application.

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954 The Allensbach Survey collected some information from the stakeholders in this respect (Q64-65). Statements of some stakeholders were also collected in 2011 by the UK IPO in a consultation concerning the *Bolar* Exemption in UK, see UK IPO (ed.), *The Research and Bolar Exception: Proposals to exempt clinical and field trials using innovative drugs from patent infringement – Government response*, available under http://webarchive.nationalarchives.gov.uk/20140603101058/ http://www.ipo.gov.uk/response-2012-*Bolar*.pdf (last access 20 March 2017).The information obtained in this way is relevant, but do not constitute conclusive evidence.

955 *Roche Products, Inc. v Bolar Pharmaceutical Co., Inc* (733 F.2d 858, 1984).

956 Drug Price Competition and Term Restoration Act of 1984.

957 35 USC § 271(e)(1): "it shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention […] solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinarian biological products."

958 Clemens Tobias Steins et al, *The EU Patent Package Handbook – A Practitioner's Guide* (Hoffmann Eitle 2014).

However, according to the prevailing view, both Directives only impose a minimum standard. The Member States are free to expand the scope of the exemption, for instance, to

- studies and trials that may be useful but are not strictly necessary for the application procedure under Art. 10(6) Dir. 2001/83/EC;
- studies and trials that are necessary to obtain not only an abridged MA, but also an MA under Art. 8 Dir. 2001/83/EC;
- studies and trials that are necessary to obtain an MA in any other state, also outside the EU;
- activities directed to obtaining data required for health technology assessments.

Since Member States can make use of one, two or all the possible options suggested above, it follows that the provisions implementing Art. 10(6) Dir. 2001/83/EC or Art. 13(6) Dir. 2001/82/EC may vary, and that different legislative models are conceivable within the legal framework of the Directive. With some simplification, the following models can be distinguished:

- a *broad* exemption that covers all acts that are necessary and useful for a study aiming to generate data for obtaining permission to market a new or generic medicinal product in Europe or abroad;
- a *narrow* exemption that just refers to the Directive or cites it verbatim and limits the scope of the exemption to acts performed within a study that is strictly necessary for obtaining an MA under Art. 10 Dir. 2001/83/EC;
- a regulation that lies *in between* the previous two models, by going beyond the wording of the Directives in one or another aspect without making use of all options mentioned above.

The majority of the EU Member States provides for a *Bolar* exemption that is at least in one aspect broader that the minimum standard laid down in Art. 10(6) Dir. 2001/83/EC or Art. 13(6) Dir. 2001/82/EC. We show more details in the following table:

Country	Provision	Wording	Comment
Austria	§22(1) Patent Act[959]	The effect of the patent shall not extend to studies and trials as well as to the consequential practical requirements, as far as they are necessary to obtain a permission, authorisation or registration for putting on the market pharmaceutical products.	The exception is **broader** than the one provided under Art. 10(6) Dir. 2001/83/EC[960] or Art. 13(6) Dir. 2001/82/EC[961]. Indeed, it is not limited to activities related to a patented reference product (i.d. generic and biosimilar marketing authorisations). Further, it includes also studies for obtaining an MA outside the EU.
Belgium	Art. 6bis §1 para. 12 Law on Medicinal Products[962]	Conducting studies, tests and trials necessary to comply with the conditions and terms laid down in paragraphs 1 to 8 and the resulting practical requirements shall not be regarded as contrary to patents and supplementary protection certificates for medicinal products for human use.	The exception is **equivalent** to that provided under Art. 10(6) Dir. 2001/83/EC or Art. 13(6) Dir. 2001/82/EC. Indeed, the provision refers to paragraphs 1 to 8 which concern generic and biosimilar products. Further, the exception does not apply to activities directed to generate data for obtaining an MA in third countries.[963]
Bulgaria	Art. 20(7) Law on Patents and Utility Model Registration[964]	The effect of a patent shall not extend to: [..] (7) the conduction of necessary	The exception seems to be **broader** than under Art. 10(6) Dir. 2001/83/EC or Art. 13(6) Dir. 2001/82/EC at least one aspect: it

959 Patentgesetz 1970 (as amended by BGBl. I Nr. 124/2017, of 29 June 2017), §22(1): Die Wirkung des Patentes erstreckt sich nicht auf Studien und Versuche sowie die sich daraus ergebenden praktischen Anforderungen, soweit sie für die Erlangung einer arzneimittelrechtlichen Genehmigung, Zulassung oder Registrierung für das Inverkehrbringen erforderlich sind.
Text in German available at https://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10002181 (last accessed 24 September 2017).
Text in English available at https://www.patentamt.at/fileadmin/root_oepa/Dateien/Patente/PA_Gesetze/PatG_englisch.pdf (last accessed 24 September 2017).

960 Art. 10(6) Dir. 2001/83/EC: "6. Conducting the necessary studies and trials with a view to the application of paragraphs 1, 2, 3 and 4 and the consequential practical requirements shall not be regarded as contrary to patent rights or to supplementary protection certificates for medicinal products."

961 Art. 13(6) Dir. 2001/82/EC "Conducting the necessary studies, tests and trials with a view to the application of paragraphs 1 to 5 and the consequential practical requirements shall not be regarded as contrary to patent-related rights or to supplementary protection certificates for medicinal products."

962 Loi sur les medicaments 25 Mars 1964 (as amended 27 December 2016), Art. 6bis §1er alinéa 12: La réalisation des études, des tests et des essais nécessaires en vue de satisfaire aux conditions et modalités prévues dans les alinéas 1er à 7 et les exigences pratiques qui en résultent, ne sont pas considérées comme contraires aux brevets et aux certificats complémentaires de protection pour les médicaments à usage humain. Text in French available at http://www.ejustice.just.fgov.be/cgi_loi/change_lg.pl?language=fr&la=F&cn=1964032530&table_name=loi (last accessed 24 September 2017).
Text in English: free translation.

963 András Kupecz et al, 'Safe harbors in Europe: an update on the research and *Bolar* exemptions to patent infringement' [2015] 33 Nature Biotechnology, Table 2: The scope of the *Bolar* exemption in several European countries. Available at https://www.nature.com/articles/nbt.3273#t2 (last accessed 13 March 2018).

964 New State Gazette No. 64/2006, in force as from 09.11.2006; deleted, State Gazette No.31/2007, in force as from 13 April 2007. Text in English available at http://www.bpo.bg/images/stories/laws/law_on_pumr_amended_2007.pdf (last accessed 24 September 2017).

		researches and tests for the purpose of filing a marketing authorisation request for a generic medical product to be used in the human medicine or a generic medical product to be used in the veterinary medicine, as well as any other act related to subsequent practical requirements in connection with the filing of the request.	encompasses also studies for obtaining an MA in third countries.
Croatia	Art. 63(2) Patent Act[965]	The patent owner's exclusive right of exploitation of the invention shall not apply to: (2) acts done for the purposes of research and development and for experiments relating to the subject-matter of the protected invention, including where such acts are necessary for obtaining registration or authorisation for putting on the market a product comprising a medicine intended for people or animals, or a medicinal product.	The exception is **broader** than provided under Art. 10(6) Dir. 2001/83/EC or Art. 13(6) Dir. 2001/82/EC. It seems to cover activities directed to generate data for an MA for any product, and not only a generic or a biosimilar. It seems to cover also studies directed to obtain an MA in third countries.
Cyprus	§10B(8) Law on Drugs for Human Use (Quality Control, Supply and Prices)[966]	The conduct of studies and the trials which are required for the application of the provisions of article 10A, of sections (1), (3), (4), (5) and (6) of the present article and the arising practical consequences are considered not to conflict with the provisions of the Patent Act.	The exception is **equivalent** to that laid down under Art. 10(6) Dir. 2001/83/EC or Art. 13(6) Dir. 2001/82/EC. It covers only activities related to a reference patented product and directed to obtain data for a generic or biosimilar MA.[967] It does not exempt studies directed to generate data for obtaining an MA in third countries.[968]
Czech Republic	§18(e) Act on Inventions and Rationalisation Proposals [969]	The rights of the proprietor of the patent shall not be infringed by use of the protected invention: e) in acts relating to the subject-matter	The exception is **broader** than under Art. 10(6) Dir. 2001/83/EC or Art. 13(6) Dir. 2001/82/EC since it is

[965] Patent Act (as amended by NN 76/2013, in force from June 29, 2013), Art. 63:
Isključivo pravo nositelja patenta na iskorištavanje izuma ne odnosi se na:
2. radnje koje se poduzimaju radi istraživanja i razvoja te pokusa, koje se odnose na predmet zaštićenoga izuma, uključujući kada su te radnje potrebne za dobivanje registracije ili odobrenja za stavljanje na tržište proizvoda koji je lijek namijenjen ljudima ili životinjama, ili medicinski proizvod.
Text in Croatian available at https://www.dziv.hr/files/File/zastita/zakon_patent_procisceni_HR.pdf (last accessed 25 September 2017). Text in English available at https://www.dziv.hr/files/File/eng/zakon_patent_ENG.pdf (last accessed 25 September 2017).

[966] Law No. 75(I)/2006, §10B(8):
Η πραγματοποίηση των μελετών και των δοκιμών, που απαιτούνται για την εφαρμογή των διατάξεων του άρθρου 10Α, των εδαφίων (1), (3), (4), (5) και (6) του παρόντος άρθρου και οι προκύπτουσες πρακτικές συνέπειες, θεωρείται ότι δεν αντιβαίνουν τις διατάξεις του περί Διπλωμάτων Ευρεσιτεχνίας Νόμου.
Text in Greek available at http://www.moh.gov.cy/MOH/phs/phs.nsf/All/D430D883637D2D2EC22572FA002A99F7/$file/Νόμος%2075(I)%20του%202006.pdf?OpenElement (last accessed 25 September 2017).
Text in English: free translation.

[967] Justine Pila, Paul LC Torremans, *European Intellectual Property Law* (Oxford 2016) p. 215.

[968] *Ibid.*

[969] Act No. 527/1990 Coll. (as amended by Act No. 519/1991 Coll., Act No. 116/2000 Coll. and Act No. 207/2000 Coll.), §18:

		of the invention done for experimental purposes, including experiments and tests necessary under special legal regulations[970] prior to being placed on the market.	not limited to generic or biosimilar products. Further, it encompasses studies directed to generate data for obtaining a marketing authorisation in third countries.
Denmark	§3(3)(iv) Patents Act[971]	The exclusive right shall not extend to: [..] (iv) acts delimited to the subject-matter of the patented invention which are necessary for obtaining a marketing authorisation for a medicinal product for humans or animals in the EU, in an EU member state or in other countries.	The exception is **broader** than that provided under Art. 10(6) Dir. 2001/83/EC or Art. 13(6) Dir. 2001/82/EC. It is not limited to activities directed to generate data for obtaining a marketing authorisation for a generics or a biosimilar product.[972] Further, it covers also studies directed to generate data for obtaining an MA in third countries.
Estonia	§16(3) Patents Act[973]	The following acts do not constitute infringement of the exclusive right of the proprietor of a patent: [..] 3) the use of the patented invention in testing related to the invention itself, including the use of a medicinal product containing the patented invention in clinical trials of the medicinal product [..].	The exception seems to be **broader** than under Art. 10(6) Dir. 2001/83/EC or Art. 13(6) Dir. 2001/82/EC. as it is not limited to generic or biosimilar products. Further, it seems to cover also studies directed to generate data for obtaining an MA in third countries.

Práva majitele patentu nejsou porušena, využije-li se chráněného vynálezu:
e) při činnosti prováděné s předmětem vynálezu pro experimentální účely včetně experimentů a testů nezbytných podle zvláštního právního předpisu (Zákon č. 378/2007 Sb., o léčivech a o změnách některých souvisejících zákonů (zákon o léčivech)) před uvedením léčiva na trh.
Text in English available at https://www.upv.cz/dms/pdf_dokumenty/zakony/2015/527_1990-072014_en.pdf (last accessed 24 September 2017). Text in Czech available at https://www.upv.cz/dms/pdf_dokumenty/zakony/527_1990-072014B (last accessed 24 September 2017).

970 Act No. 378/2007 Coll. on Pharmaceuticals and on Amendments to Certain Related Acts (Law on Pharmaceuticals).

971 Consolidate Act No. 221 of 26 February 2017, §3(3)(iv):
Eneretten omfatter ikke
4) handlinger, der er afgrænset til genstanden for den patenterede opfindelse, som er nødvendige for at kunne opnå en markedsføringstilladelse for et lægemiddel til mennesker eller dyr i EU, i en EU-medlemsstat eller I andre lande. Text in Danish available at http://www.wipo.int/wipolex/en/text.jsp?file_id=433778 (last accessed 26 September 2017). Text in English available at http://www.dkpto.org/ip-law--policy/law.aspx (last accessed 26 September 2017).

972 Raphael De Cornick et al, CRA, Assessing the economic impacts of changing exemption provisions during patent and SPC protection in Europe [2016] table 3, p. 48.

973 RT I 1994, 25, 406 (as amended by RT I 2009, 4, 24), §16:
Patendiomaniku ainuõiguse rikkumiseks ei loeta:
3) patenditud leiutise kasutamist leiutist ennast puudutavates katsetustes, sealhulgas patenditud leiutist sisaldava ravimi kasutamist ravimi kliinilistes uuringutes;
Text in Estonian available at https://www.riigiteataja.ee/akt/112072014105 (last accessed 25 September 2017). Text in English available at https://www.riigiteataja.ee/en/eli/511112013016/consolide/current (last accessed 25 September 2017).

Germany	§11.2b Patent Act[974]	The effect of a patent shall not extend to (2b) studies, experiments and the practical requirements resulting therefrom which are necessary for obtaining authorisation to place medicinal products on the market in the European Union, or which are necessary for obtaining authorisation to place medicinal products on the market in the Member States of the European Union or in third countries [..].	The exception is **broader** than under Art. 10(6) Dir. 2001/83/EC or Art. 13(6) Dir. 2001/82/EC. It covers studies directed to generate data for obtaining any MA, including an MA for innovative products.[975] Further, it covers also studies and trials directed to generate data for obtaining an MA in third countries.
Greece	Art. 11(6) Ministerial Decision DYG3(a)83657 [976] [977]	The performance of studies and tests required to implement paragraphs 1, 2, 3 and 4 and related practical requirements are not deemed contrary to the patent rights or supplementary protection certificates for medicinal products.	The exception is **equivalent** to that provided under Art. 10(6) Dir. 2001/83/EC or Art. 13(6) Dir. 2001/82/EC since it covers only studies and trials required for obtaining an MA for generic medicinal products and does not cover activities regarding obtaining MAs in third states.[978]
Finland	Chapter 1, Section 3, Para. 3 No. 4 Patents Act[979]	The exclusive right shall not apply to: [..]	The exception is **broader** than that provided under Art. 10(6) Dir. 2001/83/EC or Art. 13(6) Dir.

974 Patentgesetz (as amended 1 September 2017), §11.2b:
Studien und Versuche und die sich daraus ergebenden praktischen Anforderungen, die für die Erlangung einer arzneimittelrechtlichen Genehmigung für das Inverkehrbringen in der Europäischen Union oder einer arzneimittelrechtlichen Zulassung in den Mitgliedstaaten der Europäischen Union oder in Drittstaaten erforderlich sind. Text in German available at http://www.gesetze-im-internet.de/patg/PatG.pdf (last accessed 22 September 2017). Text in English available at http://www.gesetze-im-internet.de/englisch_patg/englisch_patg.pdf (last accessed 22 September 2017).

975 Hans-Rainer Jaenichen, Johann Pitz, 'Research Exemption/Experimental Use in the European Union: Patents Do Not Block the Progress of Science' [2015] 5(2) Cold Spring Harb Perspectives in Medicine 6, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4315916/pdf/cshperspectmed-IPM-a020941.pdf (last accessed 13 March 2018); Thomas Kühnen, *Handbuch der Patentverletzung* (10th edn, Carl Heymanns Verlag 2018) p. 722.

976 Joint Ministerial Decision DYG3(a) 83657 (GG 59 B of 24.01.2006) on the "Harmonisation of Greek legislation with the equivalent community legislation in the fields of production and marketing of medicines for human use, in compliance with Directive 2001/1983/EC on "the Community Code relating to medicinal products for human use", as amended by Directives 2004/27/EC, 2004/24/EC on traditional herbal medicinal products and Article 31 of Directive 2002/1998/EC on the adoption of standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components".

977 Άρ-θρο 11 Πα-ρά-γρα-φος 6:
Η πραγ-μα-το-ποί-η-ση των με-λε-τών και των δο-κι-μών που α-παι-τού-νται για την ε-φαρ-μο-γή των πα-ρα-γρά-φων 1, 2, 3 και 4 και οι συ-να-κό-λου-θες πρα-κτι-κές α-παι-τήσεις δεν θε-ω-ρεί-ται ό-τι α-ντι-βαί-νουν στα δι-καιώ-μα-τα που προ-στα-τεύ-ο-νται από δι-πλώ-μα-τα ευ-ρε-σι-τε-χνί-ας ή συ-μπλη-ρω-μα-τι-κά πι-στο-ποι-η-τι-κά προ-στα-σίας για τα φάρ-μα-κα. Text in Greek available at https://www.obi.gr/OBI/OBI_GR/Misc_GR/CommonMinistDec83657_GR/tabid/360/Default.aspx (last accessed 25 September 2017). Text in English available at https://www.obi.gr/OBI/OBI_EN/Misc_EN/JointMinisterialDecision83657_EN/tabid/368/Default.aspx (last accessed 25 September 2017).

978 Justine Pila, Paul LC Torremans, *European Intellectual Property Law* (Oxford 2016) p. 215.

979 Act No. 550 of December 15, 1967 (as amended by Act 295/06 of 21 April 2006), §3 Para. 3:
Yksinoikeus ei käsitä:
4) lääkevalmisteen myyntilupahakemusta varten tarvittavia tutkimuksia, kokeita tai käytännön vaatimuksista aiheutuvia toimia, jotka koskevat kyseiseen lääkevalmisteeseen kohdistuvaa keksintöä.
Text in Finnish available at http://www.finlex.fi/fi/laki/ajantasa/1967/19670550#a8.1.2016-23 (last accessed 25 September

		(4) examinations or experiments or measures arising from practical demands which are needed for an application to obtain a marketing authorisation for a medicinal product and which relate to the invention concerning that medicinal product.	2001/82/EC since it is not limited to generic or biosimilar products. Further, it includes studies directed to obtain an MA not only in Finland but also in third countries.[980]
France	French Intellectual Property Code Art. L613-5(d)[981]	The rights conferred by the patent shall not extend to: [..] d) The studies and trials required to obtain a marketing authorisation for a drug, as well as the acts necessary for their completion and for obtaining the marketing authorisation.	The exception is **broader** than that provided under Art. 10(6) Dir. 2001/83/EC or Art. 13(6) Dir. 2001/82/EC. It concerns studies necessary to obtain any MA for medicinal products, and not only MA for generics or biosimilars.[982] Further, the exception covers also activities directed to generate data for obtaining an MA in third countries.[983] [984]
Hungary	Art. 19(6)(b) on the protection of inventions by patents[985]	The exclusive right of exploitation shall not extend to: [..] (b) acts done for experimental	The exception is **broader** than under Art. 10(6) Dir. 2001/83/EC or Art. 13(6) Dir. 2001/82/EC since it is not limited to generic or

2017). Text in English available at https://www.prh.fi/en/patentit/lainsaadantoa/patenttilaki.html (last accessed 25 September 2017).

980 Government Bill (HE 225/2005), available at https://www.eduskunta.fi/FI/vaski/HallituksenEsitys/Documents/he_225+2005.pdf (last accessed 04 April 2018), pp. 2, 3.

981 Intellectual Property Code (Consolidated version 1 August 2017), Art. L613-5:
Les droits conférés par le brevet ne s'étendent pas:
d) Aux études et essais requis en vue de l'obtention d'une autorisation de mise sur le marché pour un médicament, ainsi qu'aux actes nécessaires à leur réalisation et à l'obtention de l'autorisation.
Text in French available at https://www.legifrance.gouv.fr/affichCode.do;jsessionid=22869BBDF8FB02FCD725183EEA55DFE8.tplgfr21s_3?idSectionTA=LEGISCTA000006179056&cidTexte=LEGITEXT000006069414&dateTexte=20170924 (last accessed 24 September 2017). Text in English: free translation.

982 Hans-Rainer Jaenichen, Johann Pitz, 'Research Exemption/Experimental Use in the European Union: Patents Do Not Block the Progress of Science' [2015] 5(2) Cold Spring Harb Perspectives in Medicine 8, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4315916/pdf/cshperspectmed-IPM-a020941.pdf (last accessed 13 March 2018). Further, there have been opinions that French legislature did not have the aim to restrict the French *Bolar* exemption to generic drugs. See also Jacques Armengaud, Elisabeth Berthet-Maillol, 'La loi du 26 février 2007 transposant la Directive 2004/27 CE ou le coup de pouce donné aux génériques' [20017] 23 Propriétés intellectuelles 146, 147.

983 Hans-Rainer Jaenichen, Johann Pitz, 'Research Exemption/Experimental Use in the European Union: Patents Do Not Block the Progress of Science' [2015] 5(2) Cold Spring Harb Perspectives in Medicine. See also András Kupecz et al, 'Safe harbors in Europe: an update on the research and *Bolar* exemptions to patent infringement' [2015] 33 Nature Biotechnology, Table 2: The scope of the *Bolar* exemption in several European countries, available at https://www.nature.com/articles/nbt.3273#t2 (last accesed 13 March 2018); Jacques Armengaud, Elisabeth Berthet-Maillols*, la loi du 27 févr. 2007 transposant la directive 2004/27/CE ou le coup de pouce donné aux génériques* [2007] 23 Propriétés intelectuelles 146, 147; See also High Court of Paris, Sanofi-Aventis Deutschland v Lilly France, decision of 15 December 2014, Doket No 14/58023, p. 8.

984 Thanks to Sabine Agé, Florence Jacquand from Véron & Assoviésfor provided information.

985 Act XXXIII of 1995 (consolidated text 01.01.2017), §19(6):
A kizárólagos hasznosítási jog nem terjed ki:
b) a találmány tárgyával kapcsolatos kísérleti célú cselekményekre, ideértve a találmány tárgyát képező termék vagy a találmány tárgyát képező eljárással előállított termék forgalomba hozatalának engedélyezéséhez szükséges kísérleteket és vizsgálatokat. Text in Hungarian available at http://www.hipo.gov.hu/sites/default/files/1995_xxxiii_szt_20170617_.pdf (last accessed 25 September 2017). Text in English available at http://www.hipo.gov.hu/sites/default/files/patent_act_xxxiii_1995_en_20170617_footnotes.pdf (last accessed 25 September 2017).

		purposes relating to the subject matter of the invention, including experiments and tests necessary for the marketing authorisation of the product constituting the subject matter of the invention or the product obtained through the process constituting the subject matter of the invention;	biosimilar products. Further, it encompasses also activities directed to obtain an MA in third countries.[986]
Ireland	§42(1)(g) and (h) Patents Act[987]	(g) acts done in relation to the subject matter of the relevant patented invention which consist of: (i) acts done in conducting the necessary studies, tests and trials which are conducted with a view to satisfying the application requirements of paragraphs 1, 2, 3 and 4 of Article 10 of Directive 2001/83 of the European Parliament and of the Council of 6 November 2001 (as last amended by Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004) for a marketing authorisation in respect of a medicinal product for human use, or (ii) acts done in conducting the necessary studies, tests and trials which are conducted with a view to satisfying the application requirements of paragraphs 1 to 5 of Article 13 of Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 (as last amended by Directive 2004/28/EC of the European Parliament and of the Council of 31 March 2004) for a marketing authorisation in respect of a veterinary medicinal product, or (iii) any other act which is required as a consequence of the acts referred to in subparagraph (i) or (ii) for the purposes specified in those subparagraphs, as appropriate. (h) insofar as paragraph (g) does not apply, acts done in relation to the subject matter of the relevant patented invention which consist of: (i) acts done in conducting studies, tests, experiments and trials (including clinical trials and field trials) with a view to satisfyingthe	The exception is **broader** than under Art. 10(6) Dir. 2001/83/EC or Art. 13(6) Dir. 2001/82/EC since it is not limited to generic products. Further, it encompasses also activities directed to obtain an MA in third countries. Finally, it covers also health technology assessments.

[986] Raphael De Cornick et al, CRA, Assessing the economic impacts of changing exemption provisions during patent and SPC protection in Europe [2016] table 3, p. 48.

[987] Consolidated Patents Act of 1992 and amendments up to and including the 19 May 2017, available at https://www.patentsoffice.ie/en/Legislation/Acts/Consolidated-Patents-Act-1992.pdf (last accessed 25 September 2017).

		application requirements for a marketing authorisation or similar instrument (howsoever described) that is required by the law of the State or of any other state in order to sell or supply or offer to sell or supply: (I) a medicinal product for human use, within the meaning of subsection (2), or (II) a veterinary medicinal product, within the meaning of subsection (2), or (ii) any other act done which is required as a consequence of the acts referred to in subparagraph (i) for the purposes specified in that subparagraph, as appropriate.	
Italy	Code of Industrial Property Art 68(1)(a)[988]	1. The exclusive right granted by a patent does not extend, no matter what the object of the invention, to the following: a) to acts carried out privately and for non-commercial purposes, or in an experimental manner even if aimed at obtaining, also in foreign countries, an authorisation for the release on the market of a drug and to the consequent practical fulfilments thereof, including preparation and use of pharmacologically active raw materials strictly necessary for such purpose;	The exception is **broader** than under Art. 10(6) Dir. 2001/83/EC or Art. 13(6) Dir. 2001/82/EC since it covers not only generic products but also innovative. Further, it encompasses also activities directed to obtain an MA in third countries.
Latvia	§20(3) Patent Law[989]	The exclusive rights resulting from a patent shall not be implemented in relation to: [..] (3) examination of the subject of a patented invention, as well as the research of medicinal products or plant protection products patented or protected with a supplementary protection certificate carried out in order to obtain a permission for distribution on the market thereof;	The exception is seemingly **broader** than under Art. 10(6) Dir. 2001/83/EC or Art. 13(6) Dir. 2001/82/EC since it is not limited to generic products but refers to "medicinal products". Further, although there is no legal practice, it might encompass also activities directed to obtain an MA in third countries.[990]

[988] Legislative Decree, February 10, 2005, No 30 (as amended by Legislative Decree, March 16, 2006, No 140). Text in English available at http://www.bugnion.eu/legislazione_italia_dett.php?id=1 (last accessed 25 September 2017).

[989] Patent Law, Vēstnesis, 27.02.2007, Nr. 34 (as amended on 14.10.2010 and 15.12.2011). Text in English available at https://www.lrpv.gov.lv/en/inventions/law (last accessed 25 September 2017).

[990] Eitle von Hoffmann, Thobias Steins Clemens (eds), *The EU Patent Package Handbook: A Practitioner's Guide* (Hoffmann, Eitle 2014).

Lithuania	Art. 11(13) Pharmacy Law[991]	The performance of necessary studies and trials, in order to submit an application for the marketing authorisation in the Republic of Lithuania of a medicinal product according to paragraphs 5, 10 and 11 of this Article or in the Community Register of Medicinal Products according to the requirements laid down in Regulation (EC) No 726/2004 or in other states according to legal requirements of those states, and the related practical needs, shall be without prejudice to the rights granted by the patent for a medicinal product or by a supplementary protection certificate provided for in the Patent Law of the Republic of Lithuania and in other legal acts regulating the protection of industrial property.	This exception is **broader** than the one under Art. 10(6) Dir. 2001/83/EC or Art. 13(6) Dir. 2001/82/EC since it is applicable also to innovative drugs. Further, it seems to encompass also activities directed to obtain an MA in third countries.
Luxem-bourg	Art. 1.-1.(6) Grand-Ducal Regulation 2006[992]	Conducting the necessary studies and trials with a view to the application of paragraphs 1, 2, 3 and 4 and the resulting practical requirements shall not be regarded as contrary to patent rights or supplementary protection certificates for medicinal products.	The exception is **equivalent** in the material scope and geographical applicability to that under Art. 10(6) Dir. 2001/83/EC or Art. 13(6) Dir. 2001/82/EC since it covers only studies and trials required for obtaining an MA for generic medicinal products and does not cover activities regarding obtaining MAs in third states.[993]
Malta	Art. 27(6)(d) Patents and Designs Act (Chapter 417 of The Laws of Malta) [994]	Notwithstanding subarticles (1) and (2), the proprietor of a patent shall have no right to prevent third parties from performing the acts referred to in subarticles (1) and (2)(b) in the following	The exception is **broader**[995] than the one under Art. 10(6) Dir. 2001/83/EC or Art. 13(6) Dir. 2001/82/EC since it clearly indicates that the

991 Law No. X-709 of 22 June 2006 (as amended by Law No. XIII-362 of 2017 May 11), Art. 11(13): Būtinų studijų ir tyrimų atlikimas, norint pateikti paraišką registruoti vaistinį preparatą Lietuvos Respublikoje pagal šio straipsnio 5, 10 ir 11 dalis ar Bendrijos vaistinių preparatų registre pagal Reglamentą (EB) Nr. 726/2004 arba kitose valstybėse pagal tų valstybių teisės aktų reikalavimus, ir su jais susiję praktiniai poreikiai nepažeidžia vaistinių preparatų patento ar papildomos apsaugos liudijimų suteikiamų teisių, numatytų Lietuvos Respublikos patentų įstatyme ir kituose teisės aktuose, reglamentuojančiuose pramoninės nuosavybės apsaugą. Text in Lithuanian available at https://www.e-tar.lt/portal/lt/legalAct/TAR.FF33B3BF23DD/gRoLvrgCbW (last accessed 26 September 2017). Text in English: free translation.

992 Grand-Ducal Regulation of 26 September 2006, Art. 1.-1.(6): La réalisation des études et des essais nécessaires en vue de l'application des paragraphes 1, 2, 3 et 4 et les exigences pratiques qui en résultent ne sont pas considérées comme contraire aux droits relatifs aux brevets et aux certificats complémentaires de protection pour les médicaments. Text in French available at http://legilux.public.lu/eli/etat/leg/rgd/2006/09/26/n1/jo (last accessed 26 September 2017). Text in English: our translation.

993 Justine Pila, Paul LC Torremans, *European Intellectual Property Law* (Oxford 2016) p. 215.

994 ACT XVII of 2000, as amended by Acts IX of 2003 and XVIII of 2005; Legal Notices 181 and 186 of 2006, and 426 of 2007; and Act XXX of 2014, available at http://commerce.gov.mt/en/Industrial_Property/Patents/Documents/Cap%20417.pdf (last accessed 26 September 2017).

995 So also Clement Mifsud-Bonnici, *Malta* in Pierre Kobel et al (eds), ANTITRUST IN PHARMACEUTICAL MARKETS & GEOGRAPHICAL RULES OF ORIGIN (Springer) p. 207 although without clear confirmation. The author

		circumstances: (d) when an act is done for purposes which can reasonably be related to the development and presentation of information required by the law of Malta or any other country that regulates the production, use or sale of medicinal or phytopharmaceutical products.	acts for obtaining a foreign MA are covered. It seems also not to be limited to generic products as this provision refers to "medicinal or phytopharmaceutical products".
The Nether-lands	Art. 53(4) Patents Act 1995 (as amended)[996]	The performance of necessary studies, tests and experiments in connection with the application of Article 10(1) to (4) of Directive 2001/83/EC on the Community Code relating to medicinal products for human use (Official EC Journal L 311) or Article 13(1) to (5) of Directive 2001/82/EC on the Community Code relating to veterinary medicinal products (Official EC Journal L 311) and the ensuing practical requirements shall not be deemed to constitute an infringement of patents relating to medicinal products for human use or medicinal products for veterinary use, respectively.	The exception is **equivalent** in scope to that under Art. 10(6) Dir. 2001/83/EC or Art. 13(6) Dir. 2001/82/EC. It covers only studies and trials directed to generate data for obtaining a generic or biosimilar marketing authorisation.[997] Further, it does not cover studies for obtaining an MA in third countries.[998]
Poland	Art. 69.1(4) The Act of 30 June 2000. - Industrial Property Law[999]	The following shall not be considered acts of infringement of a patent: (4) the exploitation of an invention to a necessary extent, for the purpose of performing the acts as required under the provisions of law for obtaining registration or	The exception is **broader** than that provided under Art. 10(6) Dir. 2001/83/EC or Art. 13(6) Dir. 2001/82/EC at least in one aspect: it is not limited to studies related to

admits that there is very small amount of judgments in Malta related to patents and they often touch only the surface of the substantial matter regulated under Malteese Patents Act.

996 Rijksoctrooiwet 1995, Art. 53(4): Het uitvoeren van de noodzakelijke studies, tests en proeven met het oog op de toepassing van artikel 10, eerste tot en met vierde lid, van Richtlijn 2001/83/EG tot vaststelling van een communautair wetboek betreffende geneesmiddelen voor menselijk gebruik (PbEG L 311) of artikel 13, eerste tot en met het vijfde lid van Richtlijn 2001/82/EG tot vaststelling van een communautair wetboek betreffende geneesmiddelen voor diergeneeskundig gebruik (PbEG L 311) en de daaruit voortvloeiende praktische vereisten worden niet beschouwd als een inbreuk op octrooien met betrekking tot geneesmiddelen voor menselijk gebruik, respectievelijk geneesmiddelen voor diergeneeskundig gebruik. Text in Dutch available at http://wetten.overheid.nl/BWBR0007118/2017-03-01#Opschrift (last accessed 26 September 2017). Text in English available at<https://english.rvo.nl/sites/default/files/2013/12/ ROW95_ENG_niet_officiele_vertaling_0.pdf> (last accessed 26 September 2017).

997 As pointed out by Liz Cohen with reference to Explanatory Memorandum to Artickle 53 of the Dutch Patent Act 1995 (Rijksoctrooiwet).

998 András Kupecz et al, 'Safe harbors in Europe: an update on the research and *Bolar* exemptions to patent infringement' [2015] 33 Nature Biotechnology, Table 2: The scope of the *Bolar* exemption in several European countries, available at https://www.nature.com/articles/nbt.3273#t2 (last accesed 13 March 2018).

999 Industrial Property Law, Act of 30 June 2000 (as amended by Act of 23 January 2004 and Act of 29 June 2007), Art. 69.1: Nie narusza się patentu przez:
4) korzystanie z wynalazku, w niezbędnym zakresie, dla wykonania czynności, jakie na podstawie przepisów prawa są wymagane dla uzyskania rejestracji bądź zezwolenia, stanowiących warunek dopuszczenia do obrotu niektórych wytworów ze względu na ich przeznaczenie, w szczególności produktów leczniczych. Consolidated text of 2017, Pos. 776, available in Polish at http://www.uprp.pl/uprp/_gAllery/83/65/83650/jednolity_tekst_ustawy_Prawo_wlasnosci_przemyslowej_z_2017_r.__poz._776.pdf (last accessed 25 September 2017). Text in English available at http://www.uprp.pl/uprp/redir.jsp?place=GalleryStats&id=38294 (last accessed 25 September 2017).

		authorisation, being, due to the intended use thereof, requisite for certain products to be allowed for putting them on the market, in particular those being medical products.	authorisation of generics or biosimilars.[1000]
Portugal	Art. 102(c) Industrial Property Code[1001]	The rights conferred by a patent do not extend to: [..] c) Acts performed exclusively for trial or experimental purposes, including experiments for the preparation of theadministrative processes required for the approval of products by the competent official bodies, though industrial or commercial exploitation of these products may not commence before expiry of the patent protecting them.[1002]	The exception is **broader** than under Art. 10(6) Dir. 2001/83/EC or Art. 13(6) Dir. 2001/82/EC since it is not limited to generic products. Further, it covers also activities directed to obtain an MA in third countries.
Romania	Art. 80(a) Implementing Regulations to Patent Law No. 64/1991[1003] and Law 95/2006 on healthcare reform, Title XVII – The Medicinal Product, art. 696 to 705 (in particular art. 704(1)-(6))[1004]	In the application of Art. 34 paragraph (1) letter e) of the Law, the following shall not constitute an infringement of the rights provided for in Art. 32 and 33 of the Law: a) the carrying out of the tests and studies necessary for obtaining the authorisation for placing a medicament on the market, as well as the practical requirements resulting therefrom.[1005] Law 95/2006 on healthcare reform Art. 600(4) (6) Conducting the necessary studies and trials with a view to the	The *Bolar* exemption laid down in Art. 80(a) Implementing Regulations to Patent Law No. 64/1991 seems to be **broader** than the exemption provided under Art. 10(6) Dir. 2001/83/EC or Art. 13(6) Dir. 2001/82/EC since it is not limited to generic products or to an MA for Romania or EU Member States. However, the *Bolar* provision included in the Law 95/2006 on healthcare reform is limited to

[1000] In contrast to the seemingly broad wording, the law in Poland is interpreted not to extend to activities directed to generate data for an application for an MA outside Poland or the EU. See Piotr Kostański in Piotr Kostański [ed], *Prawo własności przemysłowej* (2nd edn, 2014) Art. 69 para. 36. See also J Ożegalska-Trybalska, *The Bolar exemption – broad or narrow scope of a safe habour in the European patent law*, Zeszyty Naukowe Uniwersitetu Jagiellonskiego prace z prawa wlasnosci intelektualnej 2016, p. 153 refering to K Szczepanowska-Kozłowska, Glosa do wyroku SN z dnia 23 października 2013 r., IV CSK 92/13, OSP 2014/7-8, C 75, p. 1028.

[1001] Decree-Law 36/2003 of 5 March (as amended by Law No. 46/2011, of 24 June).

[1002] Industrial Property Code, Art. 102(c): Os direitos conferidos pela não abrangem: Os actos relizados exclusivamente para fins de ensaio ou experimentais, incluindo experiências para preparação dos processos administrativos necessários à aprovação de produtos pelos organismos oficiais competentes, não podendo, contudo, iniciar-se a exploração industrial ou commercial deses produtos antes de se verificar a caducidade da patente aue os protege; Text in Portuguese available at http://www.marcasepatentes.pt/files/collections/pt_PT/1/2/14/CPI%202003.pdf (last accessed 24 September 2017). Text in English available at http://www.marcasepatentes.pt/files/collections/eng_US/1/Industrial%20Property%20Code%20%28Searchable%20PDF%29.pdf (last accessed 24 September 2017).

[1003] Implementing Regulations to the Patent Law No. 64/1991 as republished in Official Gazette of Romania, Part I, No. 456/18.Vi.2008, Art. 80: În aplicarea prevederilor art. 34 alin. (1) lit. e) din lege, nu constituie încălcarea drepturilor prevăzute la aer. 32 şi 33 din lege: a) Desfăşurea testelor şi studiilor necesare în scopul obţinerii autorizaţiei de punere pe piaţă a unui medicament, precum şi cerinţele practice care rezultă din acestea.

[1004] See at http://www.iracm.com/wp-content/uploads/2013/01/the-medicinal-product-of-law-nr-95-2006-on-healthcare-reform-2006-4296.pdf (last accessed 24 April 2018).

[1005] Please note that the Implementing Regulations refer to the Patent Law No. 64/1991 as republished in the Official Gazette of Romania, Part I, no. 541/ 8 August 2007. There is a most recent republication of the Patent Law No. 64/1991 in the Official Gazette of Romania, Part I, No.613/19 August 2014 (under

		application of paragraphs (1), (2), (3) and (4) and the consequential practical requirements shall not be regarded as contrary to patent rights or to supplementary protection certificates for medicinal products.	activities directed to generate data for an MA filed under Art. 704(1)-(4). According to the information collected[1006], it is possible that this provision covers only activities directed to generate data for obtaining an MA in Romania or in the EU Member State. Indeed, under Art. 696 to 705 of the Law 95/2006, (especially art. 702 (3)) „ a MA may only be granted to an applicant established in Romania or a Member State". For the purpose of this Title, the term "third countries" refers to „states other than Romania and Member States".[1007]
Slovak Republic	Art. 18(1)(f) Patent Act[1008]	The rights of a patent owner shall not be infringed if an invention is exploited: f) in activity conducted for experimental purposes which shall also be studies, exams necessary for registration proceedings pursuant to a special regulation (Act No 362/2011 on Medicines and Medical Devices).	The exception is **broader** than that provided under Art. 10(6) Dir. 2001/83/EC or Art. 13(6) Dir. 2001/82/EC as it concerns also innovative drugs. [1009] Further, it encompasses studies directed to obtain an MA in third countries.
Slovenia	Art. 45 Para. 8 of the Medicinal Products Act[1010]	Notwithstanding the provisions of regulations governing the patent rights or the rights of a	The exception seems to be **broader** than that provided under Art. 10(6)

this new version, the former Art. 32 becomes Art. 31, the former Art. 33 becomes Art. 32 and the former Art. 34 becomes Art. 33). Text in Romanian Implementing Regulations to the Patent Law No. 64/1991 as republished in Official Gazette of Romania, Part I, No. 456/18.Vi.2008, available at http://www.osim.ro/legislatie/brevete/regulamentlege64.pdf (last accessed 26 September 2017). Text in English Implementing Regulations to the Patent Law No. 64/1991 as republished in Official Gazette of Romania, Part I, No. 456/18.Vi.2008, available at http://www.osim.ro/index3_files/laws/patents/implementingregmodif.pdf (last accessed 26 September 2017). Text in Romanian Patent Law No. 64/1991 as republishes in the Official Gazette of Romania, Part I, No.613/19 August 2014, available at http://www.osim.ro/legislatie/brevete/Legea_nr64_1991_ rep2014.pdf (last accessed 26 September 2017). Text in English Patent Law No. 64/1991 as republished in the Official Gazette of Romania, Part I, No.613/19 August 2014, available at http://www.osim.ro/index3_files/laws/patents/Legea_nr64_1991_ rep2014-en.pdf (last accessed 26 September 2017).

1006 Concidearations of RO NPO, correspondence between the MPI and RO NPO.

1007 *Ibid.*

1008 Act No. 435/2001 Coll. on Patents, Supplementary Protection Certificates and on Amendment of Some Acts as Amended (last amended by Act No. 202/ 2009 Coll.), Art. 18(1): Práva majiteľa patentu nie sú porušené, ak sa vynález využije:
f) pri činnosti vykonávanej na experimentálne účely, za ktoré sa považujú aj štúdie a skúšky nevyhnutné na registračné konanie podľa osobitného predpisu (Zákon č. 140/1998 Z.z. o liekoch a zdravotníckych pomôckach, o zmene zákona č. 455/1991 Zb. o živnostenskom podnikaní (živnostenský zákon) v znení neskorších predpisov a o zmene a doplnení zákona Národnej rady Slovenskej republiky č. 220/1996 Z.z. o reklame v znení neskorších predpisov). Text in Slovak available at https://www.indprop.gov.sk/swift_data/source/pdf/legislativa/platne_pravne_predpisy/pravo_01435.pdf (last accessed 25 September 2017). Text in English available at https://www.indprop.gov.sk/swift_data/source/pdf/legislation/pravo_01435.pdf (last accessed 25 September 2017).

1009 Zuzana Fialova Kamenska, 'Regulatory approval exception from patent infringement – Exactly how far does the *Bolar* exemption stretch?' A Thesis submitted to the Munich Intellectual Property Law Center, 16 September 2015, p. 26.

1010 Medicinal Products Act, Official Gazette of the Republic of Slovenia Nr. 17/14, available at http://www.pisrs.si/Pis.web/pregledPredpisa?id=ZAKO6295 Text in English available at

		supplementary protection certificate for a medicinal product, the implementation of studies necessary to comply with the requirements of this Act and other requirements related to the acquisition of marketing authorisation shall not be deemed to be a violation of patent rights or the rights arising from a supplementary protection certificate for a medicinal product.	Dir. 2001/83/EC or Art. 13(6) Dir. 2001/82/EC since it is not limited to generic products. Further, it seems to encompass also activities directed to obtain an MA in third countries.
Spain	Art. 61(1)(c) Law of Patents[1011]	The rights conferred by the patent shall not extend to: [..] (c) The studies and trials required to obtain the marketing authorisation for medicinal products in Spain or outside Spain, as well as the subsequent practical requirements, including the preparation, obtention and use of the active ingredient with these purposes.	The exception is **broader** than that provided under Art. 10(6) Dir. 2001/83/EC or Art. 13(6) Dir. 2001/82/EC since it is not limited to generic products. Further, it encompasses activities directed to obtain an MA in third countries.
Sweden	Art. 3, Para. 3(4) Patents Act[1012]	The following acts are exempted from the exclusive right: 4. studies, tests, examinations and practical measures which concern a reference medicine to the extent that these are necessary for obtaining an approval for the sale of a medicine according to Article 8 of the Act (1992:859) on Medicinal Products or for other proceedings for approval based on Article 10.1–4 of the Directive 2001/83/EC of	The material scope of Swedish *Bolar* exemption is at least in one aspect **broader** to that provided under Art. 10(6) Dir. 2001/83/EC or Art. 13(6) Dir. 2001/82/EC as it covers not only studies for obtaining an MA for generic products but also innovative products.[1013] Furthermore, it covers activities to obtain an MA

https://www.jazmp.si/fileadmin/datoteke/seznami/en/ZZdr-2_ANG.pdf (last accessed 27 October 2017).

1011 Law 24/2015, of 24 of July, of Patents, Art. 61(1): Los derechos conferidos por la patente no se extienden:
c) A la realización de los estudios y ensayos necesarios para obtener la autorización de comercialización de medicamentos en España o fuera de España, y los consiguientes requisitos prácticos, incluida la preparación, obtención y utilización del principio activo para estos fines. Text in Spanish available at http://www.oepm.es/export/sites/oepm/comun/documentos_relacionados/Propiedad_Industrial/Normativa/Ley_24_2015_de_24_de_julio_de_Patentes.pdf (last accessed 24 September 2017).
Text in English: our translation.

1012 The Patents Act (Swedish Statute Book, SFS, 1967:837, in the version in force from July 1, 2014), Art. 3, para. 3: Från ensamrätten undantas
4. studier, prövningar, undersökningar och praktiska åtgärder som hänför sig till ett referensläkemedel, i den utsträckning dessa är nödvändiga för att få ett godkännande för försäljning av ett läkemedel med tillämpning av 4 kap. 13 § läkemedelslagen (2015:315) eller i andra förfaranden för godkännande som baseras på artikel 10.1-10.4 i Europaparlamentets och rådets direktiv 2001/83/EG av den 6 november 2001 om upprättande av gemenskapsregler för humanläkemedel, i lydelsen enligt Europaparlamentets och rådets direktiv 2004/27/EG, eller artikel 13.1 i Europaparlamentets och rådets direktiv 2001/82/EG av den 6 november 2001 om upprättande av gemenskapsregler för veterinärmedicinska läkemedel, i lydelsen enligt Europaparlamentets och rådets förordning (EG) nr 596/2009, eller artikel 13.2-13.5 i direktiv 2001/82/EG, i lydelsen enligt Europaparlamentets och rådets direktiv 2004/28/EG.
Text in Swedish available at http://www.riksdagen.se/sv/dokument-lagar/dokument/svensk-forfattningssamling/patentlag-1967837_sfs-1967-837 (last accessed 26 September 2017). Text in English available at https://www.prv.se/globalassets/dokument/patent/informationsmaterial/the-patents-act---unofficial-translation.pdf (last accessed 26 September 2017).

1013 Ändring av patentlagen (1967:837), Prop. 2005/06:70, p. 179.

		the European Parliament and of the Council of 6 November 2001 on the Community Code relating to Medicinal Products for Human Use, as last amended by Directive 2004/27/EC of the European Parliament and of the Council, or Article 13.1–13.5 of Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code Relating to Veterinary Medicinal Products, as last amended by Directive 2004/28/EC of the European Parliament and the Council [..].	in Sweden and also in other EU Member States but not in third states.
United Kingdom	§60(5)(i) and §60(6D)–(6G) Patents Act[1014]	(5) An act which, apart from this subsection, would constitute an infringement of a patent for an invention shall not do so if – [...] (i) it consists of - (i) an act done in conducting a study, test or trial which is necessary for and is conducted with a view to the application of paragraphs 1 to 5 of article 13 of Directive 2001/82/EC or paragraphs 1 to 4 of article 10 of Directive 2001/83/EC, or (ii) any other act which is required for the purpose of the application of those paragraphs. […] (6D) For the purposes of subsection (5)(b), anything done in or for the purposes of a medicinal product assessment which would otherwise constitute an infringement of a patent for an invention is to be regarded as done for experimental purposes relating to the subject-matter of the invention. (6E) In subsection (6D), "medicinal product assessment" means any testing, course of testing or other activity undertaken with a view to providing data for any of the following purposes— (a) obtaining or varying an authorisation to sell or supply, or offer to sell or supply, a medicinal product (whether in the United Kingdom or elsewhere);	The exception is **broader** than that provided under Art. 10(6) Dir. 2001/83/EC or Art. 13(6) Dir. 2001/82/EC since it does not differentiate between generic and innovative products and thereby is not limited to generic products. It covers any acts necessary for obtaining an MA "whether in the UK or elsewhere" so it has no limitations of the place where the MA is applied for.[1015] Further, it covers activities necessary for health technology assessments.[1016]

[1014] Patents Act 1977, as amended 1 October 2014, available at https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/647792/Consolidated_Patents_Act_1977_-_1_October_2017.pdf (last accessed 27 October 2017).

[1015] See also House of Commons, Regulatory Reform Committee, Draft Legislative Reform (Patents) Order 2014, HC 331, published on 16 June 2014, pp. 4-5.

[1016] Joseph Straus, 'The *Bolar* exemption and the supply of patented active pharmaceutical ingredients to generic drug producers: an attempt to interpret Article 10(6) of Directive 2004/27' [2014] 9(11) Journal of Intellectual Property Law & Practice 895.

		(b) complying with any regulatory requirement imposed (whether in the United Kingdom or elsewhere) in relation to such an authorisation; (c) enabling a government or public authority (whether in the United Kingdom or elsewhere), or a person (whether in the United Kingdom or elsewhere) with functions of— (i) providing health care on behalf of such a government or public authority, or (ii) providing advice to, or on behalf of, such a government or public authority about the provision of health care, to carry out an assessment of suitability a medicinal product for human use for the purpose of determining whether to use it, or recommend its use, in the provision of health care. (6F) In subsection (6E) and this subsection— "medicinal product" means a medicinal product for human use or a veterinary medicinal product; "medicinal product for human use" has the meaning given by article 1 of Directive 2001/83/EC(2); "veterinary medicinal product" has the meaning given by article 1 of Directive 2001/82/EC(3). (6G) Nothing in subsections (6D) to (6F) is to be read as affecting the application of subsection (5)(b) in relation to any act of a kind not falling within subsection (6D).	

Table 15.1: *Bolar* exemption in the EU Member States

The provisions reported above apply to both national and European patents (Art. 64(1) EPC). However, their practical relevance will be greatly reduced with the coming into force of the Unified Patent Court Agreement (UPCA).[1017]

15.4.1.3 The impact of the UPCA on the Bolar exemption

(a) *Art. 27 (d) UPCA*

Pursuant to Art. 27(d) UPCA the rights conferred by the patent do not extend to "the acts allowed pursuant to Art. 13(6) Dir. 2001/82/EC or Art. 10(6) Dir. 2001/83/EC in respect of any patent covering the product within the meaning of either of those Directives". The provision incorporates by reference the wording of the Directives in

[1017] The UPCA and the Patent Package and their interaction with the SPC legislation are addressed in Chapter 21 of this Study.

the UPCA. In consequence, Art. 27(d) UPCA excludes the application of domestic provisions that implement the Directives and that apply at the moment to European patents under Art. 64(1) EPC. Under Art. 27(d) UPCA, only acts covered by the wording of Art. 13(6) Dir. 2001/82/EC and Art. 10(6) Dir. 2001/83/EC are exempted from infringement.

This legislative choice has positive aspects insofar as it establishes a uniform exemption that applies in all proceedings brought before the UPC.[1018] On the other hand, this means that once Art. 27(d) UPCA has become operational, some EU Member States will have to apply different types of *Bolar* exemptions to European and national patents. Further, the provision will frustrate the policy choices of some EU Member States that have decided to adopt a broader exemption than that laid down in Art. 10(6) Dir. 2001/83/EC.[1019] We explain these two points below.

(b) *Fragmentation of the applicable law in the same Member States*

In each Member State the *Bolar* exemption is currently defined by domestic legislation.[1020] It applies in that form to national and European patents alike. When the UPCA comes into force the situation will change:

- Article 27(d) UPCA will apply to European patents with unitary effect pursuant to Art. 5 Reg. 1257/2012 and to European patents without unitary effect pursuant to Art. 149a EPC.[1021]
- The domestic provisions implementing Art. 13(6) Dir. 2001/82/EC and Art. 10(6) Dir. 2001/83/EC will apply to national patents and – according to the prevailing view[1022] – to European patents litigated before the national courts in consequence of an action for infringement brought under Art. 83(1) UPCA or in

[1018] This is different from the prior use right, which is entirely left to national law; see Art. 28 UPCA.

[1019] Paul England et al, 'Going full circle: *Bolar* in Europe and the UPC' [2014] 14 Bio-science Law Review 2, 31 et seqq.

[1020] More precisely: domestic legislation implementing Art. 13(6) Dir. 2001/82/EC and Art. 10(6) Dir. 2001/83/EC.

[1021] Some are of the opinion that pursuant to Art. 7 the UPC will have to apply the national provision implementing the Directives. We cite as an example the following opinion given in Liz Cohen, Laura Peirson, 'The UK research and "*Bolar*" exemptions: broadening the scope of innovation?' [2013] JIPLP 837, 845: "The UPC Agreement could give rise to further unusual situations regarding governing law. Articles 5 and 7 of the UPC Regulations provide for the governing law for exemptions to patent infringement under the UPC system. Article 7 specifies that the laws of the country in which the applicant's principal place of business is located at the date of filing or the country in which the applicant has a place of business at the date of filing will govern proceedings involving the experimental use or EU *Bolar* exemptions. Due to the various modes of implementation of the Directive across Europe, this could cause considerable complications, particularly if the applicant's business is located in more than one EU Member State. If, however, there is no applicable place of business in a participating Member State, the law of Germany would apply as the location of the European Patent Organisation's headquarters. This may lead to a scenario whereby patent proceedings take place in the UK involving an exemption to infringement and because the applicant is based solely outside the EU/EEA, German law would apply. As German law implements the exemptions broadly, the arrival of the UPC may provide additional ammunition for broadening the scope of the UK exemptions in line with the Government's current proposal". We disagree with this opinion because Art. 5 Reg. 1257/2012 refers to the law applied to the unitary patent and not the law applied to national patents; such law will consist in each EU Member State in which the unitary effect exists in the UPCA. See Tilman Müller-Stoy, Florian Paschold, 'European patent with unitary effect as property right' [2014] 9(10) JIPLP 848, 859; see *infra* Chapter 21, Section 21.4.3.

[1022] Preparatory Committee, Interpretative note – Consequences of the application of Article 83 UPCA, available at https://www.unified-patent-court.org/news/interpretative-note-%E2%80%93-consequences-application-article-83-upca (last accessed 25 September 2017); see for an opposing view Roberto Romandini, Reto Hilty, Matthias Lamping, 'Stellungnahme zum Referentenentwurf eines Gesetzes zur Anpassung patentrechtlicher Vorschriften auf Grund der europäischen Patentreform' [2016] 65(6) GRUR Int. 554.

consequence of an opt-out declaration filed by the patent owner by the deadline stipulated in Art. 83(3) UPCA.

As a consequence, the same act performed by a third party could be considered as infringing or not infringing, depending on whether

- it is committed before or after the entry into force of the UPCA;
- the patent is litigated before the UPC or a national court;
- the patentee has opted out of the exclusive competence of the UPC or has withdrawn such opt-out.

We sum up this fragmentation in the two tables below, the first concerning the applicable *Bolar* regime before the UPCA and the second concerning the applicable *Bolar* regime after the UPCA comes into force:

Category of patents	National patents	European patents
***Bolar* exemption regime**	National provisions implementing Art. 10(6) Dir. 2001/83/EC and Art. 13(6) Dir. 2001/82/EC	National provisions implementing Art. 10(6) Dir. 2001/83/EC and Art. 13(6) Dir. 2001/82/EC apply pursuant to Art. 64(1) EPC

Table 15.2: *Bolar* exemption in Europe pre-UPCA

Category of patents	National patents	Unitary patent	European patents without unitary effect subject to the UPC exclusive competence	European patents opted out of UPC exclusive competence (Art. 83(1) UPCA)	European patents in respect to which the proprietor has withdrawn the opt-out (Art. 83(3) UPCA)
***Bolar* exemption regime**	National provisions implement-ing Art. 10(6) Dir. 2001/83/EC and Art. 13(6) Dir. 2001/82/EC	Art. 27(d) UPCA applies pursuant to Art. 5(1) Reg. 1257/2012	Art. 27(d) UPCA applies pursuant to Art. 149a EPC if litigation is started before the UPC; National provisions implementing Art. 10(6) Dir. 2001/82/EC and Art. 10(6) Dir. 2001/83/EC	National provisions implementing Art. 10(6) Dir. 2001/83/EC and Art. 13(6) Dir. 2001/82/EC shall apply to acts performed by third parties after the opt-out; Art. 27(d) UPCA shall apply to acts performed by third parties before the opt-out	Art. 27(d) UPCA shall apply to acts performed by third parties after the withdrawal of the opt-out; National provisions implementing Art. 10(6) Dir. 2001/83/EC and Art. 10(6) Dir. 2001/82/EC shall apply to acts

			apply if litigation is started before the national courts under Art. 83(1) UPCA		performed by third parties before the withdrawal of the opt-out

Table 15.3: *Bolar* exemption after the UPCA

The UPCA also entails the risk that national legislation exceeding the minimum standard enshrined in the Directives becomes ineffective in practice. The patentee could avoid the application of broad exemptions laid down in national law by filing a European application and by requesting a unitary effect or by enforcing a European patent without unitary effect before the UPC. Even if the patentee has chosen to opt out of the UPC, it can always withdraw its opt-out declaration during the lifetime of the patent, with the effect of preventing the application of more generous provisions laid down in national law.

15.4.1.4 Options and recommendation

(a) *The options*

In order to avoid the consequences potentially resulting from the reference in Art. 27(d) UPCA to Dir. 2001/82/EC and Dir. 2001/83/EC, the following options can be envisaged:

A first option (hereinafter: **Option 1**) could be for the EU Member States participating in the enhanced cooperation to amend Art. 27(d) UPCA and include a reference not only to the Directives, but to the national provisions implementing them. This solution was provided in earlier versions of the Draft Agreement on the European Union Patent Court.[1023] It ensures that the *Bolar* exemption as set forth in national law continues to apply to all patents granted with effect for the territory of the EU States, irrespective of whether they are national or European patents, and whether they are litigated before the UPC or a national court. The solution thus fully respects the policy choices of the individual Member States in designing the scope of the *Bolar* exemption. However, it has an obvious shortcoming: the deference to national law is inconsistent with the purposes of the unified patent system to ensure the correct functioning of the common market and with the operation of a unified jurisdiction that shall apply the same law of infringement in the whole territory of protection.

A second option (hereinafter: **Option 2**) would be to enact EU legislation defining the scope of the exemption not as a minimum rule, but in a mandatory manner. While

[1023] See Draft Agreement on the European Union Patent Court and draft Statute (Working document), No. prev. doc.: 11270/08 PI 32 COUR 32, 4 November 2008. Art. 14e of the Draft Agreement did not provide for a *Bolar* exemption. According to Art. 14a of the Draft Agreement the Court shall base its decision on any provision of community law and national law implementing Community law, as well as international agreements, applicable to patents, including Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions [1998] OJ L 213/13. As a result of these provisions, the Court could, in proceedings brought before it, have applied the national law implementing Art. 13(6) Dir. 2001/82/EC and Art. 10(6) Dir. 2001/83/EC. This would of course have caused a fragmentation of the law applicable to the patents enforced before the Court, but it would have prevented the application of two different regimes of law in the same Member State.

that solution has the advantage of providing for uniform conditions throughout the EU, the downside is that by eliminating the current divergences in the substantive provisions, the deference to Member States' policy choices that the first option seeks to preserve would be discarded. However, the lawmakers could opt for an exemption that is broader than the minimum standard laid down in Art. 10(6) Dir. 2001/83/EC and Art. 13(6) Dir. 2001/82/EC. Such exemption could cover studies for obtaining an MA for both generic and innovative drugs, in the EU or in third countries. In this way, the majority of the EU Member States would not be obliged to amend substantially the legislation in force.

(b) *Recommendation*

As has become clear from the options presented above, a choice must be made between a system that preserves Member States' freedom to legislate on the *Bolar* exemption and a system that provides for full harmonisation and thereby creates uniform conditions for all stakeholders acting on the common market. We are of the opinion that preference should be given to the second approach for the following reasons.

First, uniformity creates a level playing field and discourages strategic behaviour, such as opting out of (or back into) the exclusive competence of the UPC in order to avoid the application of broad national *Bolar* exemptions. Second, only a uniform regime of exemptions is truly consistent with the overarching goal of improving the functioning of the common market that the unified patent system is meant to serve. This aspect should guide the legislative action taken in this field, in particular because the provisions governing the rights and their limitations are of paramount importance for the functioning of the common market.[1024]

This leaves the question to be decided by the EU legislature which legislative model to adopt as a mandatory rule. Making that choice is primarily a policy issue which also requires some economic considerations. We are not in the position to assess the impact that a broad *Bolar* exemption would have on innovators and generic companies located in Europe.[1025] However, there are certain indications that adopting a broad *Bolar* exemption, such as that provided under German or British law, presents the most acceptable – or at least not a strongly objectionable – option for a majority of stakeholders and Member States.

This view is based on the following observations:

[1024] See Winfried Tilmann, 'The Battle about Articles 6-8 of the Union-Patent-Regulation', HC 1799 European Scrutiny Committee, available athttps://publications.parliament.uk/pa/cm201012/cmselect/cmeuleg/1799/1799vw06.htm, who in discussing the reservation against an involvement of the CJEU in interpreting the rules on infringing acts with respect to unitary patents observes "these provisions are defining the border-line of patent law to public use ie patent-free use, free commercial competitive behavior. They belong to the sort of questions the ECJ has to answer for defining the border-line of CTMs and free use. They have neighboring questions in the fields of exhaustion law and competition law and they describe the tort-law actions against infringing practices. Taken together, one can even say that the ECJ should have a say in defining these border-lines between the patent right and competition, since he is the ultimate controller of a functioning competition, of the free movement of goods and services and the functioning of the internal market the border-line of patent law to public use ie patent-free use, free commercial competitive behavior".

[1025] Such as the amount of reduction of FoA costs for companies, or whether a broad exemption could prevent a relocation of research centres and an outsourcing of clinical trials from the EU to other jurisdictions.

- The information obtained in the interviews conducted by the MPI, as well as the results of the Allensbach Survey, suggest that a broad *Bolar* exemption – such as that provided under UK legislation – is not met with profound opposition or concerns by the stakeholders. The majority of the stakeholders that answered Q65 of the Allensbach Survey (61 per cent of the total respondents) were in favour of a broad *Bolar* exemption in line with the UK legislation.[1026] The majority of the respondents to Q64 of the Allensbach Survey (57 per cent of the total respondents) were also of the opinion that the scope of the exemption is a relevant factor for the decision where to conduct clinical or pre-clinical trials.[1027] We are aware that the population consulted by the Allensbach survey can not be considered a representative sample.[1028] The same holds true for the companies interviewed. However, the fact that both sets of data showed a preference for a broad exemption (also covering activities aimed at obtaining marketing approval for any medicinal product and marketing authorisation outside the EU) cannot be discarded as completely irrelevant either. This preference reflected in the interviews and in the Allensbach Survey was also confirmed by the contributions at the MPI Workshop in Munich on 20 March 2017.
- A broad *Bolar* exemption is already provided in Germany, Italy and France, and was recently adopted in Ireland and the UK. Together these countries represent a significant portion of the common market in its current dimensions. In the UK the new infringement defence, complementing the older *Bolar* exemption under Sec. 60 Patents Act 1977 and framed as a specification of the experimental exemption, was adopted after a consultation with the stakeholders. This lends some support to the expectation that the – primarily economic – reasons for the UK and Ireland to include the broadest type of *Bolar* exemption in their domestic legislation could prove to be persuasive for other EU States as well.[1029]
- Comparative insight confirms that the tendency outside Europe leans toward exemptions with a broader scope than the scope of the defence laid down in Art. 10(6) Dir. 2001/83/EC or Art. 13(6) Dir. 2001/82/EC.[1030]

(c) *Implementation of the options*

Option 1[1031] requires an amendment of the UPCA. For such an amendment a conference for the revision of the UPCA under international law and a ratification by the Member States are necessary. It is true that the UPCA provides two options for carrying out a revision of the treaty in a simplified procedure. However, neither of these options seems to allow the inclusion of a reference to national law in Art. 27(d) UPCA, at least not in the short term. First, pursuant to Art. 87(1) UPCA, the Administrative Committee may decide to revise the Agreement with a view to improving the functioning of the Court, either after seven years from the entry into

[1026] See Annex III of this Study, pp. 251-253.
[1027] See Annex III of this Study, p. 250.
[1028] See Annex IV of this Study.
[1029] Those arguments hold that the possible effect of a broad exemption could be: to reduce legal costs (FTAs, oppositions, revocation actions) for companies located in the UK or IE, to avoid discrimination of local companies that could not afford to relocate research centres abroad, to put domestic companies on an equal footing with companies located in jurisdictions with shorter terms of protection or broader *Bolar* exemptions, and finally to prevent a relocation of clinical trials outside the UK and IE.
[1030] See Chapter 23 of this Study, Section 23.10.
[1031] That is, re-establishing the regulatory sovereignty of the Member States by including in Art. 27 UPCA a reference to the national rules implementing the Directives, see above Section 15.4.1.4 (a).

force of the Agreement, or once 2,000 infringement cases have been decided by the Court, whichever is later. Even if one would accept that changes to the substantive law of infringement may be covered by the purpose of improving "the functioning of the Court" and that the inclusion of a reference to national law can serve this purpose in some way – which is doubtful – the timing of the revision would be uncertain. Second, pursuant to Art. 87(2) UPCA, the Administrative Committee can amend the treaty to bring it into line with Union law. This would require that pertinent Union law be adopted by the EU legislature. However, the purpose of EU legislation in the case considered here would only be to make the national law implementing the Directives applicable under the UPCA. A provision of that kind seems to be outside the possible purposes of an act of EU legislation adopted under the TEU.

Option 2[1032] can be implemented by adopting Union legislation. This would allow the Administrative Committee to amend the UPCA under Art. 87(2) UPCA. The implementation of that option requires a differentiated approach depending upon the kind and purpose of the studies and activities that are to be exempted.

As regards the exemption of acts performed to obtain an approval for products on the basis of a full dossier under Art. 8 Dir. 2001/83/EC and Art. 12(3) Dir. 2001/82/EC, it is necessary, but also sufficient, to amend both Directives. A provision could be included in both Directives stipulating that the necessary studies and trials for the purpose of applying or obtaining *any authorisation* to place a medicinal or veterinary product on the market that is to be granted in accordance with a procedure laid down in Dir. 2001/83/EC or Dir. 2001/82/EC are exempted from patent infringement.

Regarding the exemption of activities directed to obtaining an approval for marketing a product in a non-EU country – for instance, in the US – the situation is more complex. The Directives concerned and the Regulations referred to have the purpose of regulating the conditions for placing medicinal products for human or veterinary use on the market in EU Member States, and of providing for centralised or harmonised procedures for granting authorisation for this purpose. Thus, the regulatory goal of Dir. 2001/82/EC and Dir. 2001/83/EC is not to harmonise patent law as such. Where provisions included in Dir. 2001/82/EC and Dir. 2001/83/EC entail such harmonising effects, this must be justified by the proper scope and purpose of the Directives. The conditions for placing a product on the market outside Europe and the activities necessary to generate the data for this purpose are not within the objectives pursued by the Directives. Therefore, it would be problematic to regulate within them exemptions concerning activities that are not necessary for, or not related to, obtaining a manufacturing licence or an MA in accordance with the procedure laid down in Dir. 2001/82/EC and Dir. 2001/83/EC.

More appropriately, the extension of the *Bolar* exemption to activities relating to non-EU product authorisations could be addressed in a separate directive aimed at harmonising certain exemptions to patent infringement. Apart from promulgating a broad *Bolar* exemption such directive could address other exemptions that are relevant for the functioning of the common market, for instance experimental use (see below, 15.4.2) and prior use rights.[1033] In addition, Reg. 1257/2012 could be amended

[1032] That is, espousing a uniform standard that is broader than the exemption currently laid down in Art. 10(6) Dir. 2001/83/EC and Art. 13(6) Dir. 2001/82/EC, see above Section 15.4.1.4 (a).

[1033] Until now the prior use right is only regulated in a uniform manner for Community designs (see Art. 22 Reg. 6/2002), while it is entirely left to national law in the UPC context; see Art. 28 UPCA.

so as to incorporate the same exemption(s) with respect to the European patent with unitary effect. Such a provision would have immediate effect in the context of UPC proceedings, due to the prerogative of EU law set forth in Art. 20 UPCA. Furthermore, based on Art. 87(2) UPCA, in conjunction with pertinent EU legislation (whether in the form of a directive or an amendment to Reg. 1257/2012), the Administrative Committee could implement such provision in the UPCA, so that it also becomes binding for European patents without unitary effect. Lastly, the obligation under EU Directives to transpose the provisions into domestic law would ensure that the same exemption(s) would apply to national patents.

15.4.1.5 Plant protection products and medical devices

No provision corresponding to Art. 13(6) Dir. 2001/82/EC or Art. 10(6) Dir. 2001/83/EC is laid down in Dir. 91/414/EEC concerning the placing of plant protection products on the market. As a consequence, activities directed to obtaining an MA under the latter Directive are not exempted from infringement, unless they are covered by the general experimental exemption. This will seldom be the case.

Some national laws, for instance the Latvian Patent Act, provide that the *Bolar* exemption applies to plant protection products as well.[1034] Also, in the process concerning the review of the UK legislation, some stakeholders expressed the opinion that "plant protection products should be included in the exemption as the logic is the same as for medicinal and veterinary products".[1035] A similar petition was submitted by the industrial association representing the plant product generic industry on the occasion of the MPI Stakeholder Seminar:[1036]

> The non-existence of the *Bolar* Exemption for plant protection products deters generic companies from carrying out the tests required to obtain marketing authorization until after patent expiry, due to the potential risk of patent infringement. This results in a delayed market entrance of generic plant protection products and has the consequence of giving the patent holder a de facto extension of the patent term beyond the 20 years (or 25 years considering the maximum duration of SPCs). This situation is in fact most derogatory to the balance sought by the patent system between rewarding innovation and allowing subsequent competition by others. The reasons for a differentiated treatment of activities directed to product approval for a medicinal product and the activities directed to authorisation for a plant protection product require a more detailed consideration that cannot be done within the time-frame of the present Study. In principle, it seems contradictory that the patentee in this field can benefit from the delay of generic competition following from the existence of an SPC and cumulate the same with the delay of generic competition following from the need for competitors to obtain product approval.

In the US model, the *Bolar* exemption and patent extension both address the same problem, namely the "the dual distorting of regulatory approval requirements".[1037] Indeed such pre-marketing regulatory approval delays both the exploitation of the invention by the patentee at the beginning of the patent term and competition by third parties after the expiration of the patent term. Thus, while the extensions compensate the patentee for this disadvantage, the *Bolar* exemption compensates the competitor who wants to enter the market after the expiration of the patent for this disadvantage.

[1034] See § 20(3) Patent Law, Vēstnesis, 27 February 2007, No. 34 (as amended on 14 October 2010 and 15 December 2011), text in English available at: https://www.lrpv.gov.lv/en/inventions/law (last accessed 25 September 2017).

[1035] UK IPO, 'The Research and *Bolar* Exception: Proposals to exempt clinical and field trials using innovative drugs from patent infringement', February 2013, available at http://webarchive. nationalarchives. gov.uk/20140603101058/http://www.ipo.gov.uk/response-2012-*Bolar*.pdf (last accessed 13 November 2017) p. 13.

[1036] MPI Stakeholder Seminar on 11 September 2017. The submissions are on record with the authors of the Study.

[1037] *Lilly & Co. v Medtronic, Inc.* 496 U.S. 661 (1990).

The American model implies a complementary relationship between the *Bolar* exemption and the patent extension. It is no surprise, therefore, that based on these considerations the Supreme Court has considered medical devices to be covered by the *Bolar* exemption, as a corollary to the fact that medical-device patents can be extended like any other patents for drugs subject to regulatory approval.[1038]

Against this background, it seems consistent with the logic of the *Bolar* exemption to extend its scope to plant protection products. For the same reason, in the case that the legislature should provide supplementary protection for all or some medical devices and companion diagnostics, introducing a *Bolar* exemption with identical scope must also be considered.

15.4.1.6 Summary

- The *Bolar* exemption at the level of Union law is narrower than the exemption provided in the national law of several EU Member States. The countries that have recently amended their patent legislation – such as the UK and Ireland – have adopted a broad exemption. This suggests a tendency to expand the scope of the defence under national law to activities directed to the generation of data for MAs for innovative products, for a product approval outside the EU or for health technology assessment.
- With the UPCA coming into force, the national provisions implementing Art. 13(6) Dir. 2001/82/EC and Art. 10(6) Dir. 2001/83/EC will no longer apply to European patents with unitary effect or to those European patents without unitary effect that are enforced before the UPC. Instead, the narrow exemption laid down in Art. 27(d) UPCA will apply.
- The Allensbach Survey, the interviews and the contributions to the MPI Workshop of 20-21 March 2017 all suggest that the majority of the stakeholders consulted in the course of this Study would favour, or at least not oppose, a broad *Bolar* exemption in line with the UK model.
- Based on the legal analysis, we recommend the adoption of a uniform exemption in national and European law which is broader than the minimum standard currently provided for under Art. 27(d) UPCA. It is suggested that the scope of the exemption be extended beyond generic products and to also cover activities directed to obtaining data for product approval outside the EU/EEA. In addition, we recommend considering whether functionally equivalent defences to infringement should be provided for plant protection products and medical devices, since the logic of the *Bolar* exemption applies to these technical fields as well.
- In order to implement the recommendations, a differentiated approach is needed:

  (i) For the exemption of acts necessary or useful for obtaining regulatory approval as innovative products, that is, pursuance of any MA that may be granted under Dir. 2001/82/EC and Dir. 2001/83/EC, it is sufficient and necessary to amend the two Directives.

  (ii) For the exemption of acts necessary or useful for obtaining regulatory approval outside the EU it is advisable to enact a separate piece of

[1038] *Ibid*.

legislation. This would probably have to be in the form of a harmonisation directive, possibly complemented by a parallel amendment of Reg. 2012/1257. Changes in Reg. 2012/1257 would be immediately binding on the UPC due to Art. 20 UPCA; EU legislation in the form of a directive could be implemented in the UPCA under the simplified procedure pursuant to Art. 87(2) UPCA.

(iii) The creation of a *Bolar* exemption for plant protection products requires an amendment of both the Directive and the UPCA. The latter may be adopted under the simplified procedure laid down in Art. 87(2) UPCA.

15.4.2 Limitation to the rights of the patents/SPCs and third-party suppliers

15.4.2.1 The issue

Pursuant to national and European law the effects of patents do not extend to acts performed for experimental purposes that relate to the subject matter of the patent or to acts covered by the *Bolar* exemption. These provisions allow, for instance, a generic company or an innovative company to make and use an active ingredient for experimental purposes or for generating the data required for obtaining a marketing authorisation.

While this is true for the party conducting the relevant acts itself (i.e. the company or institution conducting the experiments or the studies) it is contentious whether third parties supplying the required active ingredient can rely on the same exemption. Different scenarios can be distinguished in this regard:

> **Scenario I:** A third-party supplier offers and markets the patented substance to research institutions and companies. A company acquires a certain amount of this substance to perform acts that are exempted from infringement under the applicable law.
> **Scenario II:** Company A contacts a third-party supplier and commissions this third party to produce a patented substance. The third-party supplier manufactures the substance and delivers it to Company A, which uses the substance for a purpose exempted from infringement under the applicable law.
> **Scenario III:** Company A contacts a third-party supplier and orders a patented substance that the third party supplier has already manufactured and stocked before the order. The substance is used by Company A for purposes exempted from infringement under the applicable law.
> **Scenario IV:** A university contacts a potential manufacturer (third-party supplier) and instructs it to prepare specific patented cell lines. After having been ensured in writing that the use will be covered by an exemption, the third-party supplier manufactures and delivers the cell lines.

In the literature the prevailing opinion with respect to the experimental exemption is that in **scenario I** the third-party supplier directly infringes the patent.[1039] If the substance is an essential element of the invention, the third-party supplier indirectly infringes the patent. The fact that the supplied party does not infringe the patent because he/she is covered by the *Bolar* exemption or the experimental exemption is not relevant. The exemptions only assist the party that performs the specific acts listed in Art. 27 UPCA and corresponding national provisions. This conclusion is indirectly based on Art. 26(3) UPCA and corresponding provisions of national law according to which *"persons performing the acts*[1040] referred to in Art. 27(a) to (e) shall not be considered to be parties entitled to exploit the invention within the

[1039] Trevor Cook, 'A European Perspective as to the Extent to which Experimental Use and Certain Other Defences to Patent Infringement Apply to Differing Types of Research', A Report for the Intellectual Property Institute, 2006, p. 45.
[1040] Emphasis added.

meaning of paragraph 1". This implies that supplying these persons with an essential element of the invention represents a contributory infringement; *ex fortiori*, supplying them with a product incorporating all the features of the invention is a direct infringement as well.

The literature endorses the opinion that the same conclusion applies to **scenario III.** The manufacture as such for any commercial purpose amounts to an infringement.

Opinions are divided on **scenario II**: in this case one could argue that the third-party manufacturer is just an instrument of the supplied entity, that is, the very agent *(autore mediato)* of the alleged infringing acts. Neither entity (contractor or supplier) in this case should be distinguished and both should benefit from the exemption. However, this is only a position endorsed in the scholarly literature.[1041] We are not aware of case law in this respect.

The same opinion, but also the same reservations, apply to **scenario IV**.

In the case law, the UK courts have arrived at the conclusion – before the Patent Act 1977 – that supplying a patented item for experimental purposes infringes the patent.[1042] In Germany the Düsseldorf District Court has maintained – as *obiter* comment – that a third party supplying material to a specialised laboratory does not infringe the patent only if the testing of that material by the supplied laboratory occurs in the interest and on behalf of the supplier.[1043]

With respect to the *Bolar* exemption, Polish courts have come to the conclusion that the patent is infringed by the supplier even if the supplied party can invoke the *Bolar* exemption,[1044] while a German court has found arguments for questioning this conclusion and referred the issue to the CJEU.[1045] Since the parties settled the dispute, the referral was not decided by the CJEU, but the German and Polish decisions – the facts being equivalent to Scenario I[1046] – are worth analysing in more detail.

15.4.2.2 Astellas Pharma v Polpharma: German referral and Polish judgment

(a) *The factual scenario in the German and Polish proceedings*

The factual scenario of the two cases was similar, but not identical. In both cases, the plaintiff, Astellas Pharma Inc, was the holder of a European patent EP 0 801 067. The patent covers the active ingredient solifenacin, which is marketed under the product name Vesicare.

[1041] Rudolf Kraßer, *Patentrecht* (6th edn, Beck 2009) p. 789; Helmut Eichmann, 'Produktionsvorbereitung und Versuche vor Schutzrechtsablauf' [1977] GRUR 304, 307-308.

[1042] *Hoffmann-La Roche v Harris Pharmaceuticals Ltd* [1977] FSR 200, 203; Dominic Adair et al, *Patents* in Maria Isabel Manley, Marina Vickers (eds), NAVIGATING EUROPEAN PHARMACEUTICAL LAW (Oxford University Press 2015) p. 25.

[1043] District Court of Düsseldorf, *Decision of 3 July 2012*, 4a O 282/10 [2013] IIC 361.

[1044] Supreme Court of Poland, *Astellas Pharma Inc v Polpharma SA*, Decision of 23 October 2013, Case No IV CSK 92/13.

[1045] Court of Appeal of Düsseldorf, *Marktzulassungsprivileg (Marketing Authorisation Privilege),* I-2 U 68/12 [2014] GRUR-RR 100.

[1046] The German case has one additional speciality insofar as the defendants submitted a cease and desist declaration for the future which, however, explicitly did not include constellations similar to Scenario IV.

In the German case, the patentee alleged that the company Polpharma SA, based in Poland, had offered for sale and supplied solifenacin in German territory. The proceedings conducted in Germany were only concerned with the supply to the German generic manufacturer identified as Hexal AG. In the Polish proceedings, the patentee alleged that the defendant had manufactured, advertised and delivered to at least three companies the active ingredient protected by the patent. In both proceedings, the advertising and sale offers were made through the website of the defendant and an insertion in the pharmaceutical magazine SCRIP.

Faced with the allegation of infringement of EP 0 801 067, Polpharma argued in both proceedings that it delivered the active ingredient to generic companies, which should use the active ingredient only for purposes covered by the *Bolar* exemption either under German or Polish law. Polpharma claimed that if the supplied customer could rely on the *Bolar* exemption, the same should be true for the supplier. We summarise below the factual scenario and the arguments made by the defendant.

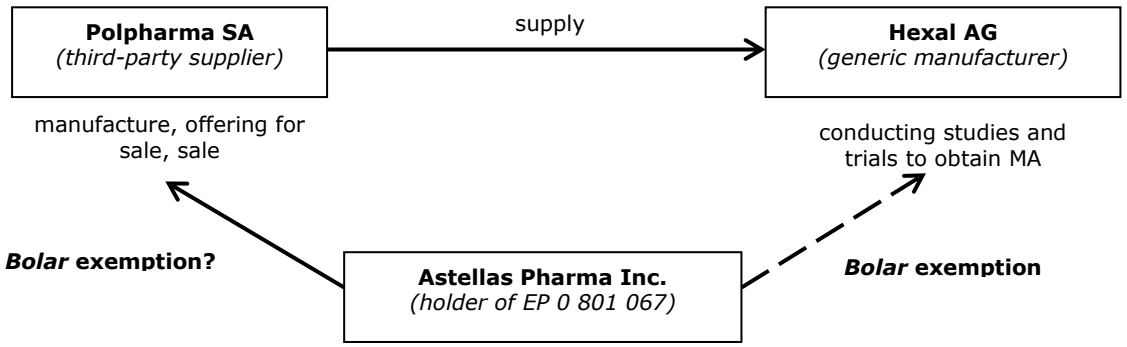

Figure 15.2: Factual constellation and arguments in *Astellas Pharma v Polpharma*

(b) *Supreme Court judgment in Poland*

The Supreme Court of Poland[1047] decided that Polpharma could not rely on the *Bolar* exemption under Polish law.[1048] This conclusion was based on two arguments. On the one hand, the *Bolar* exemption covers only the party that is testing the substance for the purpose of obtaining an MA and is seeking such MA. The exemption does not cover third-party suppliers. On the other hand, the *Bolar* exemption "concerns only the actions necessary for registration in the country where the patent was granted, due to the territorial scope of the protection arising from article 63 of the IPL". The implication of this observation is that even if the exemption could be invoked for the supply of substances, it would apply only if the supplied customer intended to perform studies or trials directed to generating data for obtaining an MA in Poland. The following considerations are relevant for understanding the construction adopted by the Supreme Court:

> This privilege does not cover the use of an invention by an entity which is not planning to move for the registration of generic medication and does not conduct studies necessary for this, but only makes the product using another person's invention in order to subsequently offer and sell it. This action does not fall within the scope of actions necessary to obtain authorisation or

[1047] Supreme Court of Poland, *Astellas Pharma Inc v Polpharma SA*, Decision of 23 October 2013, Case No IV CSK 92/13. The judgment is discussed by Joseph Straus, 'The *Bolar* exemption and the supply of patented active pharmaceutical ingredients to generic drug producers: an attempt to interpret Article 10(6) of Dir. 2004/27' [2014] 9(11) JIPL 895, 896.

[1048] Art. 69(1)(4) of the Polish Industrial Property Law *(Prawo własności przemysłowej)*.

> registration, which constitute a condition for marketing a medication, and there are no grounds to deprive the patent owner of the right to prohibit in respect to such an entity. The essence of the exception provided for in Article 69(1)(4) of the IPL is that it allows the generic medicine manufacturer to conduct bioequivalence tests while patent protection is still in force. Removing obstacles to conducting studies and tests necessary to prepare the documents required in the registration procedure means that patent-related actions are permissible while conducting such studies, and such actions are only carried out by the (future) manufacturer of a generic medicine. For these reasons, despite the complainant's view to the contrary, the opinion that the exception provided for in Article 69(1)(4) of the IPL only works in favour of such an entrepreneur who is preparing to obtain marketing authorisation for a generic medication is correct.[1049]

The court also referred in its conclusion to Arts. 28 and 30 TRIPS. It maintained that, in light of these provisions, the *Bolar* exemption as a limitation of the right of the patent holder has to be interpreted in a restrictive way so that it neither unreasonably conflicts with a normal exploitation of the patent nor unreasonably prejudices the legitimate interests of the patent owner, while taking into account the legitimate interests of third parties. The Polish court put emphasis on the fact that the limitation of the right of the patent owner was to be admitted to the necessary extent – and no further.

(c) *Referral in Germany*

In the parallel German proceedings, the Düsseldorf District Court and Higher Regional Court had to take into consideration the German version of the *Bolar* provision.[1050] At first instance, the Düsseldorf District Court denied Polpharma the defence of the *Bolar* exemption and stated that a third party may only rely on the exemption if it is (a) commercially interested in conducting the studies and trials and (b) has its *own* interest in conducting them. These two requirements must be met cumulatively. Therefore, only if both parties jointly work on the trials and studies (i.e. they are co-organisers[1051]) can they both rely on the exemption.

The Düsseldorf Court of Appeal, the appellate court in this case, was not so sure about the correct interpretation of the respective provisions. It stayed the case and referred two questions to the CJEU:[1052]

> "1. Must Article 10(6) of Directive 2001/83 be interpreted as meaning that those acts of delivery are also excluded from patent protection by which a third party offers or delivers a patented active substance to a manufacturer of generic products for purely commercial reasons, which the manufacturer of generics intends to use for studies or trials in order to obtain a marketing authorisation or approval within the meaning of Article 10(6) of Directive 2001/83?
> 2. If this question is to be answered in the affirmative:
> (a) Does the privileged status of the third party depend on whether the manufacturer of generics supplied indeed uses the provided active substance in privileged studies or trials within the meaning of Article 10(6) of Directive 2001/83? In such a case, does the exclusion from patent protection also apply if the third party is unaware of its customer's intended privileged use and has not ascertained whether this is the case?
> Or does the privileged status of the third party merely depend on whether, at the time of the act of delivery, the third party can rightly assume that, judging all of the circumstances (i.e. profile of the supplied company, small amount of the provided active substance, imminent expiration of the patent protection of the relevant active substance, experience gained concerning the customer's reliability), the supplied manufacturer of generics will use the provided active substance for privileged trials and studies in the context of a marketing approval only?

1049 Supreme Court of Poland, *Astellas Pharma Inc v Polpharma SA*, Decision of 23 October 2013, Case No IV CSK 92/13 (our translation).

1050 Section 11(2b) of the German Patent Act.

1051 Joseph Straus, 'The *Bolar* exemption and the supply of patented active pharmaceutical ingredients to generic drug producers: an attempt to interpret Article 10(6) of Dir. 2004/27/EC' [2014] 9(11) JIPL 895, 897.

1052 Court of Appeal of Düsseldorf, *Decision of 5 December 2013*, I-2 U 68/12 [2014] GRUR Int. 237.

(b) In the context of its act of delivery, is the third party obliged to take separate precautions to ensure that its customer will indeed use the active substance for privileged trials and studies only or do the precautionary measures of the third party differ, depending on whether the patented active substance is merely offered or actually delivered?"

As explained, the case was settled.

15.4.2.3 Initiatives in the EU Member States

At the moment, we are aware of only one initiative in the EU Member States that addresses the question of whether or not the supply of patent-protected APIs for *Bolar* purposes is exempted from infringement. This initiative is pending in Poland. On 17 November 2017, a bill presented by the Minister of Development and Finance to the Parliament and directed to amending the Industrial Property Act was published.[1053] In order to understand the potential impact of the proposal for the law of infringement in Poland, some preliminary information is required.

Polish law is harmonised with the CPC and therefore with the UPCA. More precisely, the right to prohibit direct infringement is provided in Art. 66 of the Act of June 30, 2000, on Industrial Property (as amended by Act of January 23, 2004, and Act of June 29, 2007; hereinafter: IPA). The wording of Art. 66 IPA is in line with Art. 25 UPCA and Art. 28 TRIPS. The limitations to the rights are addressed in Art. 69 IPA. These provisions correspond in function and purpose to Art. 27 UPCA. They also include the *Bolar* exemption, Art. 69(1) IPA, which under Polish law is broader than the minimum standard laid down in Union law.[1054]

This consistency between the UPCA and national law is subject to some exceptions, the most notable of which concerns contributory infringement. Polish law, like Italian and Austrian law until recently, does not provide the right to prohibit the indirect use of the patented invention. This does not mean that supplying an element of the invention is lawful without any qualification under Polish law. It seems likely that general rules on contribution to torts as laid down in the Civil Code could apply to the supply of essential elements of a patented device or product. The Bill of 17 November 2017 intends to introduce an explicit provision dealing with contributory infringement. The wording of the proposal is much in line with Art. 27 UPCA and Art. 30 CPC. Like the European counterpart, it includes the qualification that persons and entities performing one of the acts referred to in Art. 69 IPA shall not be considered as parties entitled to exploit the invention.[1055] The latter provision in the patent legislation of several jurisdictions is traditionally considered as an argument in favour of the thesis that supplying a party with a patented substance or with an essential element of the invention is a direct or contributory infringement, even if the use of the substance intended by the supplied customer is covered by the experimental or *Bolar* exemption. *A fortiori*, the prevailing view in the literature is that the same must be true when the third party has supplied the patented item or substance, that is, in cases of direct

[1053] See blog contribution by Ewa Kacperek, Weronika Wolosiuk, 'Advances in Polish IP law, part 1: Patents – Indirect infringement, limitation of scope & state of the art searches', available at https://www.limegreenipnews.com/2018/01/advances-in-polish-ip-law-part-1-patents-indirect-infringement-limitation-of-scope-state-of-the-art-searches/ (last accessed 15 March 2018).

[1054] Indeed, as already explained in Table 13, Art. 66(1) Sec. 4 covers activities directed to obtaining an MA in third countries and it is not limited to generic products. See J Ożegalska-Trybalska, 'The *Bolar* exemption: broad or narrow scope of safe harbour in European patent law?', Zeszyty Naukowe Uniwersytetu Jagiellońskiego prace z Prawa Własności Intelektualnej, No. 2(132), 2016, 143, 153.

[1055] See Art. 30(3) CPC.

infringement. The exemptions from infringement are considered as limited to the parties that perform the exempted activities. They do not extend to third parties that supply the substances needed for such activities.

Therefore, such provision, if enacted, would confirm the interpretation adopted by the Polish Supreme Court of Art. 69(1) Sec. 4 IPA.

For this reason, an association representing the Polish generic industry[1056] has proposed an amendment to the bill. According to this proposal, the list of activities to which the effect of the patent shall not extend laid down in Art. 69 IPA – which is the Polish counterpart to Art. 27 UPCA – shall also include the following activities:

> the exploitation of an invention involving manufacturing, using, storing, offering, placing on the market or importing, for the purpose of performing the acts as required under the provisions of law, also by third parties, for obtaining registration or authorisation, being due to the intended use thereof, requisite for certain products, in particular pharmaceutical products, to be placed on the market of the EEA or another state.[1057]

The following aspects are relevant for our analysis:

- Such provision would clarify that supplying patented active ingredients for *Bolar* purposes would not infringe the patent. It would therefore overrule the *Astella* judgment, where the Supreme Court considered *Bolar* as an exemption covering only the acts of the entity seeking the MA and not the acts of third party suppliers;
- the proposed provision would cover acts that may qualify as direct infringement as well as acts that may qualify as contributory infringement. However, the scope of the exemption would be limited to supplying for *Bolar* purposes. The supplying of patented substances for experimental purposes would not be exempted;
- the broad formulation would include any invention that has been implemented in the course of an activity aimed at obtaining a marketing approval or generating the data for such purpose. It seems not to be limited to patents covering or claiming the substance for which an MA must be requested;
- the broad formulation would also cover supply for activities aimed at obtaining a registration in third countries, and even the export for such purposes of the substances concerned.

It is unclear at the moment whether or to what extent such proposal will be considered by the Polish government or by the Parliament discussing the bill.

15.4.2.4 Opinion and recommendation

It is not the aim of this Study to discuss whether the interpretation according to which the experimental exemption does not cover third-party supply of the patented subject matter is correct or not. Nor does the Study intend to discuss the contention that the same interpretation applies to the *Bolar* exemption.

[1056] Polski Związek Pracodowców Przemysłu Farmaceutycznego, PZPPF. The information has been provided by Medicines for Europe, Email of Sergio Napolitano with Annexes of 19 January 2018.

[1057] Wording and translation provided by Medicines for Europe; Email of Sergio Napolitano of 18 January 2018.

However, the Study agrees with the opinion endorsed by several authors dealing with the issue who have identified a contradiction of values in the pertinent provisions – rules adopted by the Luxembourg Convention and reproduced by the national patent acts, as well as by the UPCA – in that they allow the use of the invention for experimental purposes, but practically restrict such use to entities that are in a position to manufacture the patented subject matter or components of it themselves. Scholars and practitioners have also observed this contradiction with respect to the *Bolar* exemption.

For instance, Professor Joseph Straus, commenting on the Polish Supreme Court judgment discussed above, has maintained:[1058]

> The court thus failed to take into account that this rule is an integral part of the broader Community legislation in the area of production and marketing of medicinal products in the Community. In particular, the court paid no attention to the key role played by API suppliers in enabling generics manufacturers in the Community to perform studies and trials necessary for obtaining MA. This decision takes away the ability of Community-based API suppliers to manufacture and offer for sale APIs needed by generic manufacturers who lack the necessary API production facilities, who are otherwise unable to produce them or who, for economic reasons, cannot afford to produce all or some of the APIs needed in conducting studies and trials of generic medicinal products for which they intend to obtain an MA. The court decision has clearly missed the underlying function of the *Bolar* rule and entirely disregarded the consequences of the absence of any third party sources of APIs supply in the Community. As revealed by the facts of *Astellas v Polpharma*, even such companies as Hexal AG (part of Swiss Sandoz AG, one of the largest generic drug producers in the world), use third-party API suppliers, seemingly for economic reasons, ie cost savings, improved competitiveness, etc. Such a business model has an obvious positive impact on the ability of generics manufacturers to offer their medicine at lower prices, which is exactly what the *Bolar* rule should achieve.

Even before that, Professor Rudolph Kraßer declared it "hard to understand" why the experimental use of the patented substance is patent-free and supplying it for the exempted use is not.[1059] Other German authors have found the legal situation contradictory, at least with respect to the rules of national law that consider as contributory infringement the supplying of means related to the invention for experimental purposes.[1060] Gilat in his book "Experimental Use and Patents" has commented on the question of supplying for research purposes with reference to Art. 26 CPC in the following terms:[1061]

> The provisions of Art. 26 CPC may be justified to the extent that they attempt to prevent unauthorized commercial production and sales under the guise of supply for experimental purposes. If indeed this was the purpose of the contracting states, this result could be achieved without hindering the experimental use exemption by imposing unnecessary difficulties upon the experimenter in obtaining assistance from third parties. It seems that a better solution to this problem could be achieved if a strict burden of proof were encumbered upon the *manufacturer of a patented product* to show that the products supplied by him were in fact used for experimental purposes.

Also, in Italian contributions, such rules were even found problematic under constitutional aspects, as they imply a discrimination between entities that can manufacture the relevant material and those that cannot do so. Some Italian scholars

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1058 Joseph Straus, 'The *Bolar* exemption and the supply of patented active pharmaceutical ingredients to generic drug producers: an attempt to interpret Article 10(6) of Dir. 2004/27/EC' [2014] 9(11) JIPL 895, 905.

1059 Rudolf Kraßer, *Patentrecht* (6th edn, Beck 2009) p. 789.

1060 Peter Chrocziel, *Die Benutzung patentierter Erfindungen zu Versuchs- und Forschungszwecke* (Heymanns 1986) p. 191; Peter Chrocziel, Frank-Erich Hufnagel, *Versuchsprivileg und Unterstützungshandlungen – Abgrenzungsfragen im "Bermuda-Dreieck" der §§ 9, 10 und 11 Nr. 2/2 b PatG* in Michael Bergermann et al (eds), FESTSCHRIFT FÜR PETER MES ZUM 65. GEBURTSTAG (Beck 2009) pp. 59, 64 et seqq.

1061 David Gilat, *Experimental Use Exemption from Patent Liability,* IIC Studies 16 (Wiley VCH 1995) p. 87 with further references.

have posited that an interpretation informed by constitutional law which takes account of the freedom of research and of the interest underlying the *Bolar* exemption must lead the courts to consider as exempted both the use and the supply of the subject matter for experimental purposes.[1062]

In line with those scholarly observations the Study highlights the following arguments.

The experimental exemption and the *Bolar* exemption are meant to ensure that the patent system takes account of all interests involved. While the two have different rationales, both share a common structure: as the speakers at the MPI Workshop pointed out, the reason for their existence is not the peculiar situation of the person performing the exempted acts, as in the case of the domestic-use exemption which only benefits the end-user, but the public interest underlying the acts performed. The activities of generic companies conducting the required studies and trials serve the public policy goal of ensuring early market entrance so as to enable efficient post-expiry competition; this is why they are exempted from the exclusive right conferred by the patent or SPC. It is consistent with this rationale to extend that exemption to the activities of suppliers who make the experiments or clinical trials possible.

Based on these considerations the Study recommends that the legislature should clarify that the supplier can also invoke the defence to infringement provided under Art. 27 UPCA and corresponding national rules. Any other solution would discriminate between companies and universities that are able on their own to manufacture the patented substances on which they intend to conduct their research, and companies and universities that do not have that possibility. Furthermore, by expanding the exemption in the manner proposed, it could be prevented that research activities must be outsourced in order to avoid the risk of infringement. Finally, if third-party supply remains prohibited, this could create dependencies, as only the patent holder would be entitled to deliver the required substances to the party conducting the research (for instance, a university). Due to that monopoly position, the patent holder might be able to impose reach-through claims on the results of the research conducted by the supplied contractual partner. This is not unrealistic in the field of such biological products as stem cells, where the technology or the law could strongly limit the option to manufacture in-house the material needed to conduct the research.

For reasons of legal certainty and in order to contain the negative impact on the position of the right holder that such legislation might entail, it could be provided that the supplier has the onus to prove that the supplied party, at the date of the order and of delivery, intended to use the product only for an exempted purpose, and that a corresponding contractual obligation forms part of the contract between the supplier and the supplied party.

15.4.2.5 Implementation of the recommendation

Regarding the implementation of the recommendation, it is appropriate to distinguish between three scenarios:

[1062] Alberto Musso, 'La contraffazione indiretta e la sua incidenza limitativa sulla esenzione sperimentale' [2016] 2 Il diritto industriale 130 et seq.; Francesca Morri, 'Why you can *Bolar* also with third parties' Riflessioni sulla portata soggettiva dell'art. 68.1 b) CPI [2016] Rivista di diritto industriale 195 et seq.

Scenario I: The supply of patented material for conducting activities related to the grant of an MA under Dir. 2001/83/EC or Dir. 2001/82/EC;
Scenario II: The supply of patented material for activities related to product approval requested and obtained in a foreign jurisdiction;
Scenario III: The supply of patented material for activities covered by the experimental exemption pursuant to Art. 27 UPCA, but not covered by the exemption provided under Art. 10(6) Dir. 2001/83/EC or Art. 13(6) Dir. 2001/82/EC.

In order for the activities in Scenario I to be covered by the *Bolar* exemption, it is necessary but also sufficient to amend Art. 13(6) Dir. 2001/82/EC and Art. 10(6) Dir. 2001/83/EC. Because of the dynamic reference to Art. 13(6) Dir. 2001/82/EC and Art. 10(6) Dir. 2001/83/EC included in Art. 27(d) UPCA, the amendment will also apply in proceedings before the UPC concerning European patents with or without unitary effect. In proceedings concerning European patents without unitary effect, or national or European patents litigated before the national courts, the domestic provisions implementing the amended Art. 13(6) Dir. 2001/82/EC or Art. 10(6) Dir. 2001/82/EC will apply. Such amendments would be within the scope of Dir. 2001/82/EC and Dir. 2001/83/EC, as they concern activities related to MAs covered by said Directives.

As to Scenario II – supply for studies directed to obtaining a product approval in non-EU countries – an amendment of Dir. 2001/82/EC or Dir. 2001/83/EC is not advisable, since the regulatory scope of the Directives covers neither activities related to product approval outside the EU, nor patent harmonisation as such. In line with what is pointed out above (15.4.1.4 (c)), it therefore appears more appropriate to enact separate legislation for the purpose.

Regarding Scenario III – supply of research material for experimental purposes that are not directed at obtaining an MA – it is even more obvious that such activities do not fall within the regulatory objectives of Dir. 2001/82/EC and Dir. 2001/83/EC. Until now experimental exemption as such is not even provided for under Union law, at least insofar as patents are concerned.[1063] Any harmonisation of patent law in this regard requires a separate act of legislation adopted in accordance with competences provided under the TEU.

The legislative options[1064] for achieving an exemption of the activities to which Scenario II and Scenario III refer are the same as those pointed out above (15.4.1.4 (c)) with regard to extending the *Bolar* exemption to activities undertaken for obtaining an MA outside the EU (or the EEA). This means that the experimental use exemption, including the possibility of third-party supply, should be regulated in a harmonisation directive to be implemented by the Member States, which can also serve as a basis for the Administrative Committee to revise the UPCA in the simplified procedure set forth in Art. 87(2) UPCA. In addition, a parallel provision could be inserted in Reg. 2012/1257 that, by virtue of Art. 20 UPCA, would be directly applicable in UPC proceedings regarding unitary patents.

[1063] For Community designs see Art. 20(1)(b) Reg. 6/2002.
[1064] As an alternative to the enactment of EU legislation, Member States could amend the UPCA through the ordinary procedure stipulated in the Agreement. However, as pointed out above (15.4.1.4 (c)), that procedure is rather lengthy and cumbersome; it is therefore not addressed in further detail.

15.4.2.6 Summary

- Under current EU law, uncertainty prevails as to the extent to which third-party suppliers can rely on the *Bolar* or experimental exemption. Some national courts have judged that supplying a third party for *Bolar* and experimental use purposes constitutes an infringing act.
- The situation is particularly disadvantageous for research institutions and SMEs that are not able to manufacture the required IP-protected active ingredients for their research and studies.
- Based on the purpose of the experimental use and *Bolar* exemptions, a broad exemption including the activity of third-party suppliers is recommended.

15.4.3 The Specific Mechanisms

15.4.3.1 Introduction

Under general rules of Union law, products being placed by the patent or SPC holder on the market in one Member State can be freely imported to any other Member State, regardless of any patents or SPCs on that product in the country of destiny (principle of exhaustion).[1065] This principle derives from the basic tenet of free movement of goods between Member States (Art. 34 TFEU). The Specific Mechanism is an exemption from that principle laid down in Annex IV of the Accession Treaty, Chapter 2 "Company Law". The provision is worded as follows:

> With regard to the Czech Republic, Estonia, Latvia, Lithuania, Hungary, Poland, Slovenia or Slovakia, the holder, or his beneficiary, of a patent or supplementary protection certificate for a pharmaceutical product filed in a Member State at a time when such protection could not be obtained in one of the abovementioned new Member States for that product, may rely on the rights granted by that patent or supplementary protection certificate ("SPC") in order to prevent the import and marketing of that product in the Member State or States where the product in question enjoys patent protection or supplementary protection, even if the product was put on the market in that new Member State for the first time by him or with his consent.
> Any person intending to import or market a pharmaceutical product covered by the above paragraph in a Member State where the product enjoys patent or supplementary protection shall demonstrate to the competent authorities in the application regarding that import that one month's prior notification has been given to the holder or beneficiary of such protection.

15.4.3.2 Historical and economic background

Until the early 1990s it was not possible to obtain a patent on a pharmaceutical substance (i.e. the active ingredient) in Poland, Hungary, the Slovak Republic, Latvia, Estonia, Lithuania, the Czech Republic and Slovenia. Before these countries became Member States of the European Union, this was a disadvantage for originator companies but it had no effect on the legal situation in the EU as such. If a medicinal product was covered in the EU by either a patent or SPC, any import from outside the EU to the country where such protection was available was an infringement of the respective right with the required protection available for the right holder. If the right holder itself or a third party with his consent exported the product to one of the countries that joined the EU in 2004, the EU principle of exhaustion did not apply and the product could not be freely reimported to the EU.

[1065] In general for the principle of exhaustion see Case C-15/74 *Centrafarm and de Peijper* [1974] ECLI:EU:C:1974:114; Case C-187/80 *Merck* [1987] ECLI:EU:C:1981:180; Case C-191/90 *Generics and Harris Pharmaceuticals* [1992] ECLI:EU:C:1992:407.

Once the countries joined the EU, the principle of exhaustion also applied to them. Therefore, without specific exemptions (i.e. the Specific Mechanism), any extension of the EU to new Member States that did not provide an equivalent level of protection for pharmaceutical products would have led to exhaustion of the respective rights, once medicinal products had been put on the market in any new Member State.[1066] On the face of it, this would only be a strict application of EU law. However, at the time of accession, the price level for pharmaceutical products in the new EU Member States was much lower than in the old EU Member States. This difference, together with the principle of exhaustion, could have resulted in companies using the system of parallel importation to purchase originator products on the cheaper markets, repackage them and import them into the old Member States for sale at a lower price. This would, of course, have undercut the prices of the originator products in the old Member States. Two possible consequences were foreseen:

- Originators could raise the prices in the new Member States to prevent such a parallel import.
- Originators could refrain from placing such products on the market in the new EU Member States for the same reason.

As a consequence, the availability of medicinal products in the new EU Member States would have been negatively impacted.

15.4.3.3 Case law of the CJEU

(a) *C-539/13 Merck Canada Inc., Merck Sharp & Dohme Ltd v Sigma Pharmaceuticals plc*

Merck Canada was the holder of EP UK 480 717 for the active ingredient montelukast, which is used in the product Singulair. Merck Sharp and Dohme (Ireland) Ltd. was the exclusive licensee of the patent and the SPC based on the patent, and the MA for Singulair. On 22 June 2009, Pharma XL Ltd, a company associated with Sigma, gave Merck Sharp & Co Ltd. (MSD – not the Irish entity) notification in the UK that it intended to import Singulair in two different dosage forms from Poland to the UK. At that time MSD was the holder of the MA for the UK but had no rights in the patent or SPC. On 14 September 2009, Pharma XL applied for and was granted on 21 May and 10 September 2010 the respective parallel import licences from the Medicines and Healthcare Products Regulatory Agency. Pharma XL gave MSD further notifications of its intention to import the repackaged product to the UK. Subsequently Sigma began with the importation of the product. On 14 December 2010, Merck Canada and MSD contacted Pharma XL and objected to the importation of Singulair, leading to an immediate cessation of imports by Sigma. Merck Canada and MSD sued Sigma and obtained a favourable judgment at first instance.

The CJEU decided that the patent or SPC holder or beneficiary is not required to indicate its intention to enforce its rights under the Specific Mechanism after having been informed of the intention to rely on the mechanism. However, if the patent or SPC owner does not indicate its intention to enforce its rights within the one-month period, it may not rely on the enforcement until it indicates such willingness to enforce the rights. While the Court acknowledged that there is no requirement for the right

[1066] Katarzyna Zbierska, *Application and Importance of Supplementary Protection Certificates for Medicinal Products in the European Union* (Shaker 2012) p. 264.

holder to express its willingness to enforce the right before doing so, it also stated that the Specific Mechanism is intended to strike a balance between the involved interests, and therefore prescribes a specific procedure.[1067]

Furthermore, the Court decided that "notification must be given to the holder, or beneficiary, of the patent or the supplementary protection certificate, the latter term designating any person enjoying the rights conferred by law on the holder of the patent or the supplementary protection certificate". According to the Court, it is always possible for the person seeking to submit the notification to submit it to the holder of the patent or SPC.[1068]

Finally, the CJEU decided that the Specific Mechanism does not require "the person intending to import or market the pharmaceutical product in question to give notification himself, provided that it is possible from the notification to identify that person clearly".

(b) *C-681/16 Pfizer Ireland Pharmaceuticals, Operations Support Group v Orifarm GmbH – Referral from the District Court of Düsseldorf*

The second case on the Specific Mechanism is still pending before the CJEU; the questions were referred by the District Court of Düsseldorf on 15 December 2016. The CJEU has not delivered its judgment yet, but the opinion of the Advocate General has recently been published.[1069]

The plaintiff in that case is the holder of an SPC based on a basic patent and the MA for the product containing the active ingredient etanercept. The defendant in the case is a Danish company active as a parallel importer. On 27 June 2013 the defendant notified the plaintiff of its intention to import the repackaged product from several Member States of the EU which are subject to the Specific Mechanism.

The issue at hand in the case is that at the time of application for the SPC in Germany, SPC protection was also available in the new Member States. However, the SPC holder did not have a basic patent in those Member States at that time. At the time that the basic patent was applied for at the EPO, equivalent protection was not available in the new Member States.

The Düsseldorf court directed the following questions to the CJEU:

> 1. Can the holder of a supplementary protection certificate that was issued to it for the Federal Republic of Germany rely on the specific mechanism to prevent the importation of products into the Federal Republic of Germany from the accession States the Czech Republic, Estonia, Latvia, Lithuania, Hungary, Poland, Slovenia, Slovakia, Bulgaria, Romania … and Croatia (Annex IV to the 2003 Act of Accession, OJ 2003 L 236, p. 797, as amended in OJ 2004 L 126, p. 4, for Estonia, Latvia, Lithuania, Poland, Slovenia, Hungary, Slovakia, the Czech Republic; Part I of Annex V to the 2005 Act of Accession, OJ 2005 L 157, p. 268, for Romania and Bulgaria; Annex IV to the 2011 Act of Accession, OJ 2012 L 112, p. 60, for Croatia) if the supplementary protection certificate was applied for in the Federal Republic of Germany at a point in time at which the laws for obtaining such a supplementary protection certificate already existed in the respective accession States but could not be applied for by, or issued to, the holder of the supplementary protection certificate issued for the Federal

[1067] Case C-539/13 *Merck Canada Inc., Merck Sharp & Dohme Ltd v Sigma Pharmaceuticals plc* [2015] ECLI:EU:C:2015:87, para. 31.
[1068] *Ibid.*
[1069] Opinion of AG Tanchev delivered on 7 February 2018, Case C-681/16 *Pfizer Ireland Pharmaceuticals, Operations Support v Oripharm GmbH* [2018] ECLI:EU:C:2018:69.

Republic of Germany because the basic patent required for the issuing of the supplementary protection certificate did not exist in the accession State?

2. Does it make any difference to the answer to Question 1 if it was merely at the time of the filing of the application for the basic patent issued for the Federal Republic of Germany that such protection through a basic patent could not be obtained in the accession State but, by the time of publication of the application on which the basic patent issued for the Federal Republic of Germany was based, it could be so obtained?
3. Can the holder of a supplementary protection certificate that was issued to it for the Federal Republic of Germany rely on the specific mechanism to prevent the importation of products into the Federal Republic of Germany from the accession States the Czech Republic, Estonia, Latvia, Lithuania, Hungary, Poland, Slovenia, Slovakia, Bulgaria, Romania … and Croatia if those products are imported after the expiry of the term of the supplementary protection certificate stipulated in the original decision to grant the patent but before the expiry of the six-month extension of the term of the supplementary protection certificate that was granted to it on the basis of Regulation (EC) No 1901/2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004?
4. Does it make any difference to the answer to Question 3, in the case of Croatia, that, on account of the accession of Croatia in 2013, the specific mechanism did not come into force until after the entry into force of Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004 on 26 January 2007 — unlike in the other Member States which acceded prior to 26 January 2007, namely the Czech Republic, Estonia, Latvia, Lithuania, Hungary, Poland, Slovenia, Slovakia, Bulgaria [and] Romania …?[1070]

The Advocate General has proposed to the CJEU to answer the questions as follows:

1. The holder of a supplementary protection certificate that was issued to it for the Federal Republic of Germany can rely on the Specific Mechanism to prevent the importation of products into the Federal Republic of Germany from the Czech Republic, Estonia, Latvia, Lithuania, Hungary, Poland, Slovenia, Slovakia, Bulgaria, Romania and Croatia (Annex IV to the Act concerning the conditions of accession of the Czech Republic, the Republic of Estonia, the Republic of Cyprus, the Republic of Latvia, the Republic of Lithuania, the Republic of Hungary, the Republic of Malta, the Republic of Poland, the Republic of Slovenia and the Slovak Republic and the adjustments to the Treaties on which the European Union is founded; Part I of Annex V to the Act concerning the conditions of accession of the Republic of Bulgaria and Romania and the adjustments to the Treaties on which the European Union is founded; Annex IV to the Act concerning the conditions of accession of the Republic of Croatia and the adjustments to the Treaty on European Union, the Treaty on the Functioning of the European Union and the Treaty establishing the European Atomic Energy Community) if the supplementary protection certificate was applied for in the Federal Republic of Germany at a time at which the laws for obtaining such a supplementary protection certificate already existed in the respective Accession States but could not be applied for by, or issued to, the holder of the supplementary protection certificate issued for the Federal Republic of Germany because the basic patent required for the issuing of the supplementary protection certificate did not exist in the abovementioned Accession State.
2. It does not make any difference to the answer to Question 1 if it was merely at the time of the filing of the application for the basic patent issued for the Federal Republic of Germany that such protection through a basic patent could not be obtained in the Accession State but, by the time of publication of the application on which the basic patent issued for the Federal Republic of Germany was based, it could be so obtained.
3. The holder of a supplementary protection certificate that was issued to it for the Federal Republic of Germany can rely on the Specific Mechanism to prevent the importation of products into the Federal Republic of Germany from the Czech Republic, Estonia, Latvia, Lithuania, Hungary, Poland, Slovenia, Slovakia, Bulgaria, Romania and Croatia if those products are imported after the expiry of the term of the supplementary protection certificate stipulated in the original decision to grant the patent but before the expiry of the six-month extension of the term of the supplementary protection certificate that was granted to it on the basis of Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004.
4. It does not make any difference to the answer to Question 3, in the case of Croatia, that, on account of the accession of Croatia in 2013, the Specific Mechanism did not come into force until after the entry into force of Regulation No 1901/2006 on 26 January 2007 – unlike in

[1070] Request for a preliminary ruling from the Regional Court of Düsseldorf (Landgericht Düsseldorf (Germany)) lodged on 27 December 2016 – *Pfizer Ireland Pharmaceuticals, Operations Support Group v Orifarm GmbH* (Case C-681/16 *Pfizer Ireland Pharmaceuticals, Operations Support Group v Orifarm GmbH* [2018] ECLI:EU:C:2018:69).

the other Member States which acceded prior to 26 January 2007, namely the Czech Republic, Estonia, Latvia, Lithuania, Hungary, Poland, Slovenia, Slovakia, Bulgaria and Romania.

15.4.3.4 Issues identified

(a) *Obligations imposed on the parties*

In our opinion, the issues identified and decided in *Merck Canada Inc., Merck Sharp & Dohme Ltd v Sigma Pharmaceuticals plc* have been sufficiently clarified by the CJEU. The Specific Mechanism is an exception from the general principle of exhaustion and its goal is to establish a balance between the rights of the patent or SPC holder and the competitors. The notification procedure is meant to provide this balance and should be interpreted as providing the right holder with an opportunity to object to a parallel importation while giving competitors who follow the procedure sufficient certainty to conduct their business.

(b) *Availability of equivalent protection*

More complicated at first sight is the recent referral from the Düsseldorf court to the CJEU. However, to anticipate our results, we agree with the opinion of the Advocate General and believe that, if followed by the CJEU, it can provide clear guidance for the stakeholders.

Since the Specific Mechanism intends to compensate the right holder for the unavailability of sufficient protection in the new EU Member States prior to their joining the EU, the question is at what time what kind of protection must have been available. The following are the key points from the case *Pfizer Ireland Pharmaceuticals, Operations Support Group v Orifarm GmbH*:

- No equivalent patent or SPC protection was available on the application date of the patent (31 August 1990) in the new EU Member States.
- Equivalent SPC protection was available on the application date of the SPC (26 June 2003) in the new EU Member States.

Does the Specific Mechanism apply in such a situation?

The MPI, in agreement with the Advocate General, is of the opinion that the Specific Mechanism does in fact apply in such a case.[1071] It is the goal of the Specific Mechanism to compensate the right holder for the lack of availability of equivalent protection for pharmaceutical products in the new EU Member States and the commercial and economic risks resulting from such a situation in the case that competitors rely on the exhaustion doctrine. Therefore, the question cannot be limited to asking whether SPC protection was available as such at the relevant date, but whether it was practically possible for the SPC holder to obtain an SPC at that time. If the SPC holder could not obtain equivalent patent protection at the date of application for the basic patent, it is a merely theoretical possibility that he may have obtained an SPC since the basic patent is a *conditio sine qua non* for the SPC. Only if equivalent patent protection was available but the patent owner failed to apply for a basic patent

[1071] The same opinion is also presented by Thomas Kühnen, *Die Eingriffsvoraussetzungen des Besonderen Mechanismus* in Bettina Limperg et al (eds), RECHT IM WANDEL DEUTSCHER UND EUROPÄISCHER RECHTSPOLITIK FESTSCHRIFT 200 JAHRE CARL HEYMANNS (Carl Heymanns 2015) p. 382.

may he not rely on the Specific Mechanism by claiming that he did not obtain an SPC.[1072] Since the paediatric extension in its present form depends on the SPC and is not in fact an independent right but an extension of the SPC term, the Specific Mechanism should also extend throughout the term of the paediatric extension.[1073]

(c) *Options*

The EU legislature has two possibilities: it can either leave the identified issues to be resolved by case law or codify possible solutions. Since the applicable law is primary EU law, a codification process would require substantial effort. At the same time, the operation of the Specific Mechanism is limited in the long term since, based on the availability of equivalent protection, its application will come to an end in the foreseeable future. Nevertheless, the questions raised by case law and identified as issues should be addressed in possible future Specific Mechanisms in case other countries join the EU where a similar situation is present.

(d) *Recommendations*

Since the question has been referred to the Court of Justice, and since it touches on principles of primary law, the MPI does not recommend any change to the law. The CJEU is the ultimate arbiter of the borders set by primary law on the options for lawmakers and courts to develop limitations to the principle of the free circulation of goods. In view of the pending referral, it seems appropriate to await the development of the case law. Further, some of the problems addressed could be of transitory importance, unless new Members join the EU in the near future.

15.4.3.5 Summary

The Specific Mechanism serves as a tool to overcome differences in patent and SPC protection between "old" and "new" Member States. It is a consequence of the principle of exhaustion. The case law regarding the Specific Mechanism has been limited so far and it can be expected that, due to the convergence of the protection regimes, the number of future decisions will remain limited. As far as the present legislation left any room for interpretation, this has been resolved by the case law of the CJEU or it can be expected that the CJEU will fill any gaps that are still remaining. From the point of view of the MPI, no imminent action on the part of the lawmakers is required.

[1072] *Ibid.*

[1073] See also Highest Court of Denmark, *Orifarm A/S v Merck Canada Inc., Merck Sharp & Dohme B.V. and MSD Danmark ApS*, Decision of 8 April 2016, Case No 214/2014.

16 DURATION OF THE SPC (ART. 13 REG. 469/2009)

16.1 INTRODUCTION

In the literature there are calls for extending the term (i.e. the duration) of protection of the SPC, as well as for reconsidering it in view of the fact that other jurisdictions provide for shorter terms of protection. However, whether the term fulfils its purposes to foster pharmaceutical innovation in Europe and whether it is excessive are questions a legal study cannot assess and even an economic study can hardly answer.

This is due to the following:

First, the actual effect of the SPC on innovation cannot be distinguished from the actual effect of patents, so it would likely be impossible to identify the effect of an additional term of protection on innovation. When companies undertake to invest in research and development activities in a particular area they base this decision on the possible – but of course never guaranteed – return on investment during the complete life-cycle of a commercial product including the possible combined term of the patent plus the SPC. This decision takes place at the very beginning of the development and includes numerous uncertainties. Whether or not an extension or reduction of the term may influence the decision, and to what extent, is difficult, if not impossible, to measure.

Second, the effect of SPCs cannot be distinguished from the effect that patent extensions granted in other jurisdictions may display. Pharmaceutical products are marketed world-wide and patent protection for the products is sought on a global basis as well. Particularly for companies who operate on a global basis, the calculation of R&D costs and the possible return on investment is made on a global basis as well. A company will include in its decision-making process not only the term of protection in the EU but also the terms of protection in other markets such as the USA or Japan. Depending on the type of product the different markets may be of differing importance for the decision and the calculation.

Finally, the term adopted for patent rights as such is arbitrary: it was adopted on the basis of international obligations (Art. 33 TRIPS), and not economic analysis.[1074] The same holds true for the term of the SPC in Europe. It was rather the result of a give and take of the industries involved than the result of a deliberated evaluation informed by objective data. The French legislation, which served as a blueprint, and the Italian legislation, which was adopted shortly thereafter, provided for longer terms of protection, as did the original proposal of the Commission.[1075]

What this Study can do, by contrast, is, first, to attempt on the basis of the available data to assess whether the situation that was taken as the starting point for the enactment of the Regulations has in the meantime changed, for better or for worse, as

[1074] See Gerald Dworkin, 'Intellectual Property Rights: What Are Appropriate Terms of Protection' [1997] 18 Sing. L. Rev. 553, 574 stating: "The recent international move to 20 years was assumed, rather than demonstrated, to be justified". See with respect to the difficulties in calculating an optimal term of patent protection across industries Mark Lemley, 'An Empirical Study of the Twenty-Year Patent Term' [1994] 22 AIPLA Quarterly Journal 369, 424.

[1075] Proposal for a Council Regulation (EEC) concerning the creation of a supplementary protection certificate for medicinal products, COM(90) 101 final [1990] OJ C 114, para. 14.

far as the length of the clinical trials and of the authorisation procedure is concerned. Second, it can offer a brief review of the literature that has dealt with the issue of the optimal term of protection and that has proposed an extension of the SPC term in Europe to evaluate what is the state of knowledge and what are the arguments brought in favour these initiatives.

Finally, the Study can identify some features that distinguish the European legal setting from the normative experience of other jurisdictions, such as the absence of due-diligence provisions or other mechanisms to ensure that the request for an approval is promptly filed.

16.2 EFFECTIVE LENGTH OF SPC PROTECTION

In the European Commission's initial explanation for the relevance of the regulation on medicinal products, it was assumed that the average length of drug development plus MA procedures in the field of pharmaceuticals amounts to 12 years.[1076] Capturing the relevance of SPCs by the number of additional terms of protection provided, Kyle compares approved drugs over different cohorts and notes that the EU has achieved faster access to new drugs by speeding up authorisation procedures, although the reduction in launch lags has not offset the overall increase in the time elapsed between patenting and first launch, resulting in a net decrease in remaining patent term.[1077] Similarly, Rollins argues that the trend towards longer development times increases the relevance of SPC protection.[1078]

However, it needs to be emphasised that the observed changes in the time between drug discovery and MA may be endogenous. That is, originators may influence development processes and deliberately pursue expansive drug projects that exhaust SPC protection to an optimum. In line with this, Kyle observes a change between cohorts in the distribution of drugs across therapeutic fields, which has increased the overall average drug development time and consequently the relevance of SPCs in terms of the time of additional protection provided.[1079]

Next to patent and SPC protection, market exclusivity may also emerge from data (and marketing) exclusivity. In general terms, data (and marketing) exclusivity means that market-authorisation bodies are not allowed to process so-called abridged applications for marketing a generic drug before a certain time span after the first MA for the originator product has elapsed.[1080] Data exclusivity therefore creates a significant barrier to entry for generic companies with arguably comparable effect to patent and SPC protection. Dir. 2001/83 harmonised data-exclusivity regulations in Europe, taking effect in November 2005. For MA applications made before November

[1076] Proposal for a Council Regulation (EEC) concerning the creation of a supplementary protection certificate for medicinal products, COM(90) 101 final [1990] OJ C 114, 10, para. 14.

[1077] See Margaret Kyle, 'Economic Analysis of Supplementary Protection Certificates in Europe' [2017] European Commission/MINES ParisTech (CERNA), Working Paper, pp. 15-18, available at https://ec.europa.eu/docsroom/documents/25621/attachments/1/translations/en/renditions/pdf (last accessed 15 January 2018).

[1078] Tony Rollins, 'How Europe's SPC regime works in practice' [2016] Managing Intellectual Property in Practice, 22 June 2016, available at http://www.managingip.com/Article/3560853/How-Europes-SPC-regime-works-in-practice.html (last accessed 6 November 2017).

[1079] Other time-correlated factors with potential effect on the length of drug development have not been subject to empirical investigation so far. These factors may be differences in the ratio of first to subsequent therapeutic indications or of biologics to chemical compound products.

[1080] European Commission, 2009, p. 124.

2005, the period of data exclusivity varied between Member States and was either six years or ten years. For MA applications made from November 2005 onwards, the period of data exclusivity in Europe has been harmonised to eight years from the date of first authorisation in Europe with an additional period of two years of "market exclusivity". Granted that data exclusivity can be seen as a substitute for patent/SPC protection, this general extension may have reduced the relevance of SPC protection. As of now, the authors of this Study are not aware of a thorough quantification of the temporal overlap between the two kinds of exclusion rights over time.

16.3 INTERNATIONAL COMPARISON: SPC OR PTE

A comparative perspective on the term of SPCs or patent term extensions (PTEs) likewise does not provide any conclusive answers to the question which term is appropriate. However, it can be said that most countries provide for a maximum extension of patent protection of five years, with Canada having a relatively short period of the newly introduced SPC of a maximum of two years. The following table provides an overview of the countries, the terms of extension and some information on the calculation of the terms, which differ in some respects. Overall it can be said that based on an international comparison, the present term of a maximum of five years' SPC protection in the EU appears to be neither too long nor too short.

Country	Duration of an SPC/PTE	The calculation of an SPC/PTE
Australia	Max. 5 years	• Grant of the patent and date of the first regulatory approval minus 5 years.[1081] • No PTE available where approval time is 5 years or less.[1082]
Canada	Max. 2 years	• Subtract 5 five years from the difference between the filing date of the patent application and the date on which the MA was issued.[1083] • If the result is zero or negative value, a certificate of supplementary protection (CSP) cannot be grantedthere will be no certificate granted.[1084] • If the holder of the MA and the patent holder are the same person and the Minister determines that it was the person's own actions that caused a delay in the process of obtaining the MA, the CSP period may be reduced.[1085]
Israel	Not more than the corresponding	• "Calculation of the patent extension period was based on a formula linking the Israeli patent extension term and expiration with that applicable to parallel patent

1081 Andrew F Christie, Benjamin Hopper, *Australia* in Annex II of this Study, Chapter 1, Section 1.5.2.5.
1082 *Ibid.*
1083 Giuseppina D'Augustino, Joseph F Turcotte, *Canada* in Annex II of this Study, Chapter 2, Section 2.6.
1084 *Ibid.*
1085 Ibid. See § 116(4) Bill C-30, An Act to implement the Comprehensive Economic and Trade Agreement between Canada and the European Union and its Member States and to provide for certain other measures, 1st Sess, 42nd Parl., 2017 at http://www.parl.gc.ca/LegisInfo/BillDetails.aspx?Language=E&Mode=1&billId=8549249 (last accessed 15 May 2018).

	PTE periods and expiry dates granted in reference countries.	extension terms in other jurisdictions which already provided PTE."[1086] • "[..] PTE in Israel is linked to that granted in other reference countries (currently the US, Italy, the United Kingdom, Germany, Spain and France) and comprises the shortest possible term, based on the following principles: 1. Shortest Period Principle—calculation of PTE in Israel (in terms of number of days) shall be based on the shortest extension term granted in any of the reference countries; 2. First to Expire Principle—PTE in Israel will expire as soon as the first reference PTE order, or patent, in any other reference country, expires.; 3. Fourteen Years from first MA Cap— the total protection of basic patent and PTE together is limited to 14 years, commencing from the date the first MA is obtained for the drug protected by the PTE in a reference country.; 4. Five Years Maximum Cap— In any event, the term of the PTE will not exceed five years beyond the elementary twenty-year period of protection granted by the basic patent."[1087]
Japan	Max. 5 years	• "The period starts on "the date of beginning the test which is required for the approval, or the date of patent registration, whichever is later" and ends not on the date of approval but on "the date immediately before the date on which the approval took effect by reaching the applicant". • The benchmarks are (i) the date of beginning the test which is required for obtaining an approval, (ii) the patent registration date, and (iii) the date immediately before the date on which the approval took effect by reaching the applicant. • If they occur in the order of (i), (ii) and (iii), the period of extension is a period of up to five years from (ii) to (iii)."[1088]
New Zealand	-	"The term of extension would be the shorter of: a. the period equivalent to the interval between the date of grant of the patent and the date on which the marketing approval is notified in the Gazette: b. the period by which period A in section 111F(1)(b) exceeds 5 years in the case of a biologic and 3 years in the case of any other pharmaceutical substance: c. 2 years."[1089]

1086 Tal Band, Yair Ziv, *Israel* in Annex II of this Study, Chapter 3, Section 3.1.
1087 *Ibid.*
1088 Yoshiyuki Tamura, Masahumi Suzuki, Ichiro Nakayama, *Japan* in Annex II of this Study, Chapter 4, Section 4.6.
1089 Susy Frankel, Jessica C Lai, *New Zealand* in annex II of this Study, Chapter 6, Section 6.7, with the reference to TPP Agreement Amendment Act 2016, s 111G.

Singapore	Max. 5 years	"The patent shall be extended by the shortest of the following periods: (i) a period equivalent to the interval between the date of issue of the certificate of grant and the date MA was granted; (ii) the period by which the interval referred to in paragraph (7)(b) exceeds 2 years; (iii) a period of 5 years."[1090]
South Korea	Max. 5 years	• "No automatic deduction of the 5 years in the added period calculation."[1091] • If there has been time period after patent registration which was necessary for clinical tests and the MFDS' document reviews, it can be included.[1092] • Time for clinical tests in foreign countries is excluded.[1093]
The USA	Max. 5 years	• "Regulatory review period" is defined as one-half "of what may be termed the "testing phase" of the product, plus the entirety of what may be termed the "approval phase" at the FDA".[1094] • The nature type of the regulated product (human drug, animal drug, veterinary biological product, food or colour additive, medical device) sets determines the precise dates that mark the beginning of the testing and approval phases that and those together comprise the regulatory review period.[1095] • "If the applicant did not act with due diligence at any time during the regulatory review period, then the length of the regulatory review period is reduced by that number of days."[1096] • "The remaining patent term, combined with the period of term extension, may not exceed 14 years."[1097] • "Any part of the regulatory review period that took place prior to the issuance of the patent is not included in this calculation."[1098]

Table 16.1: SPC/PTE terms and their calculation in extra-European states

Overall it can be said that based on an international comparison, the present term of a maximum of five years' SPC protection in the EU appears to be comparatively generous. In addition, the European law provides for an additional possibility to extend the term of protection by additional six months based on the paediatric extension. This is a possibility that cannot be found, for example, in US-law.

1090 Elizabeth Siew-Kuan Ng, *Singapore* in Annex II of this Study, Chapter 7, Section 7.7.
1091 Jun-seok Park, *Korea* in Annex II of this Study, Chapter 5, Section 5.6.
1092 *Ibid.* with a reference to Art. 4 KIPO Regulation.
1093 *Ibid.*
1094 John Thomas, *The USA* in Annex II of this Study, Chapter 8, Section 8.7.
1095 *Ibid.*
1096 *Ibid.,* with a reference to 35 U.S.C. §156(c)(1).
1097 *Ibid.* with a reference to 35 U.S.C. § 156(g)(6).
1098 Ibid. with a reference to 35 U.S.C. §156(c).

Furthermore, one shall consider that because of the rule on internal priority the owner of a European patent has a period of 21 years for developing and exploiting an invention in a regime of de facto exclusivity. Indeed, one company could file a first application for a specific class of compounds that would create a priorty right that can be claimed by a second european application under Art. 87 EPC. The patent granted on the basis of this second european application would as explained benefit of the priority date of the first application, but its term would be calculated on the basis of the filing and not priority date (Art. 63 EPC). Admittely, the applicant would benefit from a full patent right only after the grant of the patent. But because of the requirement of a MA in the pharmaceutical sector the owner of a pending patent application is not exposed to generic competition as long as data protection is not expired.

Second, since unpublished patent applications do not constitute prior art for examining the inventive step (Art. 56 EPC), an applicant could file a first application disclosing the single compound, and further applications disclosing specific salts of this compounds or combination including such compounds. These applications, even if filed after the filing date of the first European application, could lead to the grant of a patent, since as long as the first application is not published, the latter is not relevant under Art. 56 EPC for assessing the inventive character of the subject matter claimed in the subsequent applications. *De facto*, European law allows the pharmaceutical innovator to extend for some more time than the 20-year term for developing and marketing medicinal products in a regime of exclusivity.

In comparing the position of the european applicant one shall also take into accout that in Europe, unlike other jurisdictions, combinations including old active ingredients or uses of old active ingredients may be eligible for a certificate.

16.4 DILIGENCE OF THE APPLICANT

The SPC term is intended to (partly) compensate for delays in entering the market resulting from not only the authorisation procedure as such, but also the all the steps needed to apply for an MA including the required studies and trials.[1099] However, there is no provision in the SPC Regulation regarding the behaviour of the applicant and its dilingence in conducting the pre-clinical trials, the clinical trials and the whole regulatory work needed to bring a new medicinal product to the market. One could argue that such a provision is not required, since the company can commercialise the product and thus make profits only by obtaining an MA and being able to place the product on the market.[1100] Therefore, the market-driven pressure to bring the best product to the market as fast as possible should be sufficient to motivate companies to start clinical trials as soon as possible and to move the application process forward as fast as possible.

[1099] European Commission, Explanatory Memorandum to the Proposal for a Council Regulation (EEC), of 11 April 1990, concerning the creation of a supplementary protection certificate for medicinal products (COM(90) 101 final – SYN255), para. 2.

[1100] Herwig von Morze, Peter Hanna, 'Critical and Practical Observations Regarding Pharmaceutical Patent Term Restoration in the European Communities (Part II)' [1995] 77 Journal of the Patent & Trademark Office Society 505, 517. This was also pointed out by the originator stakeholders during our qualitative interviews. Furthermore, they claimed that delaying the authorisation procedure would be unethical and therefore not acceptable.

This seems reasonable for the first product incorporating for the first time a new active ingredient, that is an ingredient never authorised before. However, the same market-driven incentives may not have an equivalent effect for follow-up products, such us different salts or derivatives of the same active ingredients, new indications of the same active ingredients, or fixed combination products including the same active ingredient.

In the case of life-cycle strategies where the applicant brings to the market first the monotherapy product or a combination, then a further combination, and then a further one, there is no pressure to immediately obtain the authorisation for the secondary products, but there seem to be more reasons to delay the commencement of the MA application procedure in order to maximise the time for exploiting the product. Again, delays which cause an approval time span of ten years or more will not result in additional benefits due to the time cap.[1101]

Introducing an obligation to pursue the application for the MA with diligence will of course increase the work load for the respective offices and also impose documentation obligations on the applicants. Furthermore, since in many cases the patent holder and the applicant for the MA are not the same legal entity and may even not belong to the same company group, the question would need to be answered how a lack of diligence on the side of the MA applicant may be attributed to the SPC applicant with the consequence of a potentially shorter period of SPC protection. In any case this may give rise to additional litigation should such a provision be implemented and actually enforced by the offices. Nevertheless, other jurisdictions such as the USA or Canada provide for an obligation to pursue the MA application diligently and also for respective sanctions.

The CSP term in Canada, like in Europe, is calculated by subtracting five years from the time elapsed between the patent's filing date and the grant of an authorisation for sale of the product[1102] (i.e. a Notice of Compliance granted by the Canadian Minister of Health).[1103]

From the aforementioned provision, it can be inferred that the Canadian Minister of Health does not take into account for the calculation of the CSP term, like the USPTO, the clinical studies undertaken by the SCP applicant before the authorisation for sale procedure. Consequently, the applicant's due diligence is not controlled with regard to the clinical studies that took place before the starting date of such authorisation procedure (i.e. the new drug submission's filing date).[1104] This is suggested by the wording of the Canadian Patent Code, which refers to an 'unjustified delay in the process of obtaining the authorization for sale'.[1105]

Pursuant to § 156(c)(1) of Title 35 of the United States Code, the PTE applicant must show to have acted with due diligence during the whole drug's regulatory review

[1101] Herwig von Morze, Peter Hanna, 'Critical and Practical Observations Regarding Pharmaceutical Patent Term Restoration in the European Communities (Part II)' [1995] 77 Journal of the Patent & Trademark Office Society 505, 517.

[1102] Patent Act, RSC 1985, c P-4, s 116(3) (Government of Canada Justice Laws Website Access, current through April 24, 2018).

[1103] Food and Drug Regulations, CRC, c 870, s C.08.004(1)(a) (Government of Canada Justice Laws Website Access, current through April 24, 2018).

[1104] Food and Drug Regulations, CRC, c 870, s C.08.002 (Government of Canada Justice Laws Website Access, current through April 24, 2018).

[1105] Patent Act, RSC 1985, c P-4, s 116(4) (Government of Canada Justice Laws Website Access, current through April 24, 2018).

period by accompanying his PTE application with a brief description of the activities undertaken during such period, including the corresponding dates on which those activities took place.

The regulatory review period is divided into two phases, namely the testing phase and the approval phase. The former runs from the date on which the US Food and Drug Administration (FDA) informs the applicant that he can start the clinical studies to the date on which the applicant files a new drug application (NDA). The latter runs from the NDA date of filing to the date of grant of a premarket approval by the FDA.[1106]

According to the above-mentioned, in the US, the due diligence control does not only take place during the drug's approval procedure before the FDA, but the applicant must be able to show that he acted with due diligence also before the NDA filing, namely already at the period when the drug was being tested through clinical trials.

While, dilingence rules were not frequently applied in the USA, this does not mean that they would be useless in Europe. This assessment is based on two points. On the one side, the US-American legislation is stricter with respect to follow-up products. So for instance, combination products and new indications are not eligible for an extension, unless the active igredients concerned were never authorised before. On the other side, the effectiveness of a provision does not depend on the number of cases in which such provision is applied. A provision can exercise a deterring effect even if it is not applied frequently or at all. Such effect is attributed for example to compulsory licenses in some jurisdictions where, in the end, they are rarely granted.[1107] In consideration of some development of the case law in Europe, therefore, the oportunity of a dilingence rule could be considered. However, whether and how to design such a mechanism would require further research and analysis that cannot be offered here. Such topic is presently subject of further individual projects at the MPI.

16.5 INCENTIVE TO OBTAIN THE MA IN THE MOST IMPORTANT MARKET FOR THE MOST RELEVANT INDICATION

A further issue related to the term of protection may arise regarding the decision by the MA holder where to apply first for an MA. This is a critical point for a system of national MA. The first MA determines the term of protection of the SPC. So there is an incentive to obtain the MA first in markets where the approval procedure requires more time, particularly if these are larger markets with higher commercial importance.[1108] There is also the additional incentive to apply first for the commercially most important indication. For example, if the MA application procedure in a relatively small market such as Estonia requires six years, while the MA application procedure in the much larger market France requires nine years, there may be an incentive, at least for second-generation products, to apply first for the MA in France so that it becomes the first MA in the sense of Art. 3(d) of the Regulations. However, since

[1106] 35 USC § 156(g)(1)(B) (GPO Access, current through May 10, 2018). See also 21 CFR § 60.22 (GPO e-CFR current through May 9, 2018).
[1107] See Franz Hacker in Rudolf Busse, Alfred Keukenschrijver, *Patentgesetz* (Walter de Gruyter 2017) § 24, marginal note 16.
[1108] *Ibid.*

currently most applications for an MA are European and not national applications, this problem is most likely of lesser importance.

Finally, it needs to be pointed out that, particularly in the case of chronic diseases which require longer periods of study, the one-size-fits-all SPC term of five years may be unfairly short. This may result in a negative incentive not to develop medicinal products for such diseases.

16.6 SUMMARY AND RECOMMENDATIONS

Based on this analysis the situation regarding the term of SPC protection can be summarised as follows:

- There is no clear empirical data suggesting that the term is either too long or too short.
- From an international perspective the five-year term of protection is comparable to other developed countries that provide either for an SPC or a PTE. However, European law also provides for an additional 6-month term of paediatric extension.
- The present system may provide incentives to delay the commencement of the MA application procedure for follow-on products.
- The present system may provide incentives to apply for a first MA in larger markets and for commercially valuable indications while reducing incentives to conduct research for chronic diseases. However, since most MA applications are European applications, this issue is probably of smaller significance.

17 PAEDIATRIC EXTENSIONS

The paediatric extension of duration is a special incentive linked to the SPC system and aiming to incentivise research in paediatric indications. The legal basis for this extension is provided in Art. 36 Reg. 1901/2006, which reads as follows:

> Where an application under Article 7 or 8 includes the results of all studies conducted in compliance with an agreed paediatric investigation plan, the holder of the patent or supplementary protection certificate shall be entitled to a six-month extension of the period referred to in Articles 13(1) and 13(2) of Regulation (EEC) No 1768/92.
>
> The first subparagraph shall also apply where completion of the agreed paediatric investigation plan fails to lead to the authorisation of a paediatric indication, but the results of the studies conducted are reflected in the summary of product characteristics and, if appropriate, in the package leaflet of the medicinal product concerned.

As correctly stated in *EI Du Pont Nemours & Co v United Kingdom Intellectual Property Office*,[1109] the grant of the extension is subject to three requisites:

- The conditions and the acts in the agreed paediatric investigation plan (PIP) must have been satisfied,
- The product as authorised must include relevant information on the results of the studies,
- An authorisation for the product must have been granted in all Member States.

It is not necessary, by contrast, for the paediatric studies to have led to the authorisation of the paediatric indication. The extension is granted, indeed, as a reward for *conducting* the studies[1110] and not for having obtained the authorisation. Therefore, it is sufficient that the results of these studies be included in the summary of the product characteristics in order for the extension to be granted.

17.1 HISTORICAL BACKGROUND AND OBJECTIVES

A brief review of the particularities of paediatric medicinal products can aid the understanding of the mechanism and the incentives provided under Reg. 1901/2006.

Children are not "merely small adults",[1111] which would allow administering a smaller dosage of products tested, approved and authorised for the general population. Instead, based on children's physiology, factors such as toxicology or effectiveness may differ substantially and in some cases may even require a higher dosage of the same drug to achieve effectiveness.[1112] However, the population of children is – compared to the overall population – relatively small and provides only a small market

[1109] *EI Du Pont Nemours & Co v United Kingdom Intellectual Property Office* [2009] EWCA Civ 966.

[1110] Georgia Gavriilidou, *Pediatrics* in Maria Isabel Manley, Marina Vickers (eds), NAVIGATING EUROPEAN PHARMACEUTICAL LAW (Oxford University Press 2015) p. 191.

[1111] European Commission, 'Better Medicines for Children – From Concept to Reality', Progress Report on the Paediatric Regulation (EC) No 1901/2006, COM (2013) 443 final, p. 6; Peter von Czettritz, Christopher Brückner, *Paediatric Extension of Duration* in Christopher Brückner, SUPPLEMENTARY PROTECTION CERTIFICATES (2nd edn, C. H. Beck 2015), para. 2.

[1112] Birgit Kramer, Antje Katrin Heinemann, 'Arzneimittelforschung für Kinder in Europa' [2006] PharmR 22; Peter von Czettritz, Christopher Brückner, *Paediatric Extension of Duration* in Christopher Brückner, SUPPLEMENTARY PROTECTION CERTIFICATES (2nd edn, C. H. Beck 2015), para. 2.

for sales.[1113] Finally, children are not a homogeneous research or treatment population but must be further subdivided according to age (e.g. newborns, small children, young persons).[1114] Therefore, ordinary incentives, i.e. market competition, do not suffice to motivate pharmaceutical companies to conduct the necessary clinical studies since the sales may not necessarily cover the required costs.[1115] According to the literature, the majority of the medicines before the enactment of the Paediatric Products Regulation that were administered to children were not specifically tested for paediatric use.[1116]

Reg. 1901/2006 acknowledges this situation. As a consequence, it seeks to establish not only a framework for paediatric authorisation and studies, but also IP-based incentives for conducting such studies. According to Recital 26 Reg. 1901/2006, it is the purpose of the paediatric extension

> to grant a reward for the effort involved in evaluating the paediatric effects of the medicinal product in question, by awarding a six-month extension of the SPC to the holder of the basic patent who conducted all the research proposed in the paediatric investigation plan approved for the medicinal product in question.[1117]

17.2 REQUIREMENTS

17.2.1 Application

The paediatric extension is subject to an **application** procedure. The application must be directed to the respective NPOs which are also responsible for granting the SPCs. According to Art. 7 Reg. 469/2009 the application for a paediatric extension may be filed either together with the SPC application, while the SPC application is still pending or within a maximum period of two years before the expiry of the certificate.

17.2.2 Negative-term SPCs

According to the wording of Art. 36 Reg. 1901/2006 and its interpretation by the CJEU[1118] the paediatric extension can only be granted if an **SPC has been granted** in the first place. This means that a stand-alone paediatric extension without an SPC is not available. This may result in constellations in which the patent owner has to apply for an SPC although he is aware of the fact that his SPC will have a zero or negative term. This will be always the case if the time period between the filing of the patent application and the granting of the first MA is five years or less since according to Art. 13 of the SPC Regulation, the SPC term is the difference between the time span from patent application to MA minus five years.

[1113] European Commission, 'Better Medicines for Children – From Concept to Reality', Progress Report on the Paediatric Regulation (EC) No 1901/2006, COM (2013) 443 final, p. 6; also explained in the Swiss legislative process: Botschaft zur Änderung des Heilmittelgesetzes, dated 7 November 2012, p. 36.

[1114] European Commission, 'Better Medicines for Children – From Concept to Reality', Progress Report on the Paediatric Regulation (EC) No 1901/2006, COM (2013) 443 final, p. 6.

[1115] According to Recital 2 Reg. 1901/2006 "market forces alone have proven insufficient to stimulate adequate research into, and development and authorisation of, medicinal products for the paediatric population."

[1116] Georgia Gavriilidou, *Pediatrics* in Maria Isabel Manley, Marina Vickers (eds), NAVIGATING EUROPEAN PHARMACEUTICAL LAW (Oxford University Press 2015) p. 182 with further references.

[1117] Case C-125/10 *Merck Sharp & Dohme* [2011] ECR I-12987, para. 34.

[1118] Case C-125/10 *Merck Sharp & Dohme* [2011] ECR I-12987*;* see also UK IPO, BL O/108/08 *Merck & Co Inc*, Decision of 14 April 2008 of specifically stating that granting an SPC with a negative term for the purpose of a paediatric extension would provide "real benefits in the sense that there is value and meaning in the potential to obtain a paediatric extension.".

The CJEU has decided that the responsible office must grant such an SPC in order to provide the basis for a possible application for a paediatric extension. However, the CJEU also decided that for the calculation of the paediatric extension the negative SPC term must be taken into account with the result that a negative term of protection of the paediatric extension is possible. The court ruled:

> "Article 13 of Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products, as amended by Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006, read in conjunction with Article 36 of Regulation No 1901/2006, must be interpreted as meaning that medicinal products can be the object of the grant of a supplementary protection certificate where the period that has elapsed between the date of lodging the basic patent application and the first marketing authorisation in the European Union is less than five years. In such a case, the period of the paediatric extension provided for by the latter regulation starts to run from the date determined by deducting from the patent expiry date the difference between five years and the duration of the period which elapsed between the lodging of the patent application and the grant of the first marketing authorisation."[1119]

We agree that the grant of the SPC should be possible in these cases as well, but we disagree that the term of the SPC must be negative and reduce the term of the extension. The purpose of the six-month SPC extension is to incentivise paediatric studies. The extension is a reward for the completion of these studies. There is no reason to reduce the six-month exclusivity only because the MA procedure takes less than five years from the filing of the patent application. The SPC is only an instrument to implement the reward mechanism for paediatric studies.

17.2.3 Absence of a waiver or deferral

The applicant cannot obtain a paediatric extension in cases where it has requested and obtained a **waiver** (Art. 7(1)(b) Reg. 1901/2006), **class waiver** (Art. 7(1)(c) Reg. 1901/2006) or a **deferral** (Art. 7(1)(c) Reg. 1901/2006). The requirements for the waivers are laid down in Art. 11 et seq. Reg. 1901/2006. The main reasoning behind the issuance of waivers is that clinical trials on the paediatric population should not be conducted in cases where the medicinal product will likely be unsafe or ineffective or if the disease is one that occurs only in the adult population, i.e. there is no paediatric population to be treated.

17.3 PROCEDURE

17.3.1 Introduction

The application for the paediatric extension must be filed with the NPO that has granted the SPC. The application must include the following documents and statements:

- According to Art. 8(1)(d)(i) Reg. 469/2009 a copy of the **statement indicating compliance** with an agreed and completed investigation plan as referred to in Art. 36(1) Reg. 1901/2006.
- A **copy of the MA** (Art. 8(1)(d)(ii) of Reg. 469/2009).

[1119] Case C-125/10 *Merck Sharp & Dohme* [2011] ECR I-12987.

- In cases of a **decentralised application** for an MA the applicant has to prove that the product has obtained an MA in all Member States according to Art. 36(3) Reg. 1901/2006 (Art. 8(1)(d)(ii) Reg. 469/2009).
- If an SPC has already been granted, the applicant must include a copy of that SPC (Art. 8(3) Reg. 469/2009).
- If an SPC has not been granted yet but the application for the SPC is pending, the applicant needs to include a reference to the pending SPC application (Art. 8(3) Reg. 469/2009).

The application for an extension of the duration of an SPC already granted shall be lodged not later than two years before the expiry of the certificate. According to Art. 7(5) Reg. 469/2009, notwithstanding paragraph 4, for five years following the entry into force of Reg. 1901/2006, the final date for filing the application for an extension of the duration of an SPC was six months before the expiry of the certificate. The transitional period in which this longer deadline rule applied has now expired; the application must be filed by two years before the expiration date of the certificate. Both the statement indicating compliance with an agreed completed investigation plan and, in the case of a decentralised application for an MA, the proof that the MA has been obtained in all Member States, must be filed together with the application. Depending on the length of each national procedure for obtaining a national MA, this can result in complications. These complications have been considered by national practice.[1120]

17.3.2 Practice of the NPOs and case law

In our structured interviews both originator companies and generics companies identified this as an issue. Particularly the originator companies pointed to the fact that if the national procedures were not sufficiently fast, this may lead to a loss of the opportunity to obtain a paediatric extension. The relevance of this issue, however, was not addressed uniformly by the companies and depended on the actual use of the decentralised procedure.

As shown by *EI du Pont and Merck & Co*. and similar cases, for the applicant it can become challenging to provide an application that already includes the statement of compliance (Art. 36(1)) and the MA in all Member States. In consideration that the transitional period of Art. 7(5) has expired, the situation of the applicant has likely not improved since the first experiences with the paediatric regulation.

The NPOs have tried to provide some relief to the applicants by resorting to the extension of time rules.

In *EI Du Pont Nemours & Co v United Kingdom Intellectual Property Office*[1121] the applicant filed the application for the paediatric extension within the required term but with two deficits. First, the application did not contain an MA containing a statement according to Art. 28(3) of the Paediatric Products Regulation. Second, contrary to Art. 36(3) of the Paediatric Products Regulation the product had not yet received authorisation in all Member States. The court of appeal, overruling the lower instances, decided that these deficiencies could be remedied under Art. 10(3), 10(4) and 10(6) of Reg. 469/2009, which states:

[1120] See below for a discussion and overview.
[1121] *EI Du Pont Nemours & Co v United Kingdom Intellectual Property Office* [2009] EWCA Civ 966.

3. Where the application for a certificate does not meet the conditions laid down in Article 8, the authority referred to in Article 9(1) shall ask the applicant to rectify the irregularity, or to settle the fee, within a stated time.
4. If the irregularity is not rectified or the fee is not settled under paragraph 3 within the stated time, the authority shall reject the application.
6. Paragraphs 1 to 4 shall apply mutatis mutandis to the application for an extension of the duration.

Based on the importance of paediatric research, the court decided to give the term "irregularity" in Art. 10(3) Reg. 469/2009 a broad meaning.

According to information received from the NPOs it can be generally said that NPOs are prepared to treat the missing information as irregularities and grant an extended period of time to rectify the irregularities. These terms generally range from two to four months. All NPOs agreed, however, that if at the expiration date of the certificate the documents requested under Art. 8(i) and (ii) Reg. 469/2009 are still missing, no certificate may be granted. The table below provides an overview of the flexibilities at the patent offices. Only one patent office, the office of the Czech Republic, stated that there is no possibility to submit the missing documents at a later point in time.

NPO	Possibility to supplement application after deadline for filing	Period of extension of time	Possibility to grant the extension without the relevant documentation being submitted before expiry of the SPC
Austria	Yes	Time determined by the examiner	
Czech Republic	No	N/A	No
Germany	Yes	Time determined by examiner with possibility of extension	No
Denmark	Yes	One month with the possibility of extra time granted by the NPO in certain circumstances	No
Finland	Yes		No
France	Yes	Two months with possible extension of additional two months	No
Greece	Requirements of Art. 8(1)(d)(i) and (ii) Reg. 469/2009/ EC must by partly filed with the request. The requirements set in (ii) can be filed later	Four months	
Croatia	Yes	Two months	No

Hungary	Yes	From two to four months	No
Ireland	Yes	Four months with possibility for three additional extensions of one month each	No. On one occasion an SPC was granted because the MA was not updated within the required period of time by the authority agency
Italy	Yes	Until the end of the patent term	No
Lithuania	No practice regarding this issue		
Luxembourg	No practice regarding this issue		
Latvia	Yes	No fixed deadline	No
The Netherlands	Yes	No fixed deadline	If the variation procedure has essentially concluded with the end-of-notification letter from the reference member state but the concerned member states do not (as they are required by law) issue updated MAs within 30 days, the extension will be granted anyway.
Poland	Yes		No
Portugal	Yes	Until time of decision on extension	Yes, in cases where member states have not issued the MAs in time and the applicant has provided evidence. The MAs must be provided later
Romania	Yes	The current practice of the Office is to allow the applicant to file them later in a given term, which can be extended by proving that there were taken all the diligences for obtaining and filing the missing documents.	
Serbia	Patent Law does not prescribe extension of the duration SPC according to Art. 8(1)(d) of Reg. 469/2009/EC		

Spain	Yes	Within two months. There is extra two months extension possible	No
Sweden	Yes	Three months from the date of the issuance of the office action and request for missing documents with a possible extension of additional two months. Documents must be valid on the day of the application	No
Switzerland	The law on paediatric extension is adopted but not yet in force in Switzerland. It is expected to enter into force mid-2019.		
Slovak Republic	Yes	Determined by the office	No
United Kingdom	Yes	Determined by the office	No. SPC with extension can be granted on the condition to provide the documents before the expiry of the SPC

Table 17.1: Q69 MPI Questionnaire for the NPOs

17.4 OVERLAP WITH OTHER INCENTIVES

The paediatric extension is a very specific instrument intended to provide incentives to conduct clinical studies but not linked to the time required for the studies. There is no mentioning in the recitals or the articles of the Regulation that the right holder is to be compensated for the loss of effective time of protection. Instead the lawmaker has decided to use the exclusivity provided by the SPC and its extension as an incentive to conduct the necessary studies. The extension is also not limited to paediatric use but covers all uses of the product-patent combination that is the subject matter of the SPC. Since it is a very specific incentive the regulation also ensures that the applicant will not receive multiple incentives.

17.4.1 Data exclusivity

Article 36(5) Reg. 1901/2006 specifies that the applicant cannot obtain a paediatric extension of the SPC term in cases where a one-year extension of data exclusivity has been granted for a paediatric indication:

> "In the case of an application under Article 8 which leads to the authorisation of a new paediatric indication, paragraphs 1, 2 and 3 shall not apply if the applicant applies for, and obtains, a one-year extension of the period of marketing protection for the medicinal product concerned, on the grounds that this new paediatric indication brings a significant clinical benefit in comparison with existing therapies, in accordance with Article 14(11) of Regulation (EC) No 726/2004 or the fourth subparagraph of Article 10(1) of Directive 2001/83/EC."

According to some opinions, Art. 36(5) Reg. 1901/2006 only applies in cases where the extension of data exclusivity has been granted for new paediatric indications.[1122] If the one-year extension has been granted for a non-paediatric indication the SPC holder will be able to obtain the six months of paediatric extension.[1123]

The reason lies in the incentive structure. Market exclusivity and data exclusivity are compensations for the investment in studies required for obtaining an authorisation to place a medicinal product on the market. As explained earlier, it is unclear according to the case law of the CJEU whether the SPC is to be granted even if the patentee has not made any investment to develop a marketable product.

The same lack of clarity surrounds the paediatric extension. One could argue that the paediatric extension is an incentive to conduct clinical studies for a specific population. So the desired behaviour is equivalent to that incentivised through regulatory exclusivity. Such an assumption would be consistent with Recital 28 Reg. 1901/2006, according to which the extension is a reward is for conducting studies in the paediatric population. However, the binding part of Reg. 469/2009 does not require expressly that the patentee must be the one carrying out the paediatric study or that the applicant conducting the paediatric study must agree with the grant of the extension. So it is not clear whether an application for extension can be based on paediatric studies of third parties that do not have any relation to the SPC holder. We refer on this point to the analysis of the third-party issues in Chapter 13.

17.4.2 Orphan medicinal products

An exclusion of paediatric extension applies also in cases where the medicinal product is designated as an orphan medicinal product pursuant to Reg. 141/2000. Art. 36(4) Reg. 1901/2006 specifies

> "Paragraphs 1, 2 and 3 shall apply to products that are protected by a supplementary protection certificate under Regulation (EEC) No 1768/92, or under a patent which qualifies for the granting of the supplementary protection certificate. They shall not apply to medicinal products designated as orphan medicinal products pursuant to Regulation (EC) No 141/2000."

Here the rationale is also to exclude multiple incentives. However, in this specific case it is questionable whether there is actually a double incentive, since the two populations do not necessarily need to be the same, and in cases where a disease has been declared as an orphan disease due to a very small affected population, a potential paediatric subpopulation may be even smaller and particularly benefit from additional paediatric clinical studies.

17.5 ISSUES IDENTIFIED

17.5.1 SPCs with negative term

The first issue identified with respect to paediatric extensions are applications for SPCs with negative term. As explained, an SPC with a negative term will be granted if the time lost during the MA procedure is shorter than five years. But even in cases of SPCs

[1122] Peter von Czettritz, Christopher Brückner, *Paediatric Extension of Duration* in Christopher Brückner, SUPPLEMENTARY PROTECTION CERTIFICATES (2nd edn, C.H. Beck 2015), para. 137.
[1123] *Ibid.*

with negative term, the patent owner may obtain a paediatric extension of six months. As a prerequisite, however, the patent owner must apply for an SPC, knowing that it will have no supplementary protection, since the paediatric extension requires a granted SPC as a basis.

This required application is time consuming and costly for the patent owner. At the same time, it binds resources at the granting authorities who have to evaluate the SPC applications.[1124]

The reason for this issue is that the fixed-term paediatric extension has been linked to the SPC with a flexible term.

The Swiss legislature has decided to address this question. In the framework of the Therapeutic Product Act and the Patents Act the Swiss lawmaker has introduced a new form of SPC, the so called "paediatric supplementary protection certificate".[1125] This certificate grants an SPC-like protection that starts from the expiration date of the patent. The prerequisite for obtaining this special SPC is that no *ordinary* SPC for the same product has been granted. This creates two independent but also mutually exclusive possibilities to obtain a reward with respect to paediatric studies.

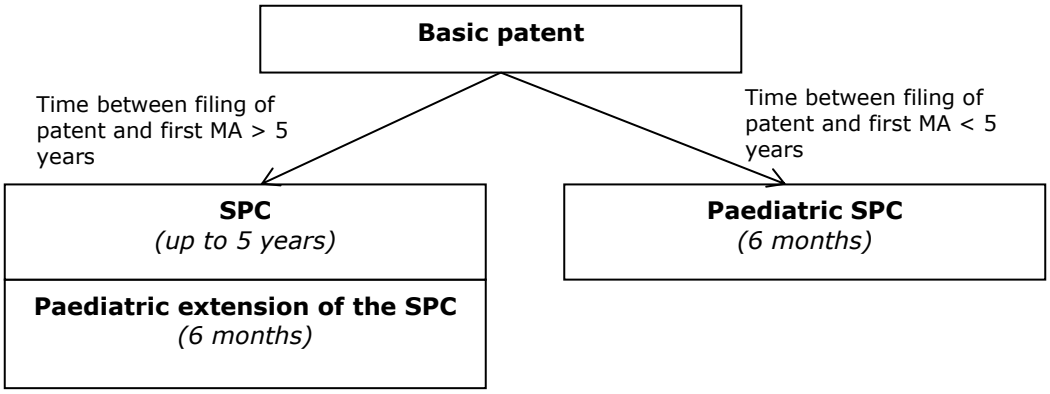

Figure 17.1: Reward with respect to paediatric studies

The option to obtain such an extension without having to rely on an SPC would render the question of SPCs with negative terms obsolete. Further, the paediatric SPC ensures a six-month term of protection in all cases in which paediatric studies were completed in accordance with the requirements of the applicable Swiss law. This solution is more consistent with the rationale of the reward.

It is worth noting that the patent holder is the only one entitled to the extension, but the issue of such extensions requires the consent of the entity that has performed the paediatric study according to the new regulations of the Swiss Patents Act. The report on the Patents Ordinance proposal observes in this regard:[1126]

> „Der Bonus des pädiatrischen Zertifikats wird für den mit dem pädiatrischen Prüfkonzept verbundenen hohen und langdauernden Forschungsaufwand erteilt. Die Zustimmung desjenigen,

[1124] According to information given by one NPO the cases of negative term SPCs are quite limited.
[1125] Pädiatrische ergänzende Schutzzertifikate für Arzneimittel, see Chapter 2(a), Art. 140(t) of the Revised Swiss Patents Act.
[1126] Art. 127(v) Abs. 1 lit. f Verordnung über die Erfindungspatente, Entwurf zur Teilrevision der Verordnung über die Erfindungspatente – Erläuternder Bericht, Bern, 22 June 2017, p. 18.

der die Studien durchgeführt hat, soll verhindern, dass Patentinhaber ohne entsprechenden Aufwand von dieser Belohnung Gebrauch machen können."

This question is not addressed in EU law.

17.5.2 Overlap with orphan drug data exclusivity

The second issue identified with respect to paediatric extensions is the overlap with orphan drug market exclusivity. The interviews with generic manufacturers have shown that the possibility of change between the incentives at a relatively late stage creates a legal uncertainty which leads to later preparation for entering into the market. At the same time, interviews with originator companies have shown that depending on the approval procedures, the decision to change from the orphan drug status to the paediatric extension sometime can only happen relatively late in the process.

From a legal point of view a question to be raised is whether it is really compelling to grant these incentives only alternatively, since the two types of populations are not necessarily the same. An overlap only exists where the orphan indication is an orphan *paediatric* indication. And in these cases the mutual benefits of the paediatric market exclusivity and the paediatric extension should apply.

From a technical point of view, a practical issue that has been subject of discussion and decisions in court proceedings concerns the factual scenario in which a product was originally designated as orphan drug but was subsequently removed by the patent proprietor from the register.[1127] In this factual situation the question discussed is whether or not a paediatric extension of the SPC shall be possible.

The MPI is aware of two decisions at the moment that have dealt with the question, one of the Court of Milan[1128] and another of the Court of the Hague.[1129] Both come to the conclusion that the mere fact that the product was once included in the register does not prevent the NPO from granting the extension. In both cases the holder of the MA and the SPC holder were granted a two-year term of orphan market exclusivity and, after withdrawing the orphan status, a paediatric extension of the SPC. In both cases, the MA holders did not enjoy the two-year period of orphan market exclusivity.

For the Court of Milan one important fact was that the SPC holder did not benefit from the additional two-year period of orphan market exclusivity (Art. 37 Reg. 141/2000). The court stated that Art. 37 Reg. 141/2000 prohibits the accumulation of both incentives – the six-month paediatric extension of the SPC and the additional two years of market exclusivity. As the court explained, it is also in line with the rationale of Reg. 141/2000 if the holder of the SPC and the holder of the MA enjoy the ten-year data/market exclusivity period and the paediatric extension of the SPC since both are incentivising different activities. There is (only) exclusion between the additional two-year period of orphan market exclusivity and the paediatric extension of the SPC.

[1127] See on this decision Bert Oosting, Hein van den Bos, 'The Hague Court confirms paediatric extension of SPC for former EU orphan drug imatinib', available at https://www.lexology.com/library/detail.aspx?g=c45e5f48-de26-46f6-afc8-8c13c2eabb63 (last accessed 6 November 2017).

[1128] Tribunal of Milan, Decision of 23 February 2016, *Teva Italia S.R.L. et al v Novartis AG et al*, Case No 52274-1/2015.

[1129] District Court of the Hague, *Novartis AG v Teva B.V. et al*, Decision of 30 March 2016, Case No C/09/500844 / KG ZA 15-1829.

The Court of the Hague also concluded from Recital 29 Reg. 141/2000 that Art. 36(4) and 37 Reg. 141/2000 want to avoid double incentives. By analysing the wording of the regulation and the rationale of the decision to exclude double incentives, the court concluded that the decisive moment should be the moment of application for the paediatric extension.[1130] However, the court did not decide until which point in time the orphan drug designation can be withdrawn from the register.

Different critical dates are possible: a liberal approach could consider sufficient that removal occurs before the two years exclusivity reward starts to run; a more restrictive approach that takes account of the interest of third parties to certainty could favour an early date. As suggested in the literature, one could argue that the removal shall take place before the MA application for the orphan indication is filed or before the studies are started. Following the reasons for the decision by the Court of the Hague it can also be argued that the decisive moment is the moment of application for the paediatric extension. However, at the same time, the rationale of Recital 29 and Art. 37 Reg. 141/2000 imply, just as the Court of Milan pointed out, that the MA holder may not have benefited from the two-year-extension of market exclusivity yet. Since it would be difficult if not impossible to deduct a partial enjoyment of the two-year period from the six months of paediatric extension, there are good arguments not to allow even a partial enjoyment of that period. In interest of legal certainty, guidance in form of soft law or secondary legislation would be helpful.

17.5.3 Application and granting procedure

The third issue identified primarily based on the interviews and on the responses from NPOs is the application procedure. There are two sides to this issue. On the one side, at the filing date, the applicant could not be in the position to include in the application the MA including an Art. 28(3) statement. On the other side it can happen that in case of mutual recognition procedures the applicant cannot prove on time that an MA has been obtained in all Member States. The latter can be caused not by delays on the side of the applicant but on the side of the authorities competent for granting the MA.

While this may result in hardship for individual SPC holders, the deadline for filing the application for an extension before the expiration of the SPC providing the mentioned documentation is in the interest of all market participants. However, in consideration that the transitional period provided under Art. 7 Reg. 469/2009 has expired, so that the application must now be filed two years before the expiration of the SPC, some relief for the applicants could be considered appropriate.

Therefore, two approaches are conceivable:

- A first option could be to request the applicant to file the application for extension before the deadline already provided in Art. 7 Reg. 469/2009, but with the option to submit the MA and the statement referred to in **Art. 28(3) statement (Art. 8(1)(d)(i)** Reg. 469/2009**)** later. The provision could be refined in different ways and could provide for different precautions. For instance, the EU legislature could provide that the interim request is possible only when at least in one Member State an MA is in force or an end-of-

[1130] *Ibid.,* para. 4.7.1.

procedure-notice exists. The model for such procedural solution would be similar to the interim request discussed in Chapter 10, Section 10.2.2.1.[1131]

- The second option is to try to address the question in regulatory law and to create the procedural option of a speedy procedure for granting the MA in the EU States when an application for a paediatric extension is pending. Of course, whether this approach is realistic has to be discussed with the competent authorities and the experts of this field. This approach would not solve the problem of the time requested for completing the paediatric studies and obtaining the **Art. 28(3) statement** (Art. 8(1)(d)(i) Reg. 469/2009).

17.6 RECOMMENDATIONS

The lawmaker could consider providing for the option of obtaining a paediatric extension whether or not the SPC was applied for and granted. The Swiss legislation described in Section 17.5.1 could provide a model for this reform. Such an option would eliminate the need for an SPC with negative term and would ensure a reward for the paediatric study of six months in all factual scenarios. This is consistent with the rationale of the paediatric reward.

According to some opinions, the lawmaker could alternatively consider removing the mutual exclusivity of orphan drug status and paediatric extension, thus allowing a parallelism of the two incentive measures based on the rationale that the two patient populations are not necessarily identical or overlapping. However, in our view this suggestion needs deeper analysis. It is for an economic study to provide a systematic review of the incentive structure in this field.

In order to reduce the burden for the applicant, the EU lawmaker could consider allowing the submission of an MA after the deadline provided for under Art. 8 Reg. 469/2009. A further approach that is outside the scope of this Study could be to provide fast-track procedures for the MA if an application for a paediatric extension has been filed.

A clarification concerning the eligibility for an SPC extension of products originally designated as orphan drugs seems to be appropriate. This legislative clarification should indicate the period within which the removal from the orphan register must take place.

To streamline the proceedings in the different national offices and to make the required information accessible to SPC applicants, NPOs, as well as the generic stakeholders, it is also possible to create a common repository where the information from the application procedure will be stored and from where it can be accessed when needed. This has also been proposed by several stakeholders at the occasion of the Allensbach Survey. We quote verbatim one statement that was repeated several times:

> "A very practical improvement could be a central repository accessible by applicants and national patent offices containing details of common application documents, such as the marketing authorisation, commission decisions, structural information and the basic patent, would avoid duplicative filings of this material. If this question is also referring to substantive issues being

[1131] See Chapter 10, Section 10.2.2.1.

considered during granting procedures, guidelines on the interpretation of CJEU case law could help patent offices."

While this statement was made specifically as a response to Q62 in the context of differences in the national procedures, the proposed repository can provide an effective means to solve some of the procedural problems with respect to paediatric extensions.

18 SPECIFIC ISSUES IN HEALTH TECHNOLOGY

18.1 INTRODUCTION

One question of this Study is whether the SPC regime for medicinal products needs to be refined with respect to specific category of products also in response to the technical developments that have taken place since the SPCs were introduced in 1992. Some of the medicinal products considered in this Chapter are relatively old and well known to the patent system, such as the antimicrobial agents. Others are comparatively new, such as nanomedicines, personalised medicines or biopharmaceuticals. Further, it is argued that the scope of the SPCs needs to be clarified or reformed with respect to medical devices.

All these topics are the subject of the next sections; some of them were partly dealt with in the analysis of the issues surrounding Reg. 469/2009. Therefore, the present Chapter must be understood as a supplement or further elaboration on those topics.

18.2 BIOLOGICAL PRODUCTS AND BIOSIMILARS

18.2.1 The key issue – the inherent variability of biological substances

In Chapter 14 on the scope of protection[1132] we have suggested that the conclusion drawn for chemical products, that the scope of protection based on the number of cases litigated before the courts seems not to be an issue, may not be valid for biological active substances.

Significant differences exist between biological substances and chemical active substances, which can readily be summarised in table form:

	Chemical medicinal products	Biological medicinal products
Product-related differences	Produced by chemical synthesis	Biotechnologically produced by host cell lines or living organisms
	Low molecular weight	High molecular weight
	Well-defined physiochemical properties	Complex physiochemical properties
	Stable	Sensitive to heat and shear (aggregation)
	Single entity, high chemical purity, purity standards well established	Heterogeneous mixture, broad specification which may change during development, difficult to standardize

[1132] See Chapter 14, Section 14.7.

Manufacturing differences	Completely characterized by analytical methods	Difficult to characterize
	Not affected by slight changes in production process and environment	Highly susceptible to slight changes in production process and environment

Table 18.1: Difference between biological medicinal products and chemical medicinal products[1133]

18.2.1.1 "The process defines the product"

A biological substance is defined in Dir. 2001/83[1134] as:

> "a substance that is produced by or extracted from a biological source and that needs for its characterisation and the determination of its quality a combination of physico-chemical-biological testing, together with the production process and its control."

It is often said that for biological products "the process defines the product"[1135]. Biological products are inherently variable, making them impossible to replicate exactly. Both the biological processes within the cellular expression system and the production process influence this variablity[1136].

The specific growing conditions for the production can affect the structure of the protein produced. According to the authors:

> "Through several enzymatic processes, each cell expression system imprints distinct post-translational modifications (PTMs), which may differ between cell lines, between different clones derived from the same parental cell line and even between individual proteins produced by the same cell."[1137]

18.2.1.2 Not identical but highly similar

In general, different batches of the same product will differ. This microheterogeneity is dealt with by EMA guidelines[1138]. The Note for Guidance on Biotechnological/Biological Products subject to changes in their manufacturing process sets out a general principle:

> Batch to batch comparability does not necessarily mean that the quality attributes of the pre-change and post-change product are identical, but rather that they are highly similar[1139]

1133 Adapted from Bhupinder Singh Sekhon, Vikrant Saluja, 'Biosimilars: an overview' [2011] 1(1) Biosimilars 1, 2, table 1.

1134 As amended by Dir. 2003/63/EC, Annex I, 3.2.1.1(b).

1135 See for example, Arnold G Vulto, Orlando A Jaquez, 'The process defines the product: what really matters in biosimilar design and production?' [2017] 56 Rheumatology.

1136 *Ibid.*

1137 *Ibid.*

1138 See for example, Nanna Aaby Kruse, 'Manufacturing process changes, biologic product comparability and post approval changes', EMA SME Workshop, 16 April 2015 at http://www.ema.europa.eu/docs/en_GB/document_library/Presentation/2015/05/WC500187356.pdf; Veronika Jekerle, 'Regulatory considerations on higher order structure determination and evaluation – an EU perspective', Presented at CASSS-HOS 11-14 April 2016, Long Beach, USA at http://c.ymcdn.com/sites/www.casss.org/resource/resmgr/HOS_Speaker_Slides/2016_HOS_JerkerleVeronika_.pdf (both last accessed 13 November 2017).

1139 EMA, 'Note for Guidance on Biotechnological/Biological Products subject to changes in their Manufacturing Process', CPMP/ICH/5721/03, in force since June 2005, section 1.4.

Although the amino acid sequence (the primary structure) of a protein must remain the same from batch to batch or after a change in production, small variations in higher order structure – such as glycosylation profile – are acceptable, provided that overall clinical safety and efficacy is not significantly changed. This is depicted in the following figure, which illustrates the variability in active substance between different batches of the same biological medicine:

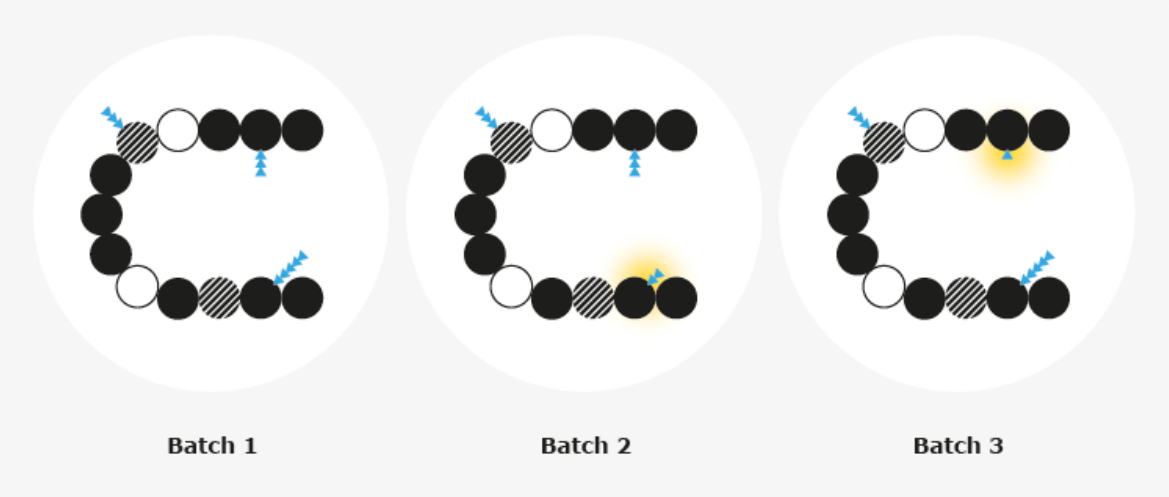

Figure 18.2: The variability in active substance between different batches of the same biological medicine[1140]

18.2.2 The identity of biological active substances – same or different?

With chemical active substances, the identity of an active ingredient is clear. It is straightforward to distinguish between different active ingredients. Equally, it is clear when different active ingredients despite their different originis are to be considered as the same active ingredient in medicinal products – as is the case in generic medicines. Art. 10(2)(b) Dir. 2001/83 states:

> "The different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance shall be considered to be the same active substance, unless they differ significantly in properties with regard to safety and/or efficacy."

But for most biological active substances, particularly those that are glycosylated, because of their inherent variability, it is not easy to draw sharp dividing lines. When is one biological active substance the same as another? And when is it different?

According to Reg. 1234/2008, replacement of a biological active substance with one of a slightly different molecular structure where the efficacy/safety characteristics are not significantly different (with certain exceptions), is considered an extension of a marketing authorisation in the same way that a chemical active substance may be replaced by a different salt/ester complex/derivative, with the same therapeutic moiety.[1141]

[1140] From 'Biosimilars in the EU: Information guide for healthcare professionals', prepared jointly by the EMA and EC, May 2017, p. 9.

[1141] See Annex 1, Reg. 1234/2008, concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products.

In effect, these "slightly different molecular structures" are treated by the EMA as though they were the same active substance. The inherent variability between biological products with the same INN - even within the same manufacturer – has long been recognised.[1142]

Proteins differing in primary structure – that is amino acid sequence – are considered as different active substances.[1143] What is less clear is to what extent differences in glycosylation profile for the same amino acid sequence might be considered to be the same or different.

18.2.3 INN Nomenclature for biological substances

The identity of non-glycosylated proteins, such as somatropin and filgrastim does not pose a problem. An INN identifying the primary sequence is a good characterisation of the protein, irrespective of source. But the majority of therapeutic proteins are glycosylated, notably epoetins and monoclonal antibodies.

Dealing with differences in glyclosylation patterns is challenging.[1144] Different factors as the proteic expression system, the fermentation conditions and downstream processing may influence the glycoform profile and consequently lead to another INN qualification (e.g. through assignment of a new Greek letter second word).[1145] Differences in the glycoform can also follow from changes to the manufacturing process, but this has not lead to a different INN.[1146] Currently, INN applicants for a glycoprotein must identify the new substance by amino acid sequence, positions of disulphide bridges and glycosylation pattern.[1147]

18.2.4 Biosimilars

18.2.4.1 Generics v Biosimilar – not the same, but "highly similar"

In essence, a generic drug can be characterized "as a medicine that contains the same active substance(s) as the reference medicine which is used in the same pharmaceutical form, at the same doses to treat the same disease(s) as the reference medicine".[1148]

A biosimilar, on the other hand, is characterised by the EMA as "a biological medicine that is highly similar to another already approved biological medicine (the 'reference medicine') that has already been authorised for use"[1149].

[1142] See for example, WHO, 'WHO Informal Consultation on International Nonproprietary Names (INN), Policy for Biosimilar Products', INN Working Document 07.211, 2006.

[1143] See for example, the insulin analogues, insulin glargine and insulin lispro, and the epoetin analogue, darbepoetin.

[1144] James S Robertson, 'The challenges of nomenclature – INN, biosimilars and biological qualifiers' [2015] 4(3) Generics and Biosimilars Initiative Journal 110-2.

[1145] See, for example, WHO, 'International Nonproprietary Names (INN) for biological and biotechnological substances', WHO.EMP/RHT/TSN/2016.1, 2016, p.1.

[1146] James S Robertson, 'The challenges of nomenclature – INN, biosimilars and biological qualifiers' [2015] 4(3) Generics and Biosimilars Initiative Journal 110-2.

[1147] See, WHO, 'Guidance on the Use of International Nonproprietary Names (INNs) for Pharmaceutical Substances', Annex 7, Request for an INN, 2017, p. 51.

[1148] See EMA, 'Questions and answers on generic medicines', EMA/393905/2006 Rev. 2, November 2012.

[1149] See EMA, 'Biosimilar Medicines', http://www.ema.europa.eu/ema/index.jsp?curl= pages/medicines/general/general_content_001832.jsp&mid=WC0b01ac0580bb8fda (last accessed 15 November 2017).

A instructive comparison is presented in the table below:

Process	Biologic	Biosimilar	Generic
Manufacturing	Produced by biological process in host cell lines	Produced by biological processes in host cell lines	Produced by using chemical synthesis
	Sensitive to production process changes – expensive and specialised production facilities	Sensitive to production process changes – expensive and specialised production facilities	Less sensitive to production changes
	Reproducibility difficult to establish	Reproducibility difficult to establish	Reproducibility easy to establish
Clinical development	Extensive clinical studies, including Phase I-III	Extensive clinical studies, including Phase I-III	Often only Phase I studies
	Pharmacovigilance and periodic safety updates needed	Pharmacovigilance and periodic safety updates needed	Short timeline for approval
Regulation	Needs to demonstrate "comparability"	Needs to demonstrate "similarity"	Needs to show bioequivalence
Prescribing	By brand name – no automatic substitution allowed	By brand name – no automatic substitution allowed	By generic name – automatic substitution allowed

Table 18.2: Comparison innovative biological products, biosimilars and generics[1150]

18.2.4.2 The Community regulatory framework

Community biosimilar legislation has been in place since 2003, although the term 'biosimilar' is not defined as such in Dir. 2001/83. Instead Art. 10(4) Dir. 2001/83 stipulates:

> "Where a biological medicinal product which is similar to a reference biological product does not meet the conditions in the definition of generic medicinal products, owing to, in particular, differences relating to raw materials or differences in manufacturing processes of the biological medicinal product and the reference biological medicinal product, the results of appropriate pre-clinical tests or clinical trials relating to these conditions must be provided. The type and quantity of supplementary data to be provided must comply with the relevant criteria stated in Annex I and the related detailed guidelines."

The first guideline issued by the EMA on similar biological medicinal products[1151] was in operation from October 2005 to April 2015, when it was succeeded by Revision 1.[1152] A further guideline[1153] effective since December 2015 outlines the quality

[1150] Adapted from Bhupinder Singh Sekhon, Vikrant Saluja, 'Biosimilars: an overview' [2011] 1 Biosimilars 1, 3, table 2.
[1151] EMA, Committee for Medicinal Products for Human Use, 'Guideline on similar biological medicinal products', CHMP/437/04, 30 October 2005.
[1152] EMA, Guideline on similar biological medicinal products, CHMP/437/04 Rev 1, 23 October 2014.
[1153] EMA, Committee for Medicinal Products for Human Use, 'Guideline on similar biological medicinal products containing biotechnology-derived proteins as active substance: quality issues (revision 1)', EMA/CHMP/BWP/247713/2012, 22 May 2014.

requirements for biosimilars. In particular, this guideline requires that the physicochemical characterisation programme should include:

> "a determination of the composition, physical properties, primary and higher order structures of the biosimilar, using appropriate methodologies. The target amino acid sequence of the biosimilar should be confirmed and is expected to be the same as for the reference medicinal product. The N- and C-terminal amino acid sequences, free SH groups and disulfide bridges should be compared, as appropriate. Any modifications/truncations should be quantified and any intrinsic or expression system-related variability should be described."[1154]

It is significant that the first guideline (2005) did not make any recommendations regarding the amino acid sequence of the biosimilar. This is likely to have raised concerns with SPC holders that biosimilar proteins could have different amino acid sequences from those of the reference medicinal product. There now seems little basis for this concern.

18.2.5 How inherent variability challenges the SPC system for biologicals

18.2.5.1 Two questions

The inherent variability of biological active substances raises two questions about the application of the SPC system to biologicals:

- What is the product that is the subject of the MA (Art. 3(a) and (b)) ?
- What is the scope of protection for the product (Art. 4) ?

For chemical substances, a straightforward answer to each of these questions can be given. The product can be named according to the active part of the active substance – e.g., as *idarubicin* or *clopidogrel*, as discussed earlier. In terms of scope, it is reasonable to propose that the certificate protects all the salt, etc, variants of the active part falling within the scope of the basic patent, irrespective of the particular form which is the subject of the marketing authorisation, e.g. both idarubicin hydrobromide and idarubicin hydrochloride would fall within the scope of protection of an SPC based on an MA having idarubicin hydrochloride as the specific form of the active substance and a basic patent claiming idarubicin and salts thereof. This is consistent with the decision of the CJEU in *Farmitalia*.

Further, this approach ensures that the SPC regulation achieves its objective – provided that the basic patent covers generic versions of the chemical substance that is the subject of the MA, then so will the SPC.

But for biological substances, the answers are not straightforward. The situation is different to that considered in *Farmitalia*, as biological active substances are not precisely defined but rather vary – whether from batch to batch of an innovative product or in going from an innovative product to a biosimilar.

A legitimate concern of the holder of an SPC for a biological substance is that the SPC does not adequately identify the active substance or variations of active substance that can be put on the market under the marketing authorisation. A greater concern is that the active ingredient of a biosimilar could be sufficiently similar to that of the reference medicine to permit marketing, whilst sufficiently different to lie outside the

[1154] *Ibid*, 5.3.1. Physicochemical properties.

scope of the SPC. This would be contrary to the very purpose of the SPC regulation, which is to delay competition.

As we shall explain, in the early days of the SPC regulation, some SPC applicants requested very broad product descriptions, perhaps in an attempt to ensure a broader scope of protection under the SPC. We have explained that the legal impact of a product definition on the scope is not clear under the SPC legislation in force. As the regulatory procedures for biosimilars have clarified, it would seem that SPC applicants have been less concerned with obtaining broad definitions.

18.2.5.2 The first question – what is the product?

(a) *Monoclonal antibodies*

(i) Early days

In the early days of SPC applications, from 1993 to about 2005, there was considerable uncertainty concerning the description of biological active ingredients. Although most applicants were content to identify the biological active ingredient as 'X' or 'X and pharmaceutically acceptable salts thereof', where X is the active substance as identified in the marketing authorisation[1155], some applicants tried definitions which resembled patent claims. A notable example was that of Chiron, who in its SPC applications for trastuzumab, the active substance of Herceptin, filed a family of SPC applications[1156], in which the active ingredient was defined as:

> "Murine monoclonal antibody which:
> (a) binds a human breast cancer antigen that is also bound by a reference antibody selected from those produced by the hybridomas obtainable from ATCC HB8488, HB8490, HB8486, HB8484, HB8485, HB8696 and HB8662,
> (b) has a G or M isotype; and
> (c) when conjugated to ricin A chain, exhibits a TCID 50% against at least one of MCF-7, CAmA-1, SKBR-3 or BT-20 cells of less than about 10nM
> preferably the monoclonal antibody which further binds to a protein of approximately 210,000 daltons found in cancerous breast tissue, particularly monoclonal antibody produced by hybridoma HB8488, HB8490, HB8486, HB8697, HB8484, HB8485, HB8696, HB8662, including a monoclonal antibody which is functionally equivalent to any one of the aforesaid antibodies and most prefereably monoclonal antibody Trastuzumab"

However, most patent offices objected to this broad definition and Chiron accepted much narrower product definitions to secure grant, for example in the Netherlands[1157] the applicant accepted 'trastuzumab optionally in the form of a salt'. Several patent offices would not go beyond accepting the definition of the product as 'trastuzumab'[1158] or Herceptin (trastuzumab).[1159] Even the UK office, which at the time was more relaxed, granted the SPC/GB01/011 with the definition:

> "trastuzumab as present in the EMEA approved product Herceptin, comprising the various forms and post- translational modifications of Trastuzumab present therein, and salts and esters thereof"[1160].

1155 See for example, UK SPC/GB99/012, basiliximab, UK SPC/GB01/046 alemtuzumab.
1156 See for example, UK SPC/GB01/011 and NL 300040.
1157 NL 300040, granted 23/10/2003.
1158 For example, Belgium and France.
1159 For example, Italy and Sweden.
1160 UK SPC/GB01/011, granted 6/02/2003; Chiron withdrew the parallel trastuzumab application SPC/GB01/010 on 3/04/2003.

This description of the active substance appears to be addressing issues associated with the inherent variation in biological products.

The *Farmitalia* decision may have prompted some applicants to attempt claim-like definitions, in the hope of covering therapeutic equivalents. Whilst Abbott sought, and was granted, SPCs for adalimumab, the active substance of Humira[1161], Yeda, who had licensed a patent to Abbott relating to adalimumab, defined the product in very broad terms:

> "Human monoclonal antibody against tumor necrosis factor alpha (TNF-alpha)"[1162]

This definition covers not only adalimumab – the first human anti-TNF alpha antibody authorised in Europe, it also covers ALL conceivable human anti-TNF alpha antibodies – several of which were in development at the time. It also covers all possible biosimilars of adilimumab.

Not surprisingly, such a formulation was not acceptable to national patent offices. In all jurisdictions, the applicant was requested to amend the definition to refer to adalimumab or similar.[1163]

The Dutch patent office intended to do the same.[1164] However, Yeda did not accept this definition and an appeal was heard in the Dutch patent office, and following rejections from the patents appeal board[1165] and the District Court of the Hague (Rechtnank's-Gravenhage)[1166], the case was heard by the Council of State[1167]. We have already discussed the decision in Chapter 14. The decision is worth considering in more detail here because it has likely affected the subsequent practice.

(ii) Yeda

In all three fora – the patent office, the District Court and the Council of State, Yeda asserted that European Court ruling in C-392/97 *Farmitalia* supported its request for a definition of product going beyond that given in the marketing authorisation, i.e. adalimumab.

The findings of the Council of State (CoS) in rejecting Yeda's appeal can be summarised as follows:

- That the basic patent protects other monoclonal antibodies does not in itself mean that a certificate with a broader product description than the antibody in question would ignore the limitation of Art. 4.

[1161] See for example, UK SPC/GB04/002 and NL 300142.
[1162] See for example, UK SPC/GB04/2004, filed 2 March 2004 and NL.
[1163] For example in the UK, the granted SPC described the product as 'Human monoclonal antibody against tumor necrosis factor (TNF) alpha (Adalimumab). In France it was granted as "Adalimumab (anticorps monoclonal d'origine humaine dirigé contre le facteur de nécrose tumorale (TNF)" and in Germany (oddly perhaps) there were two granted SPCs, one to Humira – adalimumab, the other to Trudexa-Adalimumab. In Belgium, the SPC was granted with the simple definition 'adalimumab'.
[1164] NL 300142, first grant decision, 14/06/2005.
[1165] 12/01/2007.
[1166] District Court of the Hague, *Yeda Research and Development Company Ltd v the Netherlands Patent Office,* Decision of 12 November 2008, Case No 07/3560.
[1167] Netherlands Council of State, *Yeda Research and Development Company Ltd v the Netherlands Patent Office*, Decision of 19 August 2009, Case 200809060/1/H3.

- From the *Farmitalia*-judgment it follows that there may be circumstances which justify a broader product definition – e.g., salts, esters or other chemical derivatives thereof. But this was not the case here.
- Although it is generally accepted that chemical derivatives of an active ingredient, such as salts and esters, as a rule, have the same effect as the relevant active ingredient, the same is not true for related biological medicinal products.
- Yeda has not made plausible that in the specific case of adalimumab that such an equivalence can be assumed in principle.
- The lower court was right in finding that a biological medicinal product differs fundamentally from the situation that was judged in the *Farmitalia*-judgment.
- There was no reason to deviate in the product description for the SPC from the description of the active ingredient in the market authorisation.[1168]

The District Court found that the description of the active ingredient in the medicinal product in the marketing authorisation determines the question of what must be considered as the product within the meaning of the Regulation[1169].

(iii) The current SPC practice in relation to monoclonal antibodies

Since the authorisation of Humira/adalimumab in 2003, up to the end of 2016, the EMEA/EMA has authorised some 45 monoclonal antibodies as new active substances. Many of these products have been the subject of SPC applications, often with two or more applications per MA. The applications have been spread across a wide range of stake holders, from major international companies to research institutes, universities and small and medium size enterprises. The EU has grown from 15 to 28 states and with the participation of the EFTA states, Norway and Iceland, a family of SPC applications can cover 30 states (although applications in Croatia, Malta and Iceland are still relatively rare).

However, practices both by applicants and patent offices have become much more consistent. Applicants, in particular, tend to be more coordinated in their description of 'product' in their SPC filings across the EEA. Patent offices are also more consistent in their practices in what they accept. This in part is due to greater availability of information on on-line patent registers,[1170] which seems to make applicants more realistic and also due to patent examiners meeting regularly to discuss their approaches to dealing with SPC matters.[1171]

The data gathered for this Study shows that the general rule for applicants is to identify a monoclonal active ingredient in the same way as it is defined in part 2 of the SmPC – that is by the INN of the active substance.

[1168] Summarised from Council of State decision, paras. 2.5.1 - 2.5.4.
[1169] District Court of the Hague, *Yeda Research and Development Company Ltd v the Netherlands Patent Office*, Decision of 12 November 2008, Case No 07/3560, para. 6.
[1170] The Dutch, Belgian and French registers are particularly good in this regard, as they include most, if not all, of the correspondence between applicant and office. The Irish patent office register has particularly flexible search facilities, allowing searches for truncated words, which does not seem possible in other registers.
[1171] For example, the "Meetings of National Experts" held in 1995, 2006 and 2008, as well as the subsequent fora, such as those held in Hague, Dublin and Berlin.

(b) *Other protein-based biological active substances*

Our preliminary investigations suggest that the same is true for other protein-based biological medicines, such as insulin analogues, growth hormones, epoetins and blood clotting factors VIII and IX, where the INN systems is used in the marketing authorisation and has been followed by SPC applicants. The same is also true for low molecular heparins.

However, there is little experience relevant to SPCs, as few of these active substances have been patented. The early products of recombinant DNA technology were human proteins, for example insulin, growth hormones, interferons and erythropoetins, which were not novel and so not patentable. Some of these biological medicines were approved by national regulatory agencies, but with the establishment of the European Agency for the Evaluation of Medicinal Products in 1993[1172], the precursor to the EMA, Reg. 2309/93 required that the use of the centralised procedure was compulsory for "medicinal products developed by means of recombinant DNA technology, controlled expression of genes coding for biologically active proteins in prokaryotes and eukaryotes including transformed mammalian cells, and hybridoma and monoclonal antibody methods."[1173] Of these, the most important products have been monoclonal antibodies, and all but one monoclonal antibody has been approved by the EMEA/EMA.

(c) *Biological active substances – the developing landscape*

In the context of authorised medicinal products in the Community, biological active ingredients are much more common now than when Reg. 1768/92 came into effect. In 2016, the EMA adopted recommendations on 27 new active substances for human medicines and 6 for veterinary medicines.[1174] 15 of the human medicinal products had chemical active substances and 12 had biological active substances. The biological active ingredients were dominated by therapeutic monoclonal antibodies (six) and included fusion proteins, as well as gene therapy products and one vaccine. Four of the six veterinary new active substances were biological – all vaccines.

Although stem cell therapies and nucleic acid-based products have been authorised in the Community, the majority of approved biological medicines in the foreseeable future will continue to be protein-based[1175].

Fusion proteins and antibody drug conjugates (ADCs) are addressed below, as two other areas where INN nomenclature is not widely available and alternative naming strategies are used instead – vaccines and advanced therapy medicinal products (ATMPs).

[1172] Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products.

[1173] Art. 3(1) Reg. 2309/93.

[1174] EMA, 'Medicine evaluation figures, Annual medicines highlights', 2016 at http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/document_listing/document_listing_000256.jsp&mid=WC0b01ac0580099fbb (last accessed 26 April 2018).

[1175] Miranda MC van Beers, 'Minimizing immunogenicity of biopharmaceuticals by controlling critical quality attributes of proteins' [2012] 7 *Biotechnol. J.* 1-12.

(d) *Vaccines*

As highlighted by the WHO, vaccines are not included within the INN system.[1176] Their names have been assigned according to recommendations of the Expert Committee on Biological Standardization and to the pharmacopoeial monograph.[1177]

SPC applicants seem to identify the active substances (antigens) by reference to the relevant SmPC. No examples have been identified where SPC applicants have attempted alternative naming strategies.

(e) *Advanced therapy medicinal products (ATMPs)*

The number of ATMPs[1178] authorised by the EMA to date has been low. From 2009 to September 2017, only nine products have been authorised by the EMA as ATMPs: three gene therapy products, two somatic cell products and four tissue engineered products. A further four applications are under review.[1179]

Name	MA Date	Active substance	Category	Status	SPC
ChondroCelect	10/2009	Characterised viable autologous cartilage cells expanded *ex vivo* expressing specific marker proteins	Tissue engineered	W	✓
MACI	6/2013	Matrix applied characterised autologous cultured chondrocytes	Tissue engineered	S	
Provenge	9/2013	Autologous peripheral-blood mononuclear cells activated with prostatic acid phosphatase granulocyte-macrophage colony-stimulating factor (sipuleucel-T)	Somatic cell	W	
Glybera	10/2012	Alipogene tiparvovec	Gene therapy	W	✓
Holoclar	02/2015	*Ex vivo* expanded autologous human corneal epithelial cells containing stem cells	Tissue engineered	A	✓
Imlygic	12/2015	Talimogene laherparepvec	Gene therapy	A	✓
Strimvelis	05/2016	Autologous CD34+ enriched cell fraction that contains CD34+ cells	Gene	A	

[1176] See WHO, 'International Nonproprietary Names (INN) for biological and biotechnological substance', 2016, para 2.12 at http://www.who.int/medicines/services/inn/BioReview2016.pdf (last accessed 26 April 2018).

[1177] *Ibid.*

[1178] For the notion of ATMP see EMA, 'Advanced therapy medicinal products', at http://www.ema.europa.eu/ema/index.jsp?curl= pages/regulation/general/general_content_000294.jsp&mid= WC0b01ac05800241e0 (last accessed 26 April 2018).

[1179] EMA, CAT monthly report of application procedures, guidelines and related documents on advanced therapies, EMA/CAT/674185/2017, October 2017 meeting at http://www.ema.europa.eu/docs/en_GB/document_library/Committee_meeting_report/2017/10/WC500237198.pdf (last accessed 26 April 2018).

		transduced with retroviral vector that encodes for the human ADA cDNA sequence	therapy		
Zalmoxis	08/2016	Allogeneic T cells genetically modified with a retroviral vector encoding for a truncated form of the human low affinity nerve growth factor receptor (ΔLNGFR) and the herpes simplex I virus thymidine kinase (HSV-TK Mut2)	Somatic cell	A	✓
Spherox	07/2017	Spheroids of human autologous matrix-associated chondrocytes	Tissue engineered	A	

W: Withdrawn; S: Suspended; A: Active

Table 18.3: ATMPs authorised by the EMA (September 2017), compiled from EMA data (marketing authorisations) and NPO (SPC applications)[1180]

So far at least five of the nine authorised ATMPs have been the subject of SPC applications. None has given rise to any SPC case law. In two cases (ChondroCelect and Glybera) the marketing authorisation for the ATMP has been withdrawn.

In all five SPC applications, it seems that applicants have identified the product in the SPC applications in identical fashion to the identification of the active substance in the marketing authorisation. In the two gene therapy SPC cases, the active substance has been identified by an INN (Glybera/alipogene tiparvovec[1181] and Imlygic/talimogene laherparepvec[1182]), whereas for the remaining SPC applications (ATMPs approved), a common name has been used, for example, "characterised viable autologous chondrocytes expanded *ex vivo* expressing chondrocyte-specific marker" for the SPC application based on the MA for ChondroCelect.

However, it is unlikely that there is any significant effect in the use of an INN or common name for the identification of the SPC product. The INN is merely a convenient short hand – in contrast to biological active substances such as monoclonal antibodies and fusion proteins, which can be defined in structural terms of amino acid sequence, location of disulphide bridges and glycosylation sites, ATMP tend to be named in more descriptive and functional language rather than in structural terms.

It remains to be seen whether this will give rise to issues under Art 3(a). As far as the scope of protection is concerned, it would seem that the names of the active substance for ATMPs are quite broad, suggesting the identifying the product by the common name would cover a wide range of equivalent active substances.

[1180] EMA, CAT monthly report of application procedures, guidelines and related documents on advanced therapies, EMA/CAT/674185/2017, October 2017 meeting at http://www.ema.europa.eu/docs/en_GB/document_library/Committee_meeting_report/2017/10/WC500237198.pdf (last accessed 26 April 2018).

[1181] Recommended INN List 61, alipogene tiparvovec is recombinant adeno-associated virus serotype 1 (AAV1) vector expressing the S447X variant of the human lipoprotein lipase (LPL) gene; WHO, Quality Assurance and Safety of Medicines [2009] 23(1) 'WHO Drug Information' p. 51.

[1182] Recommended INN: List 66, talimogene laherparepvec is recombinant replicating *Herpes simplex* type - 1 virus vector, with ICP47 and both copies of ICP34.5 genes deleted, expressing human granulocyte macrophage colony stimulating factor (hGM-CSF) in the ICP34.5 loci; WHO, Quality Assurance and Safety of Medicines [2011] 25(3) 'WHO Drug Information', p. 330.

But at present the area is in its infancy. There are no guidelines or reflection papers for ATMP biosimilar policy. As the marketing authorisations for the first four ATMPs have neither been withdrawn nor suspended, it would seem an application for a biosimilar to an ATMP (Holoclor) could not be granted until 2025.

Although few ATMPs have been authorised to date in the EU, an experienced group of authors from the EMA and national medicines agencies[1183] suggest that the clinical trials regulation, Reg. 536/2014, which comes into force in 2018, will speed up the clinical trial process for ATMPs and should support the entry of further ATMPs into the European market. According to the authors:

> "A survey conducted by the authors on ATMPs in clinical trials during 2010–2015 by the authors in the EU was conducted in order to study the trends of ATMP development since the earlier survey published in 2012. According to the results, the number of clinical trials using ATMPs is slowly increasing in the EU. The focus is still in early development, and the projects are mainly carried out by small and medium-sized enterprises, academia, and hospitals. Oncology is the main area of clinical development."[1184]

The authors take the view that "the balance between cell-based products and gene therapy medicinal products in this area may be changing in the future due to the new T-cell technologies."[1185]

For ATMPs, the present SPC regulation appears suitable and we do not propose any changes to take account of the developments in this area.

(f) *Antibody drug conjugates – covalent combinations?*

According to a recent review by Dennier,

> "monoclonal antibodies and their derivatives are currently the fastest growing class of therapeutics. But these "naked" antibodies have proven their value as successful biological medicines, they suffer from some limitations. To overcome suboptimal therapeutic efficacy, immunoglobulins are conjugated with toxic payloads to form antibody drug conjugates (ADCs). These could be a promising emerging therapeutic area".[1186]

ADC are made up of three components: a monoclonal antibody, which determines which cells are targeted, a toxic drug, which kills the targeted cells and a linker or trigger, conjugating the antibody to the drug, which releases the drug in the region of the targeted cell[1187]:

[1183] Tomáš Boráň et al, 'Clinical Development and Commercialization of Advanced Therapy Medicinal Products in the European Union: How Are the Product Pipeline and Regulatory Framework Evolving?' [2017] 28(3) Hum Gene Ther Clin Dev. 126-135.

[1184] *Ibid.*

[1185] *Ibid.*

[1186] Patrick Dennler et al, 'Antibody Conjugates: From Heterogeneous Populations to Defined Reagents' [2015] 4 Antibodies 197-224.

[1187] Diagram adapted from Paul Polakis, 'Antibody Drug Conjugates for Cancer Therapy' [2016] 68(1) Pharmacolgy Reviews 3-19.

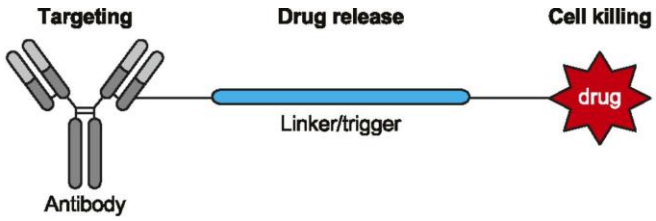

Figure 18.3: The components of an ADC[1188]

In C-631/13 *Forsgren*, the CJEU found that Arts. 1(b) and 3(a) Reg. 469/2009 must be interpreted as not precluding, in principle, the possibility that an active ingredient can give rise to the grant of a supplementary protection certificate where the active ingredient is covalently bound to other active ingredients which are part of a medicinal product.

This opens the possibility of several options for protection for an ADC, depending on whether the antibody has previously been the subject of an SPC or of a marketing authorisation whether the ADC, as a whole, is protected by a patent.

To date, three ADCs have been authorised in the EU, Adcetris/brentuximab vedotin[1189], Kadcyla/trastuzumab emtansine[1190] and Besponsa/inotuzumab ozogamicin[1191]. In all three cases, the CHMP considered the ADCs to be new active substances. It appears that patents have been granted expressly claiming each of the three ADCs and at least in the case of brentuximab vedotin[1192] and trastuzumab emtansine[1193] these have been the subject of granted SPCs.

It is far too early to comment on how the SPC system is working for this new class of therapy.

(g) *Fusion proteins*

Fusion proteins are proteins created through the joining of two or more genes that originally coded for separate proteins. The first commercially significant fusion protein medicine in the Community, was Enbrel which contained as active substance etanercept which, according to the first published EPAR, consists of the

> "extracellular ligand-binding portion of human tumor necrosis factor receptor (p75) linked to an analogue human Fc portion of human IgG1".[1194]

Etanercept was the subject of several families of SPCs in the Community,[1195] in each case, the product being referred to by its INN.

More recently, several Fc fusion proteins of coagulation factors VIII and IX have been authorised by the EMA.[1196] Each of the active substances of these products has been

[1188] Aadapted from Paul Polakis, 'Antibody Drug Conjugates for Cancer Therapy' [2016] 68(1) Pharmacolgy Reviews 3-19.
[1189] Authorised EU/1/12/794, 25.10.2012.
[1190] Authorised EU/1/13/855, 15.10.2013.
[1191] Authorised EU/1/17/1200, 29.06.2017.
[1192] Based on EP 1 545 613.
[1193] Based on EP 1 689 846; in some jurisdictions an SPC application was also made based on EP 865 448, but at least in NL this has been rejected (July 2017). We have not investigated this case.
[1194] Enbrel/etanercept, first authorised 03.02.2000, EPAR – Scientific discussion 18.10.2006.
[1195] See for example, Dutch SPCs 30008, 30009, 30013 and 30129 (NL NPO website).

classed by the EMA as a "new active substance", although each could be considered to be derivatives of the previously authorised octocog alfa[1197] or nonacog alfa[1198] as appropriate. A preliminary survey of the SPC applications made in relation to these fusion proteins suggests that SPC applicants are treating these medicines as having new active substances.

Although for this class of active substances most SPC applicants are identifying the product using the INN as it is referred to in the marketing authorisation and SmPC, there was a single example of an alternative approach, where the applicant sought a broader product definition:

> "Efmoroctocog alfa or a biosimilar product pursuant to Article 10(4) of Directive 2001/83, as protected by the basic patent"[1199].

However, this seems an isolated attempt to get a broad product definition. Where the SPC has been granted,[1200] the applicant has accepted conventional product description for the SPC, based on the INN.

(h) *The first question – conclusions*

Although there may still be uncertainties as, for example, what precisely the INN of a biological active substance represents, the overwhelming current practice of SPC applicants is to identify the active ingredient using common name as used in the marketing authorisation and the SmPC. There appears to be only one exception to this in the last 10 years – where the SPC applicant sought protection for biosimilars of efmoroctocog alfa. Even so, the applicant dropped this request to secure grant, without attempting to challenge the stance of the patent offices.

The conclusion must be that as first as the identification of the biological products is concerned, the SPC system does not require any change. The new therapeutic area of ADCs may give rise to clarification on the meaning of combination and the application of the ruling from C-631/13 *Forsgren*, but it is much too early to comment or make proposals. Overall, SPCs are being granted to biological substances. It remains to be seen whether these SPCs have been validly granted. The issue of scope is the subject of our second question.

18.2.5.3 The second question – what is the scope of a biological SPC?

(a) *The absence of case law*

If one excepts the EFTA case, discussed in Chapter 14, there is no case law at present relating to the scope of an SPC for a biological active substance. Further, there is no case law of which we are aware that address the question whether or not an SPC covers biosimilars to the reference product having the relevant active ingredient(s). In part, this is because relatively few active substances have been the subject of

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1196 For example, Vihuma/simoctocog alfa, Afstyla/lonoctocog alfa, Alprolix/eftrenonacog alfa and Idelvion/abutrepenonacog alfa (source: EMA website).
1197 See for example, Kogenate Bayer/octocog alfa, first authorised 04.08.2000.
1198 See for example, BeneFIX/nonacog alfa, first authorised 27.08.1997.
1199 See for example, NL SPC application 300799, based on EP 1625 209 and EU/1/15/1046, granted 23.11.2015.
1200 According to online inspections of patent office registers, in NL, FR and SE, 06.11.2017.

biosimilars – to date thirteen active substances. Few of these active substances have been protected by SPCs.

(b) *The biosimilar landscape*

The following classes of biological medicines for which a biosimilar has been approved by CHMP, together with the earliest EC authorisation and SPC expiry date is set out below:

Classes of Biological Molecules	Active substance	Earliest EC authorisation	SPC, expiry date
Polysaccharides			
Low Molecular Weight Heparins	Enoxaparin sodium	09/2016	None
Proteins			
Growth factors	Epoetin	08/2007	None
	Filgrastim	08/2008	None
Hormones	Foliotropin alfa	09/2013	None
	Insulin glargine	09/2014	05/2015
	Insulin lispro	09/2017	04/2011
	Somatropin	04/2006	None
	Teriparatide	01/2017	None
Fusion proteins	Etanercept	01/2016	01/2015
Monoclonal antibodies	Adalimumab	03/2017	10/2018
	Infliximab	09/2013	02/2015
	Rituximab	02/2017	None
	Trastuzumab	11/2017	07/2014

Table 18.4: Classes of biological medicines for which a biosimilar has been approved[1201]

(c) *Absence of litigation*

To October 2017, only six active substances which have been approved as the active substances of biosimilars have been the subject of SPCs. Three of these SPCs – to etanercept, insulin lispro and trastuzumab – relate to biosimilar products authorised after SPC expiry, so no conclusions can be drawn about their effect in controlling access to the market. However, in patent litigation relating to the secondary patents

[1201] Adapted from Table 2, 'Biosimilars in the EU', prepared jointly by EMA and EC, published May 2017 , with supplementary SPC data gathered from patent office registers.

protecting trastuzumab, Hospira indicated that it wished to sell its biosimilar to trastuzumab after SPC, rather than patent expiry.[1202]

The three SPCs protected active substances have been the subject of biosimilars approved before SPC expiry – insulin glargine, infliximab and adalimumab. In the case of insulin glargine, the first commercial launch in a major European market (UK) took place in August 2015, after SPC expiry, although the biosimilar was introduced in Eastern European markets, for example in Czech Republic, Slovak Republic and Estonia, where there was no SPC protection, earlier in 2015[1203]. Similarly, Inflectra (biosimilar to Remicade/Infliximab) was first launched in February 2014 in Central and Eastern European countries (Bulgaria, Croatia, Estonia, Hungary, Latvia, Lithuania, Poland, and Romania), where it had no SPC protection following authorisation in September 2013[1204], but it was not launched in the rest of Europe until late February 2015, following SPC expiry.[1205]

The SPC for adalimumab will not expire until October 2018, but four biosimilar versions have already been authorised in the EU. However, none has been launched. In UK patent litigation, relating to secondary adalimumab patent, the biosimilar MA holders declared their intention to market a biosimilar product in Europe, including the UK, after the expiry of the adalimumab SPC (and provided they could clear away the secondary patents).[1206]

This very preliminary experience could be interpreted as indicating that biological SPCs are achieving their intended effect of delaying generic/biosimilar entry until after SPC expiry. It is clear that there are at least minor differences, particularly in glycosylation patterns, between the active substance of the reference product and that of the biosimilar, which is discussed below.

What we do observe is that irrespective of these minor differences, the biosimilar in each case identifies the same active substance in terms of INN as the reference medicinal product.

(d) *How significant are the "minor" differences in structure*

According to two Amgen authors:

> "Biosimilars are required to be similar or highly similar in structure to their biologic reference product but are neither expected nor required to contain identical active substances. For example, glycosylated biosimilars approved to date demonstrate quantitative and qualitative structural differences from their reference product and exemplify the latitude of variations permitted for biosimilars."[1207]

1202 *Hospira UK Ltd v Genentech Inc* [2014] EWHC 1094 (Pat) (10 April 2014).

1203 Phil Taylor, *PMLive*, 'Lilly and Boehringer Ingelheim launch Lantus biosimilar in UK' of 26 August 2015 at http://www.pmlive.com/pharma_news/lilly_and_boehringer_launch_lantus_biosimilar_in_k_806879 (last accessed 26 April 2018).

1204 See Alvogen press release of 13 February 2014, 'Alvogen launches Inflectra in Europe with Hospira' at https://www.businesswire.com/news/home/20140213005477/en/Alvogen-launches-Inflectra-Europe-Hospira (last accessed at 26 April 2018).

1205 See report of 25 February 2015 by Andrew Ward, 'Hospira and Celltrion launch biosimilars,' Financial Times, at https://www.ft.com/content/ebfba63c-bc3d-11e4-a6d7-00144feab7de (last accessed 26 April 2018).

1206 *Fujifilm Kyowa Kirin Biologics Company Ltd v Abbvie Biotechnology Ltd (Rev 1*) [2017] EWHC 395 (Pat) (03 March 2017).

1207 Gustavo Grampp, Sundar Ramanan, 'The Diversity of Biosimilar Design and Development: Implications for Policies and Stakeholders' [2015] 29 BioDrugs 365-372.

The authors go on to compare structural differences between the active substances of biosimilars and their relevant reference products, in the following table:

Approved biosimilar	Reference product	Structural differences relative to reference product
Retacrit® (epoetin zeta; SB309)	Eprex®/Erypo® (epoetin alfa)	Higher levels of glycoforms lacking occupied O-glycan site Lower levels of N-glycolylneuraminic acid and O-acetylneuraminic acid
Binocrit® (epoetin alfa; HX-575)	Eprex®/Erypo® (epoetin alfa)	High Man-6-P levels detected in clinical study batches
Remsima™ (infliximab; CT-P13)	Remicade® (infliximab)	Lower levels of afucosylated variants
Ovaleap® (follitropin alfa; XM17)	Gonal-f® (follitropin alfa)	Slight shift in sialic acid content and increase in nonhuman sialic acid variants with N-glycolylneuraminic acid
Bemfola® (follitropin alfa)	Gonal-f® (follitropin alfa)	Minor differences in glycosylation profile Ratio of tetra-antennary:di-antennary structures slightly higher Slight differences in distribution of fucosyl residues in relation to antennarity O-acetyl–containing sialic residues of α-subunit below level of detection

Table 18.5: Structural differences between the active substances and their relevant reference products[1208]

Epoetin has not been the subject of SPC protection, so there has not been an opportunity to test the significance of these differences in terms of the scope of an SPC. However, questions are raised. Would an SPC based on a marketing authorisation for epoetin alfa (a specific glycosylated form) cover the medicinal product Retacrit with active substance epoetin zeta (a different glycosylated form, but authorised as a biosimilar)? Further, although Binocrit is said to have epoetin alfa as active substance, there are substantial differences in glycosylation patterns, according the EMA's European Public Assessment Report (EPAR) for Retacrit[1209]. Which of these products would have been covered by an SPC based on the first marketing authorisation for epoetin alfa? All? Some? None?

(e) *How should "stand alone" products be dealt with?*

According to the EMA's Guideline on similar biological medicinal products,[1210] "if the biosimilar comparability exercise indicates that there are relevant differences between the intended biosimilar and the reference medicinal product making it unlikely that

[1208] Adapted from Grampp and Ramanan, *ibid.*
[1209] EMA web site, Retacrit: EPAR – Scientific Discussion, published 15 January 2008.
[1210] EMA, Committee for Medicinal Products for Human Use, 'Guideline on similar biological medicinal products', CHMP/437/04 Rev 1, 23.10.2014, p. 6.

biosimilarity will eventually be established, a stand-alone development to support a full Marketing Authorisation Application should be considered instead."

Several medicinal products have been authorised as stand-alone products, including Eporatio/epoetin theta[1211] and Rixubis/nonacog gamma[1212]. In the case of Rixubis, authorisation followed a complete and independent application under Art. 8(3) Dir. 2001/83. The applicant indicated nonacog gamma was considered to be a known active substance.[1213] Should the use of an independent application for a marketing authorisation, under Art. 8(3), rather than as a biosimilar, under Art. 10(4) Dir. 2001/83 make any difference to the question whether a product infringes a SPC? The matter has not been tested. The EFTA Court seems to consider not relevant what the regulatory route of the allegedly infringing product is, but it has denied in the case infringement of a product that was authorised on the basis of a stand-alone application.[1214]

The fact that the applicant may decide whether to obtain a generic application or stand-alone application for a chemical substance that is identical to a substance already authorised, shall exclude in the chemical field that that regulatory route as such is sufficient to deny an infringement. The same principle applies to biological products. However, it remains unclear what are the criteria to decide when a substance is the same and infringe the certificate, and when it is not.

(f) *Uncertainties in relation to INN names and biosimilars*

Some commentators take the view that use of the same INN for the active substance of both biosimilar and reference product obscures potentially clinical differences.[1215] Grampp and Ramanan of Amgen have argued that

> "because the quality attributes of a biosimilar will likely vary from those of the reference product, biosimilars should not be considered to have the 'same' active substance as their reference product or other biosimilars of the same reference product".[1216]

To address these concerns, the WHO Programme on INN has proposed the use of a "Biological Qualifier" (BQ) to be

> "assigned to all biological substances having (or eligible to have) INNs. The BQ is an additional and independent element used in conjunction with the INN to uniquely identify a biological substance to aid in the prescription and dispensing of medicines, pharmacovigilance and the global transfer of prescriptions."[1217]

It seems unlikely that the scheme will help resolve problems which may arise in the application of the SPC system to biologicals.

As the WHO proposal points out:

1211 EU/1/09/573, first authorised 29.10.2009.
1212 EU/1/14/979, first authorised 19.12.2014.
1213 Rixubis, EPAR-Scientific Discussion, p.4, published 10 February 2015.
1214 See Chapter 14, Section 14.2.2.4.
1215 Edward T Maggio, 'Critical immunogenicity differences will be obscured by a common INN for biosimilars' [2013] 2(4) GaBI Journal 1.
1216 Gustavo E Grampp, Sundar Ramanan, 'The Diversity of Biosimilar Design and Development: Implications for Policies and Stakeholders' [2015] 29 BioDrugs 365-372.
1217 WHO, Biological Qualifier, An INN Proposal, INN Working Doc. 14.342 Rev. Final October 2015 at http://www.who.int/medicines/services/inn/WHO_INN_BQ_proposal_2015.pdf (last accessed 26 April 2018).

> "an INN is specific to a given defined substance regardless of the manufacturer and manufacturing site even though the profile of impurities may not be qualitatively or quantitatively the same. While a single INN has been adequate to identify simple, well-characterised chemical substances, the complex, microheterogeneous nature of biological medicines does lead to differing efficacy and safety profiles of these substances. For this reason differing glycoforms of the same protein were distinguished by adding a Greek letter to the INN."[1218]

But none of this answers the question how different does a biological active substance has to be to no longer be within the scope of an SPC based on the first authorisation of a substance with the same INN.

(g) *The question of scope: some tentative conclusions*

The question of the effective scope of an SPC for a biological substance is complex. Because of the intrinsic variability of biological substances it is difficult to draw precise boundaries without seeming arbitrary.

The essence of the problem can be summed up diagrammatically, with reference to three different epoetin glycoforms, alfa (the reference product), theta (stand-alone authorisation) zeta (a biosimilar) and darbepoetin (a "biobetter", which has modified amino acid sequence compared to epoetin[1219]:

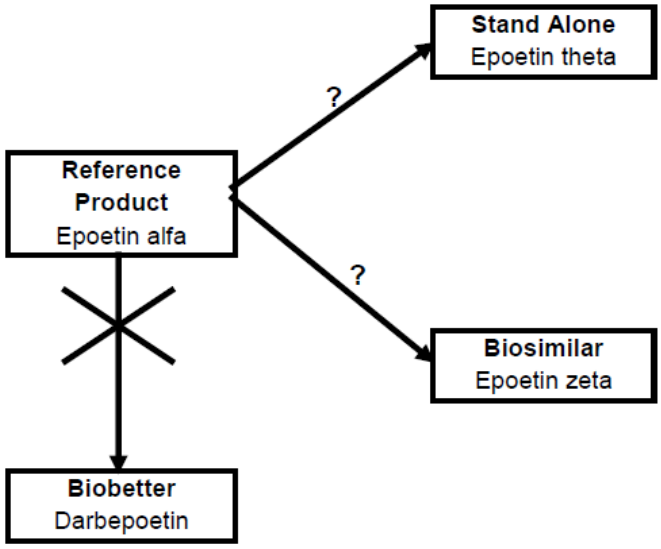

Figure 18.4: Scope of the SPC: biological substance, biobetters and biosimilars

There can be little doubt that an SPC based on the reference product epoetin alfa cannot cover darbepoetin, which has a different amino acid sequence and improved pharmacokinetic properties. Although some might argue that the SPC should only cover the biosimilar, as comparison was made to the reference product to secure authorisation under Art. 10(4) Dir. 2001/83. Although the route of authorisation of the two epoetin glycoforms is different, there is nothing in Art. 4 SPC Regulation to

[1218] *Ibid.*

[1219] Aranesp/darbepoetin, authorised 08.06.2001, is a bioengineered form of epoetin containing 5 amino acid changes creating new glycosylation sites which in turn dramatically increases the serum half-life of the substance compared to epoetin.

suggest that the scope of an SPC should be limited by the regulatory route by which the potential infringing product came to the market.

A strict interpretation of the Art. 4 (and referring to Recital 10, that the protection granted be "strictly confined to the product which obtained authorisation to be placed on the market") would seem to rule out protection covering epoetin zeta or epoetin theta. One could wonder, however, whether such an interpretation would render an SPC for a biological of little value.

A pragmatic approach is to interpret the scope of protection of the SPC as covering products with the same INN, and ignoring the glycoform. This approach seems to be consistent with the effect of the approach taken with chemical substances in *Farmitalia*. Further it would give certainty for third parties.

18.2.6 Scope of protection and biosimilars: the opinion of the stakeholders

The qualitative interviews did not reveal significant difficulties in the application of the present Regulations to biological drugs. In the interviews the participants – representatives of originators and generics – were of the opinion that it is not more difficult to apply the present Regulations to biological drugs than to small molecule products. The answers were consistent with respect to the availability of protection for biological drugs as well as the possibility to enforce an SPC based on a biological drug and the respective MA against biosimilars.

On the other hand, the online survey revealed a much more mixed perspective of the stakeholders. While 46 per cent of the stakeholders were of the opinion that the present system adequately accommodates the technical development, 32 per cent were of the opinion that it did not, and 22 per cent had no opinion in this respect.[1220]

Of those who were of the opinion that the current law does not adequately accommodate the technical developments, a majority of 72.58 per cent stated that Reg. 469/2009 needs to be changed or amended in order to better accommodate biopharmaceuticals and products of recombinant DNA technology.[1221] 12.90 per cent were not of the opinion that changes to the regulation were required and 14.52 per cent had no opinion on this.

Some stakeholders[1222] provided additional comments and proposals as to possibly required changes. The picture presented in these comments was very diverse and does not provide a basis for a clear recommendation. However, in essence, approximately one fourth of the comments were directed to changes of the product definition and/or the definition of the scope of protection of the SPC but without providing any proposals or examples. One stakeholder was of the opinion that the best way to deal with the development may be relying on the evolution of the case law. In qualitative interviews, one stakeholder has observed that the problem of biosimilars is likely a transitory one. With the technological development it is possible that it will become possible to manufacture products that are more similar to the reference product than nowdays it is the case.

[1220] Q27 of the Allensbach Survey, Annex III of this Study.
[1221] Q29 of the Allensbach Survey, Annex III of this Study.
[1222] Question 30; N=26.

At the Stakeholders seminar in Munich the representatives of the originators agreed that an SPC not covering at least biosimilars would be of little value for the patentee. At the same time, it was pointed out that the regulatory route shall not be decisive for deciding over infringement. This means that, while a biosimilar shall be considered covered by the SPC granted for the reference product, the mere fact that a biological product was not authorised as biosimilar under Art. 10(4) Dir. 2001/83 shall not exclude *a priori* an infringement.

18.2.7 Summary

Biological products are eligible for SPC protection under the same general conditions as any other substance. We do not see any need at present to amend the SPC Regulation because of differences between generics and biosimilars according to regulatory law. Although differences in manufacturing processes may give rise to differences in the properties of a biosimilar product compared to the reference product, the fact that the EMA approves such biosimilars with the same INN as the original product shall be necessary, but also sufficient for them to be considered to fall within the scope of an SPC based on a marketing authorisation relating to that original product.

18.3 PERSONALISED MEDICINES AND COMPANION DIAGNOSTICS

18.3.1 Definition

The conventional medicine offers specific treatments for diseases and disorders placed in certain organs or tissues. Based on empirical therapies, it uses universal drugs for prevention and treatment of a certain disease.[1223] Although differentiations in dosage and contraindications may be applied in case of distinct patient characteristics, such as age, gender, weight, previous diagnoses, etc. – whether aimed at humans, animals or plants – the option to provide therapy differentiations according to individual characteristics of each patient remained limited in the last century.

This scenario, however, has changed. As a consequence of the technological advances, particularly in the field of pharmacogenetics and pharmacogenomics,[1224] the pharmaceutical industry has evolved to predict with better certainty the outcome of a treatment for a given group of patients.[1225] Through the identification of biological and molecular characteristics inherent in specific subgroups, such as the existence of a specific gene, enzyme or receptor (so-called *biomarkers*[1226]), it is possible to predict the effectiveness, compatibility, tolerance and optimum dosage of a given drug when

[1223] Kewal K Jain, *Textbook of Personalized Medicine* (2nd edn, Springer 2015) p. 20.

[1224] See also Kewal K Jain, *Textbook of Personalized Medicine* (2nd edn, Springer 2015) p. 91; Marina Kohake, *Personalisierte Medizin und das Recht – Medizinische Untersuchung unter besonderer Berücksichtigung persönlichkeitsrechtlicher Belange beim Umgang mit genetischen Gesundheits-informationen* (Nomos 2016) p. 29.

[1225] Alexander Albrecht et al, `Personalized Medicine: Patentability before the European Patent Office and the USPTO´ [2015] GRUR Int. 1, 2.

[1226] For the defition of biomarker, see Kewal K Jain, *Textbook of Personalized Medicine* (2nd edn, Springer 2015) p. 91; Marina Kohake, *Personalisierte Medizin und das Recht – Medizinische Untersuchung unter besonderer Berücksichtigung persönlichkeitsrechtlicher Belange beim Umgang mit genetischen Gesundheitsinformationen* (Nomos 2016) p. 32; Christina M Berchtold, *Der Wandel genetischer Information – Personalisierte Medizin zwischen Informations- und Verschweigenheitsinteressen* (Duncker & Humblot 2016) p. 78; Christina M Berchtold, Manja Epping, `Markteinführung personalisierter Arzneimittel: Life Sciences inmitten Persönlichkeit und Recht´ [2014] GRUR-Prax 492.

applied to a member of this subgroup.[1227] This medicine applicable to individuals of certain specific subgroups is called *personalised medicine*.[1228]

Essentially relevant to the success of the development and application of personalised medicines are devices that promote the identification of patients who are most likely to benefit from the corresponding medicinal product as well as of those likely to be at increased risk of serious adverse reactions as a result of treatment with the corresponding medicinal product.[1229] These devices are called *companion diagnostics*.

Personalised medicines and companion diagnostics have been developed, for example, for cancer treatments. While conventional medicine offers targeted therapy to affected organs (e.g. against breast cancer), medical advances allow specific genes to be identified (biomarkers) whose mutations or action can give rise to different types of cancer (e.g. breast cancer, colon cancer, endometrial cancer).[1230] In this case, a drug used to treat breast cancer can also be effective against colon cancer or endometrial cancer if they have a common genetic mutation.[1231] In addition, it is possible to identify genes that give rise to resistance to an anticancer therapy. As a result, it becomes possible to indicate that the use of a more efficient alternative drug is recommended for the subgroups of individuals who have this gene.[1232] Similar procedures are currently found in therapies against infectious diseases, neurological disorders, cardiovascular disorders, immunity disorders, etc., areas in which personalised medicine has also advanced.[1233]

Therefore, in the framework of personalised medicines and companion diagnostics, studies and treatments for prevention and control of diseases and disorders do not necessarily focus on the affected organ or tissue, but rather on biomarkers whose existence or anomalous evolution can generate such diseases and disorders or inhibit the effects of drugs traditionally applied on their treatment.

18.3.2 Patentability

Inventions concerning biomarkers, personalised medicines and companion diagnostics are in principle patentable under Art. 52-57 EPC. The peculiarities of each field will be presented below.

1227 Christina M Berchtold, Manja Epping, `Markteinführung personalisierter Arzneimittel: Life Sciences inmitten Persönlichkeit und Recht´ [2014] GRUR-Prax 492; see also Kewal K Jain, *Textbook of Personalized Medicine* (2nd edn, Springer 2015) p. 2.

1228 It should be highlighted that although the term "personalized medicine" has been widely established in the medical field, its utilization has been criticized, since it does not consist in a drug intended for an individual patient, but rather for a specific subgroup of individuals with similar characteristics. For this reason, some authors prefer to use the concept of "stratified medicine". See Marina Kohake, *Personalisierte Medizin und das Recht – Medizinische Untersuchung unter besonderer Berücksichtigung persönlichkeitsrechtlicher Belange beim Umgang mit genetischen Gesundheitsinformationen* (Nomos 2016), pp. 19, 21, 22; Christina M Berchtold, *Der Wandel genetischer Information – Personalisierte Medizin zwischen Informations- und Verschweigenheitsinteressen* (Duncker & Humblot 2016) pp. 77-78.

1229 Definition provided by Art. 2(7) of the Regulation 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU.

1230 Alexander Albrecht et al, `Personalized Medicine: Patentability before the European Patent Office and the USPTO´ [2015] GRUR Int. 1, 2.

1231 *Ibid*.

1232 *Ibid.,* 1, 2, 3.

1233 See also Kewal K Jain, *Textbook of Personalized Medicine* (2nd edn, Springer 2015) p. 199.

18.3.2.1 Biomarkers

The patentability of isolated genes, genetic sequences and biological materials is guaranteed in the European Union by Arts. 3(3), 5(2) and Recitals 17, 20 and 21 Dir. 98/44/EC on the legal protection of biotechnological inventions, even if it occurred in nature or if the structure of that element is identical to that of a natural element. These provisions have in principle codified the previous practice of the European Patent Office, that under Art. 52 EPC had already recognised the patentability of isolated genetic sequences.

However, the case *Monsanto Technology* (C-428/08) imposed an important restriction of the scope of protection of isolated biological materials. In its opinion, the CJEU seems to have interpreted Art. 9 Dir. 98/44/EC as meaning that the isolated gene is protected only with respect to the function performed according to patent application, justifying the inference that only a function-limited product protection in this field is possible.

18.3.2.2 Personalised medicines

In contrast to biomarkers, however, there are some challenges to patentability regarding personalised medicines as such in the European Union.

One of the main challenges might arise from the exclusion from patent protection of "methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body", as ruled in Art. 53(c) EPC. However, the Enlarged Board of Appeals of the European Patent Office (EPO), based on a narrow interpretation of the EPC´s exceptions and limitations, ruled that new methods of medical treatment may be patentable when the therapy is novel and inventive.[1234] As a consequence, not only personalised medicines based on a new active ingredient, but also those which consist of second and further medical indications, fall within the scope of the patent protection provided by the EPC if the patentability requirements are fulfilled. This holds true even in the case of a second medical use of an already known compound for specific subgroups, as stated by the Board of Appeals of the EPO in Case T 19/86 (*Pigs II*).[1235]

However, the EPO case law has established that, for purposes of patenting personalised medicines based on second medical uses, it is not enough to indicate any subgroup for the application of the drugs, but rather necessary that the indication of novel subgroup of users are clearly distinguishable from the groups and subgroups to which the drugs were originally indicated. A new subgroup has actually to be physiologically and pathologically well-defined.[1236]

[1234] EPO, Case G 0005/83 *Second medical indication* of 5 December 1984, available at https://www.epo.org/law-practice/case-law-appeals/pdf/g830005ep1.pdf (last access August 14th, 2017). See also Emma Macfarlane, Konrad A Sechley, 'Personalized medicine: patent issues in Canada and Europe'. Lexicology: October 2014, available at https://www.lexology.com/library/detail.aspx?g=bda258d0-e5cf-4bb1-9e52-1ea45cc2a6d8 (last accessed 14 August 2017).

[1235] EPO, Case T 19/86 *Pigs II/Duphar* of 15 October 1987, available at https://www.epo.org/law-practice/case-law-appeals/pdf/t860019ex1.pdf (last accessed 14 August 2017).

[1236] See *ibid*.; EPO, Case T 1031/00 [2002] ECLI:EP:BA:2002:T103100.20020523; T 1399/04 *Combination therapy HCV/SCHERING* [2006] ECLI:EP:BA:2006:T139904.20061025.
See also Alexander Albrecht et al, `Personalized Medicine: Patentability before the European Patent Office and the USPTO´ [2015] GRUR Int. 1, 3, 4; Christina M Berchtold, Manja Epping, *Markteinführung*

Consequently, a subgroup composed of people incapable of properly performing exercises may not be considered sufficiently distinguishable for the purposes of a second therapeutic indication, since this subgroup overlaps with a group of patients for whom medical use of the drug has already been approved as first indication.[1237] Likewise, the subgroup of patients characterised by their blood type would hardly be considered sufficiently distinguishable to justify the patentability of a second medical use when no differentiation of blood types was made for the purposes of the first medical indication.[1238] In contrast, a new indication can be eligible for a patent if the subgroup, even belonging to the same specie to which the first indication is applied, has specific physiological or pathological characteristics (biomarkers) and even if there is a not-evidenced probability that the therapy based on the new medical indication would also succeed for individuals who are not part of this subgroup.[1239]

In a nutshell, although personalised medicines may – as a rule – be patented in the European Union even when they consist of a second or further therapeutic indication, there may be restrictions on patentability depending on the subgroup indicated in the therapy application as well as on its relation to the group encompassed by the first therapeutic indication.

18.3.2.3 Companion diagnostics

In the decision G1/04, the Enlarged Board of Appeal ruled that the patentability exception from Art. 53(c) EPC only applies where all the steps of the diagnostic method are practiced on the human or animal body, namely (i) examination phase including the collection of data, (ii) comparison of these data with standard values, (iii) identification of a deviation from the normal or desired state, (iv) attribution of the observed deviation to a particular clinical picture and (v) any other steps of technical nature.[1240]

As a consequence, the diagnostic companion that does not fulfil all steps set in the decision G1/04, as the case of methods associated with personalised medicine which rely on in-vitro testing of a previously obtained sample, do not fall under the exclusion of Art. 53(c) EPC and are, therefore, subject to patent protection.[1241]

personalisierter Arzneimittel: Life Sciences inmitten Persönlichkeit und Recht [2014] GRUR-Prax 492, 493.

1237 See EPO, Case T 0233/96 *Adrenaline/MEDCO RESEARCH* [2000] ECLI:EP:BA:2000:T023396.20000504. See also Alexander Albrecht et al, `Personalized Medicine: Patentability before the European Patent Office and the USPTO´ [2015] GRUR Int. 1, 4.

1238 Alexander Albrecht et al, `Personalized Medicine: Patentability before the European Patent Office and the USPTO´ [2015] GRUR Int. 1, 5.

1239 EPO, Case T 1399/04 *Combination therapy HCV/SCHERING* [2006] ECLI:EP:BA:2006:T139904. 20061025.

1240 EPO, Case G 0001/04 *Diagnostic methods* [2005] ECLI:EP:BA:2005:G000104.20051216. See also Christina M Berchtold, Manja Epping, `Markteinführung personalisierter Arzneimittel: Life Sciences inmitten Persönlichkeit und Recht´ [2014] GRUR-Prax 492, 493.

1241 Emma Macfarlane, Konrad A Sechley, 'Personalized medicine: patent issues in Canada and Europe. Lexicology'. *October 2014*, available at https://www.lexology.com/library/detail.aspx?g=bda258d0-e5cf-4bb1-9e52-1ea45cc2a6d8 (last accessed 14 August 2017); Isabelle Huys et al, `Gene and genetic diagnostic method patent claims: a comparison under current European and US patent law´, [2011] 19(10) Eur J Hum Genet. 1104-1107, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3190248/ (last accessed 14 August 2017).

18.3.3 Regulatory aspects

18.3.3.1 Personalised medicines

Personalised medicines require prior approval from the competent (centralised or decentralised) health authority in order to be commercialised. This holds true for both new substances and combination of substances to be used in therapies and substances which, although already known, have a new therapeutic indication applicable to a specific subgroup. The justification for the latter case is that the variation related to the therapeutic indication may have a significant impact on the quality, safety and efficacy of the medicinal product, being therefore a variation of type II according to Art. 2(a) of the Annex II Reg. 1234/2008 (Variations Regulation).[1242] In contrast to light variations of type IA and IB, the mere notification to the competent health authority is not sufficient to ensure the commercial use of a new indication.

18.3.3.2 Companion diagnostics

Regarding companion diagnostics, there are, at regulatory level, some uncertainties concerning not only the statute applicable to them, but also the degree of review, timing and outcomes of the conformity assessment by EMA, the interaction between EMA and other Notified Bodies for the purposes of conformity assessment as well as the expected evidence of the ability of the companion diagnostic to appropriately select patients.[1243] Further, there is little clearance regarding the clinical evidence to be revealed for the approval of a companion diagnostic. This is because companion diagnostics, which promote the choice of a specific therapy for a patient, differ from the usual In-Vitro-Diagnostics (IVDs), which do not directly interact with patients. For this reason, their approval may require different and additional documents.[1244] This

[1242] Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products, Annex II - „Art. 2 - The following variations shall be classified as major variations of type II: (a) variations related to the addition of a new therapeutic indication or to the modification of an existing one (…)". Art. 10 of this regulation states that type II variations need prior approval of the competent health agency. See also the EC Guidelines on the details of the various categories of variations. Available at https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-2/c_2013_2008/c_2013_ 2008_pdf/c_2013_2804_en.pdf (last accessed 14 August 2017).

[1243] EDMA, 'Value of Companion Diagnostics in Personalised Medicines – Stimulating innovation for improving health through companion diagnostics'. Position Paper of 5 March 2015, pp. 3-4, available at http://www.medtecheurope.org/sites/default/files/EDMA_2015-12-03_value_of_CDx_PP_FIN.docx% 5B1%5D.pdf (last accessed 14 August 2017). See also TaylorWessing, `Personalised medicine – challenges of authorisation and reimbursement', available at https://united-kingdom. taylorwessing.com/synapse/regulatory _personalised_medicines.html (last accessed 14 August 2017); Amanda Craig, `Personalised Madicines with Companion Diagnostics: The Interceipt of Medicines and Medical Devices in the Regulatory Landscape´ [2017] 1(1) EMJ Innov. 47, 50, available at http://emjreviews.com/wp-content/uploads/Personalised-Medicine-with-Companion-Diagnostics-The-Intercept-of-Medicines-and-Medical-Devices-in-the-Regulatory-Landscape.pdf (last accessed on 14 August 2017).

[1244] EDMA, 'Value of Companion Diagnostics in Personalised Medicines – Stimulating innovation for improving health through companion diagnostics'. Position Paper of 05 March 2015, pp. 4, 5, available at http://www.medtecheurope.org/sites/default/files/EDMA_2015-12-03_value_of_CDx_PP_FIN.docx% 5B1%5D.pdf (last accessed 14 August 2017). See also Amanda Craig, `Personalised Madicines with Companion Diagnostics: The Interceipt of Medicines and Medical Devices in the Regulatory Landscape´ [2017] 1(1) EMJ Innov. 47, 50, available at http://emjreviews.com/wp-content/uploads/Personalised-Medicine-with-Companion-Diagnostics-The-Intercept-of-Medicines-and-Medical-Devices-in-the-Regulatory-Landscape.pdf (last accessed 14 August 2017).

also leads to uncertainty about the application of in-house-exemption for companion diagnostics.[1245]

It remains unclear whether these uncertainties were completely cleared after Reg. 2017/746 on in vitro diagnostic medical devices (IVDR), which addresses some of the abovementioned challenging aspects, was introduced.[1246] A more accurate analysis must be reserved to other contributions.[1247]

18.3.4 SPC eligibility

18.3.4.1 Personalised medicines

As already considered in Chapter 9[1248] and Chapter 11[1249] of this Study, second medical indication patents and type-II variations of an existing medical indication may be the basis for granting an SPC in the practice of the majority of NPOs, where the second medical indication patent is designated as the basic patent and the variation is treated as a new MA under Arts. 3(b), 7 and 13 of Reg. 469/2009, provided that amended MA can be considered as the first permission that falls under the scope of the basic patent. As a result, personalised medicines covered by a second medical use patent and which are subject of an MA could be eligible for a certificate.

Further, it has to be considered that even minor changes in the administration of a product oriented to a specific subgroup (e.g. frequency of administration) which impact on the product information and description require the amendment of the existing MA. Following a broad understanding of the CJEU decision to the case *Neurim* (C-130/11), if (i) these changes consist in a type II variation in terms of the Reg. 1234/2008, (ii) this variation is subject of a patent and (iii) the amended MA is the first that falls under the scope of that patent, this variation could be eligible for SPC protection. However, if one understands *Neurim* as allowing an SPC only when the patent covers a new indication intended as a new illness or a new population group not covered by the previous MA, then such a variation may not be eligible for an SPC. Therefore, the question whether personalised medicines are eligible for an SPC when they consist only in a new regimen of administration applicable to a specific subgroup characterised by a specific biomarker remains unclear. From a policy perspective, the considerations made for second medical use patents should in general apply also to the specific area of second medical use patents granted for a personalised application of a therapeutic ingredient. The question is whether a market failure exists in this field as for the development of new molecules and new therapeutic agents. We refer to the

[1245] EDMA, 'Value of Companion Diagnostics in Personalised Medicines – Stimulating innovation for improving health through companion diagnostics'. Position Paper of 5 March 2015, p. 4, available at http://www.medtecheurope.org/sites/default/files/EDMA_2015-12-03_value_of_CDx_PP_FIN.docx%5B1%5D.pdf (last accessed 14 August 2017).

[1246] Particularly Arts. 48 and 58 as well as Annexes VII, IX and X of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU. For further information, see Christian Johner, 'IVDR – In-vitro-Diagnostic Device Regulation', March 2017, available at https://www.johner-institut.de/blog/regulatory-affairs/ivdr-in-vitro-diagnostic-device-regulation/ (last accessed 14 August 2017)

[1247] For critical remarks, see also TaylorWessing, 'Personalised medicine – challenges of authorisation and reimbursement', available at https://united-kingdom.taylorwessing.com/synapse/regulatory_personalised_medicines.html (last accessed on 14 August 2017).

[1248] Chapter 9, Section 9.3.3.1 (d).

[1249] Chapter 11, Section 11.3.1.2.

analysis of *Neurim* in Chapter 11[1250] and to the analysis of the purposes of the SPC legislation in Chapter 2[1251].

18.3.4.2 Companion diagnostics

The scope of SPC in the European Union does not encompass companion diagnostics – even if they are patentable – since these diagnostics do not fall within the definition of "medicinal products" provided by the Reg. 469/2009 concerning the supplementary protection certificate for medicinal products. Indeed, companion diagnostics are generally not products that are "*administered to human beings or animals with a view of to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human or on animals*" as provided in Art. 1(a) Reg. 469/2009. Only diagnostics that are administered *in vivo* to the patient may satisfy such a definition.[1252] We refer in this respect also to Section 18.6 of this Chapter that deals specifically with medical devices.

18.3.5 Recommendation

Personalised medicines and companion diagnostics are promising areas in the pharmaceutical sector. Their development can result in great health benefits to the population. As a rule, there is no obstacle to the eligibility of personalised medicines for patent and SPC protection, even in cases where they consist of second medical indications, when such medicines include a new active ingredient. This will be seldom the case. Uncertain is, however, whether a personalised medicine is eligible for SPC protection in cases of changes in the administration of an approved medicine or where its specific subgroup was already part of the group comprised by a medical indication. At present, it is not possible to predict whether the case law will apply the same criteria set out in *Neurim* to these cases in the future.

Despite this uncertainty, it is still unclear whether specific adjustments of the SPC Regulation are necessary to increase the incentive to R&D in the field of personalised medicines at this moment. Then there is still no evidence that justifies a broader scope of protection in this sector. The expansion of protection without a due impact analysis can result in dysfunctional results that threaten the exercise of competition by other market players and, consequently, may hamper innovation. Therefore, before increasing the level of protection in this area, the European Commission should request market studies regarding personalised medicines and companion diagnostics in order to assess the real need for intervention in the current regulation and – if appropriate – to evaluate to which extent the protection should be strengthened.

As already mentioned in Chapter 2 and Chapter 11, the decision to introduce SPCs was based on the assumption that the regulatory work needed to show safety and efficacy of a new active ingredient reduced the effective term of the patent to an extent that the required research and investments could turn not to be profitable anymore. We refer again for a more detailed analysis to Chapter 2 and Section 18.6 of this Study.

1250 Chapter 11, Section 11.3.1.2.
1251 Chapter 2, Section 2.1.3.2.
1252 See already Herwig von Morze, Peter Hanna, `Critical and Practical Observations Regarding Pharmaceutical Patent Term Restoration in the European Communities´ [1995] 11 J. pat. & trademark Off. Soc'y 479, 490.

18.4 NANOMEDICINES

Nanotechnology is often said to bring about the next technological revolution. This assessment – whether you agree with it or not – is inevitably based on the pervasive nature of the technology. Although there is (as yet) no consensus definition of nanotechnology, it is generally acknowledged that it deals with control and manipulation of matter at the nanoscale, i.e. the scale set by a billionth of a meter: a nanometer (nm).[1253] For comparison, human hair has a diameter of 60,000 to 100,000 nm, rendering the nanoscale primarily the domain of atoms and molecules which begins at around 0.1 nm.

With virtually everything consisting of atoms and molecules, there is hardly any part of human life in which the application of nanotechnology is not perceived to promise highly desirable advances. Of course then, the application of nanotechnology to medicine is of particular interest.

18.4.1 Concept

It is exactly that notion of applying nanotechnology to medicine that usually serves as definition for the very concept of nanomedicine. Not only does nanomedicine pioneer Robert A. Freitas Jr. use that definition.[1254] The EMA in 2006 adopted a somewhat similar definition, as well, stating that nanomedicine is "the application of nanotechnology in view of making a medical diagnosis or treating or preventing diseases."[1255] Neither does the definition adopted by the European Commission and the European Technology Platform (ETP) for Nanomedicine in 2009 differ much.[1256] Unfortunately though, this approach imports the definitional ambiguities of the umbrella term nanotechnology into nanomedicine. Put differently, the scope of nanomedicine is similarly vast and its contours just as elusive as those of nanotechnology itself.[1257]

However, one can discern (at least) three general streams in the development of nanomedicine: (1) wholly novel pharmaceutical and diagnostic substances, (2) new formulations of existing drugs, and (3) advances concerning medical devices. Just as with nanotechnology more generally, lines are blurry, though. This holds true especially in cases where nanomedical devices are concerned. That being said, this fading of differences is in fact a cornerstone of personalised medicine, which

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1253 According to the European Patent Office "[t]he term nanotechnology covers entities with a controlled geometrical size of at least one functional component below 100 nanometers (nm) in one or more dimensions susceptible of making physical, chemical or biological effects available which are intrinsic to that size", European Patent Office, 'Nanotechnology and Patents', 2013, p. 2, available at http://www.epo.org/news-issues/issues/classification/nanotechnology.html (last accessed 4 April 2018). Interestingly enough, IPC class B82 for nanotechnology follows essentially the same approach. For an overview of definitional aspects see Marius Fischer, *Upstream-Patente in der Nanotechnologie* (forthcoming 2018) pp. 11-13.

1254 Robert A Freitas, `What is Nanomedicine?´ [2005] 1(1) Nanomedicine 2, 2.

1255 European Medicines Agency, 'Reflection Paper on Nanotechnology-Based Medicinal Products for Human Use', 2006, p. 3, available at http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2010/01/WC500069728.pdf (last accessed 4 April 2018).

1256 "Nanomedicine as a translational science has the goal to provide cost effective novel therapies and diagnostics using the expanding world of Nanotechnology", European Commission and ETP Nanomedicine, 'Roadmaps in Nanomedicine Towards 2020', 2009, p. 6, available at http://www.etp-nanomedicine.eu/public/press-documents/publications/etpn-publications/091022_ETPN_Report_2009.pdf (last accessed 4 April 2018).

1257 Turning to IPC subclass B82Y 5/00 for nanobiotechnology or nanomedicine is of no help here as it does not give a definition, but rather only two examples.

nanotechnology is seen to enable as will become apparent in a moment.[1258] In nanomedicine – in this regard again very similar to nanotechnology as a whole[1259] – it can be hard to tell fact and fiction apart. Literature is often split between optimistic extrapolation and cautious restraint when reporting on the state of the art and current developments. Either way, it makes sense to flesh out the three streams.[1260]

Nanotechnology is expected to yield (1) new pharmaceutical and diagnostic substances. The control of matter at the molecular scale that is at the very heart of nanotechnology could one day allow for substances to be created from the bottom up, i.e. to be made to measure. That way, pharmaceuticals could be rid of any side effects, and contrast agents could be adjusted for better sensitivity, perhaps even for several imaging techniques at once. Notably, nanoscale substances are inherently small enough to circulate through blood vessels and cannot be blocked by the microstructures of the lungs, capillaries, kidneys and liver. It is assumed that even the blood-brain barrier will be traversable at some point in time with the help of nanomedicine. Furthermore, and maybe even most importantly, such nanoscale substances could be delivered in a targeted fashion, i.e. specifically guided to a diseased region of the body. Once there, they could then be activated, optionally by external means as appropriate. Nanoscale substances could be of particular use in antitumor drug delivery as cancerous cells are proven to retain certain sizes of molecules more strongly than healthy cells (so-called enhanced permeability and retention, or EPR effect).[1261] For example, one of the concepts currently being researched and developed is to transport iron atoms within C_{60} molecules – the famous "fullerenes" or "buckyballs" of nanotechnology – to tumorous tissue and subsequently heating those atoms up by applying an external magnetic field, hence destroying the particularly thermosensitive infected cells.

Since many of the aforementioned advantageous properties do in fact not necessarily flow from the (hypothetical) novel substances as such, but rather from their nanoscale size, they could also be exploited in (2) new formulations of existing, well-known drugs. In principle, already known agents could be targeted exactly the same way when presented in nanoscale form. As necessary, these nanoscale versions could also be combined with other nanostructures, e.g. fullerenes, that act as carriers and hence enable targeted delivery in the first place. Administering a drug in this manner is, after all, closely related to the commonly evoked image of nanoscale machines crawling through the body to deliver their payload. Essentially, this close relationship is due to the interchangeability of the terms substance and device arising on the nanoscale, which has been particularly emphasised by the German patent literature.[1262] The maybe most intuitive, albeit non-medical, illustration of this is the so-called nanocar that substantially consists of four fullerenes representing its wheels.[1263] Quite

[1258] Cf. Ana Nordberg, *Patenting Nanomedicine in Europe* (Djøf Forlag 2017) p. 217.
[1259] Cf. Marius Fischer, *Upstream-Patente in der Nanotechnologie* (forthcoming 2018) pp. 11-46.
[1260] The following is based in its entirety on European Commission and ETP Nanomedicine, 'Roadmaps in Nanomedicine Towards 2020', 2009, pp. 10-43, available at http://www.etp-nanomedicine.eu/public/press-documents/publications/etpn-publications/091022_ETPN_Report_ 2009.pdf (last accessed 4 April 2018), and Ana Nordberg, *Patenting Nanomedicine in Europe* (Djøf Forlag 2017) pp. 197-223.
[1261] For a review of the EPR effect see Het Maeda et al, `Tumor vascular permeability and the EPR effect in macromolecular therapeutics: a review´ [2000] 65(1-2) J. Control Release 271.
[1262] Ralf Uhrich, Herbert Zech, `Patentierung von Nanomaschinen – Stoffschutz versus Vorrichtungsschutz´ [2008] GRUR 768; André Sabellek, *Patente auf nanotechnologische Erfindungen* (Mohr Siebeck 2014) pp. 125-175.
[1263] Cf. Yashuhiro Shirai et al, `Directional Control in Thermally Driven Single-Molecule Nanocars´ [2005] 5(11) Nano Letters 2330.

obviously, this structure can either be described as a large molecule or as a device, i.e. a car.

The potential of nanotechnology to yield (3) advances concerning medical devices probably extends farthest. On the one hand, one of the more humble perspectives of nanomedicine is to miniaturise existing imaging apparatus. This would not only allow storing corresponding apparatus on-site with the healthcare facility, hence mitigating the disadvantages connected to the lengthy process of collecting a probe, analysing it off-site, and eventually returning the results to the facility for discussion in a follow-up consultation. In the long run, this might even make it possible to store the apparatus with the patient at home. Especially when multiple functions were integrated in a single device (so-called lab-on-a-chip), this could well be seen as a leap towards personalised medicine. On the other hand, the more general concept of nanomedical devices points in the direction of rather futuristic concepts like the one made famous by Nobel Prize-winning physicist Richard P. Feynman, who in 1960 envisaged that, one day, "you could swallow the surgeon. [...] Other small machines might be permanently incorporated in the body to assist some inadequately-functioning organ."[1264] Whilst the former image is somewhat similar to the one commonly evoked in the context of drug delivery as described above, the latter alludes to the opportunities that could arise from integration of nanoscale diagnostic devices, especially miniaturised labs-on-a-chip, and medication mechanisms, an approach often labelled with the neologism "theragnostics". Beyond diagnostics and therapeutics, nanomedicine also promises advances in regenerative medicine. Considering that the DNA double helix is about two nm wide, nanotechnology could eventually allow engineering biological materials comparable in complexity to human tissues which could in turn replace their malfunctioning or diseased counterparts. In another approach, certain bioactive molecules – identified, manufactured, and potentially even applied with the help of nanotechnology – could be deliberately deployed to trigger the natural regeneration process, i.e. certain nanostructures could be used as scaffolds that support, stimulate, and enhance the repair of tissue and the (re)growth of cells. It is noteworthy that such bioactive materials could not only be used to grow cells – particularly stem cells – *in vitro* and *in vivo* alike. They could also be used in coatings enhancing the adhesion and/or acceptance of common implants or even transplants due to the strengthened growth of surrounding tissue. In a sense, the wheel comes full circle at this point since such bioactive materials may also be seen as wholly new substances developed with the help of nanotechnology.

18.4.2 Patentability

With nanomedicine being a very broad and versatile field, a sweepingly general assessment of its patentability can hardly be given with complete certainty. Yet, it stands to reason that the overall patentability of nanotechnology translates to nanomedicine, as well. The former has been affirmed by the literature[1265] and the EPO alike; the latter doing so indirectly by creating the ECLA class Y01N specifically for nanotechnology in 2005 which was eventually merged in the IPC class B82 in 2011.[1266]

[1264] Richard P Feynman, `There's Plenty of Room at the Bottom´ [1960] 23(5) Engineering and Science 22, 27.

[1265] See André Sabellek, *Patente auf nanotechnologische Erfindungen* (Mohr Siebeck 2014) pp. 48-75.

[1266] See European Patent Office, 'Nanotechnology and Patents', 2013, p. 5, available at http://www.epo.org/news-issues/issues/classification/nanotechnology.html (last accessed 4 April 2018) as well as note 1253.

In this context, it is also worth noting that, on a more abstract level, biotechnology might well be seen as a trailblazer for the patentability of nanotechnology and nanomedicine.[1267]

That being said, the literature does indeed discuss some problems substantive patent law might have in store for nanotechnology. Their severity and relevance largely remain to be seen, though. Mostly, these problems concern Art. 54 and 56 EPC, i.e. the requirements of novelty and inventive step. The former is often questioned with reference to macroscopic counterparts to the nanomaterials in question and/or their potential natural occurrence, while the latter is usually questioned with reference to the general, overarching trend towards miniaturisation. The literature agrees, however, that these arguments can be successfully rebutted.[1268] First of all, "non-nanoscale" state of the art will usually not enable a person skilled in the art to obtain a nanoscale product and thus not anticipate it. In a similar vein, viewing nanoscale inventions as mere miniaturisations of their alleged macroscopic counterparts falls short since, in all but the rarest cases, nanoscale inventions serve a wholly different purpose. The nanocar mentioned above is an intuitive example. And it is well settled that the natural occurrence of a substance does not affect its patentability as long as it has not been provided, i.e. isolated or synthesised, in identical form before.

An obstacle potentially arising from substantive patent law not commonly relevant to nanotechnology as a whole, but to nanomedicine specifically so, is the "medical methods exception" of Art. 53(c) EPC. Albeit discussing the intricate details of the law and purpose behind Art. 53(c) EPC is beyond the scope of this report, it should be noted that, generally speaking, the disparate treatment of diagnostic, therapeutic, and surgical methods in the jurisprudence of the EPO could in principle lead to inconsistencies when applied to nanomedicine, especially as the latter transcends exactly these boundaries.[1269] Anyhow, these inconsistencies would presumably be second-order effects. It seems possible – and therefore probable – that the limitations set by Art. 53(c) EPC will largely be evaded in practice. Nanomedicine is closely linked to the use of nanostructures. Hence, most of it could likely be claimed as a device or substance rather than as a method. This would make the medical methods exception inapplicable according to the text of the norm itself. And even if the respective device or substance were already part of the state of the art, Art. 54(4) and (5) EPC would allow for patenting of its medical use. The scope of application of the exception is further reduced with a view to nanomedicine as it necessarily requires the treatment of or, respectively, the practice on the (living) human (or animal) body. Hence, the exception only extends to *in-vivo* methods and does therefore not affect a significant portion of nanomedicine. Lastly, even where an invention in the field of nanomedicine pertains to an *in-vivo* method, it can be assumed that there is sufficient leeway in the drafting of claims to circumvent Art. 53(c) EPC. For example, the methods in question could be claimed as methods of operating a nanoscale device rather than methods of treatment by surgery and therapy or diagnostic methods.[1270]

All in all, there do not seem to exist serious hurdles for patents on nanomedicine. A simple, yet effective clue supporting this assessment can be gathered from the patent

[1267] Marius Fischer, *Upstream-Patente in der Nanotechnologie* (forthcoming 2018) p. 83.
[1268] Cf. Maurice Schellekens, `Patenting Nanotechnology in Europe: Making a Good Start? An Analysis of Issues in Law and Regulation´ [2010] J. World Intellect. Prop. 47, 51-54, 54-56, 60; André Sabellek, *Patente auf nanotechnologische Erfindungen* (Mohr Siebeck 2014) pp. 61-64, 68-73, 76-124.
[1269] For details see Ana Nordberg, *Patenting Nanomedicine in Europe* (Djøf Forlag 2017) pp. 229-307.
[1270] Ana Nordberg, *Patenting Nanomedicine in Europe* (Djøf Forlag 2017) p. 306 et seq.

database Espacenet of the EPO. A search for documents in IPC subclass B82Y 5/00[1271] returns roughly 5,200 entries.[1272]

18.4.3 Regulatory aspects

When approaching regulatory aspects, it is important to distinguish between health and safety issues concerning nanomaterials more generally and those arising specifically in conjunction with an MA for and/or clinical testing of a nanomedicine product. Nanomaterial toxicology and nanomedicine safety are distinct concepts, and only the latter will be addressed in the following.

Given the scope of what is understood as nanomedicine, the regulatory framework governing respective products is somewhat fragmented and hence complex. With respect to medicinal products for human use, Reg. 726/2004 on authorisation and supervision of medicinal products for human and veterinary use and Dir. 2001/83 on medicinal products for human use are applicable. With a view to medical devices, Dir. 93/42/EEC on medical devices, Dir. 90/385/EEC on active implantable medical devices, and Dir. 98/79/EC on *in-vitro* diagnostic medical devices are applicable until effectively repealed and replaced by Reg. 2017/745 on medical devices and Reg. 2017/746 on *in-vitro* diagnostic medical devices in 2020 and 2022, respectively. Besides these quite general pieces of legislation, there are, of course, further guidelines and principles to be obeyed, such as those laid down in Dir. 2001/20/EC and Dir. 2005/28/EC on good clinical practice and Dir. 2003/94/EC on good manufacturing practice for medicinal products; all set to be repealed and replaced by Reg. 536/2014 on clinical trials on medicinal products for human use and accompanying legislation Dir. 2017/1572 and Reg. 2017/556 in 2019. In addition, there exist further regulatory provisions potentially relevant to nanomedicine detailing the framework for specific types of uses and products, such as Reg. 1901/2006 on medicinal products for paediatric use or Reg. 141/2000 on orphan medicinal products, not to mention national laws.[1273]

A review of all the requirements and procedures laid down by the main EU-level regulations and directives is far beyond the scope of this report. It suffices to say that differences can be extensive and substantial.[1274] Hence, it is crucial to comprehend which regulation is applicable to which product, preferably early in the process. Generally speaking, nanomedicine is perceived to make this judgment difficult since it blurs several lines drawn by existing regulation. One of those cases in which the regulatory setting is ambiguous is that of drug delivery products since they have the terms substance and device converging as explained above. On the one hand, the whole product can be seen as a "combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis" in accordance with Art. 1(2)(b) Dir. 2001/83. However, Art. 1(3) Dir. 93/42/EEC stipulates that "[w]here

[1271] Cf. note 1257.

[1272] Search performed on 4 April 2018 using the advanced search function and entering „B82Y5" in the field „IPC". Note that not every entry represents a patent, however. Rather, a large number of entries may only represent patent applications.

[1273] Pachi Spyridoula, 'Nanomedicine in Europe', 2013, p. 32 et seq, available at http://arno.uvt.nl/ show. cgi?fid=132431 (last accessed 4 April 2018).

[1274] Ruben Pita et al, `Nanomedicines in the EU-Regulatory Overview´ [2016] 18(6) AAPS J. 1576, 1580; Nassim Parvizi, Kent Woods, `Regulation of medicines and medical devices: contrasts and similarities´ [2014] 14(1) Clin. Med. 6.

a device is intended to administer a medicinal product within the meaning of Art. 1 of Dir. 2001/83, that device shall be governed by this Directive, without prejudice to the provisions of Dir. 2001/83 with regard to the medicinal product", which may in principle be equally applicable. Art. 1(9) Reg. 2017/745 contains an almost identical provision and will thus not change the law in this respect. Hence, whether a drug-delivery product is subject to Dir. 2001/83 alone or to Dir. 93/42/EEC or Reg. 2017/745, respectively, as well, seems to depend on the extent to which it is divisible into its components.[1275] It may be worth noting that this assessment seems to be supported by the second part of Art. 1(3) Dir. 93/42/EEC, which lays down that where "the device and the medicinal product form a single integral product which is intended exclusively for use in the given combination and which is not reusable, that single product shall be governed by Dir. 2001/83." Again, Art. 1(9) Reg. 2017/745 contains an almost identical provision and will thus not change the law in this respect. The "principal mode of action of the product" referred to by Art. 1(5)(c) Dir. 93/42/EEC and Art 1(6)(b) Reg. 2017/745 poses another criterion for deciding which regulation applies, although it has been criticised as too simplistic an approach.[1276] Other cases outlining the ambiguity of the regulatory framework as applied to nanomedicine arise in conjunction with diagnostic medical devices. An extreme, but hence vivid, example is a miniaturised lab-on-a-chip. Such a product could in principle be used in *in-vitro* applications and hence be subject to Dir. 98/79/EC or Reg. 2017/746, respectively, in the future. At the same time however, the exact same lab-on-a-chip may be the core component of an active implantable medical device and hence subject to Dir. 90/385/EEC or Reg. 2017/745, respectively, in the future. Spoken in more abstract terms, ambiguities arise wherever nanomedicine undermines the distinction between *in vitro* and *in vivo* the regulatory framework adheres to. These ambiguities are not easily resolved since the manufacturer may not have a primary use in mind such that the approaches usually employed to settle such ambiguities come to nothing.[1277] The foregoing outline of problematic cases is, of course, by no means exhaustive. Given the scope of nanomedicine, one can imagine many more difficult configurations testing the regulatory framework.

Apart from difficulties arising from "mere" ambiguities in the application of the law, accompanying procedures are expected to grow more complex and costly, as well. Increased complexity of nanomedicines is anticipated to warrant a case-by-case approach. Also, robust, sensitive, and accurate methodology – and, as the case may be, specific and novel instrumentation – informed by state-of-the-art scientific insights is perceived to be essential to identify and quantify the nanomedicine under investigation as a whole as well as its component parts.[1278]

All that being said, quite a few, somewhat simpler, "first-generation" nanomedicines have been established as safe and effective.[1279] Still, this has by no means made discussions about the regulation of nanomedicine dispensable. Rather, it has added another dimension. On the one hand, discussions concerning more complex products

[1275] Pachi Spyridoula, 'Nanomedicine in Europe', 2013, p. 37 et seq, available at http://arno.uvt.nl/show.cgi?fid=132431 (last accessed 4 April 2018).
[1276] *Ibid.,* p. 39.
[1277] *Ibid.,* p. 41.
[1278] Falk Ehmann et al, `Next-generation nanomedicines and nanosimilars: EU regulators' initiatives relating to the development and evaluation of nanomedicines´ [2013] 8(5) Nanomedicine 849, 850 et seq.
[1279] Cf. Anita Hafner et al, `Nanotherapeutics in the EU: an overview on current state and future directions´ [2014] 9(1) Int. J. Nanomed. 1005.

resembling the more futuristic concepts of nanomedicine – now accordingly dubbed "next-generation" nanomedicines by some – are very much ongoing, as the foregoing exemplary cases have at least already hinted at. On the other hand, the discussion has by now also appreciated the concept of similar nanomedicines, or "nanosimilars".[1280]

The European Medicines Agency addressed the general topic of nanomedicine for the first time in an initial reflection paper in 2006.[1281] Subsequently, it reacted to the uncertainty surrounding the regulatory framework for nanomedicines by creating a cross-agency nanomedicine expert group in 2009, composed of academics and regulatory-science specialists. In 2011 that group was expanded with members from the Committee for Medicinal Products for Human Use.[1282] Among other things, the expert group has developed a series of four further reflection papers addressing specific technological aspects and developments.[1283] Since its inception, the expert group has collaborated with foreign regulatory agencies, in particular those of the US and Japan.[1284] Partly, this collaboration spawned the first international scientific workshop on nanomedicines held in London in September 2010. International collaboration was substantiated and somewhat formalised in shape of the International Pharmaceutical Regulators Forum Nanomedicines Working Group in which the European Medicines Agency participates along with its Brazilian, Taiwanese, US, Canadian, Singaporean, Japanese, and Swiss counterparts.[1285] Another notable development regarding international collaboration is the formation of the European Nanomedicine Characterisation Laboratory funded under the Horizon 2020 scheme, representing a joint venture between Europe and the United States.[1286]

18.4.4 SPC eligibility

Considering the first of the three streams discussed above, it seems possible that the application of nanotechnology to medicine will yield wholly new active ingredients which will be patented and can consequently become subject of an SPC since the MA granted for the corresponding nanomedicine will be the first one within the meaning of Art. 3(a) Reg. 469/2009.

At least for the foreseeable future, however, nanomedicine will likely rather yield new formulations of already known active ingredients – including their transport by means of nanoscale carriers. In these cases, i.e. for innovation belonging to the second of the three streams discussed initially, SPC protection will not be available under current law since usually the MA granted for the corresponding product will not be the first one for the respective active ingredient(s). The legal assessment would of course be different if the combination of a new carrier and an old active ingredient could be considered a

[1280] Falk Ehmann et al, `Next-generation nanomedicines and nanosimilars: EU regulators' initiatives relating to the development and evaluation of nanomedicines´ [2013] 8(5) Nanomedicine 849, 850.

[1281] European Medicines Agency, 'Reflection Paper on Nanotechnology-Based Medicinal Products for Human Use', 2006, available at http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_ and_ procedural_guideline/2010/01/WC500069728.pdf (last accessed 4 April 2018).

[1282] Ruben Pita et al, `Nanomedicines in the EU-Regulatory Overview´ [2016] 18(6) AAPS J. 1576, 1577.

[1283] Cf. http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_ 000564.jsp&mid=WC0b01ac05806403e0 (last accessed 4 April 2018).

[1284] Ruben Pita et al, `Nanomedicines in the EU-Regulatory Overview´ [2016] 18(6) AAPS J. 1576, 1577.

[1285] Cf. IPRF Nanomedicines Working Group, see at https://www.i-p-r-f.org/index.php/en/working-groups/nanomedicines-working-group/ (last accessed 4 April 2018). Also Ruben Pita et al, `Nano-medicines in the EU-Regulatory Overview´ [2016] 18(6) AAPS J. 1576, 1580.

[1286] Cf. European Nanomedicine Characterisation Laboratory is born, see at https://ec.europa.eu/jrc/en/ news/eu-ncl-launched (last accessed 4 April 2018).

new product within the meaning of Art. 1(b) Reg. 469/2009. But at the moment, this is clearly not the position of the CJEU. It is unclear, however, whether *Neurim*[1287] might nevertheless allow for the grant of an SPC in such cases, given the MA in question is the first one within the scope of the basic patent. This question was referred to the CJEU by the High Court of Justice in *Abraxis* and is still pending.[1288] That being said, *Neurim* may indeed constitute a limited caveat in cases where the designated medical use was never authorised before and the scope of the corresponding basic patent does not include any other medical use cited in previous MAs for the active ingredient in question. We refer to Chapter 11.[1289] This very specific caveat will presumably only be of minor importance in practice, though, since nanomedicine seems, at least for now, primarily concerned with new formulations within known medical indications.

Two cases in point are *Abraxis*[1290] and *Myocet-Doxorubicin*[1291] as resolved by the German Patent and Trademark Office. The subject of *Abraxis* was the product marketed under the name Abraxane containing nanoparticle albumin bound paclitaxel, or short "nab-paclitaxel". Put simply, paclitaxel is coated with and/or bound to (and hence stabilised with the help of) the protein albumin, yielding particles having a diameter of approximately 130 nm. This in turn allows the intravenous, potentially targeted, administration of the otherwise insoluble paclitaxel. In particular, the invention avoids the use of emulsifiers that are usually employed to achieve this end, but commonly evoke allergic reactions in the patients.[1292] The Patent Office refused the grant of an SPC. It considered albumin as a mere stabiliser and/or carrier and hence paclitaxel as the only active ingredient, albeit in a new formulation. Since paclitaxel had already been the subject of earlier MAs for the same indications, the Patent Office held that, *inter alia*, the requirements of Art. 3(d) of Reg. 469/2009 were not satisfied. The patentee disagreed, arguing at length that nab-paclitaxel is indeed a new active ingredient as a whole since it differs substantially from paclitaxel in various aspects, and that – alternatively – the decision in *Neurim* would allow for the grant of an SPC as the (later amended) MA for nab-paclitaxel contained a previously unknown indication. Nevertheless, the Patent Office kept to its initial assessment, following neither the patentee's argument regarding nab-paclitaxel being a new active ingredient as a whole on the one hand, nor the argument that *Neurim* presents a caveat on the other hand since the previously unknown, but only later added, indication was not covered by the basic patent in question. The patentee appealed. The case is currently pending before the German Federal Patent Court (BPatG).[1293] We refer to Chapter 11 for a short discussion of the corresponding case before the High Court of Justice.[1294]

The subject of *Myocet-Doxorubicin* was a liposomal formulation of the antineoplastic agent doxorubicin. As the overarching name suggests, doxorubicin suppresses neoplasms, i.e. the growth of new tissue as particularly induced by cancer. However, doxorubicin has many side effects, simply put due to its propensity to also attack healthy cells. Its toxicity can be significantly reduced when it is encapsulated in

[1287] Case C-130/11 *Neurim Pharmaceuticals* [2012] EU:C:2012:489.
[1288] Cf. EWCH, *Abraxis Bioscience LLC v The Comptroller General of Patents*, 14 (Pat) [2017].
[1289] Chapter 11, Section 11.3.
[1290] File reference 12 2009 000 065.6.
[1291] File reference 101 99 004.9.
[1292] Cf. the corresponding basic patent EP 0961612 (B2). Notably, the basic patent has been classified as belonging to IPC class B82 for nanotechnology, cf. note 1253.
[1293] File reference 14W(pat)5/18.
[1294] Chapter 11, Section 11.3.2.2.

liposomes.[1295] Liposomes in turn are spherical vesicles that are formed with the help of at least one lipid bilayer. They are hence predestined for the transport of agents.[1296] Liposomes exist in various sizes, ranging from 25 nm to 100 µm. Although they therefore do not entirely qualify as part of nanotechnology in a strict sense, the literature agrees that liposomes are an essential part of current nanomedicine.[1297] The Patent Office refused the grant of an SPC. It contended that the only active ingredient is doxorubicin, hence implicitly categorising the liposomes as mere carriers. Since doxorubicin had already been the subject of earlier MAs, the requirements of Art. 3(d) of Reg. 469/2009 were not satisfied, rendering the decision in this respect very similar to the later issued one in *Abraxis*.[1298]

Lastly, SPC protection is neither available to the advances nanomedicine is expected to yield in the area of medical devices, i.e. the third stream fleshed out above. The case law has been unambiguous in that Reg. 469/2009 does not extend to medical devices.[1299] That being said, there remains a certain grey area with respect to integrated medical devices making use of ancillary medicinal products as discussed later in this Chapter in detail.[1300] As far as nanotechnology and nanomedicine are concerned, however, these specific cases belong to a different stream of innovation and hence rather pertain to the question of whether or not new formulations of existing medicinal products are – or should be – SPC eligible.

18.4.5 Conclusion

Nanomedicine promises numerous desirable advances in diagnostics, therapeutics, and regenerative medicine. Although these advances are, as a general rule, patentable, SPC protection will, under current law, not be available for what is presumed to be a significant part of them. It is still too early to assess whether this limited SPC eligibility will jeopardise the economic effect of the patent system and hence chill innovative activity in the field. The MPI can only identify the problem and suggest further research.

18.5 ANTIBIOTICS

18.5.1 The problem

As described in several contributions,[1301] the field of antibiotics has faced two main challenges in recent years. On the one hand, microbes show an increasing resistance

[1295] Cf. the corresponding basic patent EP 0290296 (B1).

[1296] Anita Hafner et al, `Nanotherapeutics in the EU: an overview on current state and future directions´ [2014] 9(1) Int. J. Nanomed. 1005, 1007 et seqq.

[1297] Cf. *ibid.,* Interestingly enough though, the corresponding basic patent EP 0290296 (B1) was not classified as belonging to IPC class B82 for nanotechnology, cf. note 1253.

[1298] It is worth noting, however, that either way any SPC would have been void as the basic patent had been cancelled in the meantime.

[1299] See in this Chapter, Section 18.6.

[1300] Section 18.6.2.2.

[1301] See, for instance, David L Gollaher and Peter G Milner, 'Promoting Antibiotic Discovery and Development – A California Healthcare Institute Initiative', 2012, p. 12-14, available at www.chi.org/uploadedFiles/Industry_at_a_glance/CHI%20Antibiotic%20White%20Paper_FINAL.pdf (last accessed 20 June 2017); Brad Spellberg et al, `Societal Costs Versus Saving from Wild-Card Patent Extension Legislation to Spur Critically Needed Antibiotic Development´ [2007] 35 Infection 167; C Lee Ventola, `The Antibiotic Resistance Crisis – Part 1: Causes and Threats´ [2015] 40(4) Pharmacy and Therapeutics 277-283; Saswati Sengupta et al, `The multifaceted roles of antibiotics and antibiotic resistance in nature´ [2013] 4 Frontiers in Microbiology 47; Aaron S Kesselheim, Kevin

to existing antibiotics. On other hand, there is an insufficient development of new antibiotics.[1302]

The reasons for both phenomena are related but complex.

Microbes' resistance to antibiotic drugs may derive from the natural characteristics of certain organisms or from genetic mutations arising either from natural evolution or from horizontal gene transfers (HTG) that allow the resistance to be transferred among different species of bacteria.[1303] In general, the use of antibiotics tends to increase antimicrobial resistance, as it forces a natural selection process in which only the biological organisms that are resistant to the drug are able to survive and reproduce.[1304] Additionally, because of their increased proliferation caused by the natural selection, resistant microbes are more likely to transfer their genetic characteristics horizontally, extending their resistance to species that were not originally resistant. For this reason, the misuse and overuse of antibiotics (e.g. unnecessary prescription in cases of viral or non-infectious diseases, prescription of doses higher than necessary, undertreatment through suboptimal doses, inadequate treatment durations, and extensive agricultural use)[1305] are considered the main factors responsible for the perceived increase of antimicrobial resistance worldwide.

From the increase of antibacterial resistance arises the need for new antimicrobial drugs. On the contrary, however, several sources point to an innovation crisis in this area.

This market failure[1306] is due mainly to the fact that antibiotics tend to yield lower revenues than other types of drugs, such as life style drugs. This is particularly relevant in view of the high costs required for the development of a new antibiotic.[1307]

Outterson, `Fighting Antibiotic Resistance: Marrying New Financial Incentives To Meeting Public Health Goals´ [2010] 29(9) Health Affairs 1689-1690. Also, the World Health Organisation has concerns related to the growth of antibiotic resistance. For these see http://www.who.int/antimicrobial-resistance/en/ and http://www.who.int/mediacentre/factsheets/ antibiotic-resistance/en/ (last accessed 20 June2017); World Health Organization, 'Antimicrobial Resistance – Global Report on Surveillance', 2014, pp. 69-71, available at http://www.who.int/drugresistance/documents/ surveillancereport/en/ (last accessed 20 June 2017).

1302 A different view is presented by Kevin Outterson et al, `Will longer antimicrobial patents improve global public health?´ [2007] 7 Lancet Infect Dis. 559-560. The authors relativise the innovation crisis, arguing that the creation of new classes of antibiotics between 2000 and 2005 reveals a degree of innovation in the antibiotic sector.

1303 C Lee Ventola, `The Antibiotic Resistance Crisis – Part 1: Causes and Threats´ [2015] 40(4) Pharmacy and Therapeutics 277-283; Saswati Sengupta et al, `The multifaceted roles of antibiotics and antibiotic resistance in nature´ [2013] 4 Frontiers in Microbiology 47.

1304 Saswati Sengupta et al, `The multifaceted roles of antibiotics and antibiotic resistance in nature´ [2013] 4 Frontiers in Microbiology 47; C Lee Ventola, `The Antibiotic Resistance Crisis – Part 1: Causes and Threats´ [2015] 40(4) Pharmacy and Therapeutics 277-283.

1305 See, for instance, Aaron S Kesselheim, Kevin Outterson, `Fighting Antibiotic Resistance: Marrying New Financial Incentives To Meeting Public Health Goals´ [2010] 29(9) Health Affairs 1690; John B Horowitz, H Brian Moehring, `How property rights and patents affect antibiotic resistance´ [2004] 13 Health Econ. 577; Kevin Outterson et al, `Will longer antimicrobial patents improve global public health?´ [2007] 7 Lancet Infect Dis. 564; C Lee Ventola, `The Antibiotic Resistance Crisis – Part 1: Causes and Threats´ [2015] 40(4) Pharmacy and Therapeutics 277-283; Saswati Sengupta et al, `The multifaceted roles of antibiotics and antibiotic resistance in nature´ [2013] 4 Frontiers in Microbiology 47.

1306 President's Council of Advisors on Science and Technology, 'Report to the President on Combating Antibiotic Resistance', 2014, p. 35, available at https://www.cdc.gov/drugresistance/pdf/report-to-the-president-on-combating-antibiotic-resistance.pdf (last accessed on 20 June 2017). "The inadequate state of antibiotic development reflects a market failure: while society's need for new antibiotics is great, the economic return on developing new antibiotics is currently too low to elicit adequate private investment and innovation."

1307 For Joseph A DiMasi et al, `The price of innovation: new estimates of drug development costs´ [2003] 22 Journal of Health Economics 166, 180, the average cost of creation and approval of a new drug in

Three factors are supposed to hamper the achievement of satisfactory revenues in this area.

Firstly, health policies aimed at reducing the consumption of antibiotics and thus preserving their efficacy are increasingly being adopted worldwide. An example of this is the Swedish Strategic Programme for the Rational Use of Antimicrobial Agents and Surveillance of Resistance (STRAMA), which through guidelines and comparative studies aimed at more conscious consumption and prescription of antibiotics has contributed to a 22 percent reduction of outpatient sales of antibiotics.[1308] In a similar way, the Obama administration launched the National Strategy for Combating Antibiotic-Resistant Bacteria in order to improve antibiotic use, development and preservation.[1309] The US Centers for Disease Control (CDC) attempts to achieve similar objectives through their initiatives "Get Smart" and "Antibiotic Stewardship Drivers and Change Package".[1310] International actions such as ReAct,[1311] Antibiotic Action[1312] and Transatlantic Task Force on Antimicrobial Resistance (TATFAR)[1313] are further examples of initiatives against the misuse of antibiotics. As a consequence, the pressure from public policies and specialised literature to lower demand for antibiotics contributes to the drop-in incentives for investment in R&D in the field of antibiotics.[1314]

Secondly, it should be noted that the periods of time in which antibiotics are needed are limited when compared to other drugs. While medicines for the treatment of heart disease, psychiatric disorders or diabetes have to be taken by the patient periodically throughout their entire life, most antibiotic-treatable diseases have a higher incidence only at certain times of the year and antibiotic treatments are usually time-limited.[1315] Again, the lower demand in comparison to other areas reduces the revenue outlook in this field.

Thirdly, the risk of antimicrobial resistance, which may reduce the real market lifetime of the drug, increases the business risk for investing companies.[1316] A treatment based

2002 was estimated to be about $400 million and $800 million, respectively. More recently, the Association of the British Pharmaceutical Industry estimated the average cost at £1.15 bn per new drug (see https://www.theguardian.com/healthcare-network/2016/mar/30/new-drugs-development-costs-pharma).

1308 Sigvard Mölstad, Otto Cars, `Major Change in the Use of Antibiotics Following a National Programme: Swedish Strategic Programme for the Rational Use of Antimicrobial Agents and Surveillance of Resistance (STRAMA)´ [1999] 31(2) Scandinavian Journal of Infectious Diseases 191-195.

1309 See White House, *National Strategy for Combating Antibiotic-Resistant Bacteria*, 2014, p. 20-22, available at https://obamawhitehouse.archives.gov/sites/default/files/docs/carb_national_strategy.pdf (last accessed 20 June 2017).

1310 See details about these initiatives at https://www.cdc.gov/getsmart/ and https://www.cdc.gov/ getsmart/ healthcare/pdfs/antibiotic_stewardship_change_package_10_30_12.pdf (last accessed 20 June 2017).

1311 See https://www.reactgroup.org/ (last accessed 20 June 2017).

1312 See http://antibiotic-action.com/ (last accessed 20 June 2017).

1313 See https://www.cdc.gov/drugresistance/tatfar/index.html (last accessed on 20 June 2017).

1314 President's Council of Advisors on Science and Technology, 'Report to the President on Combating Antibiotic Resistance', 2014, p. 36, available at https://www.cdc.gov/drugresistance/pdf/report-to-the-president-on-combating-antibiotic-resistance.pdf (last accessed on 20 June 2017); C Lee Ventola, `The Antibiotic Resistance Crisis – Part 1: Causes and Threats´ [2015] 40(4) Pharmacy and Therapeutics 277-283.

1315 C Lee Ventola, `The Antibiotic Resistance Crisis – Part 1: Causes and Threats´ [2015] 40(4) Pharmacy and Therapeutics 277-283. "Because antibiotics are used for relatively short periods and are often curative, antibiotics are not as profitable as drugs that treat chronic conditions, such as diabetes, psychiatric disorders, asthma, or gastroesophageal reflux. … Because medicines for chronic conditions are more profitable, pharmaceutical companies prefer to invest in them."

1316 Jessica P Schulman, `Patents and Public Health: The Problems with Using Patent Law Proposals to Combat Antibiotic Resistance´ [2009-2010] 59 DePaul Law Review 235; C Lee Ventola, `The Antibiotic Resistance Crisis – Part 1: Causes and Threats´ [2015] 40(4) Pharmacy and Therapeutics 277-283.

on a given antibiotic may lose effect after a few years due to the emergence and increase of antimicrobial resistance. In such a case, the antibiotic, regardless of the state of amortisation of the investment on R&D and market entry, will no longer be prescribed for the treatment of infectious diseases. The investment risk is enhanced by the unpredictability of resistance, whose emergence and dimension cannot be objectively estimated.[1317] This risk is also a negative factor to be considered by pharmaceutical companies when deciding in which sector to invest their resources.

Different alternative solutions for the abovementioned problems are discussed in the literature. In order to reduce antimicrobial resistance, the main suggestion is antimicrobial conservation based on the reduction of the consumption of antibiotics.[1318] This goal can be reached through policies of dissemination of information about the correct use of antibiotics, infection control, sanitation, improvement of diagnostic testing, improvement of tracking methodologies, optimisation of therapeutic regimens, stewardship of available antimicrobial drugs, subsidies for preferred therapies, treatment guidelines, limits on antibiotics in clinical use or prior authorisation for their use.[1319]

The financial incentive for conservation could basically come from public resources (e.g. public reimbursement for conservation efforts),[1320] but could also be achieved through conservation-based market exclusivity.[1321] Another method to combat resistance is the reduction of the demand for antibiotics through mechanisms to suppress competition and maintain high prices, which could be obtained through permanent exclusivity rights, the creation of antibiotic cartels and the creation of a monopsonistic market for antibiotics.[1322]

In order to support the creation of new antibiotics, some authors suggest other regulatory alternatives: public investments (e.g. direct funding of R&D, value-based reimbursement of costs, tax credits for manufacturers, a prize fund for new

[1317] A factor that aggravates this unpredictability is the possibility of cross-resistance between different antibiotic classes, which means that the overuse of antibiotics from one class can lead to resistance to an antimicrobial drug from another class. For more information, see John B Horowitzand, H Brian Moehring, `How property rights and patents affect antibiotic resistance´ [2004] 13 Health Econ. 577-578.

[1318] Jessica P Schulman, `Patents and Public Health: The Problems with Using Patent Law Proposals to Combat Antibiotic Resistance´ [2009-2010] 59DePaul Law Review 252-254; Aaron S Kesselheim and Kevin Outterson, `Fighting Antibiotic Resistance: Marrying New Financial Incentives To Meeting Public Health Goals´ [2010] 29(9) Health Affairs 1690-1691. A critical view is presented by Brad Spellberg, `Reflection and Reaction – Antibiotic Resistance and Antibiotic Development´ [2008] 8(4) Lancet Infect Dis. 211-212. The author stresses that the primary limitation of antibiotic conservation is that it does not eliminate the need to develop new antibiotics; it only buys us more time to come up with new antibiotics. As a consequence, antibiotic conservation as such does not represent a full solution to the antibiotic crisis.

[1319] President's Council of Advisors on Science and Technology, 'Report to the President on Combating Antibiotic Resistance', 2014, pp. 42-55, available at https://www.cdc.gov/drugresistance/pdf/report-to-the-president-on-combating-antibiotic-resistance.pdf (last accessed 20 June 2017); C Lee Ventola, `The Antibiotic Resistance Crisis – Part 2: Management Strategies and New Agents` [2015] 40(5) Pharmacy and Therapeutics 344-352; Kevin Outterson et al, `Will longer antimicrobial patents improve global public health?´ [2007] 7 Lancet Infect Dis. 563; David L Gollaher, Peter G Milner, 'Promoting Antibiotic Discovery and Development – A California Healthcare Institute Initiative', 2012, p. 19, available at www.chi.org/uploadedFiles/Industry_at_a_glance/CHI%20Antibiotic%20White%20Paper_FINAL.pdf (last accessed 20 June 2017).

[1320] Kevin Outterson et al, `Will longer antimicrobial patents improve global public health?´ [2007] 7 Lancet Infect Dis. 563.

[1321] Aaron S Kesselheim, Kevin Outterson, `Fighting Antibiotic Resistance: Marrying New Financial Incentives To Meeting Public Health Goals´ [2010] 29(9) Health Affairs 1693-1694.

[1322] John B Horowitzand, H Brian Moehring, `How property rights and patents affect antibiotic resistance´ [2004] 13 Health Econ. 578-579.

antibiotics,[1323] direct federal partnership in antibiotic development),[1324] an antibiotic user fee,[1325] reduction of drug development costs through flexibilisation of clinical trials' benchmarks[1326] and reduction of uncertainty about the health authority's expectations for clinical trials.[1327]

In that regard, patent protection is also conceivable as a way to promote R&D incentives in the field of antimicrobial drugs. However, it has been observed that the patent system is not able to address the deficiencies in the field of antibiotics. On the contrary, patent protection can even increase the problem of antimicrobial resistance.

Considering that the patent as such does not provide its holder with the amortisation of investments and profits, but only a market chance to achieve them, and that this market chance can only be realised when a sufficient amount of drugs is sold, the exclusive rights are an incentive for the patent holder to sell as many drugs as possible during the term of protection. This is particularly noticeable at the end of the term of patent protection, when the patent holder attempts to maximise short-term economic returns before the patent falls into the public domain (so-called "patent-holder waste").[1328] It is also held that the pressure for sales can lead to an imprudent use of antibiotic drugs, which contributes to the increase of resistance and conflicts with the policy purposes of preserving the efficacy of the antimicrobial agent.

[1323] Recently, in the framework of the bill H.R. 1776 (Improving Access To Affordable Prescription Drugs Act), US Democrats suggested amending the Public Health Service Act in order to establish the "Antibiotics Prize Fund" in the amount of $2 billion. The bill of law is available at https://www.govtrack.us/ congress/bills/115/hr1776/text (last access 20 June 2017). A critical view of the prize system is presented by Jessica P Schulman, `Patents and Public Health: The Problems with Using Patent Law Proposals to Combat Antibiotic Resistance´ [2009-2010] 59 DePaul Law Review 221-255. The author argues that a patent prize could lead to a system in which all antibiotics would presumably cost about the same price (the price of manufacture). In this case, the low price would likely facilitate overuse. Moreover, such a system would discourage drug developers from filing for patents.

[1324] David L Gollaher, Peter G Milner, 'Promoting Antibiotic Discovery and Development – A California Healthcare Institute Initiative', 2012, p. 16, available at www.chi.org/uploadedFiles/Industry_at_a_glance/CHI%20Antibiotic%20White%20Paper_FINAL.pdf (last accessed 20 June 2017); Aaron S Kesselheim, Kevin Outterson, `Fighting Antibiotic Resistance: Marrying New Financial Incentives To Meeting Public Health Goals´ [2010] 29(9) Health Affairs 1691-1693; President's Council of Advisors on Science and Technology, 'Report to the President on Combating Antibiotic Resistance', 2014, pp. 37-38, available at https://www.cdc.gov/drugresistance/pdf/report-to-the-president-on-combating-antibiotic-resistance.pdf (last accessed 20 June 2017).

[1325] President's Council of Advisors on Science and Technology, 'Report to the President on Combating Antibiotic Resistance', 2014, p. 41, available at https://www.cdc.gov/drugresistance/pdf/report-to-the-president-on-combating-antibiotic-resistance.pdf (last accessed 20 June 2017).

[1326] Aaron S Kesselheim, Kevin Outterson, `Fighting Antibiotic Resistance: Marrying New Financial Incentives To Meeting Public Health Goals´ [2010] 29(9) Health Affairs 1692; Infectious Diseases Society of America (IDSA), 'Bad Bugs, No Drugs – As Antibiotic Discovery Stagnates … A Public Health Crisis Brews', 2014, p. 25, available at https://www.idsociety.org/uploadedFiles/IDSA/Policy_and_Advocacy/Current_Topics_and_Issues/Advancing_Product_Research_and_Development/Bad_Bugs_No_Drugs/Statements/As%20Antibiotic%20Discovery%20Stagnates%20A%20Public%20Health%20Crisis%20Brews.pdf (last accessed 20 June 2017). Regarding the regulatory challenges for approval of a new antibiotic drug, see also C Lee Ventola, `The Antibiotic Resistance Crisis – Part 1: Causes and Threats´ [2015] 40(4) Pharmacy and Therapeutics 277-283; David L Gollaher, Peter G Milner, 'Promoting Antibiotic Discovery and Development – A California Healthcare Institute Initiative', 2012, p. 14-16, available at www.chi.org/uploadedFiles/Industry_at_a_glance/CHI%20Antibiotic%20White%20Paper_FINAL.pdf (last accessed 20 June 2017).

[1327] Aaron S Kesselheim, Kevin Outterson, `Fighting Antibiotic Resistance: Marrying New Financial Incentives To Meeting Public Health Goals´ [2010] 29(9) Health Affairs 1692.

[1328] Jessica P Schulman, `Patents and Public Health: The Problems with Using Patent Law Proposals to Combat Antibiotic Resistance´ [2009-2010] 59 DePaul Law Review 235-237; John B Horowitzand, H Brian Moehring, `How property rights and patents affect antibiotic resistance´ [2004] 13 Health Econ. 577; Aaron S Kesselheim, Kevin Outterson, `Fighting Antibiotic Resistance: Marrying New Financial Incentives To Meeting Public Health Goals´ [2010] 29(9) Health Affairs 1690; Kevin Outterson et al, `Will longer antimicrobial patents improve global public health?´ [2007] 7 Lancet Infect Dis. 563.

Moreover, the current patent protection does not seem *per se* to be sufficient to solve the problem of underdevelopment of new antibiotics. Although the 20-year patent term and the possibility of obtaining SPCs also apply to new antimicrobial drugs provided that the requirements under Art. 3 Reg. 469/2009 are met, the innovation crisis in this specific pharmaceutical field still persists. A similar rationale can be applied to the extension of the term of clinical data protection suggested by several stakeholders, since a longer exclusivity neither excludes the problem of overutilisation in view of the maximisation of short-term economic returns nor is sufficiently capable of generating sufficient incentives for investments in view of the external effects (e.g. antibiotic resistance, restricted use of antibiotics and limited market).

Particularly in view of the innovation problem, the question is whether a reform of the SPC regime can improve the effect of patent protection on the behaviour of the relevant players. Indeed, the creation of SPCs was based on the assumption that a longer period of protection would prevent a market failure and foster investment in pharmaceutical innovation.[1329] By taking account of the US-American literature in the field, we have identified two options that are of interest. Both are explained in the next sections.

18.5.2 Options

18.5.2.1 Extension of SPCs

One conceivable option to solve the problem of lacking incentives for innovation would be a longer term of SPC protection for antibiotic drugs. In this instance, SPCs for antibiotics should have a longer duration than those for other drugs.[1330] This additional period of exclusivity in the market would give the antibiotic SPC holders a greater chance to amortise the investments made in R&D and to obtain a satisfactory economic result, which could encourage new investments in this field. In such a case, therefore, the SPC for antibiotics would not only have the function of extending the protection term in order to compensate for the long time necessary to obtain the MA from the responsible health authority, but also the function of promoting drug development in a field that, for different reasons, does not provide satisfactory (and necessary) incentives for innovation.

One could assume that if the protection lasts longer, the patent holder will also not be under as much pressure to sell as many drugs as possible during the patent term. As a consequence, one could assume that health measures aiming to reduce or postpone consumption of new antibiotics will have a minor effect on companies' decision to invest or not in the development of new antibiotics.

Moreover, the implementation of such a reform in the field of antibiotics does not seem to conflict with international patent law. Even if the prohibition of discrimination under Art. 27 (1) TRIPS applied to SPCs and patent extensions[1331], it would not

[1329] See Recitals 3-4 Reg. 469/2009.

[1330] Infectious Diseases Society of America (IDSA), 'Bad Bugs, No Drugs – As Antibiotic Discovery Stagnates … A Public Health Crisis Brews', 2014, p. 24, available at https://www.idsociety.org/uploadedFiles/IDSA/Policy_and_Advocacy/Current_Topics_and_Issues/Advancing_Product_Research_and_Development/Bad_Bugs_No_Drugs/Statements/As%20Antibiotic%20Discovery%20Stagnates%20A%20Public%20Health%20Crisis%20Brews.pdf (last accessed 20 June 2017).

[1331] See Chapter 3, Section 3.2.1 and 3.2.3(c).

prevent the EU states from treating differently situations that are not similar.[1332] Even if the paediatric extension model is not co-extensive with an extension that applies to a specific category of invention, it still constitutes a model of differentiation in the term of protection[1333] that has not so far been criticised from the perspective of the international obligations and the principle of equal treatment of all applicants.

However, the extension of the term of exclusivity may not fully eliminate the toughest barriers that hamper further investments in the field of antimicrobial drugs. Since the revenues sought by an investor do not arise from the patent or SPC protection as such, but are caused by the actual commercialisation of the product in the market, factors such as public policies contrary to the use of antibiotics and increasing antimicrobial resistance, whose emergence, effects and duration are – to a certain extent – unpredictable, can make the investment disadvantageous even in case of an exclusive right with a longer term.[1334] Additionally, the SPC extension would not fully prevent the abovementioned patent-holder waste, which could contribute to an overuse of antibiotics that might promote the undesirable antimicrobial resistance.[1335]

All these elements suggest a further solution in providing adequate revenues for antibiotics-related innovation.

18.5.2.2 Wild-card SPC or wild-card patent extensions

One strategy discussed at academic level in the US-American legal literature is the wild-card patent extension. This term refers to an extension that could be granted to any drug patent of a company when this company receives the approval for a new antibiotic that treats a targeted pathogen. Since the EU law, in contrast to the US-American legal system, does not provide an extension of the patent term as such, a possible suggestion would be the granting of wild-card SPC extensions as a way of encouraging innovation in the field of antibiotics.

According to this alternative, the incentive for investment in R&D in the field of antibiotics would arise primarily from the possibility of extending the term of exclusivity in the commercialisation of another drug contained in the active patent portfolio of the company (e.g. patented blockbuster drugs). According to the Infectious Diseases Society of America (IDSA), this additional term of protection should last up to two years.[1336] Thus, the risky investment in the area of antibiotics would be offset by continued sales, at higher prices, of other commercially successful

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1332 Reto M Hilty, Matthias Lamping (eds), 'Declaration on Patent Protection – Regulatory Sovereignty under TRIPS', 2014, p. 4, available at https://www.mpg.de/8132986/Patent-Declaration.pdf (last accessed 20 June 2017).

1333 See for instance the Orphan drugs regime of protection.

1334 Kevin Outterson et al, `Will longer antimicrobial patents improve global public health?´ [2007] 7 Lancet Infect Dis. 562; Jessica P Schulman, `Patents and Public Health: The Problems with Using Patent Law Proposals to Combat Antibiotic Resistance´ [2009-2010] 59 DePaul Law Review 239-240; Infectious Diseases Society of America (IDSA), 'Bad Bugs, No Drugs – As Antibiotic Discovery Stagnates … A Public Health Crisis Brews', 2014, p. 24, available at https://www.idsociety.org/uploadedFiles/ IDSA/Policy_and_Advocacy/Current_Topics_and_Issues/Advancing_Product_Research_and_Development/Bad_Bugs_No_Drugs/Statements/As%20Antibiotic%20Discovery%20Stagnates%20A%20Public%20Health%20Crisis%20Brews.pdf (last accessed 20 June 2017).

1335 Kevin Outterson et al, `Will longer antimicrobial patents improve global public health?´ [2007] 7 Lancet Infect Dis. 563.

1336 Infectious Diseases Society of America (IDSA), 'Bad Bugs, No Drugs – As Antibiotic Discovery Stagnates … A Public Health Crisis Brews', 2014, p. 24, available at https://www.idsociety.org/uploadedFiles/IDSA/Policy_and_Advocacy/Current_Topics_and_Issues/Advancing_Product_Research_and_Development/Bad_Bugs_No_Drugs/Statements/As%20Antibiotic%20Discovery%20Stagnates%20A%20Public%20Health%20Crisis%20Brews.pdf (last accessed 20 June 2017).

drugs. Additionally, the patent holder could benefit from the incomes generated by the commercialisation of the patent-protected, new antimicrobial drug as well as from possible tax credits for orphan drugs and government research funding.[1337]

This alternative, however, would probably not result in great benefits to companies and institutions with a small active drug patent portfolio (e.g. universities, small pharmaceutical companies) or to companies that invest only in antibiotics.[1338] That is because, in these cases, the wild-card SPC extension would likely be applied only to unprofitable patents and therefore might not be sufficient to obtain the satisfactory incentives for investment in R&D. As a consequence, it could be conceivable to implement "transferable" wild-card SPC extensions, which could be sold or licensed by their holders to third parties who are interested in extending the period of exclusivity of their own patent.[1339] The disposal of rights in return for payment could be sufficient to incentivise smaller companies to invest in antibiotic innovation.[1340]

This regulation would have the great advantage that it would not require direct appropriation from the public budget for fostering innovation in the antibiotic sector, but rather leave innovation decisions up to the free market.[1341] As a consequence, it is expected that the development of new effective antibiotics will occur at a quicker speed.[1342] In addition to addressing the incentive problem, wild-card SPC extensions could likely contribute to the conservation of antimicrobial agents' efficacy by reducing the use of antibiotics or even by withdrawing them from the market. Since the market failure related to the investment in antibiotics should be corrected by the possibility of extending the exclusivity term of a more profitable drug patent, the antibiotic patent holder could be more inclined to accept and contribute to conservation-related public policies instead of practicing overzealous marketing or the abovementioned patent-holder waste.

The implementation of wild-card SPC extensions, however, could result in high social costs. The extension of SPCs' protection and the consequent maintenance of high prices could lead consumers, health insurance providers and taxpayers to spend far more on medicines than they would if competing generic drugs could be put on the market.[1343] In the USA, for instance, the extension of the protection of a successful

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1337 Aaron S Kesselheim, Kevin Outterson, `Fighting Antibiotic Resistance: Marrying New Financial Incentives To Meeting Public Health Goals´ [2010] 29(9) Health Affairs 1691-1692; Kevin Outterson et al, `Will longer antimicrobial patents improve global public health?´ [2007] 7 Lancet Infect Dis. 561.

1338 Otto Cars et al, `Innovating for Antibacterial Resistance´ [2007] 2 ESCMID News 23.

1339 President's Council of Advisors on Science and Technology, 'Report to the President on Combating Antibiotic Resistance', 2014, p. 40, available at https://www.cdc.gov/drugresistance/pdf/report-to-the-president-on-combating-antibiotic-resistance.pdf (last accessed 20 June 2017).

1340 David L Gollaher, Peter G Milner, 'Promoting Antibiotic Discovery and Development – A California Healthcare Institute Initiative', 2012, p. 17, available at www.chi.org/uploadedFiles/Industry_at_a_ glance/CHI%20Antibiotic%20White%20Paper_FINAL.pdf (last accessed 20 June 2017).

1341 David L Gollaher, Peter G Milner, 'Promoting Antibiotic Discovery and Development – A California Healthcare Institute Initiative', 2012, pp. 16-17, available at www.chi.org/uploadedFiles/ Industry_at_a_ glance/CHI%20Antibiotic%20White%20Paper_FINAL.pdf (last accessed 20 June 2017); President's Council of Advisors on Science and Technology, 'Report to the President on Combating Antibiotic Resistance', 2014, p. 40, available at https://www.cdc.gov/drugresistance/pdf/report-to-the-president-on-combating-antibiotic-resistance.pdf (last accessed 20 June 2017).

1342 Jorn Sonderholm, `Wild-Card Patent Extensions as a Means to Incentivize Research and Development of Antibiotics´ [2009] 27 Journal of Law, Medicine & Ethics 242.

1343 According to Kevin Outterson et al, `Will longer antimicrobial patents improve global public health?´ [2007] 7 Lancet Infect Dis. 561, in 2007, "A 2-year wildcard patent extension on the top ten selling drugs would protect more than $125.3 billion in global annual sales from generic competition. The global cost of granting just ten wildcard patent extensions will likely exceed $40 billion, more than $4 billion per new drug". A critical view is presented by Jorn Sonderholm, `Wild-Card Patent Extensions as a Means to Incentivize Research and Development of Antibiotics´ [2009] 27 Journal of Law, Medicine &

patent on blockbuster drugs in the way suggested by IDSA (up to two years) could have caused a social cost of $7.7 billion in the early 21st century.[1344] This amount is considerably higher than the estimated $400-800 million for the creation of new antibiotic drugs in the same period. With this in view, it is argued that the profits derived from wild-card SPC extensions will be considerably higher than the necessary amount for investment in antibiotic innovation.[1345]

Moreover, it is argued that the granting of wild-card SPC extensions would be a very bureaucratic and even unfair process. For instance, the lack of qualitative differentiation between new antibiotics could result in great benefits derived from wild cards based on mere follow-on antibiotic drugs, while profits from wild cards derived from disruptive antibiotic drugs might be lower.[1346] Furthermore, in order to receive more wild-card extensions, the pharmaceutical industry would increasingly attempt to interpret the concept of antibiotic more widely (even for drugs with a reduced practical effect or very restrictive indication), which – if consciously or erroneously accepted by state authorities – would be harmful for society without bringing significant benefits.[1347]

Finally, some scholars suggest that the implementation of wild-card SPC extensions could lead to ethical and transparency problems. Indeed the financial burden of the creation of new antibiotics would be borne by people who do not necessarily need antibiotics, but other drugs (i.e. blockbuster drugs).[1348] The relevance of this argument, however, is questionable, since public funds usually support consumers in need of these pharmaceutical products. Further, the existence of antimicrobial resistance and the lack of antibiotics are a matter of public interest and not only the interest of patients in need of an antimicrobial treatment.

In a nutshell, although the benefits derived from the creation of new antimicrobial drugs may extend beyond the two-year time frame suggested for wild-card SPC extensions, which could lead to the amortisation of social costs and even to a real

Ethics 243, who argues that the patent extension does not necessarily have to last two years. A shorter extension time could be enough to promote innovation without causing excessive social costs.

1344 Brad Spellberg et al, `Societal Costs Versus Saving from Wild-Card Patent Extension Legislation to Spur Critically Needed Antibiotic Development´ [2007] 35 Infection 169-170.

1345 Amy Kapczynski, `Commentary: Innovation Policy for a New Era´ [2009] 37(2) Journal of Law, Medicine & Ethics 265-266. The author argues that with wild-card term extensions, the size of the bonus is less predictable, less transparent, and less explicitly justified. Although this extension would be attractive to leading pharmaceutical companies, it would not make sense from the perspective of innovation economics. See also Kevin Outterson et al, `Will longer antimicrobial patents improve global public health?´ [2007] 7 Lancet Infect Dis. 561.

1346 Kevin Outterson et al, `Will longer antimicrobial patents improve global public health?´ [2007] 7 Lancet Infect Dis. 562.

1347 *Ibid.,* 561.

1348 See President's Council of Advisors on Science and Technology, 'Report to the President on Combating Antibiotic Resistance', 2014, p. 40, available at https://www.cdc.gov/drugresistance/pdf/report-to-the-president-on-combating-antibiotic-resistance.pdf (last accessed 20 June 2017); Otto Cars et al, `Innovating for Antibacterial Resistance´ [2007] 2 ESCMID News 22-24; Kevin Outterson et al, `Will longer antimicrobial patents improve global public health?´ [2007] 7 Lancet Infect Dis. 562. This criticism is minimized by Jorn Sonderholm, `Wild-Card Patent Extensions as a Means to Incentivize Research and Development of Antibiotics´ [2009] 27 Journal of Law, Medicine & Ethics 243-244. In his opinion, the costs of the antibiotic innovation would be mostly shared by all private medical insurance customers, or by all taxpayers in countries which provide universal public health care. Moreover, the state can regulate that wild-card extensions should apply only to drugs to which there exists a therapeutic alternative when their normal patents run out.

long-term social benefit,[1349] a part of the literature questions whether this form of regulation is the most reasonable and beneficial for society.[1350]

18.5.3 Opinion of the stakeholders

A question whether amendment to the SPC legislation could contribute to the antibiotics issues (Q35) has been included in the Allensbach Survey.[1351] Further, it was addressed in qualitative interviews by the MPI and at the Stakeholder seminar of September 11th by one participant.

The results of the Allensbach Survey[1352] show that almost every second respondent (49 per cent) opposed changing of the Reg. 469/2009 in response to the deficiency of development of new antibiotics. Amendments to the regulation are rejected not only by the relative majority of representatives of generic companies (46 per cent), but also by the majority of representatives of originator companies (56 cent) and associations (65 per cent). The percentual of positive, negative and neutral answers to Q35 can be visualised in the figure below:

[1349] Brad Spellberg et al, `Societal Costs Versus Saving from Wild-Card Patent Extension Legislation to Spur Critically Needed Antibiotic Development´ [2007] 35 Infection 169-170. The authors' experimental analysis demonstrates that, since the introduction of a new antibiotic drug would reduce treatment costs, the cost-neutrality of a wild-card patent extension derived from the creation of specific drug in the US market (antibiotic against multi-drug-resistant *Pseudomonas aeruginosa*) would be achieved ten years after the drug's approval. Twenty years after the approval, the social benefits would be estimated at $4.6 billion. Critical positions are presented by Jorn Sonderholm, `Wild-Card Patent Extensions as a Means to Incentivize Research and Development of Antibiotics´ [2009] 27 Journal of Law, Medicine & Ethics 243 and Jessica P Schulman, `Patents and Public Health: The Problems with Using Patent Law Proposals to Combat Antibiotic Resistance´ [2009-2010] 59 DePaul Law Review 242-245.

[1350] Aaron S Kesselheim, Kevin Outterson, `Fighting Antibiotic Resistance: Marrying New Financial Incentives To Meeting Public Health Goals´ [2010] 29(9) Health Affairs 1691. "Shifting funds among disease categories in a haphazard fashion, detached from market signals, might hurt more patients than the strategy would help." See also Jonathan Anomaly, 'Ethics, Antibiotics, and Public Policy' [2016] Georgetown Journal of Law and Public Policy 12-13.

[1351] Allensbach Survey, Annex III of this Study, p. 56. Q35 reads as follows: "It is sometimes said that there is insufficient investment in the development of new antibiotics. Would you favour or oppose changing Regulation 469/2009/EC in response to this assumed deficit?".

[1352] *Ibid*., p.26.

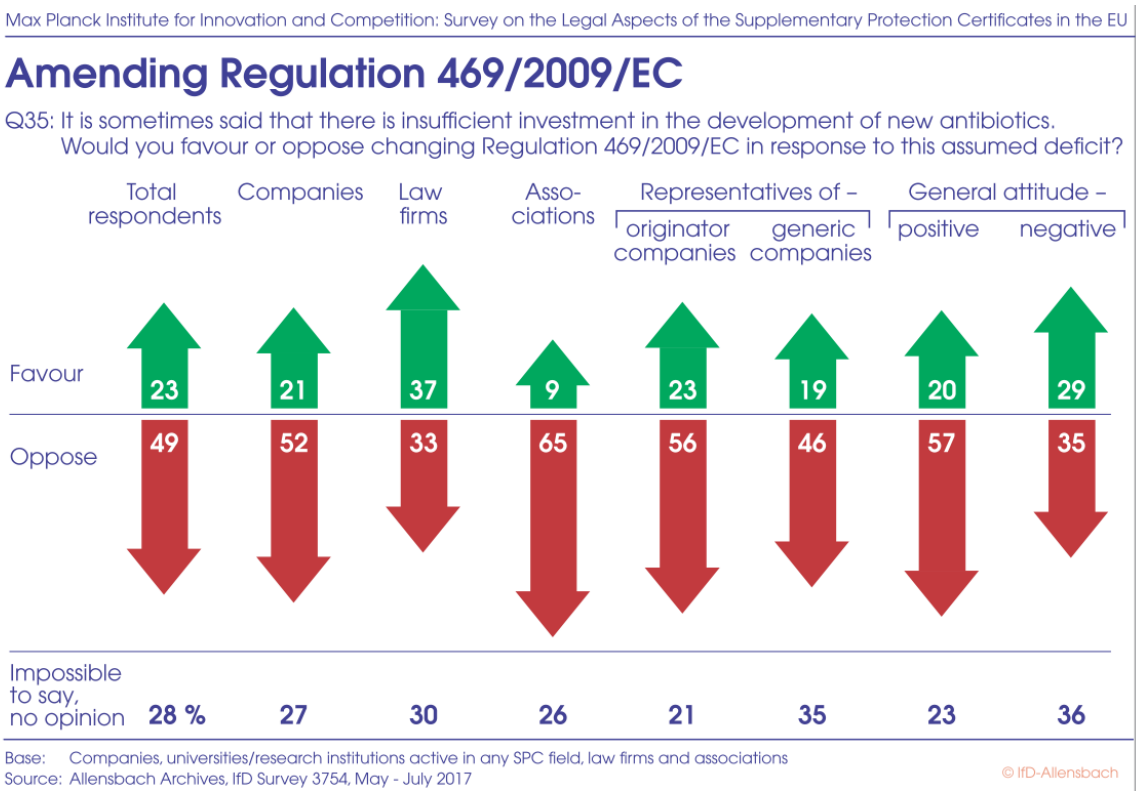

Figure 18.5: Q35 of the Allensbach Survey

At Q36, that asked for propositions on how to deal with insufficient investments in the development of new antibiotics,[1353] most suggestions focused on the suitability of the extension of the term of the patent and/or SPC protection. The following comments were made:

> "Extended SPC terms specifically for new antibiotics."
>
> "New antibiotics will be restricted in use to avoid developments of resistant bacteria - this is fundamentally not a good business model for the inventive companies developing these drugs."
>
> "Compensation could be an "antibiotic extension" of an existing SPC for a new antibiotic in analogy to the present pediatric extension, but should be longer than 6 months, possibly up to an additional 5 years."
>
> "Incentivising the companies. Similar to the US model (GAIN Act), eg. 10 years of Data Exclusivity."
>
> "Increased length of patent protection for the development of new antibiotics."
>
> "I would incentive investment in the development of antibiotics giving them a similar regulatory legal frame as Orphan drugs."

These points were also addressed in the overall assessment of the survey by some respondents in the following ways:[1354]

> "New antibiotics should be administered to the right patient, at the right time, and in the right way and so a range of incentives outside the SPC system is better placed to encourage research in this area. The SPC system is not the best tool to encourage further antibiotic research."
>
> "[…] the UK and European bioscience sector has been and continues to strongly support the use of market incentives to increase investment in the development of new antibiotics. However, we do not believe that the SPC regime is an appropriate mechanism to achieve this."

[1353] *Ibid.*, pp. 332-333.
[1354] *Ibid.*, p. 413 f.

> "[…] the link between the SPCs and the development of antibiotics or orphan medicines is misguided. While antibiotics were not developed for different reasons (including the downward pressure on demand due to AMR), orphans have a specific set of incentives, which work well. Revising the SPC Regulation would not bring any improvement in that respect."

With a different view, some stakeholders considered the funding of public research and a national reimbursement system as ways to promote innovation in the antibiotic sector:[1355]

> "If the market for development of a new antibiotic is too small to be attractive, public research should be encouraged."

> "[…] The SPC Regulations are not an appropriate mechanism for encouraging investments in antibiotics which need to be useful for many years in medical practice and only used with the right patient at the right time. Other incentives are more suitable such as can be found in national reimbursement systems."

Further, one stakeholder considered the introduction of a wild-card protection extension as a possible approach, which can be observed in the following comment:[1356]

> "A mixture of push and pull incentives. Notwithstanding my previous answer, I am not sure that the answer lies in changing the SPC regulation since even a prolongation of patent term/exclusivity by many years would be insufficient to make antibiotics research commercially attractive. Thus, looking at the problem, the notion of a "transferable patent/exclusivity voucher", whereby a company successfully investing in new antibiotics would get a voucher for another product, has the potential for an effective market-based incentive. In contrast to alternatives such as Market Entry Rewards - who would fund the pool to raise sufficient money? what happens if the pool is depleted? - the transferable voucher which could be linked with some qualifiers against abuse would not require immediate upfront signing of big checks."

The critical attitude toward SPC wild-card extension for antibiotics were also expressed in a qualitative interview by one stakeholder in the term as follows:

> "There are in fact not enough antibiotics. However, traditional IP-based incentives will not work. The problem is that IP-based incentives are linked to the volume of production and sale. In the field of antibiotics you do not want to increase the volume of production but limit as much as possible. In some cases the numbers will be comparable to orphan drugs.
> Marketable SPCs or wild card patent extensions could be an option. However, the political acceptability of such a solution will be difficult. At the moment we see a broad challenge of the concept of incentives. A further issue would be that the risk of invalidity of the patent on the other product remains. So a company can lose the reward even if it provides a new antibiotic. We do not think that this approach is worth being evaluated.
> An alternative may be to introduce an insurance license fee or market entry awards which would not be linked to the sale volumes."

The Allensbach Survey was partially criticised for not directly considering the resistance and restrictive health policies when addressing the question about SPCs and antibiotics.[1357] The reason for this is that the explicit mention of such aspects could to some extent influence or even head the response of the stakeholders, which would be undesirable for the purposes of this Study. These aspects, however, were anyway duly considered in our legal analysis and covered in the qualitative interviews. Further, the model of the wild-card extension as a possible remedy in view of the assumed suboptimal level in the development of antibiotics was already discussed in the literature.

[1355] *Ibid.,* pp. 332 and 428.
[1356] *Ibid.,* p. 332.
[1357] *Ibid.,* pp. 423-426.

18.5.4 Recommendation

In the USA, the academic discussion regarding the extension of patent protection and the creation of wild-card patent extensions in the field of antibiotic drugs has seen great advances, especially after the publication of the IDSA Report in 2004. Although the legislation has not yet evolved to the stage of implementing the relevant proposals, there are several legal and economic studies which seek to assess the impact that this regulation would have on the market for antibiotic drugs as well as the social costs it would entail.

Since the dearth of innovation in the area of antimicrobial drugs also affects the internal market and the public health in the EU States, the MPI suggests considering the options proposed in the USA with respect to the European SPC legislation. For this purpose, a prior economic analysis should be carefully carried out regarding the implementation of longer SPC duration for antibiotics as well as the introduction of the wild-card SPC extensions (transferable or not) in the regulatory framework. To this end, advantages and disadvantages related to this extended protection should be considered. Increased incentive for innovation may be countered by the reduction of antibacterial resistance and the social costs arising from the extension of exclusivity rights over medicines. The problems that the US-American literature has anticipated, however, seem to be manageable. For instance, the option of wild-card extension could be limited only to completely new classes of antibiotics, excluding from such privilege any modification of existing antibiotics. Further, the field in which wild-card extensions may be used could be limited to specific diseases in order to keep the possible financial implications under control.

The fact that the patent designated for benefiting a wild card extension may be declared void does not represent an insurmountable obstacle in our view. The reasons for that are manifold.

First, the choice of which patent shall attract SPC protection would be in the hands of the patentee. The latter can assess what are the strong patents and what are the weak ones. If, for some reasons, he decides to apply his wild-card extension to a selection patent or a formulation patent, and the latter turns to be obvious, he will have to bear the consequences of his choice. The situation is not different than for other ordinary SPCs under the law in force: the patentee may designate the patent, but if the latter is void, the SPC will be void as well, even if the product is protected by another patent that could have been designated by the applicant.

Second, for the case of revocation of the patent selected for the extension, one could eventually consider the option to grant another wild extension with a reduced term – the term in which the revoked patent has been in force before revocation – that could be used with respect to another patent.

Of course, the technicalities of the legislation must be left to further contributions. The same holds true for its implication for health costs and competition. A consultation of the stakeholders and an economic assessment will be necessary to justify the decision of the European Commission to ignore or to consider the options explored in this section.

18.6 MEDICAL DEVICES

18.6.1 Premises

In European law, plant protection products and medicinal products are not the only items whose marketing requires permission or a certification. Other products across different industries have to undergo some form of approval procedure as well. Particularly relevant in this regard are medical devices,[1358] cosmetics,[1359] chemical compounds[1360] and food products.[1361] Further examples exist in the automotive[1362] and aircraft industry.[1363] The existence of these regulatory regimes raises two issues.

De lege lata, in consideration of the prohibition of discrimination enshrined in WTO law, the question is whether the CJEU must consider permission or certification required and granted under other pieces of Union legislation than Dir. 2001/82/EC or Dir. 2001/83 as enabling the grant of an SPC for the product concerned. The question has been raised with respect to medical devices incorporating active ingredients with an action that is ancillary to that of the device. Indeed, an ancillary active ingredient may fulfil the notion of product laid down in Art. 1(b) Reg. 469/2009. By contrast, it is a common opinion that for other categories of products, such as food or cosmetics, it would be difficult to argue for an application by analogy of the SPC Regulation. They do not include an active ingredient within the meaning of Art. 1(b) Reg. 469/2009.

De *lege ferenda* the issue is whether an SPC-like compensation regime must also be created for products in other technical fields that can be placed on the market only after an approval has been obtained. The question follows not only from the prohibition of discrimination laid down in Art. 27(1) TRIPS that could apply to SPCs as well.[1364] The principle of equal treatment that is recognised by primary Union law[1365] and by the constitutions of all EU Members is also relevant in this respect.

1358 Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Medical Devices Regulation).

1359 Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products [2009] OJ L 342/59.

1360 Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC [2006] OJ L 396/1.

1361 Fundamental principles are defined in Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety [2002] OJ L 31/1; specific requirements are set out for food additives in Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives [2008] OJ L 354/16.

1362 Directive 2007/46/EC of the European Parliament and of the Council of 5 September 2007 establishing a framework for the approval of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles, OJ L 263/1.

1363 For example Regulation (EC) No 216/2008 of the European Parliament and of the Council of 20 February 2008 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency, and repealing Council Directive 91/670/EEC, Regulation (EC) No 1592/2002 and Directive 2004/36/EC [2008] OJ L 79/1.

1364 See Chapter 3, Section 3.2.1 and 3.2.3(c).

1365 On the principle of equality as a general principle of union law see Case-280/93 *Germany v Council* [1994] EU:C:1994:367, para. 67; Manfrad Zuleeg, *Betrachtung zum Gleichheitssatz im Europäischen Gemeinschaftsrecht* in Jürgen F Baur et al (eds), EUROPARECHT ENERGIERECHT WIRTSCHAFTSRECHT FESTSCHRIFT FÜR BODO BÖRNER (Carl Heymanns Verlag 1992) pp. 473 et seqq.; Christian Crones, *Selbstbindung der Verwaltung im Europäischen Gemeinschaftsrecht* (Nomos 1997) pp. 55 et seqq.; On the application of this principle in the field of SPC legislation see Case C-127/00 *Aktiebolaget Hässle v*

The question is complex and one of broad ramifications. In this Study we will limit our analysis to medical devices for the following reasons.

Firstly, it is with respect to medical devices, and above all for class III medical devices incorporating an ancillary medicinal product, that the question whether or not an SPC may be granted has previously been discussed and decided by the NPOs or national courts.[1366]

Secondly, the reasons and policy arguments that are at the basis of the SPC Regulations were considered pertinent for medical devices by a part of the literature,[1367] so that a teleological extension of the scope of Reg. 469/2009 was deemed to be possible or justified.

Thirdly, medical devices are subject matter eligible for PTEs in several jurisdictions,[1368] including the US. As mentioned in Chapter 2, the existence of PTEs in USA was one of the reasons for the decision to create SPCs in Europe in 1992.

Finally, when asked to specify for what category of products the adoption of an SPC Regulation *ad hoc* or an extension of the existing SPC legislation could be appropriate, the overwhelming majority of the stakeholders that would favour an extension of the existing SPC legislation indicated patented medical devices as the main candidate for such a reform. We refer to the answers and the comments to Q41-Q42 of the Allensbach Survey,[1369] as well as to Chapter 8 of this Study, Section 8.1.7.

Against this background, in the following sections we will first briefly examine the patentability of medical devices (18.6.2) and review the applicable regulatory regime (18.6.3). Then we will address the case law that has dealt with the SPC eligibility of combinations including medical devices. Thirdly, we will discuss the proposals advanced in a part of the literature[1370] for implementing an SPC protection for all or some categories of medical devices (18.6.4).

18.6.2 Patentability of inventions related to medical devices

Inventions concerning medical devices are patent-eligible, provided that the general requirements are met. Some specific issues follow, however, from the exclusion of medical methods from patent protection pursuant to Art. 53(c) EPC.

Admittedly, Art. 53(c) EPC, second sentence, specifies that this exclusion does not apply to products, in particular substances and compositions, used in a medical method. However, if such product is already known, a product claim will not be

Ratiopharm GmbH [2002] EU:C:2002:120, Opinion of AG Stix-Hackl, paras. 42 et seqq.; Case C-127/00 *Aktiebolaget Hässle v Ratiopharm GmbH* [2002] EU:C:2003:661, paras. 37 and 42.

1366 See in the recent literature the overview offered by Andrew Hutchinson et al, 'Is there a future for medical device SPCs? Past, present and future perspectives' [2017] 16(3) BioScience Law Review 143 et seq.

1367 Ulrich M Gassner, `Ergänzende Schutzzertifikate für Medizinprodukte?´ [2014] 4 Medizinprodukte Journal 318; Christian B Fulda, Niklas Piening, `Patentschutzverlängerung für Kombinationsprodukte – oder doch nicht?´ [2011] 2 Zeitschrift für das gesamte Medizinproduktenrecht 37.

1368 Medical devices are SPC/PTE eligible for instance in: Canada, see Annex II of this Study, Chapter 2, Section 2.5.1.1; Israel, see Annex II of this Study, Chapter 3, Section 3.2 et seqq.; USA, see Annex II of this Study, Chapter 8, Section 8.5.1.1. In Korea it is not clear if medical devices could be PTE eligible, see Annex II, Chapter 5, Section 5.4.1.1.

1369 Annex III of this Study, pp. 334-338.

1370 Robert Wenzel, *Analoge Anwendung der Verordnung über das ergänzende Schutzzertifikat für Arzneimittel auf Medizinprodukte?* (Nomos 2017) p. 236.

admitted by the examiner, because it would be anticipated under Art. 54(2) EPC. A use or Swiss-type claim is equally excluded. It would concern a medical method and would violate Art. 53(c) EPC.

Art. 54(4) and (5) EPC makes patent protection possible for known substances that are used in a medical method, allowing claims for the first and further medical uses of such substances. Such rules, however, do not apply to medical devices. This follows from the wording of the relevant provisions: Art. 53(c), second sentence, refers to "products, in particular substances and compositions", while Art. 54 (4) and (5) EPC only mention "substances and compositions". According to the case law of the EPO the notion of products is broader than that of substances and compositions, and includes manufactures that are covered by Art. 53(c), second sentence, EPC, but not by Art. 54(4) and (5) EPC. The distinction between products that are "substances and compositions" and products that are not and do not benefit from the rules laid down in Art. 54 (4) and (5) EPC is based on two criteria:[1371]

- "the means by which the therapeutic effect is achieved"[1372] and
- whether the element "which achieves the therapeutic effect is a chemical entity or composition of chemical entities".[1373]

Products that achieve the therapeutic effect by a mechanical/physical action do not qualify as "substance or composition" within the meaning of Art. 54(5) EPC. As a consequence, new and inventive medical uses of a known active ingredient are eligible for the purpose-bound product protection laid down in Art. 54(5) EPC, while new and inventive medical uses of a known device are not.

The reason given for this distinction is that a medical device, in contrast to a medicine, is not consumed during the treatment and can be re-used.[1374] If the EPO allowed claims for the new and inventive use of a device, the granted patent would limit the reuse of the device. Such a limitation does not follow from granting a product patent for the device. Once the patentee has marketed the device the patent rights are exhausted. This is not necessarily true for patents granted for a medical method,[1375] such as a method for using the device on the human body. Each single application of the patented method would need the approval of the patent owner.[1376]

However, in the case that the invention concerns the use of a drug/device-combination, the EPO allows a second-medical-use patent under specific conditions.[1377] The conditions are that the active ingredient perform the main therapeutic function in the treatment and that the combination product is consumed during the use on the human body. In this case, the combination is considered to be a substance or composition within the meaning of Art. 54(5) EPC. If, by contrast, the action of the substance is ancillary to that of the device, the combination is considered

[1371] EPO, Case T 1758/15, *Decision 11 July 2017*, ECLI:EP:BA:2017:T175815.20170711.
[1372] *Ibid.*
[1373] *Ibid.*
[1374] EPO, Case T 227/91 *Second surgical use/CODMAN* [1992] OJ 1994, 491; see also Markus Meyer et al, 'Patentability of Known Medical Devices with a New Medical Use – Case Law of the European Patent Office' [2016] GRUR Int. 109, 110.
[1375] Rudolf Kraßer, *Patentrecht* (6th edn, Beck 2009) p. 214.
[1376] *Ibid.*
[1377] See Markus Meyer et al, 'Patentability of Known Medical Devices with a New Medical Use – Case Law of the European Patent Office' [2016] GRUR Int. 109, 110 et seq., with references to the case law.

to be a medical device[1378] and Art. 54(5) does not apply. Such a distinction exists – for other purposes and with other consequences – in the regulatory framework as well.

18.6.3 Regulatory provisions applicable to medical devices

18.6.3.1 General remarks

The placing on the market and the use of medical devices is subject to regulatory procedures as currently set out in Dir. 90/385/EEC,[1379] Dir. 93/42/EEC,[1380] Dir. 98/79/EC[1381] and national implementing legislation. The legal regime in force will be replaced by the Medical Devices Regulation (Reg. 2017/745[1382]) and by in the *In vitro* diagnostics Regulation (Reg. 2017/746[1383]). More precisely, Reg. 2017/745 will apply from 26 May 2020, and Reg. 2017/746 will apply from 26 May 2022. References to Dir. 90/385/EEC and Dir. 93/42/EEC will be interpreted as references to Reg. 2017/745, while references to the Dir. 98/79/EC will be interpreted as references to Reg. 2017/746[1384].

The new Medical Devices Regulation will apply to standard medical devices as well as to active implantable medical devices. Basic principles of the existing regulatory regime remain valid.[1385] This is true in particular for "key features such as the supervision of notified bodies, conformity assessment procedures, clinical investigations and clinical evaluation, vigilance and market surveillance".[1386]

Other than in the case of medicinal and plant protection products, the placing on the market of medical devices is not subject to a prior administrative authorisation to be granted by a competent authority. Rather, the manufacturer must ensure that its product complies with the requirements set out in the medical devices legislation. To this end, depending on the applicable class, a mere self-declaration may be sufficient (as regards class I medical devices), or a more or less complex procedure involving the so-called notified body may need to be undertaken (as regards class IIa, IIb and III medical devices).

These principles are confirmed by the new legislation. According to Art. 52 Reg. 2017/745 and Art. 48 Reg. 2017/746, "prior to placing a device on the market, manufacturers shall undertake an assessment of the conformity of that device, in accordance with the applicable conformity assessment procedures set out in Annexes IX to XI." The requirements to be complied with under Reg. 2017/745 will continue to differ depending on the classification of the medical device, as the following table illustrates:

1378 *Ibid.*

1379 Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices [1990] OJ L 189/17.

1380 Directive 93/42/EEC of 14 June 1993 concerning medical devices [1993] OJ L 169/1.

1381 Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices [1998] OJ L 331/1.

1382 Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Medical Devices Regulation) [2017] OJ L 117/1.

1383 Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU [2017] OJ L 117/176.

1384 See Art. 112 Reg. 2017/746.

1385 See Recital 4 Reg. 2017/745 and Reg. 2017/746.

1386 *Ibid.*

Conformity assessment procedures for medical devices			
class I	**class IIa**	**class IIb**	**class III**
Manufacturer declares the conformity of a product by issuing the EU declaration of conformity referred to in Art. 19 after drawing up the technical documentation set out in Annexes II and III.	• Conformity assessment as specified in chapters I and III of Annex IX including assessment of technical documentation as specified in Section 4 of Annex IX, or • Manufacturer draws up the technical documentation set out in Annexes II and III coupled with a conformity assessment as specified in Section 10 or Section 18 of Annex XI.	Conformity assessment as specified in: • Chapters I and III of Annex IX including assessment of technical documentation as specified in Section 4 of Annex IX, or • Annex X coupled with a conformity assessment as specified in Annex XI.	Conformity assessment as specified in: • Annex IX, or • Annex X coupled with a conformity assessment as specified in Annex XI.
Involvement of notified body pursuant to Art. 53 Reg. 2017/745.	Involvement of notified body pursuant to Art. 53 Reg. 2017/745.	Clinical evaluation consultation procedure to be followed by the notified body pursuant to Art. 54 Reg. 2017/745 for active class IIb medical devices.	Clinical evaluation consultation procedure to be followed by the notified body pursuant to Art. 54 Reg. 2017/745 for implantable class III medical devices.
NOTE: As a particularity for any medical device that incorporates a medicinal substance, para. 5.2(a) Annex IX Reg. 2017/745 provides that the quality, safety and usefulness of the substance must be verified by analogy with the methods specified in Annex I to Dir. 2001/83/EC. Para. 5.2(b) states: *"Before issuing an EU technical documentation assessment certificate, the notified body shall, having verified the usefulness of the substance as part of the device and taking account of the intended purpose of the device, seek a scientific opinion from one of the competent authorities designated by the Member States in accordance with Dir. 2001/83/EC or from the EMA (…) on the quality and safety of the substance including the benefit or risk of the incorporation of the substance into the device."*			

Table 18.6: Conformity assessment procedures for medical devices

These rules reflect the difference in approach between the Medical Device Regulation and the Medicinal Products Regulation. The medical device legislation follows the so-called "new approach": the EU legislature defines some essential requirements that the product must comply with and the examination and authorisation of the product

by a public authority are replaced by conformity assessment procedures conducted either by the manufacturer itself or by a private third party (the notified bodies). The Medicinal Products Code entrusts a public authority with the task and the burden of examining whether the requirements laid down in the legislation are met. If the latter is the case, the authority grants a formal administrative authorisation.

However, the purpose of both Reg. 2017/745 and Reg. 2017/746 is to provide for high quality and safety standards to protect consumers and to ensure at the same time a "smooth functioning of the internal market".[1387] Only products that meet the general safety and performance requirements that are applicable to the respective medical device may be placed on the market.[1388] As regards standard medical devices and implantable medical devices, such demonstration of conformity with the general safety and performance requirements must include a clinical evaluation.[1389] *In vitro* diagnostic medical devices are subject to a performance evaluation which includes as well the need to submit clinical evidence.[1390]

Under certain circumstances, however, even for standard medical devices and implantable medical devices subject to Reg. 2017/745, the device manufacturer may rely on clinical trial data established by a third party that manufactures an equivalent medical device rather than conducting clinical trials itself. According to Art. 61(5) Reg. 2017/745, the conduct of one's own clinical investigations is not necessary. The manufacturer may rely on trials conducted by another manufacturer when:

- the "device is demonstrated to be equivalent to the already marketed device not manufactured by the applicant";
- a contractual agreement is in place between the two manufacturers that allows the manufacturer of the second device "full access to the technical documentation on an ongoing basis"; and
- the "original clinical evaluation has been performed in compliance with the requirements of Reg. 2017/745 and the manufacturer of the second device provides clear evidence thereof to the notified body".

Upon completion of the conformity assessment, the device manufacturer finally attaches the CE marking to its devices and is then entitled to place these products on the market.[1391]

18.6.3.2 Drug/device combinations

The distinction between medical devices and medicinal products is based in the Union legislation on the intended action of the product. Under Art. 2(1) Dir. 93/42 medical device means

> "any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

[1387] Recital 2 Reg. 2017/745 and Reg. 2017/746.
[1388] Art. 5(2) Reg. 2017/745 and Reg. 2017/746.
[1389] Arts. 5(3) and 10(3) Reg. 2017/745. The specific requirements for corresponding clinical evaluations are set out in Art. 61 et seqq. Reg. 2017/745.
[1390] Art. 5(3) Reg. 2017/746. The specific requirements for corresponding performance evaluations are set out in Arts. 56 et seqq. Reg. 2017/746.
[1391] See Arts. 19, 20, 52 Reg. 2017/745 and Arts. 17, 18, 48 Reg. 2017/746.

— diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
— diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
— investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
— providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations, and **which does not achieve its principal intended action by pharmacological, immunological or metabolic means**, in or on the human body, but which may be assisted in its function by such means."

Under Art. 1 Dir. 2001/83 medicinal products are "substances or combinations of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis." As consequence, a positive element of the legal notion of medicinal product under Dir. 2001/83 represents a negative element of the legal notion of medical device under Reg. 2017/745. Accordingly, no overlap between the two pieces of legislation should be possible: a product is either a medicinal product or it is a medical device. *Tertium non datur*.

These principles are challenged by combination products, that is, medical devices that incorporate an active ingredient or are designed to administer an active ingredient. Three factual scenarios are considered by the EU legislation.

The first scenario concerns devices that are intended to administer a medicinal product, but that do not form with the latter a single integral product. Examples for that are nebulisers or syringes that are marketed empty and then filled by the user with a specific medicinal product. In these cases the devices are authorised under the Medical Device Regulation, while the medicinal products remain subject to the Medicinal Products legislation.

The second scenario concerns medical devices that are intended to administer a medicinal product and are placed on the market "in such a way that they form a single integral product which is intended exclusively for use in the given combination and which is not reusable".[1392] In this case the "single integral product shall be governed by Directive 2001/83 or Regulation (EC) No 726/2004 as applicable", but the relevant requirements set out in the Medical Device Regulation "shall apply as far as the safety and performance of the device part are concerned".[1393]

The third factual scenario concerns devices that incorporate a medicinal product as an integral part. Here the criterion for identifying the applicable legislation is the action of the active substance in relation to the action of the medical device. If such action is principal with respect to that of the device, the combination product is governed by the Medicinal Products legislation (Dir. 2001/83 or Reg. 726/2004). Again in that case, the relevant general safety and performance requirements set out in Annex I to the Medical Device Regulation will apply as far as the safety and performance of the device part are concerned. If the action of the substance is ancillary to that of the

[1392] See Art. 1(9) Reg. 2017/745.
[1393] *Ibid.*

medical device, the Medical Devices legislation applies.[1394] One example of this category of products is catheters coated with heparin.[1395]

As anticipated in Table No. 19, in this latter case, the combination product is considered to be a class III medical device. A special consultation procedure takes place within the notification procedure concerning the medical device directed to assess the quality, safety and usefulness of the substance. As provided under Annex I, 7.4 of Dir. 93/42/EEC and as confirmed by Annex IX, 5.2(a) of Reg. 2017/745, this assessment shall occur "by analogy with the methods specified in Annex I to Directive 2001/83/EC". The notified body shall therefore seek an opinion from one of the authorities designated by the EU States for examining medicinal products under Dir. 2001/83 or from the EMA. In selecting the "medicinal products authority", the notified body enjoys discretion. However, if the active substance concerned falls under the mandatory scope of the centralised procedure, the notified body must seek the opinion of the EMA.

The authority consulted shall express its opinion "on the quality and safety of the substance including the benefit and risk of the incorporation of the substance into the device". Under Annex IX, 5.2 (e) Reg. 2017/745 the notified body is prevented from delivering the certificate when "the scientific opinion is unfavourable".

18.6.4 SPC eligibility of medical devices *de lege lata*

Turning now to the question of the SPC eligibility of medical devices, it is necessary to distinguish two different factual scenarios.[1396]

18.6.4.1 Medical devices as such

The first scenario is the case of patented medical devices that do not include an active substance and exert only a mechanical action on the human body. Under a literal interpretation of the SPC legislation, these medical devices are not eligible for a certificate under Reg. 469/2009.

Three reasons account for this result. First, they do not represent a product within the meaning of Art. 1(b) Reg. 469/2009 since they do not exert a pharmacological, immunological or metabolic action on their own. Secondly, they are not subject to an authorisation under Dir. 2001/83 as medicinal product within the meaning of Art. 2 Reg. 469/2009 and Art. 3(b) Reg. 469/2009. Thirdly, they are not even subject to an equivalent procedure since they do not include any active substance that must undergo tests concerning its safety, usefulness and quality.

A teleological approach can hardly change this result.[1397] The purpose of the SPC legislation is to foster research in "new medicinal products", intended as "active

[1394] Art. 1(8) Reg. 2017/745.

[1395] See Medicines and Healthcare Products Regulatory Agency, 'Borderlines between medicinal devices and medicinal products - Guidance on legislation', June 2013, available at https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/284493/Borderlines_between_medical_devices_and_medicinal_products.pdf (last accessed 12 April 2018).

[1396] See analysis by Robert Wenzel, *Analoge Anwendung der Verordnung über das ergänzende Schutzzertifikat für Arzneimittel auf Medizinprodukte?* (Nomos 2017) p. 175 et seqq. and p. 181 et seqq.

[1397] See also Robert Wenzel, *Analoge Anwendung der Verordnung über das ergänzende Schutzzertifikat für Arzneimittel auf Medizinprodukte?* (Nomos 2017), pp. 180-181.

ingredients" of "proprietary medicinal products".[1398] Medical devices do not exert a pharmacological action and are ontologically different from a medicinal product. On this point the attitude of the NPOs is consistent.[1399]

18.6.4.2 Drug/device combinations

The second factual scenario is more controversial. It is the case of medical devices that are combined with a chemical compound or a biological substance that exerts an ancillary function to that of the device.

In this case, as explained in the previous sections, after "having verified the quality of clinical data supporting the clinical evaluation report" provided by the manufacturer, the notified body must prepare a report "which sets out its conclusions concerning the clinical evidence provided by the manufacturer, in particular concerning the benefit-risk determination, the consistency of that evidence with the intended purpose".[1400] This clinical evidence must show that the active ingredient is safe and effective.[1401] Under Dir. 93/42/EC and Dir. 90/385/EC as well as under Reg. 726/2004 the notified body is required to verify the safety, efficacy and usefulness of the substance and to seek the opinion of a competent national authority or of the EMA. In making its decision whether to grant the certificate the notified body must follow the opinion of the authority consulted. In this scenario, the question is whether the corresponding CE certificate shall be considered equivalent to an authorisation granted under Dir. 2001/83. In respect to this question, we found in the past two different approaches in the case law.

According to the first approach, such a certificate is considered equivalent to an MA issued under the Dir. 2001/83. The SPC can be granted if the other requirements as set out by the SPC Regulation are met. This approach was followed by one decision of the German Federal Patent Court[1402] and one decision of the District Court of the Hague.[1403]

According to a second opinion, also in the scenario considered here, the grant of an SPC is not possible. The reason is that the consultation procedure according to Dir. 93/42/EEC cannot be equated with an authorisation procedure as set out in Dir. 2001/83.[1404] This position was adopted by two decisions of the German Federal Patent Court[1405] and by three decisions of the UK Patent Office: *Leibniz*[1406], *Cerus*[1407] and *Angiotech*.[1408]

[1398] See analysis in Chapter 2, Section 2.1.3.2.
[1399] For the practice of the NPOs see below in text, Table No. 18.7
[1400] Annex IX, Reg. 2017/745, para. 5.1.
[1401] See Annex IX, Reg. 2017/745, para. 4.6.
[1402] BPatG, *Decision of 26 January 2010*, 14 W (pat) 12/07 [2010] PharmR 237.
[1403] *Genzyme Biosurgery Corp v Industrial Property Office*, BIE 70 (2002) 360-362, quoted after Andrew Hutchinson et al, 'Is there a future for medical device SPCs? Past, present and future perspectives' [2017] 16(3) BioScience Law Review 147.
[1404] See also Peter von Czettritz, `Schutzzertifikate auch für Medizinprodukte?´ [2016] PharmR 349.
[1405] BPatG, *Decision of 8 March 2010*, 15 W (pat) 25/08 [2011] MPR 23; BPatG, *Aminosylan beschichtete Eisenoxid-Nanopartikel*, 14 W (pat) 45/12 [2016] GRUR 582.
[1406] UK IPO, BL O/328/14, *Leibniz-Institut für Neue Materialien Gemeinnützige GmbH*, Decision of 29 July 2014.
[1407] UK IPO, BL O/141/14, *Cerus Corporation*, Decision of 31 March 2014.
[1408] UK IPO, BL O/466/15, *Angiotech Pharmaceuticals Inc. and University of British Columbia*, Decision of 6 October 2015.

In *Cerus* and *Angiotech* the Hearing Officer acting for the Comptroller General of Patents, Dr. Lawrence Cullen, rejected the argument of the applicant that the EC Design Examination certificate issued after an assessment of the quality, safety and usefulness of the substance incorporated in the medical device according to Dir. 93/42/EEC shall be considered as equivalent to the grant of an MA under Dir. 2001/83. Indeed, the assessment of the substance "*is focused on making sure that exposure to the physical elements of the device does not cause any problems for the user and that there are no unintended side effects arising from the normal use of the device*".[1409] The examination of usefulness concerns the usefulness of the entire device, including the physical component and the active ingredient. By contrast, "*an assessment of efficacy under Directive 2001/83/EC would consider the efficacy of the active ingredient alone and would relate to the ability of the active ingredient to exert a pharmacological, immunological or metabolic action with a view to restoring, correcting or modifying physiological functions*".[1410]

18.6.4.3 Recent practice of the NPOs

The MPI Questionnaire for the NPOs included two questions concerning medical devices. The first is whether the NPO considers medical devices to be medicinal products within the meaning of Art. 1(a) Reg. 469/2009/EC. The second question concerned medicinal products that are administered through an implantable medical device.

The following table reports the questions and sums up the answers of the NPOs:

NPO	Does your Office consider medical devices to be medicinal products within the meaning of Art. 1(a) Reg. 469/2009/EC?	What is the practice of your Office with respect to medicinal products that are to be administered as a medicinal product through an implantable medical device?
Austria	No. Up to now no final decisions of the courts.	
Croatia	Given that our Office has not received any SPC application for medical devices yet, we have not practice to discuss about.	
Czech Republic	Our office does not have any experience with SPC applications for purely medical devices. But meeting conditions based on Art. 3 (b) of the Regulation seems to be crucial in this issue.	
Denmark	DKPTO does in principle not consider a medical device as a product within the meaning of the Regulation.	The MA of an application for an SPC has to be issued according to Directives 2001/83/EC or 2001/82/EC. The active ingredient of the device is the product within the meaning of the Regulation.

[1409] UK IPO, BL O/466/15, *Angiotech Pharmaceuticals Inc. and University of British Columbia*, Decision of 6 October 2015, para. 89.
[1410] *Ibid.*, para. 92.

Finland	Yes, if the medical device, implantable or not, is subject to a marketing authorisation according to Directives 2001/83/EC or 2001/82/EC.	-
France	Medical devices are not to be considered as "products" in our practice.	When the basic patent concerns a medicinal product administrated through a medical device, the only product taken into consideration is the medicinal product itself. The product is required to have exclusively been authorised according to directive 2001/83/EC or 2001/82/EC, and not registered according to directive 93/42/EC.
Germany	Art. 1(a) of Reg. 469/2009/EC currently does not give a clear indication whether medical devices are included in its meaning. According to German case law, medical devices are usually not regarded to fall under the scope of the regulation, because usually no MA in accordance with Directive 2001/83/EC or 2001/82/EC has been granted (Art. 2 and 3(b) of Reg. 469/2009; see e.g. BPatG 14 W (pat) 45/12 Eisenoxid-Nanopartikel).	The second question regarding implantable medical devices is not clearly distinguished from the first question. In Germany there is no difference in practice for "medical devices" and "implantable medical devices" (BPatG 14 W (pat) 45/12 Eisenoxid-Nanopartikel).
Greece	No. The practice of our office is to examine only the products, for which have been issued authorizations according to Directives 2001/83/EC and 2001/82/EC.	
Hungary	No, medical devices are not considered to be medicinal products.	The HIPO does not have any experience regarding medicinal products administered through an implantable device.
Ireland	No. However, we have yet to come across a new active substance whose 1st authorisation is as a medical device. Might be persuaded in that case??	
Italy	The medical devices are not considered medicinal products as a MA is not issued for them	
Latvia	We have not had any application where product is incorporated in a medical device yet. Had that been the first SPC application for the medicine we would grant the SPC, in a case of the second application for the same medicine we would reject application.	
Lithuania	No practice, but it is most probable that medicinal devices would not be considered medicinal products	

Luxembourg	Our office has granted at least one SPC for a medical device with an EC certification.	
The Netherlands	There was a court case in the early 2000s which allowed an SPC on the basis of a medical device authorization, provided that it could be established that it incorporated a substance which could also qualify as an active substance under the medicinal product regulation because such substances also have to undergo some form of testing for safety and efficacy. Although there have been less than a handful of SPC applications since, it would surely be welcomed if the Regulation would make explicit if SPCs can be granted on the basis of medical device authorizations.	
Poland	Our Office does not consider medical devices to be medicinal products within the meaning of the Art. 1(a) Reg. 469/2009/EC.	
Portugal	No, our office does not consider medical devices to be medicinal products. Yes, we grant the SPC but only for the medicinal product, provided that it meets the criteria of Art. 3 of Reg. 469/2009/EC.	
Romania	The medicinal product must have a MA granted in accordance with Art. 4 of the Directive 2001/82/EC and Directive 2001/83/ EC. As a medical device is to be assessed and authorised pursuant to a procedure of the Directive 93/42/EEC and this procedure does not constitute an equivalent to the procedure pursuant to Directive 2001/82/EC and Directive 2001/83/EC, the practice in our Office is to reject a protection certificate for medical product that have only undergone proceedings of the Directive 93/42/EEC. Only if the authorization also satisfies the requirements of Directives 2001/82/EC and Directive 2001/83/EC could be granted a SPC for such a medical product (device).	
Serbia	We have not yet received an SPC application for a basic patent relating to a medical (implantable) device. However, in our opinion, the wording of the definition of the medicinal product set out in Article 1 of the Reg. 469/2009 seems not to offer the possibility to interpret it as if it encompassed medical devices.	
Slovak Republic	Medical devices seem not to be covered by the definition of the medicinal product within the meaning of Art. 1(a) Reg. 469/2009/EC.	In respect of the second question, if the medicinal product is a product which obtained an administrative authorization in accordance with Directive 2001/83/EC or Directive 2001/82/EC and if all the other conditions are met our Office would grant the SPC.
Spain	No, it does not. In our practice, the only medicinal products allowed are those whose MA has been grantedunder Directive 2001/82/EC or Directive 2001/83/EC.	

Sweden	No, the Directives in article 3b do not concern medical devices. If there is a valid marketing authorisation in accordance with Directive 2001/83/EC or Directive 2001/82/EC the application is treated as any other SPC application.
Switzerland	Medical devices are not considered as medical products under the Swiss Patents Act (no MA provided). The MA for medical devices does not comply with the MA for a medicinal product issued by the regulatory agency. In absence of a MA the issue of an SPC for a medical device is not possible.
UK	The definitions in Article 1 are such that they would encompass both medical devices and medicinal products, but Article 2 and 3b limit the scope to products authorised in accordance with 2001/83/EC as currently drafted. Therefore, the UK IPO does not consider medical devices per se to be medicinal products within the scope of the SPC Regulation (see IPO hearing decisions BL O/141/14 and BL O/466/15, in which the assessment for safety and usefulness of Class III devices, which contain a substance which if used on its own would be a medicinal product, was not found to be equivalent to that undertaken under 2001/83/EC.) When considering an SPC application, UK IPO takes account of the granted marketing authorisation. As medical devices are not authorised in accordance with 2001/83/EC, they do not meet the requirement of Art 3(b) and hence are considered ineligible for an SPC. A product is either a medicinal product, authorised under medicines legislation, or a medical device, authorised under different legislation. Only products authorised under 2001/83/EC are eligible for SPC protection.

Table 18.7: The practice of NPOs regarding medical devices

The majority of the NPOs that have dealt with SPC applications for medical devices seem to have developed a uniform understanding of the SPC legislation. In this understanding, medical devices are not medicinal products. Therefore, they are excluded from SPC protection. Active ingredients incorporated in a Class III medical device are not eligible for a certificate unless an authorisation granted under Dir. 2001/83 is submitted in support of the application.

18.6.4.4 Referral of the German Federal Patent Court of 18 July 2017 (C-527/17)

After a first draft of this Study was completed, in view of the two different approaches adopted in the case law with respect to EC certificates issued for drug-device combinations, the German Federal Patent Court considered opportune to refer the following question to the Court of Justice on 18 July 2017:[1411]

[1411] We quote the referred question in the translation provided by SPC blog, 'New CJEU referral - C527/17 - Does Regulation (EC) No. 469/2009 apply to CE-marked drug/device combinations?', available at http://thespcblog.blogspot.de/2017/11/new-cjeu-referral-c52717-does.html (last accessed 9 November 2017). The decision is published in the original language in the MPI Journal [2017] GRUR Int. 861 et seq.

> "Is Art. 2 of the Regulation (EC) No. 469/2009 of the European Parliament and the Council dated May 6th, 2009, concerning the supplementary protection certificate for medicinal products to be interpreted such that an authorization according to Directive 93/42/EEC for a drug-device-combination in the sense of Art. 1(4) of Directive 93/42/EEC has to be considered as equivalent to an marketing authorization according to Directive 2001/83/EC, if the drug component, in the course of the approval procedure according to Annex I, Section 7.4, Paragraph 1 of the Directive 93/42/EEC, was scrutinized for quality, safety and usefulness according to Directive 2001/83/EC by an authority for a medicinal product of an EU member state?"

Prima facie, the issue whether the assessment of the drug-device combination under the medical device legislation can be considered equivalent to the assessment of a medicinal product made under the Dir. 2001/83 could appear to be a minor one. It really matters only when the application for a certificate meets all other requirements of the SPC legislation.

In particular, it would be necessary first that the patent designated for the procedure protects the product, or the application of the product or the process for manufacturing the product (Art. 1(c) in conjunction with Art. 3(a) Reg. 469/2009). In the case of ancillary substances integrated in a medical device this requirement is not satisfied, if the basic patent was granted for the drug-device combination. The device as such is not an active ingredient. As consequence, the combination "device + ancillary substance" is not a combination of actives within the meaning of Art. 1(b) Reg. 469/2009. The certificate can be requested for the active ingredient, but not for the combination "device + ancillary substance". If the patent claims the latter and not the former, Art. 3(a) is not complied with.

Second, if the core inventive advance shall apply under Art. 3(a), then it would also be necessary that the ancillary substance or the use of the ancillary substance as such, and not the combination "medical device + ancillary substance", embodies the core inventive advance of the patent.

Third, for the ancillary substance to be eligible for a certificate it would be further necessary – under a literal interpretation of Art. 3(d) – that the EC certificate submitted by the SPC applicant represents the first permission to use the active ingredient as a medicinal product. At least two NPOs have confirmed that they were never confronted with a situation where the ancillary medicine was an active ingredient never authorised before. Also practitioners have confirmed that the drug component of this combination consists mostly of old active ingredients.[1412]

It is apparent that by a literal reading of the legislation the issue here discussed could be relevant only where an entity has developed a new active substance and obtained a patent claiming such substance as such or its medical use as individual active ingredient but, for some reasons, the first permission to use that substance for medicinal purposes submitted for the SPC procedure is an EC design certificate granted for a class III medical device including that substance. We think that this case is absolutely rare. And in fact it was not the factual scenarios underlying the decisions of the UK IPO in *Cerus* and *Angiotech.*

The reasons why nevertheless the question of equivalence between a conformity assessment procedure under Dir. 93/42/EEC and the authorisation procedure laid down in Dir. 2001/83 could be relevant in practice must be found in the case law,

[1412] Christian B Fulda, Niklas Piening, `Patentschutzverlängerung für Kombinationsprodukte – oder doch nicht?´ [2011] 2 Zeitschrift für das gesamte Medizinproduktenrecht 37.

above all in *Neurim*.[1413] Indeed, if one is of the opinion that the *Neurim* logics is of general application, then also application for a certificate for an old active ingredient used as ancillary substance of a medical device could satisfy the requirement laid down in Art. 3(d), provided that the submitted EC certificate is the first that falls under the scope of the basic patent.

This was indeed the situation at basis of the referral C-527/17. As in *Angiotech*, the application for a certificate concerned the substance paclitaxel. The basic patent – EP 0 681 475 B1 – claimed the use of cytoskeletal inhibitors for treating restenosis. Paclitaxel was identified as example for the inhibitors claimed by the patent. It was specifically mentioned in one of the dependent Swiss-type claims of the basic patent. An EC Certificate for the use of Paclitaxel as ancillary substance in a stent was submitted in support of the application for the certificate. Paclitaxel was authorised as medicinal product in Europe for treating cancer in 1993. Therefore, even though this is not discussed in the referral, it is likely that the German Federal Patent Court considered the EC certificate to be the first relevant permission for paclitaxel that would fall under the scope of EP 0 681 475 B1 because of *Neurim*. This is a necessary assumption. The BPatG could have not referred the case without considering *Neurim* applicable to drug/device combination, because the application for a certificate would have failed anyway for Art. 3(d) Reg. 469/2009 reasons.

However, the assumption that *Neurim* applies to the factual scenario at the basis of the referral is still untested by the CJEU. One could wonder whether this question should not have been asked first.

D*e lege lata* the German Federal Patent Court has provided a teleological argument for giving a positive answer to the question referred. This argument is that the purpose of the SPC legislation is to offer a compensation for the time invested in the studies and in the authorisation procedures required to market a patented product. Only if one would subsume the conformity assessment procedure under Art. 2 SPC it could be possible to offer such compensation. Indeed the grant of MA under Dir. 2001/83 for the exploitation of the active ingredient according to the patented invention was not possible.

Now, *in abstracto*, the arguments made by the German Federal Patent Court are valid. The purpose of the SPC legislation is to foster research in "new medicinal products". As followed from the analysis in Chapter 2, new medicinal products are those that include a new active substance or a new combination. A new active substance is a substance that was never authorised before as medicinal product. If a company has developed a new active substance, has obtained a patent for it and for same reasons it decides to place on the market such active substance *for the first time* as ancillary component of a medical device, we do not see any reason why an SPC should be denied. The applicant cannot choose the regulatory venue. When he/she intends to use the active ingredient as an ancillary drug integrated in a medical device, Dir. 93/42/EEC and related national rules apply. If the substance was never authorised before, a significant amount of regulatory work is needed even if the latter shall be used as component of a medical device.

However, the scenario suggested above is hypothetical. In any case, it was not the factual scenario at the basis of the referral C-527/17. The safety, efficacy and quality

[1413] See Chapter 11, Section 11.3.1.2.

of paclitaxel were already demonstrated many years ago. In the proceedings before the UK IPO concerning *Angiotech*, the applicant has even stated that one could have obtained a separate MA for paclitaxel as medicinal product under the abridged procedure (Art. 10 Dir. 83/2001).[1414] The arguments based on the length of the procedure made by the German Federal Patent Court is fully convincing only in cases where the length of this procedure – *rectius* the length of the studies requested for generate the data needed for that procedure – is due to the tests and studies made for proving for the first time the safety, efficacy and quality of the substance paclitaxel. If the time elapsed between the filing date of the patent and the issue of an EC certificate was due to studies concerning the medical device as such, or its interaction with the drug, the teleological argument is less convincing.

18.6.5 Should the grant of SPCs be made possible for medical devices?

18.6.5.1 Introduction

De lege ferenda, the case law discussed in the previous section raises two issues. On the one hand the question is whether the Europeam Commission shall by instruments of soft law clarify the status of medical device combinations and EC Design certificates issued under the Medical Devices legislation in order to ensure a uniform practice. At least one NPO has welcomed such a clarification. However, the question whether an authorisation under Dir. 93/42/EEC shall be treated as an MA granted under Dir. 2001/83 is now pending before the CJEU. Such an initiative, at the moment, would be premature.

The other question is whether the SPC Regulation shall be amended in order to make SPCs protection possible for some or all categories of medical devices. The answer to this question is not affected by the outcome of the reference C-527/17. This is true, unless the CJEU would adopt a teleological approach and would justify this step with arguments based on primary law or international commitments that bind the lawmakers.

18.6.5.2 Comments of the stakeholders

The opinions of the stakeholders addressed for the conduct of this Study are divided on this point. We refer in this regard to p. 29-30 of Annex III, pp. 29-30; for comments on pros and contras of introducing SPCs for medical devices or other products mentioned in Q41-42 we refer to p. 334 et seqq. of Annex III.

Stakeholders welcoming SPCs for medical devices argue that the latter may require safety testing that implies a loss of effective patent protection and that could be comparable to that requirement for a medicinal product. Following comments are exemplary for this attitude.

> "In addition to biopharmaceuticals and products of recombinant DNA technology, there are other types of innovative products not explicitly falling under the scope of the two present SPC Regulations. For example, medical devices or even biosimilars also play a decisive role in the continuing improvement of public health. In many cases, the development of these products is very costly. Moreover, such products often have to undergo safety testings, which are in scope and time schedule similar to authorisations granted under Directive 2001/83/EC or Directive

[1414] UK IPO, BL O/466/15, *Angiotech Pharmaceuticals Inc. and University of British Columbia*, Decision of 6 October 2015.

> 2001/82/EC. An exemplary medical device with a long development period is for example the cochlear implant (CI), a surgically implanted electronic device that provides a sense of sound to a person who is profoundly deaf or severely hard-of-hearing. To sum up, it is very important that a new, additional SPC Regulation be created that provides adequate effective protection to the holder of patents of innovative products, which are on the "borderline" of fallingunder the present SPC Regulations, or which are not covered by the present SPC Regulations at all, but which suffer from loss of effective protection due to nationally required certification or authorisation procedures. In an ideal world, such a new SPC Regulation should be flexible and provide also adequate protection to future technologies."[1415]

> "In my opinion any technological development, which requires a time consuming authorisation before it can be brought on the market, should be able to enjoy protection by SPCs. Thus, also e.g. medical devices should be eligible for SPC protection. "[1416]

> "Medical device are more and more sophisticated. their development may request long investment, which may justify the grant of the SPC. The duration of the SPC may be shorter than one for a drug."[1417]

> "The purpose of SPCs is to compensate for the lengthy development process and the time needed to undergo the regulatory approval procedures. If other industries are facing similar requirements and lose part of the effective patent protection period, we believe they should be equally entitled to a compensation in the same way pharmaceuticals are."[1418]

Some comments refer specifically to drug/device combinations:

> "The present SPC system excludes a number of important trends, most importantly combinations of drugs with medical devices. Such combinations often have to be authorized according to Directive 93/42/EEC and not Reg. 469/2009/EC. These combinations may not fall in the scope of the SPC directive due to non-compliance to Art. 2. This results in the rather unfair situation that a newly developed drug that has to be deployed from a medical device cannot obtain SPC protection merely due to its mode of administration."[1419]

In the view of some stakeholders SPCs for medical devices could generate new research-based jobs in the EU, enable innovative products to reach the EU market earlier and make the EU more attractive as a market, considering that in the USA and Japan PTEs for medical devices are available.[1420]

Opinions against introducing SPCs for medical devices were based on the fact the efforts and the work needed to generate the data for bringing the medical device to the market are not as burdensome as for a medicinal product.[1421] One commentator pointed to the longer entry period for substitute products and higher healthcare costs.[1422] Another stakeholder observed that the developing costs of the products mentioned in Q41-42 of the Allensbach Survey, including medical devices, is lower than that of medicinal products. Higher prices for the SPC-protected goods and transfer of activities to SPC-free countries were also mentioned as arguments against allowing SPC protection.

In the event of a reform, several comments express a preference for adopting an SPC Regulation *ad hoc* instead of expanding the scope of the Medicinal Products Regulation.[1423] One of the reasons is that the technologies mentioned in Q41-42 differ in terms of market conditions, technical requirements and existing incentives.[1424]

[1415] Annex III ofthis Study, p. 307.
[1416] *Ibid.,* p. 327.
[1417] *Ibid.,* p. 334.
[1418] *Ibid.,* p. 335.
[1419] *Ibid.*, p. 310.
[1420] *Ibid.,* p. 335.
[1421] *Ibid*., p. 337.
[1422] *Ibid*., p. 335.
[1423] *Ibid*., p. 334.
[1424] *Ibid.,* p. 337.

18.6.5.3 Recommendations

(a) *Medical devices in general*

The key questions, whether creating SPCs for medical devices would be beneficial to European companies and consumers, whether it would create incentives needed for fostering innovation in the field of medical devices in Europe, and whether it would make possible innovation that otherwise would not take place, are economic questions. Therefore, this Study cannot provide a recommendation. However, the MPI can identify some criteria that should govern the action of the lawmakers in this field. These criteria are of a legal nature: they ensure the respect of international law and primary Union law on the one hand and consistency within the SPC system on the other hand.

There are reasons for arguing that TRIPS, and more precisely, the prohibition of discrimination laid down in Art. 27 TRIPS, could apply to SPCs.[1425] Prohibition of discrimination means that similar situations must be treated similarly, and different situations must be treated differently. This basic principle also has a backing in primary Union law.[1426] Its practical implications must be evaluated in view of the purposes of the applicable legislation.

The crucial question consequently is whether, in view of the *ratio legis*, i. e. the purpose of the SPC Regulation, the situation which the manufacturer of a medical device is confronted with can be considered similar or analogous to that of the manufacturer of a new medicinal product.

If the reason for having SPCs were simply the necessity to conduct regulatory approval procedures prior to placing a patented product on the market, the situation of medical devices could be considered to be comparable with that of medicinal products. The only question that would remain to be answered from an economic empirical perspective is whether or not the lengths of the studies required for such procedures are equally long on average.

Still, in our opinion, the reason why medicinal products can be protected by SPCs is not just the existence of prior regulatory approval proceedings. Indeed, also in the field of medicinal products, not all patented medicines should be eligible for a certificate in the intention of the lawmakers.

There are by contrast two further reasons that are interrelated and evoked by the Medicinal Products Regulation. The first is that such regulatory procedures are preceded by clinical trials that require considerable investments. The second is the assumption of the lawmakers that the ordinary term of patent protection would not be sufficient to make such investments in research profitable. As a consequence, if a term of extended exclusivity were not granted a *market failure* would occur. By market failure we mean in this specific context a situation where research that is particularly beneficial for the public health would not take place or would be reduced because imitation and competition are free.

[1425] See Chapter 3, Section 3.2.1 and 3.2.3(c).
[1426] See Section 18.1 of this Chapter and accompanying footnotes.

That the risk of a market failure is the major justification for the SPC regime follows in our view clearly from Recitals 3-6 Reg. 469/2009, according to which "the period that elapses between the filing of an application for a patent for a new medicinal product and authorisation to place the medicinal product on the market makes the period of effective protection under the patent insufficient to cover the investment put into the research". As a consequence, "the European industry would not continue to invest in research in new medicinal products if the term of the patent would not be extended in order to compensate the time lost".

The lawmakers were of the opinion in 1992 that these risks existed only for new active ingredients, and not new formulations, new indications of old active ingredients, new excipients or new adjuvants. For this reason, not any new patented medicine brought to the market should benefit from a certificate, but only a "new medicinal product". "New medicinal products", as explained in Chapter 2[1427], were only products that included a new active ingredient or a new combination of active ingredients never authorised before. This policy choice was implemented by Art. 3(d) and Art. 3(c).

Now one could argue that the standard proposed here for a legislative action is too high. Indeed for adopting the Plant Protection Product Regulation conclusive evidence of the risk of a market failure was not given and not required by the EU legislature. However, as *Schennen* confirmed, some unpublished Memoranda from the industry suggested that the regulatory work required for plant protection products had led to an erosion of the effective patent term since 1977 from an average of 13 to 10 years.[1428] The Explanatory Memorandum to the Proposal for a European Parliament and Council Regulation (EC), of 9 December 1994, concerning the creation of a supplementary protection certificate for plant protection products (COM(94) 579 final) referred to another study of the industry, according to which the average duration of patents for plant protection products had fallen from 13 to 9 years. The existence of an erosion of the patent term documented by some studies and the requests of the affected industry for a compensation were also considered as indicia of a risk of a market failure by the drafters of the Proposal of the European Commission in 1990.

In light of this consideration, we believe that the SPC protection regime should be extended accordingly only if a similar risk of reduced research activities could be equally proved at least by the same indicia that were considered relevant in 1990 and in 1994 by the drafters of the explanatory Memoranda. One of these indicia could be evidence that the average time of effective patent protection is shortened in a relevant way. By contrast, specific requests and pressure from the affected industry, as implicitly suggested by the Explanatory Memoranda[1429], should not be a decisive criterion. Indeed, the level and the quality of the pressure an industry may exercise depends on its structure. Highly concentrated industry faces fewer collective action issues than industries dominated by small and medium enterprises.

[1427] Chapter 2, Section 2.1.3.2.

[1428] Detlef Schennen, 'Auf dem Weg zum Schutzzertifikat für Pflanzenschutzmittel' [1996] GRUR Int. 103 quotes in particular the Memorandum Nr. 3 of the International Group of National Associations of Manufacturers of Agrochemical Products (GIFAP) of March 1992 – unpublished.

[1429] European Commission, Explanatory Memorandum to the Proposal for a Council Regulation (EEC), of 11 April 1990, concerning the creation of a supplementary protection certificate for medicinal products (COM(90) 101 final – SYN255), paras. 3-4; Explanatory Memorandum to the Proposal for a European Parliament and Council Regulation (EC), of 9 December 1994, concerning the creation of a supplementary protection certificate for plant protection products (COM(94) 579 final), para. 6.

With this in mind, the EU legislature would need to pay attention to the new medical device regulation which may have an impact in this regard, as the industry assumes a significant increase in terms of the investments required prior to the placing on the market of a new medical device.[1430] At least with regard to certain class IIb and class III medical devices, the conduct of clinical trials is indeed mandatory pursuant to Art. 61 Reg. 2017/745 and involves a complex administrative procedure pursuant to para. 5.1 Annex IX of Reg. 2017/745. The need to conduct clinical trials as such may further cause longer delays as regards the placing of the market of new medical devices.[1431] Therefore, it would be necessary to assess to what extent the new regulatory regime in general and the need to conduct clinical trials in particular reduce the term of effective patent protection for medical devices.

Of course, in comparing different technical fields in order to ensure equal treatment a holistic approach is needed: in fact several other aspects are relevant.

On the one hand one should take into account differences in the protection offered by other pieces of legislation. At the moment, indeed, the medical device legislation does not provide for a time-limited regulatory exclusivity for the clinical data. Art. 61(5) Reg. 2017/745 allows the use of third-party data only subject to a contractual agreement between the device manufacturer and the manufacturer of the equivalent prior device. Therefore, clinical trial data is *per se* under the control of the manufacturer. Access can be made subject to conditions to be decided upon by mutual agreement.

On the other hand, in assessing whether or not to introduce SPC protection to ensure equal treatment of the manufacturers concerned, one must also consider the role of the patents in the relevant market, and precisely whether the expiration of a potential "basic patent" leads to a significant reduction of the prices of the medical devices concerned. If a form of generic competition does not take place after the expiration of the patent for a whatever reason[1432] then the case for having a further SPC regime would be weakened. In this regard, a single patent granted for the active ingredient of a medicinal product or the active substance of a plant protection product can have a significant impact on competition, so that its expiration or extension has a direct effect on the price of the final product. It is not obvious that the same situation occurs in the field of medical devices.

From a technical point of view, the implementation of an SPC regime for medical devices poses some practical questions. For instance, it could be also more difficult to identifiy the subject matter eligible for a certificate. The SPC regime in force makes a distinction between active substances and excipients, and between new active

[1430] 'BVMed-Konferenz zur neuen europäischen Medizinprodukte-Verordnung (MDR): „Deutlich höherer Aufwand und steigende Kosten für die KMU-geprägte MedTech-Branche"', available at https://www.bvmed.de/de/bvmed/publikationen/bvmed-newsletter/bvmed-newsletter-26-17/bvmed-mdr-konferenz-deutlich-hoeherer-aufwand-und-steigende-kosten-fuer-die-kmu-gepraegte-medtech-branche?pk_campaign=tsr_CHK&pk_kwd=startseite_tsr-aktuelles-gT_mi_bvmed-mdr-konferenz-deutlich-hoeherer-aufwand-und-steigende-kosten-fuer-die-kmu-gepraegte-medtech-branche (last accessed 11 April 2018).

[1431] An exemplary overview on the duration of clinical trials for class III medical devices is present by Robert Wenzel, *Analoge Anwendung der Verordnung über das ergänzende Schutzzertifikat für Arzneimittel auf Medizinprodukte?* (Nomos 2017) p. 190.

[1432] For instance, because no single patent is so significant to affect alone the price of the final product or to prevent the availability of equivalent products, or because the imitation costs are high, or because competition of equivalent products takes already place under the period of patent protection because patents covers only specific aspects of the products concerned whose reproduction is not material for offering equivalent products or service.

ingredients and new formulation of old active ingredients. An analogous distinction with respect to medical devices would be problematic to make. What is a patented core component and and what a peripheral component of the medical device ? What is the active part of a medical device? How to draw a distinction between an improvement of an old product and the development of a new product?

(b) *Drug/medical device combinations*

Concerning the specific situation of borderline products including an ancillary active substance as an integral element, we shall distinguish two scenarios.

If the substance concerned was *never authorised before* as a medicinal product ("new active ingredient"), and for marketing the combination drug/device the applicant had to generate data for the first time to evidence the safety, efficacy and uselfulness of that substance, it is consistent with the rationale of the SPC legislation to allow SPC protection in this case.

If the drug/medical device combination by contrast includes an "old active ingredient", it is not consistent with the intention of the lawmakers in 1992 to allow a certificate in this case. The SPC regime should address a decline in the development of new active ingredients. The protection should be reserved and limited to applications filed on the basis of the first MA given for a specific active (Art. 3(d) Reg. 469/2009).

Neurim[1433] has partly changed this principle; *Abraxis*[1434] could provide clarity on the extent of this change. As explained in Chapter 11, the question whether this change should be codified, reinforced or overruled is a question of policy.

If the lawmakers consider the arguments that in *Neurim* induced the CJEU to develop the law convincing, and they decide to extend the principles of *Neurim* to all patented uses or formulations of an old active ingredient, then there is no reason to deny an SPC only because the first relevant "permission" to use, for a medicinal purpose, the active ingredient that falls under the scope of the basic patent was issued under Reg. 2017/745 and not under Dir. 2001/83. If one accepts *Neurim*, also the argument that the "efforts needed to obtain CE marking cannot be compared with those needed for obtaining marketing authorisation"[1435] would hardly be relevant. Under *Neurim* also an abridged or even generic MA could support an application for a certificate. Finally, the argument that the CE Certificate as such is not an authorisation in legal terms would be a formal one with respect to the substance of the problem, that is, to ensure an equal treatment. If any delay due to the regulatory work required by the applicable legislation to exploit a patented medicine is to be compensated – this is the outcome of generalising the logic of *Neurim* – it should not matter whether this delay is the consequence of a legislation that follows the new approach or a legislation that requires a formal MA. What is more, the applicant cannot influence the qualification of the product as a medicinal product or as a medical device. The applicant cannot choose the applicable regulatory route unless it decides to change the way of administering the ancillary active substance. This is not the purpose and should not be the effect of the SPC legislation.

[1433] See Chapter 11, Section 11.3.1.2.
[1434] See Chapter 11, Section 11.3.2.2.
[1435] So the opinion of Christopher Brückner, *Supplementary Protection Certificates with Paediatric Extension of Duration* (2nd edn, Heymanns 2015) Art. 2, marginal note 102.

If the lawmakers, by contrast, consider as still valid the reasons that led the drafters of the Medicinal Products Regulation to limit the SPC regime to new active ingredients, then new uses or new formulations of old active ingredients should not be eligible for a certificate. This conclusion should apply also to patented new uses of the active ingredient that involve a medical device. An SPC should in consequence fail on Art. 3(d) Reg. 469/2009.

18.6.6 Some conclusions also valid for other technical fields

The above considerations on whether to extend the subject matter eligible for SPC protection to other fields where – at the moment – no supplementary protection appears to be possible apply to all technical fields. The prohibition of discrimination requires a similar approach and a similar analysis.

The questions to be answered are whether:

- because of the applicable regulatory approval systems the time to bring the product to the market is longer than the average in the other technical fields and is analogous to that of medicinal products including a new active substance (unless *Neurim* is adopted and generalised), so that a regulatorily induced erosion of effective patent protection occurs;
- the resources needed to develop a patented product, the level of imitation costs and the role of patents in ensuring a market position with respect to a product are such that profitable generic competition takes place immediately after the expiry of the relevant patent.

If these questions are answered in the affirmative, a risk of market failure that would call for a legislative action could be assumed.

18.6.7 Summary

- Medical devices are not eligible for SPC protection under the current SPC legislation and the practice of the NPOs. They are not medicinal products within the meaning of Art. 1(a) and Art. 2 Reg. 469/2009 and they are not authorised as a medicinal product within the meaning of Art. 3(b) Reg. 469/2009. A teleological approach cannot affect this result. The purpose of the SPC legislation is to foster research in new active substances and not in new medical devices.
- It is unclear whether this conclusion is also valid for medical devices with ancillary active ingredients (drug/medical device combinations) that are subject to a consultation procedure that requires clinical data. The German Federal Patent Court takes the view in the referral decision of 18 July 2017 that SPCs may be available in this regard, but it referred the question to the CJEU for a preliminary ruling whether "Art. 2 Reg. 469/2009 is to be interpreted to mean that an authorisation according to Directive 93/42/EEC for a drug-device-combination in the sense of Art. 1(4) of Directive 93/42/EEC has to be considered as equivalent to an MA according to Directive 2001/83 if the drug component, in the course of the approval procedure according to Annex I, Section 7.4, Paragraph 1 of Dir. 93/42/EEC, was scrutinised for quality, safety and usefulness according to Directive 2001/83 by an authority for medicinal products of an EU Member State". However, this question really matters only

when the applicaton meets all the other requirements of the SPC legislation, including Art. 3(a) and Art. 3(d) Reg. 469/2009. Since such drug/medical device combinations usually involve old active ingredients, the application for a certificate could meet Art. 3(d) Reg. 469/2009 only when, *inter alia*, the principles stated in *Neurim* apply. The question whether *Neurim* also applies to the use of an old active ingredient as an ancillary substance integrated in a medical device was not addressed by the CJEU. It has not been referred so far. If the drug/medical device combination includes a new active ingredient, so that the EC Design Certificate submitted in support of the application for a certificate is the first "permission" to use the active ingredient for a medicinal purpose, the grant of a certificate is in our view consistent with the rationale of the SPC legislation, provided that the other requirements of Art. 3 Reg. 469/2009 are met.

- The issue whether, under what conditions and for which class of medical devices an SPC should be made available is of an economic nature. The MPI has formulated some criteria to inform the exercise of legislative discretion in this respect. These criteria are based on the theory that not the mere existence of an approval procedure, but the risk of a market failure, is the justification of the existence of SPCs in Europe.

19 SPCs FOR PLANT PROTECTION PRODUCTS

19.1 INTRODUCTION

To a large extent the Reg. 469/2009 concerning SPCs for medicinal products and the Reg. 1610/96 concerning SPCs for plant protection products are almost identical leading to the same questions, issues and recommendations. This is particularly the case regarding basic definitions, calculation of terms and the like. However, there are important differences between the two industrial areas and their legal framework. For one, the procedures for obtaining an MA are very different and there is still no centralised MA for plant protection products in the EU. This situation and the possible issues for a unitary SPC arising from it will be addressed in Chapter 22.[1436] This Chapter will instead focus on differences between the two industries and to what extent these differences are reflected in the Regulations. Furthermore, the Chapter will highlight some of the issues identified for SPCs on medicinal products insofar as the options or recommendations differ from what has been laid out in the other Chapters.

With respect to the economic situation in the plant protection sector, there are only a very small number of studies, which is quite different from the pharmaceutical sector. According to a study by *Phillips McDougall* from 2010[1437] which was updated in 2016[1438], the total costs of a new crop protection product from research through registration are currently around USD 286 million (approx. 215 million EUR). From 1995 to 2014 there was an increase of costs of 88.2 per cent.

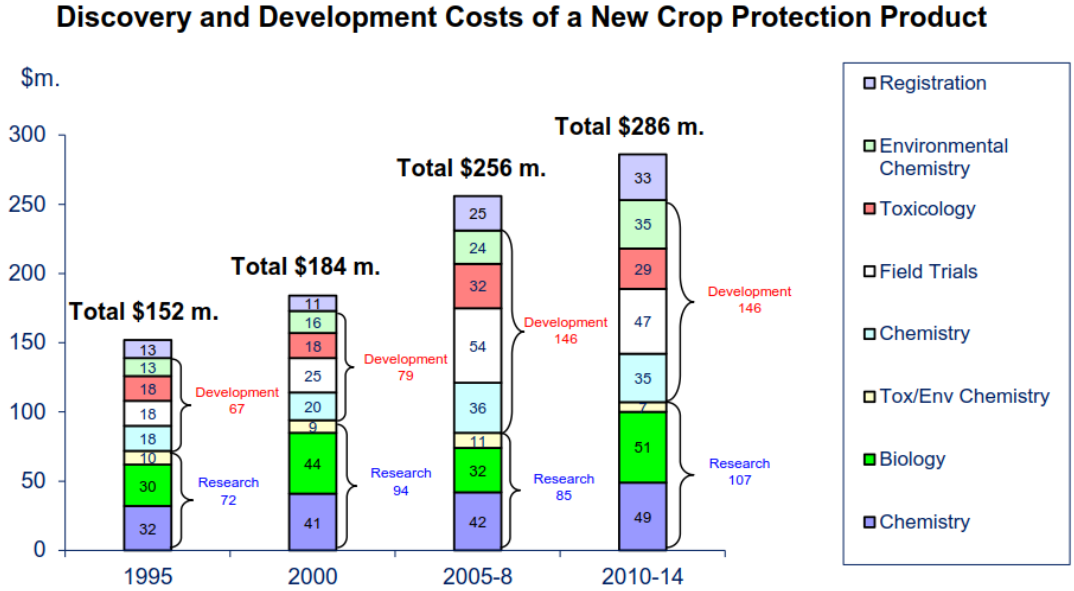

Figure 19.1: Discovery and development costs of a new crop protection product (Source: McDougall, 2016, 3)

[1436] Chapter 22, Section 22.3.4.3.

[1437] Phillips McDougall, The Cost of New Agrochemical Product Discovery, Development and Registration in 1995, 2000 and 2005-8. R&D expenditure in 2007 and expectations for 2012, January 2010. Available at: https://croplife.org/wp-content/uploads/2014/04/Phillips-McDougal-Research-and-Development-study.pdf (last accessed July 7, 2017).

[1438] Phillips McDougall, The Cost of New Agrochemical Product Discovery, Development and Registration in 1995, 2000, 2005-8 and 2010-2014. R&D expenditure in 2014 and expectations for 2019, March 2016. Available at: http://191hmt1pr08amfq62276etw2. wpengine.netdna-cdn.com/wp-content/uploads/2016/04/Phillips-McDougall-Final-Report_4.6.16.pdf (last accessed July 7, 2017).

19.2 MOTIVATION FOR SPCS FOR PLANT PROTECTION PRODUCTS

In principle the motivation for the lawmaker to introduce SPCs for plant protection products was similar to that regarding the creation of SPCs for medicinal products: both categories of products require a prior approval and thus are subject to a shorter effective term of patent protection.[1439] However, while Reg. 469/2009 is also based on direct benefits for the general population ('continuing improvement of public health')[1440] there is no such direct reference to public needs in Reg. 1610/96. It has been pointed out in the legal literature that there is a link to indirect benefits for the general public through improvements in the production of food, the improvement in the quality of food and the prices of food.[1441] At the same time Reg. 1610/96 clearly states that "one of the main objectives of the supplementary protection certificates is to place European industry on the same competitive footing as its North American and Japanese counterparts."[1442]

This is clear evidence of the Plant Protection Regulation as an economic policy measure aimed to strengthen the European economy.[1443]

The differences of both, the market conditions and the motivations for the introduction of SPCs for medicinal products and plant protection products, respectively, need to be kept in mind in the analysis of the legal framework.

19.3 DIFFERENCES AND SIMILARITIES

19.3.1 Similarities

Medicinal products and plant protection products are to some extent similar:

- Both require an MA.
- Both address "diseases" in the broader sense. This can be germs, fungi, bacteria, viruses, cancer etc. Medicinal products address them in the human or animal body and plant protection products in crops, trees and other plants.
- Both were largely based on chemical compounds (small molecules) in the past but can also employ biological products.
- Both require extensive research and development and the associated costs.

19.3.2 Differences in the markets

However, some substantial differences need to be taken into account during the analysis of the law applied to the two industry sectors.

- An MA for a plant protection product must be renewed every 10 years including the required studies.

1439 Recital 5 Reg. 1610/96.
1440 Recital 2 Reg. 469/2009.
1441 Daniel Felix Schiopu, *Ergänzende Schutzzertifikate auf der Grundlage vorläufiger Zulassungen* (Herbert Utz Verlag 2014) p. 40 et seq with reference to Recitals 1 and 2 Reg. 1610/96.
1442 Recital 7 Reg. 1610/96.
1443 Daniel Felix Schiopu, *Ergänzende Schutzzertifikate auf der Grundlage vorläufiger Zulassungen* (Herbert Utz Verlag 2014) p. 41.

- The market structure and therefore, the stakeholder structure differ. Medicinal products are produced by companies, prescribed by doctors, used by patients and – usually – paid for by insurance companies. Plant protection products are produced by companies and bought, used and paid for by farmers.
- Also, while – except of vaccines – it is often desirable to limit the number of active ingredients in one medicinal product, it is the opposite case regarding plant protection products. To be able to target different species of pests while reducing the number of application rounds, two or more active substances are usually combined in one product thus making combination products much more a rule rather than an exception in this particular market.[1444]
- The differences in the market structure can also be seen when taking the numbers of granted SPCs and SPC applications in various jurisdictions into account. The table below compares the applications and grants of SPCs in the Netherlands, Germany and the UK from 1997 to 2015 and shows that SPCs for medicinal products by far outweigh those for plant protection products (PPP).

	State	Medicinal Product SPC	PPP SPC
Total	UK	930	167
	DE	994	198
	NL	875	115
Granted	UK	559	127
	DE	496	112
	NL	582	95
Withdrawn/ rejected	UK	140	20
	DE	192	55
	NL	136	15

Table 19.1: SPCs for plant protection products and medicinal products 1997-2015 (source: Arunasalam/De Corte, JIPLP 2016, 833, 840)

It is more difficult to establish the importance and impact of generic products in the plant protection product industry. The generic sector is less visible, and it was also apparent during this Study that the respective stakeholders were less interested to participate.[1445] However, based on the available information it can be estimated that

[1444] V-Cumaran Arunasalam and Filip De Corte, 'Supplementary protection certificates for plant protection products: the story of 'The Ugly Duckling'' [2016] Journal of Intellectual Property Law & Practice 833; Euros Jones, 'On the Relevance of Supplementary Plant Protection Certificates on the Basis of Marketing Authorizations for Combination Products' [2011] GRUR Int. 1017.

[1445] However, a representative of the European Crop Care Association (ECCA) attended the MPI stakeholder seminar that took place in Munich on 11th September 2017; further, ECCA also filed a written submission after the seminar that has been considered in drafting the section on *Bolar* in Chapter 15 of this Study.

more than 50 per cent of available plant protection products are based on substances where the patent or SPC protection already expired.[1446]

19.3.3 Differences in law

Although they do not seem to play a substantial role in practice, there are several differences in the definitions included in Art. 1 of both Reg. 469/2009 and Reg. 1610/96. Some of the differences are obviously based on clear differences between the two industries, such as the additional definitions of 'plants' and 'plant products'. However, there are also differences that do not seem to be the direct result of differences between the two fields of application.

19.3.3.1 Recital 17 Reg. 1610/96 and Art. 22 Reg. 469/2009

Some differences in the legal texts applicable to the two industries might be explained because of the lapse of time between the enactment of Reg. 1768/92 and Reg. 1610/96. Indeed, between the drafting of the two regulations, the lawmaker realised that some issues had been overlooked in the first regulation. To avoid the need to pass an amended version of Reg. 1768/92 the law-maker included Recital 17 in Reg. 1610/96:

> Whereas the detailed rules in recitals 12, 13 and 14 and Articles 3 (2), 4, 8 (1) (c) and 17 (2) of this Regulation are also valid, mutatis mutandis, for the interpretation in particular of recital 9 and Articles 3, 4, 8 (1) (c) and 17 of Council Regulation (EEC) NO 1768/92.

Since Reg. 469/2009 replaced Reg. 1768/92, Art. 22 Reg. 469/2009 states:

> Regulation (EEC) No 1768/92, as amended by the acts listed in Annex I, is repealed.
>
> References to the repealed Regulation shall be construed as references to this Regulation and shall be read in accordance with the correlation table in Annex II.

Recital 17 Reg. 1610/96 and the provisions listed therein are relevant for the interpretation of Reg. 469/2009. However, Recital 17 Reg. 1610/96 has not amended Reg. 1768/92 or does not derogate to Reg. 469/2009.

19.3.3.2 Substances and active substances

Reg. 1610/96 defines **"substances"** as

> "chemical elements and their compounds, as they occur naturally or by manufacture, including any impurity inevitably resulting from the manufacturing process".

'Active substances' are defined as „substances or micro-organisms including viruses, having general or specific action: (a) against harmful organisms; or (b) on plants, parts of plants or plant products".

Reg. 469/2009 does not include any definition of either "substance" or "active substance". Instead, Art. 1(b) simply states that "product" means the active ingredient or a combination of active ingredients of a medicinal product. Thus Reg.

[1446] See in this regard for example the proposal for a European Parliament and Council Regulation (EC) concerning the creation of a supplementary protection certificate for plant protection products, COM (94) 579 final, p. 15.

469/2009 relies on the definitions of regulatory law on the question of what an active ingredient is while Reg. 1610/96 defines this itself.

In practice, the question arose, whether or not certain substances can be considered "product" for the purpose of the Regulations. It follows from the case law of the CJEU that a "safener" with respect to Reg. 1610/96[1447] and an "adjuvant" with respect to Reg. 469/2009[1448] cannot be treated in the same way.[1449] However, it is also clear from the case law that the regulatory procedures for obtaining an MA for a safener "are very largely the same as those required for the approval of an active substance"[1450]. By contrast, as explained in Chapter 9, under Dir. 2001/83 adjuvants represents a specific type of excipient.[1451] So the reason why the "safeners" have been accepted as a "product" for the purpose of Reg. 1610/96, while adjuvants have not, follows from regulatory law, and not from the definition of product included in Reg. 1610/96.

19.3.3.3 Differences regarding the requirements for obtaining an SPC

Art. 3 Reg. 469/2009 and Art. 3(1) Reg. 1610/96 are almost literally the same. The only differences are the reference to Dir. 2001/83 and Dir. 2001/82 for the MA for medicinal products and Art. 4 Dir. 91/414 for plant protection products. For the sake of clarity, it is important to remember that Dir. 79/117 and Dir. 91/414 have been repealed through Reg. 1107/2009. Art. 3(1) Reg. 1610/96 still refers to Dir. 91/414. However, Art. 83 Reg. 1107/2009 specifies that "references to the repealed Directive shall be constructed as references to this Regulation".

Art. 3 Reg. 1610/96 also contains an additional second paragraph which reads:

> "The holder of more than one patent for the same product shall not be granted more than one certificate for that product. However, where two or more applications concerning the same product and emanating from two or more holders of different patents are pending, one certificate for this product may be issued to each of these holders".

Under Recital 17, this provision is relevant for the interpretation of Art. 3(c) Reg. 469/2009.

19.3.4 Combination products

As already indicated above, according to information collected in the qualitative interviews, combination products play an important role in the area of plant protection products. However, the situation regarding plant protection products also differs substantially for example compared to vaccines. While vaccines are often combined to reduce the required number of vaccinations, each active ingredient in a vaccine usually receives a separate MA before an MA for the combination product is applied for. This does not seem to be the case with plant protection products. Stakeholders in the structured interviews have emphasised that companies apply for an MA on the combination product even before applying for the MA on the product containing a

[1447] Case C-11/13 *Bayer CropScience AG* [2014] ECLI:EU:C:2014:2010.
[1448] Case C-631/13 *Forsgren* [2015] ECLI:EU:C:2015:13.
[1449] For a discussion of *Forsgren* see Chapter 9, Section 9.2.3.3.
[1450] Case C-11/13 *Bayer CropScience AG* [2014] ECLI:EU:C:2014:2010, para. 25 and para 43.
[1451] See Chapter 9, Section 9.2.3.2.

single active ingredient.[1452] In fact, MAs for combinations of active substances are claimed to be "the standard case in the crop protection industry".[1453] The reason for this behaviour is the demand on the market, which has a preference for combination products. Therefore, development primarily takes place with combination products in mind.[1454]

19.4 CASE LAW OF THE CJEU

19.4.1 Introduction

As described above, Reg. 1610/96 and Reg. 469/2009 share a lot of similarities and case law on the medicinal SPC regulation also applies to the plant protection products SPC regulation insofar as it does not deal only with medicinal questions. Furthermore, some of the issues that were addressed through referrals to the CJEU based on Reg. 1768/92 have been addressed by the lawmaker in the wording of Reg. 1610/96. This, together with the differences in market structure and the different commercial relevance of human drugs and plant protection products, may explain why there have only been two decisions by the CJEU specifically addressing Reg. 1610/96. Both decisions circled around the questions of what type of marketing authorisation may qualify as an MA in the sense of Art. 3(1)(b) and 7(1) Reg. 1610/96.

19.4.2 Hogan Lovells International LLP v Bayer CropScience AG[1455]

In the first of the two decisions, the CJEU was asked by the German Federal Patents Court whether "for the purpose of the application in Art. 3(1)(b) of Reg. 1610/96, account [must] be taken exclusively of [an MA] under Art. 4 of Dir. 91/414/EEC […] or [whether] a certificate [can] also be issued pursuant to [an MA] which has been granted on the basis of Art. 8(1) of Dir. 91/414/EEC". As described earlier, Art. 4 Dir. 91/414/EEC (today art. 28 and 29 of Reg. 1107/2009) sets out the requirements for a definite MA while Art. 8(1) Dir. 91/414/EEC (today art. 30 of Reg. 1107/2009) sets out the requirements for a provisional MA. Art. 3(1)(b) of Reg. 1610/96 literally states:

> "1. A certificate shall be granted if, in the Member States in which the application referred to in Article 7 is submitted, at the date of that application:
> […]
> (b) a valid authorisation to place the product on the market as a plant protection product has been granted in accordance with Article 4 of Directive 91/414/EEC or an equivalent provision of national law.
> […]"

Therefore, prima facie, an SPC can only be based on a definitive MA.

[1452] See also Euros Jones, 'On the Relevance of Supplementary Plant Protection Certificates on the Basis of Marketing Authorisations for Combination Products' [2011] GRUR Int. 1017, 1017 stating that *"today, the first marketing authorisation for a new active ingredient in a plant protection product often relates to a combination product"* based on an internal survey from October 2010 by the European Crop Protection Association (ECPA).

[1453] Euros Jones, 'On the Relevance of Supplementary Plant Protection Certificates on the Basis of Marketing Authorisations for Combination Products' [2011] GRUR Int. 1017, 1017.

[1454] *Ibid.*

[1455] Case C-229/09 *Hogan Lovells International* [2010] ECR I-11335.

In the case at hand, Bayer was the owner of an EP covering *iodosulfuron*. On 13 December 1998 an application to include *iodosulfuron* in Annex I of Dir. 91/414/EEC was lodged with the respective national authorities. On 9 March 2000, the competent authority issued a provisional MA for the product *'Husar'* which includes *iodosulfuron*. On 17 July 2003, the German Federal Patents Court granted Bayer an SPC based on the provisional MA. On 25 September 2003, *iodosulfuron* was added in Annex I of Dir. 91/414/EEC by the European Commission. Finally, on 13 January 2005, a definitive MA was issued to Bayer for '*Husar'*. Hogan Lovells brought a nullity suit against the grant of the SPC before the German Federal Patents Court. The following figure lays out the timing of the various decisions:

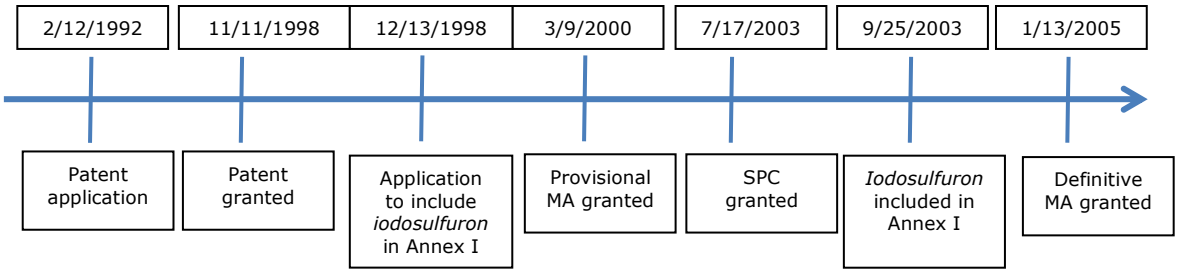

Figure 19.2: *Hogan Lovells International LLP v Bayer CropScience AG* – timing of decisions

The CJEU decided that the provisions must be interpreted as also allowing grant of an SPC based on a valid MA granted pursuant to Art. 8(1) Dir. 91/414. The reason for this decision was that according to the CJEU a "link of **functional equivalence**[1456] exists between the criteria set out in Art. 8(1) of Dir. 91/414/EEC and those laid down in Article 4 of that directive".[1457] Since the requirements for obtaining a provisional MA and a definite MA are mostly the same and therefore lead to an equivalent reduction of effective time of protection for the purpose of commercial exploitation, the rationale of the SPC applies to both and thus justifies the protection.[1458] Furthermore, the CJEU pointed out that if the provisional MA was not considered the first MA, issues may arise leading to difficulties considering other provisions of Reg. 1610/96 and to the calculation of the SPC term.[1459]

In general, the decision by the CJEU has been approved by legal literature.[1460] However, it has been pointed out that basing an SPC on a provisional MA may increase the legal uncertainty since the "application for a provisional authorisation is by nature prospective".[1461]

[1456] Emphasis added.
[1457] Case C-229/09 *Hogan Lovells International* [2010] ECR I-11335, para. 46.
[1458] *Ibid.,* para. 43.
[1459] *Ibid.,* para. 52 et seq.
[1460] Daniel Felix Schiopu, *Ergänzende Schutzzertifikate auf der Grundlage vorläufiger Zulassungen* (Herbert Utz Verlag 2014) p. 161.
[1461] Enrico Bonadio, 'Supplementary Protection Certificates for Plant Protection Products and Provisional Marketing Authorisation: The ECJ's Decision in Lovells v. Bayer' [2011] EJRR 115, 118.

19.4.3 Sumitomo Chemical Co. Ltd. v Deutsches Patent- und Markenamt[1462]

In the second case, the core of the dispute was the question whether or not an emergency MA based on Art. 8(4) Dir. 91/414/EEC (now Art. 53 of Reg. 1107/2009) could qualify as an MA for the purpose of Art. 3 and 7 Reg. 1610/96. Again, reading the legislation literally would speak against this since Art. 3 Reg. 1610/96 refers only to an MA according to Art. 4 Dir. 91/414/EEC.

In the case Sumitomo was the holder of European patent EP 0 376 279 directed, *inter alia*, to the active substance *clothianidin* which could be used as an insecticide. On 19 February 2003, a provisional MA was issued to a company in the Bayer group for a product containing *clothianidin* in the UK. On 2 December 2003, an emergency MA was issued to another company in the Bayer group for a product containing *clothianidin*. On 14 May 2004, Sumitomo applied for an SPC in Germany and referred to the MA granted in the UK on 19 February 2003 as well as to the emergency MA granted in Germany on 2 December 2003. On 8 September 2004, a provisional MA was granted in Germany.

The German Patent and Trademark Office rejected the application for an SPC. The opinion of the latter was first that an emergency MA would not meet the requirements for an MA in the sense of Reg. 1610/96 and second that an SPC application could not be based on an MA that was not granted yet at the time of the SPC application (the German provisional MA). The matter came to the German Federal Patents Court which decided to refer to the CJEU the question whether or not an emergency MA can be an MA according to Reg. 1610/96. The CJEU answered the question in the negative and stated:

> Article 3(1)(b) of Regulation (EC) No 1610/96 of the European Parliament and of the Council of 23 July 1996 concerning the creation of a supplementary protection certificate for plant protection products must be interpreted as precluding the issue of a supplementary protection certificate for a plant protection product in respect of which an emergency marketing authorisation has been issued under Article 8(4) of Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market, as amended by Commission Directive 2005/58/EC of 21 September 2005.

The CJEU furthermore decided:

> "Articles 3(1)(b) and 7(1) of Regulation No 1610/96 must be interpreted as precluding an application for a supplementary protection certificate being lodged before the date on which the plant protection product has obtained the marketing authorisation referred to in Article 3(1)(b) of that regulation."

The CJEU highlighted that the emergency MA literally concerns "plant protection products not complying with Article 4" and therefore cannot be seen a functionally equivalent to the MA on the basis of Art. 4 Dir. 91/414.[1463] The emergency MA also does not require the same risk evaluation as the MAs according to Art. 4 and Art. 8(1) Dir. 91/414. This is even clearer under Reg. 1107/2009, where emergency MA are clearly isolated from the other MAs in an undersection 6 with the title "Derogations" While the Court has not pointed it out, this also eliminates any justification for an SPC. Since the emergency MA does not require extensive studies, obtaining it does not reduce the effective commercial time span of patent protection. Even more, it is questionable whether the emergency MA can be seen as an MA for commercial

[1462] Case C-210/12 *Sumitomo Chemical* [2013] EU:C:2013:665.
[1463] *Ibid.,* para. 36.

purposes anyway since it is strictly limited in time and can only be granted in emergency situations.

19.4.4 Conclusions

In the only two decisions specifically dealing with SPCs for plant protection products, the CJEU dealt with the question, which of the various types of MAs can be used as the basis for an SPC. Since no further questions have been referred to the CJEU in the past four years and since none of the stakeholders have raised any issues in this respect, it can be assumed that the Plant Protection Products Regulation does not pose specific legal questions for the market participants in this specific regard.

19.5 ISSUES

19.5.1 SPC based on an MA for a combination product

In principle, the decisions on combination products like *Medeva*, and the related decisions are applicable.[1464]

As a consequence if the MA was granted for a number of active compounds, such MA can support an application for a certificate directed to only one of these active compounds. it is sufficient for the subject matter of the SPC to be comprised by the MA.

19.5.2 Calculation of the duration of the certificate

Art. 13(3) Reg. 1610/96/EC foresees that:

> "For the purposes of calculating the duration of the certificate, account shall be taken of a provisional first marketing authorization only if it is directly followed by a definitive authorization concerning the same product."

The wording of this provision could raise some uncertainty as to its application in situations where there is no definitive authorisation available at the time of grant. Indeed, whereas the Court of Justice states that the granting of an SPC could be based upon a provisional MA, Art. 13(3) Reg. 1610/96/EC could be read as allowing taking into account the provisional marketing authorisation only if the definitive authorisation is available at the date of grant.

Asked to comment on this particular question, most of the NPOs declared that they never had to deal with the issue.[1465] Other NPOs explained that they will interpret Art. 13(3) of Reg. 1610/96/EC in accordance with the jurisprudence of the CJEU considering as the critical date for calculating the duration of the SPC the date on which the provisional MA was granted.[1466] In particular, the UK Patent Office has observed:

[1464] For the analysis of these decisions see supra chapter 10, Section 10.2.4.

[1465] In that sense, see the responses of Lithuania, Croatia, Denmark, Finland, Hungary, Ireland, Luxemburg, Lithuania, the Netherlands, Poland, Slovakia, Spain and Sweden.

[1466] In that sense, the responses of Austria, Croatia, Germania, Great Britain, Greece, Ireland, Latvia, the Netherlands, Spain and Switzerland.

> "For the purposes of calculating the duration of the SPC certificate, account is taken of the date of the provisional first marketing authorization – on the assumption that it will be directly followed by a definitive authorization concerning the same product – if is not, a third party has the basis to seek revocation of the SPC as the SPC is not validly granted – as there is not a valid Marketing authorization granted under the relevant EC legislation (previously Directive 91/414/EEC which has been repealed and replaced by Regulation (EC) No 1107/2009 with effect from 14 June 2011). The procedure is laid down in Article 30 of Regulation (EC) No 1107/2009 (formerly Article 8(1) of Directive 91/414) and has now lapsed."

According to the information collected during the Study, the question posed by the MPI has no practical relevance. Nevertheless, Art. 13(3) Reg. 1610/96 could be clarified in the sense that even if no definitive MA is available at the time of grant, the provisional MA shall be taken into account for calculating the duration of the SPC.

19.5.3 Core inventive advance and SPCs for combination of actives substances of plant protection products

At the Stakeholder Seminar on 11 September 2017 and in qualitative interviews the question was posed whether it is appropriate to treat combinations in the same way in the field of plant protection products and of medicinal products, or by contrast whether it shall be possible to adopt a less strict approach for plant protection products. In particular, it has been questioned whether the core inventive advance shall apply to combinations including active substances of a plant protection products. In fact the market structure and the interests involved are qualitatively different from those of medicinal products. While this consideration is understandable, we are of the opinion that if the core inventive advance shall apply to medicinal products, then it shall apply also to plant protection products. Indeed the rationale and the reasons for the two pieces of legislation, in the perspective of the lawmakers, are considered to be identical. This conclusion finds its basis in the wording of two Regulations that shares with few exceptions identical recitals and identifies similar purposes. Also the Plant Protection Products Regulation is aimed at establishing a balanced system, "whereas all the interests at stake" must be taken into account.[1467]

19.5.4 Further issue: unitary SPC and plant protection products

The specific features of the regulatory framework applicable to plant protection products call for a particular design of the unitary SPC. These issues are discussed in Chapter 22, Section 22.3.4.3.

19.5.5 Summary

With respect to the question of the relevant MA for the granting of the SPC, the lawmaker may amend Reg. 1610/96 so that the wording of it also refers to the provisional MA in Art. 30(1) Reg. 1107/2009 (before Art. 8(1) Dir. 91/414).

Since Art. 28(1) Reg. 1107/2009, in opposition to Art. 48(1) Dir. 91/414, refers to authorisations "in accordance with this Regulation", a reference to the latter could already be sufficient to encompass both the general and the provisional MA. It could also be argued that such a reference would not include the emergency MA since the latter is expressly classified as a "derogation" under Reg. 1007/2009.

[1467] Recital 12 Reg. 1610/1996. European Commission, Explanatory Memorandum to the Proposal for a European Parliament and Council Regulation (EC), of 9 December 1994, concerning the creation of a supplementary protection certificate for plant protection products (COM(94) 579 final), para. 68.

Nevertheless, to increase transparency, we would recommend the legislator to adopt one of the two following clarifications:

> **Article 3 (1):**
> (b) a valid authorisation to place the product on the market as a plant protection product has been granted in accordance with Article 28 (1) of Regulation 1107/2009, Article 30 (1) of Regulation 1107/2009 or an equivalent provision of national law.
> or:
>
> (b) a valid authorisation to place the product on the market as a plant protection product has been granted in accordance with Article 28(1) of Regulation 1107/2009 or an equivalent provision of EU or national law.

The first version would merely codify the case law of the CJEU. The second version would also provide additional flexibility for future changes to the regulatory framework.

Art. 13(3) Reg. 1610/96 could be amended in the sense that the provisional MA shall be taken into account for calculating the duration of the SPC, even if no definitive MA is available at the time of grant.

We do not see reasons for excluding the application of the core inventive advance test to plant protection products if the latter shall apply to medicinal protections products.

Finally, as we will see in Chapter 22, when designing a unitary SPC, we recommend considering the specific features of the regulatory framework applicable to plant protection products. At the moment such regulatory framework do not contemplate Union authorisations that grant the uniform right to place the product on the market in in all EU States.

20 PROCEDURE AND FURTHER SUBSTANTIVE ASPECTS

20.1 INTRODUCTION

Although the SPC Regulations have created an autonomous regime under EU law that is directly applicable in all EU Member States, national law and national practices continue to play an important role within that regime. Several factors account for this.

First, Art. 19(1) Reg. 469/2009 and Art. 18(1) Reg. 1610/96 stipulate that national law applies to the procedural issues not regulated by the SPC Regulations. Second, national law is usually applied, though without a clear legal basis,[1468] where issues of substantive law were left open in the SPC Regulations. Third, in absence of uniform implementing regulations[1469] and common guidelines assisting decision-makers at the national level, details of the examination or other administrative issues remain subject to national guidelines and/or practice.

This lack of harmonised guidance could be one of the reasons for discrepancies perceived by stakeholders,[1470] both in the way and the speed with which the NPOs deal with SPC applications.

Against this background, this Chapter pursues two purposes. Firstly, it provides a review of the national legislation implementing the SPC Regulations, in particular where Art. 18 and Art. 19(1) Reg. 469/2009, and Art. 17 and Art. 18(1) Reg. 1610/96 point to national law. Secondly, this Chapter addresses the questions of whether the harmonisation of specific procedural and substantive issues might be appropriate and useful. The latter aspect is necessarily inexhaustive, as the Study can only provide individual examples.

[1468] As explained in Chapter 3, Section 3.3, the SPC Regulations do not contain a general reference to the national law applicable to national patents, which must be applied in case of default, as for instance Art. 2 EPC does with respect to European patents.

[1469] In the first proposal of the SPC Regulation on medicinal products, Art. 14 had envisaged that the Commission should be entitled to adopt "detailed rules for the application" of the Regulation in so far as they were necessary; see Proposal for a Council Regulation (EEC) concerning the creation of a supplementary protection certificate for medicinal products (COM(90) 101 final – SYN 255) [1990] OJ C 114, Art. 14. However, that provision was later deleted from the proposal and did not become a part of Reg. 1768/92.

[1470] See Chapter 8.

20.2 NATIONAL PRACTICES

20.2.1 Premise

This Chapter contains information that we collected from the NPOs of 22 EU countries:

- Austria (AT)
- Czech Republic (CZ)
- Germany (DE)
- Denmark (DK)
- Spain (ES)
- Finland (FI)
- France (FR)
- Greece (GR)
- Croatia (HR)
- Hungary (HU)
- Ireland (IE)
- Italy (IT)
- Lithuania (LT)
- Luxembourg (LU)
- Latvia (LV)
- Netherlands (NL)
- Poland (PL)
- Portugal (PT)
- Romania (RO)
- Slovak Republic (SK)
- Sweden (SE)
- United Kingdom (UK)

Further, we collected information from the NPOs of two EPC countries – Switzerland (CH) and Serbia (RS),– which have adopted legislation consistent with the EU SPC legal framework.

The NPOs of all these countries answered the MPI Questionnaire for the National Patent Offices of the EU Member States in 2017[1471] (hereinafter: countries examined). Additionally, a group of these countries was asked to draft or to review reports about their national practice (DE, DK, ES, FR, HU, LT, NL, PL, PT, RO, SE and UK; hereinafter: reported countries).[1472]

20.2.2 Sources of law

All countries selected are signatories of and/or contracting parties to TRIPS, the PCT and the EPC. Further, some countries have ratified the Patent Law Treaty and the Strasbourg Convention. All the EU Member States, except for Croatia, Poland and Spain, are parties to the UPCA.

The provisions concerning the requirements for patent protection, the extent of protection and the rights conferred by national patents in the examined countries are uniform. The wording of the relevant provisions is aligned with Arts. 52–57 EPC, Art. 69 EPC and Art. 28 TRIPS.

Only in France[1473] and Italy[1474] was a certificate for medicinal products already available under domestic law before the entry into force of the SPC Regulations.

The majority of the countries examined (AT, DE, DK, FI, HR, HU, IE, IT, LT, LU, NL, PL, PT, SE, and UK) have adopted some rules implementing Reg. 469/2009 and Reg.

[1471] See for the text of the MPI Questionnaire for the National Patent Offices of the EU Member States Annex VI of this Study.
[1472] See Annex I of this Study.
[1473] See Law No. 90 – 510 of 25 June 1990 which introduced the *certificat complémentaire de protection*.
[1474] See Law No. 349 of 19 October 1991 which introduced the so-called *certificato di protezione complementare*. This law extended the patent term up to 18 years after the expiration date. This is far longer than the extension provided under the EU SPC regime. As a consequence, several laws reduced the term of the 400 SPCs granted under the former law retroactively; further, the Italian legislature introduced a manufacturing waiver in order to increase the competitiveness of generic manufacturers located in Italy.

1610/96. Other states that have not adopted specific implementing rules apply their national (patent) laws.

According to Art. 19(1) Reg. 469/2009 and Art. 18(1) Reg. 1610/96 EU Member States can adopt "special procedural rules for certificates".[1475] Several countries have made use of this option (DE, DK, ES, HR, LU, SE, UK).

20.2.3 Guidelines for the examination of SPC applications

Several countries have issued publicly available guidelines for examining SPC applications.[1476] In other states, for example in Portugal,[1477] the NPO relies on the internal procedure documents. The Greek NPO[1478] conducts an examination based on the implementation of the SPC Regulations and Ministerial Decisions, while the NPOs of Luxembourg and Latvia check guidelines published by other NPOs when faced with new situations or when looking to improve the granting procedure.

There are various reasons why some countries have not adopted guidelines. In the case of the Italian NPO, the decision not to adopt guidelines was mainly based on the grounds that the burden of adopting such guidelines was considered too high in comparison to the low number of SPC applications filed every year (i.e. less than 100). Furthermore, the Italian NPO has only one examiner entrusted with SPC issues, who as the only decision-maker is in the position to ensure a uniform practice.

20.2.4 Granting authorities

In all countries examined, the institution competent for granting SPCs is the same institution that is competent for granting national patents. No country has made use of

[1475] Art. 19(1) Reg. 469/2009: "In the absence of procedural provisions in this Regulation, the procedural provisions applicable under national law to the corresponding basic patent shall apply to the certificate, unless the national law lays down special procedural provisions for certificates."
Art. 18(1) Reg. 1610/96: "In the absence of procedural provisions in this Regulation, the procedural provisions applicable under national law to the corresponding basic patent and, where appropriate, the procedural provisions applicable to the certificates referred to in Reg. 1768/92, shall apply to the certificate, unless national law lays down special procedural provisions for certificates as referred to in this Regulation."

[1476] Croatia: http://www.dziv.hr/hr/prirucnik-za-ispitivanje-patenata/;
Denmark: http://paguidelines.dkpto.dk/;
Czech Republic: https://www.upv.cz/cs/publikace/metodicke-pokyny-pro-rizeni-pred-upv/metodicke-pokyny.html.
Finland: https://www.prh.fi/stc/attachments/patentinliitteet/4palvelutjatietokannat/Patenttikasikirja_ 2017.pdf;
France: https://www.inpi.fr/sites/default/files/directives_brevets_ccp_gt_en.pdf;
Germany: https://www.dpma.de/docs/service/formulare_eng/patent_eng/p2799_1.pdf;
Lithuania: https://www.e-tar.lt/portal/lt/legalAct/TAR.E273B78140F1/fpTHMoMexn;
In Poland: Poradnik wynalazcy edn. Andrzej Pyrża, 2017, published by the Polish Patent Office in the form of a printed handbook, concerns SPC examination procedures.
Romania: http://www.osim.ro/index3_files/patents/INSTRUCTIUNICSP_ENG_11aug.pdf;
Slovakia: http://www.indprop.gov.sk/swift_data/source/pdf/metodika_konania/Mk_2_5_2011doo.pdf;
Sweden: https://www.prv.se/sv/patent/lagar-och-regler/riktlinjer/del-b---nationell-patentansokans-innehall/;
Switzerland: https://www.ige.ch/fileadmin/user_upload/schuetzen/patente/d/richtlinien_patente/RiLi_Sachpruefung_CH-Patent_DE.pdf;
UK: https://www.gov.uk/guidance/manual-of-patent-practice-mopp/supplementary-protection-certificates-for-medicinal-and-plant-protection-products, https://www.gov.uk/guidance/manual-of-patent-practice-mopp/regulation-ec-no-1610-96-of-the-european-parliament-and-of-the-council-plant-protection-products (all of aforementioned last accessed 14 December 2017). In Poland: Poradnik wynalazcy edn. Andrzej Pyrża, 2017, published by the Polish Patent Office in the form of a printed handbook, concerns SPC examination procedures.

[1477] Answer of the Portuguese NPO to Q2 of MPI Questionnaire for the National Patent Offices of the EU Member States.

[1478] Answer of the Greek NPO to Q2 of MPI Questionnaire for the National Patent Offices of the EU Member States.

the option provided for under Art. 9 SPC Regulations to entrust another authority with the granting of SPCs.

20.2.5 Filing an SPC application

20.2.5.1 Persons entitled to apply for an SPC

(a) *Licensee as an SPC applicant*

According to Art. 6 SPC Regulations, the certificate is granted to the patent owner. However, the provision does not state that only the patent owner may apply for a certificate. Despite that, in the majority of countries examined (AT, CZ, DE, DK, ES, FI, FR, GR, HR, HU, IE, LT, PT, RS, SE) a licensee of the basic patent is not entitled to file an application for a certificate, regardless of whether the patentee has given express authorisation to do so. In Germany,[1479] for instance, if the applicant for a certificate and registered owner of the basic patent are not identical at the filing date of the SPC application, the DPMA invites the applicant to correct the deficiency. Some NPOs (CH, NL, SK, UK) accept applications filed by licensees. As pointed out by the Dutch and the UK NPOs, anyone can file an application for a certificate under the SPC legislation.[1480] Nonetheless, if granted, the SPC would be awarded to the holder of the basic patent.

(b) *Transfer of a basic patent and entry into a register*

If the basic patent has been transferred, but the transfer has not been registered in the national or European register, the majority of the NPOs (AT, CZ, DE, ES, FI, FR, GR, HR, HU, IE, LU, LV, NL, PL, PT, RO, RS, SE, UK) considers only the registered patent holder as entitled to file the SPC application and to be granted an SPC.

As explained by the Irish NPO, if the transfer of ownership has not been registered, the NPO cannot be aware of it. If the new patent proprietor files the application before registration of the transfer, the Irish NPO puts the application on hold until the transfer's registration is made.[1481] However, some NPOs can grant the certificate to the new patent holder, even if at that moment the transfer is not yet registered, if the applicant for the certificate who is the new patent holder is able to prove the transfer of the basic patent (AT, CH, CZ, DK).[1482] In jurisdictions where any person can file an application for a certificate, as in NL or UK, the assignee of a patent can also file an application for a certificate on the basis of a transfer that has still to be registered. However, the NPO will grant the certificate to the original proprietor (assignor) and not to the more recent patent proprietor (assignee) of the patent if the assignment has not been registered.

[1479] Answer of the German NPO to Q3 of MPI Questionnaire for the National Patent Offices of the EU Member States.

[1480] Answers of the Dutch and the UK NPOs to Q3 of MPI Questionnaire for the National Patent Offices of the EU Member States.

[1481] Answer of the Irish NPO to Q4 of MPI Questionnaire for the National Patent Offices of the EU Member States.

[1482] Answers of the Austrian, Czech, Danish and Swiss NPOs to Q4 of MPI Questionnaire for the National Patent Offices of the EU Member States.

(c) *Multiple proprietors of a basic patent*

In the case of multiple proprietors of the basic patent, most of the NPOs request an SPC application to be filed by all proprietors of the basic patent either jointly or through a common representative (CH, CZ, DK, ES, FI, FR, GR, HR,[1483] HU, IE, IT, LT, LU, LV, PL, PT, RO, RS, SE).[1484]

The Austrian NPO, however, allows an SPC application to be filed by one of the proprietors provided that this applicant submits evidence of the consent of the other proprietors of the basic patent.

The UK NPO stated that the identity of the applicant in this case is not relevant as an SPC would in any case be granted to all proprietors of the relevant basic patent. The UK NPO[1485] informs other holders of the basic patent that an SPC application has been filed.

In the Netherlands, SPC applications in this case are always filed by a common representative. Furthermore, it is not necessary to prove the authorisation of this representative to act on behalf of all the proprietors of the basic patent.[1486]

(d) *The relation between an SPC applicant and a holder of an MA*

In none of the countries examined is an SPC applicant required to be the holder of the MA submitted in support of the application. The reason referred to in this regard by the Serbian NPO[1487] is that there is no provision in the SPC Regulations that precludes the patent holder from applying for an SPC based on the MA obtained by another, unconnected party. In Chapter 13 we agree with the opinion that *Biogen* (implicitly) supports this understanding of the legislation.[1488]

In all the countries examined, an SPC applicant may refer in principle to a third-party MA even if no contractual relationship between them exists and no evidence of consent is submitted. Several NPOs also justify this practice by reference to *Biogen*. Accordingly, in France, Germany, and Switzerland there are no limits to or preconditions for using a third-party MA. In Germany and France, however, diverging ownership of the MA and the patent can matter for the substantive examination of Art. 3(a) Reg. 469/2009.[1489]

(e) *The requirement of a copy of a third-party MA pursuant to Art. 8(1)(b) SPC Regulations*

The practice of NPOs differs in situations where the SPC applicant cannot provide the NPO with a copy of a third-party MA to which the application refers as required by

[1483] If there are multiple proprietors of the basic patent "they are obligated to designate who of them will act as their common representative or appoint a professional representative". Answer of the Croatian NPO to Q9 of MPI Questionnaire for the National Patent Offices of the EU Member States.
[1484] Answers to Q9 of MPI Questionnaire for the National Patent Offices of the EU Member States.
[1485] Answer of the UK NPO to Q9 of MPI Questionnaire for the National Patent Offices of the EU Member States.
[1486] Answer of the Dutch NPO to Q9 of MPI Questionnaire for the National Patent Offices of the EU Member States.
[1487] Answer of the Serbian NPO to Q5 of MPI Questionnaire for the National Patent Offices of the EU Member States.
[1488] See Chapter 13, Section 13.2.1.
[1489] See Chapter 13, Section 13.3.1.2.

Art. 8(1)(b) SPC Regulations. With the growing number of applications for a certificate based on centralised MAs, this situation has become rare according to one NPO.

In accordance with *Biogen*, the NPOs try to obtain a copy of the MA themselves. In Romania, for instance, the NPO searches online for the MA (in the Official Journal of the European Union and/or in the European Commission Register).[1490] In Switzerland, the office checks the database of the Swiss regulatory agency *Swissmedic*. Also, regulatory authorities can be contacted to check the corresponding data.[1491] In the case of a centralised MA, if the applicant is unable to provide a copy of the MA, the Irish NPO would consult the online Community Register of Medicinal Products. For national MAs, the Irish NPO would "request a copy from the appropriate body, which in Ireland is the Health Products Regulatory Authority for medicinal products or the Department of Agriculture for plant protection products".[1492]

Similarly, the NPOs in Austria, Germany, Luxembourg, Poland, Sweden, and the UK obtain a copy of the MA by cooperating with the competent regulatory authority. The Austrian, Finnish, and the UK offices will not reject an SPC application only because of the reason that the MA is not provided together with the application. In the UK, however, this is subject to the precondition that applicants must provide evidence of being unable to provide the copy.[1493] In contrast, the Greek,[1494] Lithuanian and Portuguese NPOs reject the application in such circumstances.

For an analysis of this aspect we refer to Chapter 13.[1495]

20.2.5.2 The language of an SPC application

In the majority of the reported countries the filing of the SPC application must be submitted in the official language of the country. Some NPOs accept the filing of SPC applications in an additional language (other than the official language of the country); for example, in Denmark, Luxembourg and Sweden SPC applications can also be filed in English.

20.2.5.3 Deadlines for filing an SPC application

While in relation to the deadlines for filing an SPC application all NPOs apply Art. 7 SPC Regulations,[1496] there are some minor differences concerning the calculation of deadlines and the conditions for re-establishment of rights. While one office (UK) considers the Euratom Reg. 1182/71 applicable,[1497] the vast majority of offices (AT,

[1490] Mirela Georgescu et al, *Romania* in Annex I of this Study, Chapter 9, Section 9.4.
[1491] Answer of the Swiss NPO to Q5 of MPI Questionnaire for the National Patent Offices of the EU Member States.
[1492] Answer of the Irish NPO to Q5 of MPI Questionnaire for the National Patent Offices of the EU Member States.
[1493] Fiona Warner et al, *United Kingdom* in Annex I of this Study, Chapter 13, Section 13.5.
[1494] So far, the Greek NPO has not had such a case.
[1495] See above Chapter 13, Section 13.3.1.1.
[1496] The relevant text reads as follows: "within six months of the date on which the patent is granted" or "within six months of the date on which the authorisation referred to in Article 3(b) to place the product on the market as a medicinal product was granted".
[1497] Regulation (EEC, Euratom) No 1182/71 of the Council of 3 June 1971 determining the rules applicable to periods, dates and time limits [1971] OJ L 124/1. See Fiona Warner et al, *United Kingdom* in Annex I of this Study, Chapter 13, Section 13.3: "IPO calculates time periods expressed in Article 7 of the two [SPC] Regulations in accordance with the Euratom Regulation (No. 1182/71)".

CH, CZ, DE, DK, ES, FI, FR, GR, HR, HU, IE, IT, LU, NL, PL, PT, RO, RS, SE, SK) apply national law in this regard.

The vast majority of the countries examined seem to have provisions governing the *restitutio in integrum* applicable in cases where the deadline set in Art. 7 SPC Regulations is met (AT, CH, CZ, DE, DK, FI, FR, HR, HU, IE, IT, LT, LV, PL, RO, RS, SK, SE, UK). However, corresponding provisions cannot be relied upon in cases where the MA was not granted until the date of expiry of the basic patent. By contrast, if the applicant has not submitted a copy of the MA, but the MA was granted before the filing of an application for a certificate, such defect can be rectified in accordance with Art. 10(3) SPC Regulations.

20.2.5.4 Content of an application for a certificate: a product definition

We have already explained that, in our view, a definition or a description of the product in the application for a certificate is not required by the plain wording of the SPC Regulations. The product must be identified on the basis of the MA supplied in support of the application for a certificate. A definition of the product that shall undergo the examination and for which the certificate shall be granted became necessary in consequence of the case law, in particular *Medeva*. Indeed, if an MA issued for A-B-C can support an application for a certificate for A, or A-B or A-C, or A-B-C, the examiner cannot know on the basis of the mere MA what the product is to which the application relates.

It is not surprising, therefore, that in all the countries examined, an application for a certificate must not only provide the content prescribed by Art. 8 Reg. 469/2009, but also indicate the "product" for which the certificate is sought for.

In this regard the application forms of the NPOs for grant of an SPC differ slightly. Some NPOs, such as the French,[1498] the Swedish[1499] and the Swiss, require the applicant to indicate the product covered by the MA and protected by the patent. Other NPOs ask the applicant to indicate the product that the applicant wants to protect or for which the certificate is requested (e.g. DE,[1500] DK,[1501] ES,[1502] FI,[1503]

[1498] As stated in French SPC application form "CERTIFICAT COMPLÉMENTAIRE DE PROTECTION, N° 10390*05": "PRODUIT OBJET DU CERTIFICAT COMPLÉMENTAIRE DE PROTECTION (Dénomination Commune Internationale du ou des principe(s) actif(s) couvert(s) par l'autorisation de mise sur le marché et protégé(s) par le brevet)". See at https://www.inpi.fr/sites/default/files/db15_1.pdf (last accessed 14 December 2017).

[1499] As formulated in Swedish SPC application form "authorised product's [trivial/generic name]". See Application for SPC for medicinal products at https://www.prv.se/globalassets/dokument/english/patent/forms/ansokan_lakemedel_en.pdf (last accessed 13 December 2017).

[1500] See German SPC application form "Antrag auf Erteilung eines ergänzenden Schutzzertifikats": "Bezeichnung des Erzeugnisses (Wirkstoff oder Wirkstoffzusammensetzung), für das ein Zertifikat erteilt werden soll". See at https://www.dpma.de/docs/formulare/patent/p2008.pdf (last accessed 14 December 2017).

[1501] In Danish "Guide for filing an Application for grant of a Supplementary Protection Certificate" the DKPTO requires that in the relevant box the applicant "shall state the product you want to protect, i.e. the active ingredient or a combination of active ingredients of the medicinal product" and "the name under which the medicinal product is sold, i.e. the trade name". See at http://iprights.dkpto.org/media/20504430/application%20for%20paediatric%20extension%20of%20a%20supplementary%20protection%20certificate%20for%20a%20medicinal%20product.pdf (last accessed 14 December 2017).

[1502] See Spanish SPC application form at http://www.oepm.es/es/propiedad_industrial/formularios/las_invenciones/certificados_complementarios_de_proteccion/ (last accessed 14 December 2017). As stated in the instructions of the form 3104 ("Instrucciones 3104X1", section 4, point (8)), the applicant has the option to indicate the INN ("Denominación Oficial Española (DOE)" – Spanish equivalent of the INN) and optionally the chemical formula or the common chemical name or the name given to it by the

HU,[1504] IE,[1505] LV,[1506] RO,[1507] UK[1508]). Some countries' SPC application forms just have a box under the heading "product" which must be filled in by the applicant (for instance, AT, GR,[1509] IT) without any further indication. Several countries ask expressly for the chemical name or the chemical designation of the product (ES,[1510] NL,[1511] SE,[1512] UK), preferably in the form of an international non-proprietary name (INN) (CH,[1513] FR, LV, UK).

The UK[1514] NPO requires the "product" to be defined with reference to the relevant international non-proprietary name(s) if such exist(s), or, for instance, according to IUPAC rules where there is no INN. Common names are admitted for biological active ingredients. In accordance with the office's understanding of *Farmitalia*,[1515] "UK practice is to require applicants to specify the forms identified in the basic patent in the product definition; e.g. if the basic patent claims 'pharmaceutically acceptable

IUPAC. Further it is explained that "the name of the authorized product must be given as specified in the MA".

1503 As stated in the Finnish SPC application form: (Box 4: "Tuote (lisätietoja seuraavalla sivulla)". See Finnish SPC application form at https://www.prh.fi/stc/forms/hakemus_lisasuojatodistuksen_myontamiseksi.pdf (last accessed 14 December 2017).

1504 Question 1 of the request form for the grant of a supplementary protection certificate (Kiegészítő oltalmi tanúsítvány iránti kérelem) reads: "Name of the product (Title of the certificate)". See Hungarian SPC application form at http://www.sztnh.gov.hu/sites/default/files/files/professional/02spcbejkerelem2016.pdf (last accessed 14 December 2017).

1505 See Irish SPC application form at https://www.patentsoffice.ie/en/About-Us/Forms/Patent-Application-Forms/ (last accessed 13 December 2017). "Product Identity (i) Product (i.e. active ingredient or combination of active ingredients) for which a certificate is requested. (ii) Information to satisfy the Controller that the product at 7 (i) above is protected by the basic patent identified at 5 above."

1506 See Latvian SPC application form at https://www.lrpv.gov.lv/sites/default/files/media/dokumenti/izgudrojumi_veidlapas/spc_veidl.pdf (last accessed 14 December 2017).

1507 As stated in the Romanian Guide to filing the supplementary protection certificate application form, the applicant must indicate the name of the product for which the certificate is required, i.e. the active substance or combination of active substances. For this purpose, the chemical name of the substance and the international common name are used. See at http://www.osim.ro/csp/cert_suplimentar.html (last accessed 14 December 2017).

1508 See the UK Patent Form SP1, available at https://www.gov.uk/government/publications/application-for-grant-of-a-supplementary-protection-certificate (last accessed 14 December 2017). The following information from the applicant is requested: "What is the product that you want to protect? (Identify the active ingredient(s) or active substance(s). If possible use chemical or generic names)".

1509 The Greek NPO has pointed out that in this box the applicant must indicate the active ingredient or the combination of active ingredients. Later on the examiner assesses if the "product" is covered by the MA and is protected by the basic patent.

1510 See Spanish SPC application form at http://www.oepm.es/es/propiedad_industrial/formularios/las_invenciones/certificados_complementarios_de_proteccion/ (last accessed 14 December 2017) In the instruction of Spanish application form there is explained that the applicant has to indicate the INN and optionally the chemical name or name given by the IUPAC. As explained further, the name of the authorised product must be given as specified in the MA. See this instruction at http://www.oepm.es/es/propiedad_industrial/formularios/las_invenciones/certificados_complementarios_de_proteccion/ (last accessed 14 May 2018).

1511 See Dutch SPC application form at https://www.rvo.nl/onderwerpen/innovatief-ondernemen/octrooien-ofwel-patenten/octrooi-anders-beschermen/octrooirecht/abc (last accessed 13 December 2017).

1512 As explained in the Swedish Patent and Registration Office's Instruction to application for SPC for medicinal products, the applicant must state "the authorised product's trivial/generic name". Further it is explained that "the product is the active ingredient or combination of active ingredients of a medicinal product". This name is included in the official publication, but the authorised medicinal product's trade name, which the applicant is not obliged to indicate, is not published. See Swedish NPO's instructions for SPC application at https://www.prv.se/globalassets/dokument/english/patent/forms/ansokan_lakemedel_en.pdf (last accessed 14 December 2017).

1513 As stated in the Swiss NPO's explanations of the SPC application form, the INN is preferable, but if there is none, IUPAC or WHO developed names or naturalised trivial names can also be used. Switzerland also requires a description of the product, especially its connection to the basic patent. See at https://www.ige.ch/de/etwas-schuetzen/patente/nach-der-erteilung/ergaenzendes-schutzzertifikat.html (last accessed 14 December 2017).

1514 Fiona Warner et al, *United Kingdom* in Annex I of this Study, Chapter 13, Section 13.3.

1515 Case C-392/97 *Farmitalia* [1999] ECR I-5553.

salts and esters', this would form part of the product definition".[1516] In relation to biosimilars, by contrast, there is no accepted standard wording to include them in the protection. If the basic patent protects the process for manufacturing the product, it is not considered to be part of the product definition. The same holds true for the therapeutic indication. At least in the UK, the *Neurim*-style application for a certificate shall refer to the active ingredient as such.

In France[1517] the SPC application must contain the name of the product, designated either by its INN as formulated in the SmPC in the MA or, if there is no INN, by a functional name. References to an adjuvant or excipient in combination with the active ingredient are not permitted, because they are not considered a combination within the meaning of Art. 1(b) Reg. 469/2009. The definition in the form of "product X in any form protected by the basic patent" is accepted. The wording of the definition "product X and its salts and esters" is accepted if these forms are protected by the basic patent. By contrast, a product description with the wording "product X and its mutants and variants" is not admissible under French practice, "because the mutants and variants are not considered to be the same active ingredient as the product".[1518] Also, wording of the kind "product X and biosimilar within the meaning of Art. 10(4) of Dir. 2001/83, as protected by the basic patent" is not allowed as a definition under French practice.

In Sweden,[1519] it is preferred that the designation of the product is identical to the designation of the active ingredient(s) as stated in the relevant MA, although the active ingredient(s) may also be designated in a different way, provided that the definition is clear. Also, both the INN and the chemical name are accepted. The same as in France, references to non-active ingredients (adjuvants and excipients) are not accepted in the product definition. According to Swedish practice and similar to French practice, the wording of a product definition "in all acceptable salts" is accepted if such derivatives are protected by the basic patent. However, product definitions including general expressions such as "in any form protected by the basic patent", "derivatives", "biosimilars" and "therapeutic equivalents" are not accepted as they are not considered by the Swedish NPO as clearly identifying and defining the product. If it is a second-medical-use patent is designated for the procedure, the second medical use is not accepted as part of the product definition.

Dutch practice follows the *Yeda* decision.[1520] In the case of biological products, the Netherlands Patent Office does not accept a broad definition including products other than the product strictly covered by the MA. With respect to chemical substances, the Netherlands Patent Office allows the product definition to include pharmaceutically acceptable salts and esters of the basic substance even if the MA was issued for a specific salt or for the basic form of the active ingredient, provided that these derivatives are also protected by the basic patent in the sense of Art. 3(a) Reg. 469/2009.

[1516] Fiona Warner, *United Kingdom* in Annex I of this Study, Chapter 13, Section 13.3.
[1517] Mathilde Junagade, Anais Collin, *France* in Annex I of this Study, Chapter 3, Section 3.3.
[1518] *Ibid.*
[1519] Joakim Sånglöf et al, *Sweden* in Annex I of this Study, Chapter 11, Section 11.3.
[1520] District Court of the Hague, *Yeda Research and Development Company Ltd v the Netherlands Patent Office*, Decision of 12 November 2008, Case 07/3560. See on this decision Chapter 18, Section 18.2.

The Danish[1521] NPO does not accept a product definition that reiterates the wording of the patent claim, nor does it accept a product description with the wording "as protected by the basic patent". It is acceptable for biological products to include in the product description possible future biosimilars like "bio-product and biosimilar thereof". In Denmark, the wording of the product definition like "compound y in all acceptable salts and derivatives" is admitted as long as the wording of the claim reflects "all acceptable salts and derivatives". The second medical use is not accepted in the product definition.

The Polish[1522] NPO does not accept the wording "compound in all acceptable salts and derivatives" if the word "all" is not contained in the claims of the basic patent. It has been pointed out that, because of the unclear understanding of the term "derivatives", derivatives such as esters and solvates must be specified in the product definition. Regarding a process patent, the wording "product obtained by a method in accordance with patent No. ..." must be included in the product definition. Unlike in Denmark and Sweden, in Poland the second medical use with wording like "the product for use..." has to be included in the product definition in the case of a *Neurim*-style application for a certificate. If possible, the use must be specified taking into account its wording and content in the basic patent claim(s). If for some reason this is not possible, the Polish NPO accepts product definition with the following wording: "Product for use in accordance with the patent No. ...".

20.2.5.5 The obligation to submit complete and true information

The SPC Regulations do not provide for an obligation to submit complete and true information. Therefore, they do not provide any sanctions for untrue statements. The majority of the countries examined (AT, CZ, FR, GR, HR, LT, NL, PL, RO, RS, SE, SK, UK) do not provide for an express obligation to state the truth in relation to SPC applications under domestic law. In some countries, such obligation follows from administrative law (CH, HU, PT) or criminal law (DK, ES,[1523] FI, IT, LV, PO).

German law provides for a corresponding obligation in the German Patent Act which applies to SPCs as well.[1524]

In all countries examined, of course, primary Union law applies. False statements by the applicant in procedures before an NPO may trigger sanctions under Art. 102 TFEU, provided that the applicant benefits from a dominant position in the specific market to which the active ingredient relates.[1525]

20.2.5.6 Publication of an SPC application by the NPOs

Regarding the information on SPC applications there are some differences between the practices in the countries examined. Some NPOs publish almost the entire file (e.g.

[1521] Dorte Krehan et al, *Denmark* in Annex I of this Study, Chapter 2, Section 2.3.
[1522] Wiolwta Świerczyńska, *Poland* in Annex I of this Study, Chapter 7, Section 7.3.
[1523] In Spain the obligation to state the truth also follows from the general principles of administrative and civil law.
[1524] See Sec. 16a(2) and Sec. 124 of the German Patent Act. Section 124 of German Patent Act: "In proceedings before the German Patent and Trade Mark Office, the Federal Patent Court and the Federal Court of Justice the parties shall make their statements on facts and circumstances in full and truthfully."
[1525] See Case C-457/10 P *AstraZeneca AB and AstraZeneca plc v European Commission* [2012] ECLI:EU:C:2012:770.

DE, FI, FR, NL, SE). Since Spanish Patent Law 24/2015 is in force, Spain makes its files public once an SPC application has been published (except confidential information or information subject to laws on the protection of personal data). Other countries make only such information public as is referred to in certain provisions of the SPC Regulations.[1526] Still others publish the information required by the SPC Regulations as well as additional information, e.g. on the applicants' agent(s) and the status of the application.

A clear majority of NPOs (AT, CH, DE, DK, ES, FI, FR, GR, HR, HU, IE, LT, LU,[1527] LV, NL, PT, RS, SE, SK, UK) allow for public access to almost all information concerning the procedure of granting an SPC with exceptions regarding business secrets, personal data, records of consultations and parts of files relating solely to internal office procedure, trade or business secrets, documents protected by copyright law, documents containing sensitive information about individuals or documents the applicant has asked to be kept confidential.

20.2.5.7 Public inspection

Regarding public inspection, the general tendency is that any person is entitled to inspect the files upon request. In the Czech Republic, a person applying for access to a file has to prove relevant legal interest.

In Austria, in the case of published SPC applications that have not yet been granted, the NPO informs the applicant if somebody applies for an inspection of the respective file in order to give the applicant the possibility to request an exemption from the file inspection on justified grounds.

20.2.6 Examination of an SPC application

20.2.6.1 Formal examination

The formal examination in most of the countries examined refers to the content of the application as determined by Art. 8 SPC Regulations and to the payment of the application fees. If information or documents are missing, a considerable number of the NPOs examined treat this as an irregularity that can be corrected after the SPC application is filed. Applicants are usually notified and given time to correct such irregularities. The time given for applicants to rectify the irregularities may differ – from three months in Sweden, or two months in France and Portugal, to ten days in Spain.[1528] This also applies in principle to an MA, but on the condition that the MA was granted before the filing date of the application for a certificate. In Lithuania, however,

[1526] Art. 9(2) Reg. 469/2009 (HR, LT, RO); Art. 11 Reg. 469/2009 (IT); Arts. 9 and 11 Reg. 469/2009 and Reg. 1610/96 (ES); Art. 9(2), Art. 11 or Art. 17 Reg. 469/2009 (FI); Art. 9(2)(3), Art. 11, Art. 16 Reg. 469/2009 and Art. 11(1)(2), Art. 9(2), Art. 16 Reg. 1610/96 (IE).

[1527] Due to technical reasons online access to files only exists for SPC applications made after 1 January 2017, information provided by the Luxembourg NPO, email with the authors of the Study.

[1528] In Spain there are two situations where the irregularities regarding an SPC application can be rectified. After receiving the SPC application the Spanish NPO verifies if payment has been made and if the application contains all the information necessary for publication according to Art. 9(2) SPC Regulations. Here the given time period for rectification is ten days. A time period of two months can be obtained to correct irregularities when publication has already been made and the examination of the substantive requirements set by Art. 8 SPC Regulations is introduced. It is possible to extend this period by a further two months.

the failure of an applicant to provide a copy of the MA would result in the rejection of an SPC application.

20.2.6.2 Substantive examination

(a) *General considerations*

The examination of SPC applications in the various NPOs differs significantly. According to the approach of the national offices to the examination of patents, one can traditionally differentiate between examining NPOs, where offices perform a full substantive examination of patent applications (this is the majority of the countries examined), and non-examining countries that have never conducted a full examination (FR, GR, IT, LT, LU, LV) or have recently abolished full examination (NL). As regards the non-examining countries, the following particularities need to be noted: in France,[1529] technical character, novelty, industrial applicability are assessed by the INPI and an application can be rejected if the claimed subject matter for instance is anticipated by a piece of prior art; in Italy, the EPO makes prior art research for national patent applications that do not claim a (foreign) priority, and the Italian NPO considers this prior art search in the examination; in the Netherlands, a written opinion on novelty and inventive step is produced but the patent is granted regardless of the outcome;[1530] in Spain, a substantive examination of patents has recently been introduced with Law 24/2015.[1531] In Ireland substantive examination was re-introduced in May 2017 as part of the Knowledge Development Box (Certification of Inventions) Act 2017.

The background of examiners in the NPOs differs. In a number of NPOs, the examiners assessing SPC applications have a technical qualification (e.g. degree in chemistry, biotechnology, biology or pharmaceuticals) and legal training (AT, CH, CZ, DE, ES, IT, SK) or a full legal education (FR), including post-graduate legal qualifications (UK). In other NPOs, the examiners entrusted with the examination of SPC applications are required to have only a technical qualification (FI, GR, HU, IE, LT, PL, PT, RO). In Luxembourg, the examiners have legal training concerning the SPC Regulations and patent law, with a focus on administrative aspects. In some NPO (e.g. DK) technical examiners cooperate with the legal department in examining the SPC application.

(b) *Scope of examination*

A majority of the NPOs (CH, CZ, DE, DK, FR, HR, HU, IE, IT, LT, LV, NL, PL, PT, RS, SE, SK, UK) have declared that they provide for an examination of all four requirements stipulated in Art. 3 SPC Regulations. The NPOs of Austria and Luxembourg examine only Art. 3(a) and 3(b) Reg. 469/2009. The Finnish, Greek, Romanian, and Spanish NPOs do not examine compliance with the requirements under Art. 3(d) Reg. 469/2009. Several NPOs have confirmed that the capabilities to examine Art. 3(d) Reg. 469/2009 are limited. For example, the Latvian NPO has pointed out that it is difficult to examine compliance with Art. 3(d) SPC Regulations concerning the first MA; therefore, in case of doubt the Latvian NPO requires the applicant to clarify this by confirming that the information provided is correct. Ireland

[1529] Mathilde Junagade, Anais Collin, *France* in Annex I of this Study, Chapter 3, Section 3.5.
[1530] Information provided by the Dutch NPO to the authors of the Study.
[1531] See Gabriel González Limas, Maria Victoria Rivas Llanos, *Spain* in Annex I of this Study, Chapter 10, Section 10.5.

stated that it does not perform an *ex officio* search for all MAs and makes the examination of Art. 3(d) by searching for MAs in the online register of the Health Products Regulatory Authority. Such difficulties are relevant according to the German NPO with respect to the application of Art. 13 SPC Regulations[1532], when the first relevant MA in the EU is a national MA granted in another EU Member States.

The UK IPO informed that examination of Art. 3(d) is conducted on the basis of an "informal (basic internet) search" using information provided by the applicant, a third party, or information that can be obtained by consulting other SPC applications concerning the same product.[1533] However, the IPO does not conduct a formal search in order to establish compliance of SPC applications with the requirements of Art. 3(d). Similar practice is also followed by the Danish NPO.

As already explained, the case law has made the examination of SPC applications technically more complex by introducing the concept of "core inventive advance" with respect to Art. 3(c) Reg. 469/2009,[1534] by formulating the *Medeva*-requirement[1535] and by adopting an interpretation of Art. 3(d) Reg. 469/2009 that obliges the NPOs to examine whether or not the first MA granted for the active ingredient falls under the scope of the basic patent.[1536] Some NPOs consider that the analysis concerning the existence of a "separate innovation" under Art. 3(c) Reg. 469/2009 is comparable to analysis of inventive step for patent applications.[1537] In this respect, although the French NPO's examiners have the expertise to examine inventiveness, the representatives of the French NPO have clarified that the INPI does not examine whether a combination represents the core inventive advance of the basic patent designated for the procedure. The reason is the French NPO's view that it is not the role of the NPO to re-examine the basic patent when examining an SPC application.[1538] Some NPOs have declared this growing complexity of the examination as challenging, at least for "small offices".[1539] With respect to the application of a core-inventive-advance test, the implementation of *Medeva/Eli Lilly* and *Neurim*, some NPOs have confirmed that legal uncertainty exists.

(c) *Timing and length of the examination*

In the majority of countries examined there are no rules to determine that the examination must be started and/or completed within a specific deadline. Such a rule does, however, exist in France,[1540] Germany,[1541] Greece,[1542] Italy, Luxembourg, Spain[1543].

[1532] See Art. 8.1(c) Reg. 469/2009.
[1533] Fiona Warner et al, *United Kingdom* in Annex I of this Study, Chapter 13, Section 13.5.
[1534] Chapter 10, Section 10.2.4.
[1535] *Ibid.*
[1536] Chapter 11, Section 11.3.1.2.
[1537] Discussion at workshop hosted by the MPI and DPMA, Munich, March 2017.
[1538] Presentation by Anais Collin, Mathilde Junagade, INPI France, MPI Workshop with the NPOs, Munich, 21 March 2017.
[1539] Chapter 8, Section 8.3.
[1540] 12 months from date of filling of the SPC application, see French Intellectual Property Code, Arts. R617-2-1 and R617-2-2.
[1541] Eight months from the date of filing of the SPC application. Hovewer, there are no concequences for not meeting the deadline. See Examination Guidelines for Supplementary Protection Certificates of 23 January 2015, 3. Examination of the request for the grant of a certificate at https://www.dpma.de/docs/english/formulare/patent_eng/p2799_1.pdf (last accessed 15 May 2018).
[1542] The applicant must submit all the necessary information within four months from the submitting the SPC application. If it is not done within this deadline, the application is deemed to be rejected. See Art.

In France, the SPC application is deemed to be rejected if the SPC is not granted within one year from the filing date.[1544] In Spain, a certificate shall be granted within 10 months from the publication date of the SPC application in the Official Gazette;[1545] If the SPC application presents some irregularities in the submitted documentation, the deadline is extended to 15 months.[1546] In the case of pending EU proceedings, such as pending CJEU referrals which are relevant for the SPC application, the applicant has the right to request a stay of the granting proceedings.[1547]

While some stakeholders have confirmed that there are significant differences as regards the length of examination and expressed their wish for a uniform deadline, others have criticised rules imposing a deadline such as those provided under French law.[1548] Both originator and generic companies in the course of the interviews have highlighted the importance of a quick decision on a product's eligibility for an SPC.

The question whether a rule imposing a uniform deadline for granting or refusing the certificate would be appropriate at European level, was the subject of parliamentary questions to the European Commission just after the enactment of Reg. 1768/92.[1549]

20.2.7 Third parties

(a) *Third party observations*

A majority of the NPOs of the countries examined (AT, CZ, DE[1550], DK, ES, FI, HR, HU, IE, IT, LU, LV, NL, PL, PT, RO, RS, SE, SK, UK) allow the submission of third-party observations. In some states there is an express legal basis for third party submissions (DE[1551], DK, FI, HU, IE,[1552] NL, PL, PT,[1553] RS, SE, SK, UK); in others it is just standard practice to accept third party observations (AT, HR, ES, IE, RO, LU, LV). In Greece, Lithuania and Switzerland it is not possible for a third party to file observations regarding SPC applications.

With the exception of Denmark,[1554] none of the countries examined informs the third party about the reasons why his or her observations were not taken into account and

6 Ministerial Decision 14905/EFA/3058 at 12 months from date of filling of the SPC application (last accessed 15 May 2018).

1543 Ten months from the publication of the SPC application, see order ETU/296/2017 of 31 March 2017, Art. 1, point c) of Law 24/2015 and Art. 22.1, point c) of the Law 39/2015.

1544 French Intellectual Property Code, Arts. R617-2-1 and R617-2-2.

1545 Order ETU/296/2017 of 31 March 2017.

1546 Information provided by the Spanish NPO to the authors of the Study.

1547 *Ibid*. with reference to Article 22.1, point c) of Law 39/2015 on the Common Administrative Procedure of the Public Administration.

1548 Annex III of this Study, comments to Q62, pp. 374-378. See also *infra* in this Chapter, Section 20.3.3.3 (c).

1549 See *infra*, Section 20.3.2.

1550 See DE answer to Q57 of MPI Questionnaire for the NPOs: "Sec. 16a [on SPCs] does not explicitly refer to Sec. 43 (3) German Patent Act, which deals with third party observations. But since the DPMA follows the principle of *ex officio* examination [Sec. 49a (5) and 46 (1)], third party observations have to be taken into account on a regular basis."

1551 In view of Sec. 49a(5) and 46(1) applied in analogy to Sec. 43(3) German Patent Act.

1552 Introduced as a part of the Knowledge Development Box (Certification of Inventions) Act 2017.

1553 There is a disposition in the general part of the Industrial Property Code of Portugal that allows third-party observations, though not specifically for SPCs.

1554 Dorte Krehan et al, *Denmark* in Annex I of this Study, Chapter 2, Section 2.6: "The DKPTO always takes third-party observations into account when examining an application. When DKPTO's decision is final, the third-party is informed about the decision. If the observation was not regarded, the third-party will also receive a short explanation of why. Further, the third-party will be informed about the possibility of requesting administrative re-examination of the SPC."

the SPC was granted. In no country does the third party become a party to the procedure, which remains *ex parte*.

In DE, DK, FI, HR, IE, NL, PL, PT, SE, SK and UK it is possible to file observations anonymously and/or through a front man.

(b) *Oppositions*

According to the prevailing view, Art. 19(2) Reg. 469/2009 and Art. 18(2) Reg. 1610/96 prohibit post-grant and also pre-grant oppositions. However, this understanding is not supported by the English version of Art. 19(2) Reg. 469/2009 and Art. 18(2) Reg. 1610/96, which refer only to "the procedure for opposition to the *granting* of a certificate" (emphasis added).[1555] Other language versions of the SPC Regulations[1556] use wording that clearly refers to the post-grant opposition.

With the exception of Denmark,[1557] no country allows for opposition to SPCs.

20.2.8 Grant of an SPC and rejection of an SPC application. Appeal and revocation proceedings

20.2.8.1 Hearing before a national office

In case of objections to the grant of an SPC, in some countries an applicant has the right to request a hearing (DE, FR, IE, NL, PL, SE, UK).[1558] The NPOs of Portugal and the Czech Republic might provide meetings with applicants to discuss some issues regarding the SPC application. A majority of the states examined, however, does not provide for a formal right to request a hearing. The French and Swiss NPOs acknowledge that a hearing may be held at the request of the applicant and at the office's discretion. In the UK, a right to a hearing is general practice when a decision adversely affecting the applicant is to be made. The UK considers such right a fundamental principle of natural justice; however, it is provided by the discretionary power of the Comptroller and not by law. Only in a few of the countries examined is such right determined explicitly by legal norms (DE[1559], IE, NL, PL, SE).

20.2.8.2 Appeal against rejection of the application for a certificate

All countries examined provide a legal basis for filing an appeal against the rejection of an SPC application within the meaning of Art. 18 Reg. 469/2009 and Art. 17 Reg. 1610/96. Corresponding appeals must be brought before national courts (administrative, patent and general jurisdiction courts) or NPOs. Exceptions are

[1555] Herwig von Morze, Peter Hanna, 'Critical and Practical Observations Regarding Pharmaceutical Patent Term Restoration in the European Communities' [1995] 77(7) Journal of the Patent and Trademark Office Society 479, 490.

[1556] See for instance the German ("das Einspruchsverfahren gegen ein *erteiltes* Zertifikat"), Italian ("opposizione a un certificato *già rilasciato*"), Latvian ("procedūra *piešķirtam* sertifikātam nav paredzēta"), and Spanish ("queda excluido el procedimiento de oposición a un certificado *expedido*") versions of Art. 19(2) Reg. 469/2009.

[1557] Denmark allows third parties to request a re-examination of the SPC on a basis that would justify its revocation under Art. 15 Reg. 469/2009; see Dorte Krehan et al, *Denmark* in Annex I of this Study, Chapter 2, Section 2.6.

[1558] Answers to Q55 of MPI Questionnaire for the National Patent Offices of the EU Member States, see Annex VI.

[1559] Sec. 49a(5) and 46(1) German Patent Act.

Greece,[1560] where the competent authority is the Council of State, and Serbia,[1561] where the Administrative Council of the Government is competent for appeals.

In some jurisdictions, the NPO (FR, NL, SE, UK) that has rejected the application for a certificate is a party in the appeal proceeding and/or is entitled to be represented, to file submissions and to participate in the hearing. This model, in accordance with the aim of creating a balanced system that takes into account all involved interests, could be considered in refining a possible procedure for granting unitary SPCs.

20.2.9 Impact of pending patent revocation or opposition proceeedings on the SPC granting procedure

If patent revocation proceedings are pending and a third party or an applicant has informed the NPO of these circumstances, the majority of states examined may suspend the SPC granting procedure (CZ, DK, FI, HR, IE, IT, LT, NL[1562], PT, RO, SK).[1563] As pointed out by the Romanian NPO, such postponement of an SPC examination is based on considerations that "the opposition of the basic patent is prejudicial, because the patent can be revoked or altered in such a way that the product is no longer protected by the basic patent".[1564] In the remaining countries, the fact that revocation or opposition proceedings against the patent designated for the purpose of the proceedings are pending is not regarded as prejudicial and has no influence on the procedure for granting the SPC. If there have been opposition proceedings, or if such proceedings are ongoing, the UK NPO asks the applicant to confirm the status of those proceedings, and checks that the product is protected by the most recent claims.[1565]

20.2.10 Calculation of the patent term

Article 63(1) EPC stipulates that "the term of the European patent shall be 20 years from the date of filing of the application". Some EPC Contracting States examined (CH, CZ, FR, UK) interpret this wording as meaning that the last day when a patent can be in force is the day before the 20th anniversary of its filing. The same approach is about to be implemented in Luxembourg. Other EPC Contracting States take the view that the last day when a patent is in force is the 20th anniversary of its filing. Furthermore, the majority of countries examined (AT, DE, DK, ES, HR, HU, IT, LT, LU, LV, NL, PL, RO, RS, SE, SK) apply Rule 131(3) EPC to calculate the term of a European patent pursuant to Art. 63 EPC; some NPOs apply national provisions that are however similar in the effect to Rule 131(3) (CZ, PT[1566]). In spite of a broad application of Art. 63 EPC and Rule 131(3) EPC, the expiry date of the same european patent or of national patents sharing the same priority date may differ in the EPC States. As the

[1560] Answer of the Greek NPO to Q62 of MPI Questionnaire for the National Patent Offices of the EU Member States.

[1561] Answer of the Serbian NPO to Q62 of MPI Questionnaire for the National Patent Offices of the EU Member States.

[1562] The representatives of the Dutch NPO stated that they had never had a situation where a third party has communicated to them about pending patent revocation or opposition proceedings. Furthermore, "[t]he Dutch patent office and applicant can always by mutual agreement decide to postpone further examination of the case. Sometimes the applicant proposes it (and we nearly always accept), sometimes we do." Answer of the Dutch NPO to Q59 of MPI Questionnaire for the National Patent Offices of the EU Member States.

[1563] Also, LU, LV and PL may stay the proceedings of the grant of an SPC if the applicant has requested it.

[1564] Mirela Georgescu et al, *Romania* in Annex I of this Study, Chapter 9, Section 9.7.

[1565] Information provided by the UK NPO to the authors of the Study.

[1566] Although Portugal has national legal provisions, Rule 131 EPC is also taken into account.

information provided by the NPOs of Denmark and Netherlands show, although both NPOs apply Rule 131(3) EPC or rules consistent with this provision, when determining the expiry date of a patent, the approach and thus the final results are different. In Denmark, as confirmed by the National Report,

> "according to Section 40 of the Danish Consolidate Patents Act No. 221 of 26 February 2017, a granted patent may be maintained until 20 years have elapsed from the date of filing of the patent application. On this basis, the patent term is calculated from and including the date of filing. The patent term expires 20 years later on the day having the same number as the date of filing. In practice this means that the DKPTO applies a "20 years + 1 day" rule, in compliance with Rule 131 of the EPC. However, the SPC duration is not calculated with a "+ 1 day" rule."[1567]

In the Netherlands "[t]he expiry date of the patent, i.e. the last day of protection, is calculated as 20 years minus 1 day from the filing date of the patent. E.g. a patent filed 1 January 2000 will be valid up to and including 31 December 2019."[1568]

20.2.11 Calculation of the SPC term

At the MPI Workshop in Munich on 20–21 March 2017, some speakers pointed out that the different members of an SPC family in Europe do not expire on the same date. These variances are due to different criteria for computing the 20-year term of the basic patent and the duration of the associated certificate.

The information collected by the MPI confirmed these statements, as table 20.1[1569] below presents.

	Filing date of the basic patent	Expiry date of the basic patent	Start date of the SPC	Latest expiry date of the SPC without paediatric extension	Latest expiry date of the SPC with paediatric extension
Austria	15.10.2015	15.10.2035	16.10.2035	15.10.2040	15.04.2041
Croatia	15.10.2015	15.10.2035	16.10.2035	15.10.2040	15.04.2041
Czech Republic	15.10.2015	15.10.2035	16.10.2035	15.10.2040	15.04.2041
Denmark	15.10.2015	15.10.2035	16.10.2035	15.10.2040	15.04.2041
Finland	15.10.2015	15.10.2035	16.10.2035	15.10.2040	15.04.2041
France	15.10.2015	14.10.2035 at midnight	15.10.2035	14.10.2040	14.04.2041
Germany	15.10.2015	15.10.2035	16.10.2035	15.10.2040	15.04.2041
Greece	15.10.2015	16.10.2035	17.10.2035	16.10.2040	16.04.2041

[1567] Dorte Krehan et al, *Denmark* in Annex I of this Study, Chapter 2, Section 2.9.2.
[1568] MW Martijn de Lange, Peter R Slowinski, *the Netherlands* in Annex I of this Study, Chapter 12, Section 12.9.1.
[1569] In Table 20.1 it is assumed that the MA supplied in support of the application for a certificate was granted more than ten years since the filing date of the basic patent.

Hungary	15.10.2015	15.10.2035	16.10.2035	15.10.2040	15.04.2041
Ireland	15.10.2015	14.10.2035	15.10.2035	14.10.2040	14.04.2041
Italy	15.10.2015	15.10.2035 (excluded)	15.10.2035	15.10.2040 (excluded)	15.04.2041
Latvia	15.10.2015	15.10.2035	16.10.2035	15.10.2040	15.04.2041
Lithuania	15.10.2015	15.10.2035	16.10.2035	15.10.2040	15.04.2041
Luxembourg	15.10.2015	14.10.2035 at midnight	15.10.2035	14.10.2040	14.04.2041
The Netherlands	15.10.2015	14.10.2035	15.10.2035	14.10.2040	14.04.2041
Poland	15.10.2015	15.10.2035	15.10.2035	15.10.2040	15.04.2041
Portugal	15.10.2015	15.10.2035	16.10.2035	15.10.2040	15.04.2041
Romania	15.10.2015	15.10.2035	16.10.2035	15.10.2040	15.04.2041
Serbia	15.10.2015	15.10.2035 included	16.10.2035	15.10.2040 included	15.04.2041
Slovak Republic	15.10.2015	15.10.2035	16.10.2035	16.10.2040	16.04.2041
Spain	15.10.2015	15.10.2035	16.10.2035	15.10.2040	15.04.2041
Sweden	15.10.2015	15.10.2035	16.10.2035	15.10.2040	15.04.2041
Switzerland	15.10.2015	14.10.2035 at midnight	15.10.2035	-	-
UK	15.10.2015	14.10.2035	15.10.2035	14.10.2040 (expiry 5 years from the legal term of the patent)	14.04.2041.

Table 20.1: Calculation of the SPC term

The different duration of the SPCs follows from the fact that the manner of computing the 20-year term of the patent and the SPC term is not uniform in the EU States. This is true also for European patents. Indeed, several NPOs do not apply Rule 131 EPC, but national law for computing their expiration date.

As consequence, if the EU lawmakers would incorporate in the SPC legislation a criterion for calculating the periods of time that are relevant for the operation of the SPC legislation, including Art. 13 Reg. 469/2009 and Reg. 4009/2009, this would not be sufficient for having all members of the same SPC family expiring the same date. However, one could argue that the issue is of little practical relevance. The difference

in time is limited to 1 or 2 days. For a unitary SPC uniform rules for calculating the term of the granted certificate are needed.

20.2.12 Rules applicable to the calculation of deadlines for SPC granting procedures

The majority of the countries examined apply national rules to the calculation of deadlines laid down in the SPC Regulations or the granting procedure. In most cases such rules are at least similar to Rule 131 EPC.

The UK NPO states that "administrative deadlines prescribed in the legislation are defined so that they begin on the day immediately after the date that triggers the period".[1570] Deadlines in relation to examination procedure are not prescribed in legislation, but are specified by the UK NPO; such deadlines are "usually provided as a specific date for response, rather than a period for response".[1571]

20.2.13 Relief for missed deadlines

The majority of the states have adopted provisions similar to Art. 12 PLT and Art. 122 EPC. According to these provisions, the right holder or applicant is entitled to request re-establishment of rights when a failure to comply with a time limit has occurred in spite of due care and the failure has the direct consequence of causing a loss of rights (restitution in integrum). Most NPOs apply these provisions also to SPCs (exceptions are LT and SE).

The *restitutio in integrum* applies only to time limits and not to substantive requirements. In Germany, as a consequence, it is not possible to invoke the provisions on re-establishment of rights in order to file an application for a certificate just after the MA is granted, if the patent at the SPC filing date had already expired.

20.2.14 The date of the MA

20.2.14.1 Introduction

Several times the SPC Regulations mention the date of the authorisation to place the product on the market. The relevant provisions present a slightly different wording: Art. 7 Reg. 469/2009, in particular, refers to "the date on which the authorisation […] was granted"; Art. 13 Reg. 469/2009 to the "date of the first authorisation"; Art. 20 Reg. 469/2009 to the "date on which the first market authorisation was obtained". What is to be understood by "the date of the MA" or "the date the authorisation was granted", or "the date the authorisation was obtained" is not clarified by the SPC Regulations. This has given rise to some case law, since at least four options are possible:

- the date the decision granting the authorisation is adopted by the competent agency;
- the date the decision is published and a third party may have knowledge of it;

[1570] Answer of the UK NPO to Q45 of MPI Questionnaire for the National Patent Offices of the EU Member States.
[1571] *Ibid*.

- the date the decision is notified to the applicant;
- the date on which the decision according to applicable law has effect.

Preliminary questions that need to be answered are whether the date of the MA should be considered as a concept under the SPC Regulations, which call for an autonomous interpretation, or whether the absence of a definition of the critical date should be intended as referring to national law, which is the law of the country that grants the SPC or the law of the country that issues the MA, for the purposes of Art. 13 Reg. 469/2009.

20.2.14.2 The case law

The CJEU has only dealt with the question of the date of the first authorisation to place the product on the market in the EU within the meaning of Art. 13 Reg. 469/2009. The Higher Regional Court of Vienna had referred the following two questions to the CJEU:

> "Is the "date of the first authorisation to place the product on the market in the [European Union]", within the meaning of Article 13(1) of Regulation No 469/2009, an independent concept?
>
> Does the "date of the first authorisation to place the product on the market in the [European Union]" referred to in Article 13(1) of Regulation No 469/2009 correspond to the date of the decision granting marketing authorisation or the date on which notification was given of that decision? (The second question)."[1572]

In the preliminary proceedings, the MA at issue was a European marketing authorisation granted by the EMA. Dependent on whether the critical date considered by the NPO was the notification date or the date the decision was adopted, the SPC could enjoy a longer or shorter term.

The CJEU answered the question in its decision in *Seattle Genetics*.[1573] Following the suggestions of the Advocate General, the CJEU stated first that

> "the concept of the "date of the first authorisation to place the product on the market in the [European Union]", referred to in Article 13(1) of Regulation No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products, is an independent concept of EU law."

As such, the interpretation must be autonomous and uniform for all the Member States. The reason for this approach is that otherwise the elements of an SPC family sharing the same MA and basic patent would not expire on the same date. This would lead to a fragmentation of the common market.

Second, the CJEU states that

> "Article 13(1) of Regulation No 469/2009 must be interpreted as meaning that the "date of the first authorisation to place the product on the market in the [European Union]", is the date on which notification of the decision granting marketing authorisation is given to the addressee of the decision."

The reason for this opinion is the fact that a European MA – in accordance with Art. 297(2) TFEU – becomes effective only at the date of notification. Therefore, it would not be fair to consider the date of the decision, since the owner of an MA "is entitled to market his product only from the date on which he is given notification of the decision

[1572] Higher Regional Court of Vienna (OLG), Decision of 2 October 2014, Case 34 R 87/14k.
[1573] Case C-471/14 *Seattle Genetics* [2015] ECLI:EU:C:2015:659.

granting the marketing authorisation in question, not from the date on which that decision was adopted".[1574]

The dispositive part of *Seattle Genetics* only refers to Art. 13 Reg. 469/2009. Further, the decision deals expressly only with European MAs. In assessing the implications of the judgment for MAs granted under national law, it is important to highlight the principles that have informed the decision of the Court of Justice. First, the argument made was that if a Member State defines the relevant date of the European marketing authorisation according to its national law for the purposes of the SPC legislation, then this would lead to certificates with different expiration dates. And second, the date of the notification would not lead to significant problems for third parties since such date is published in the OJ.

20.2.14.3 The practice of NPOs

Most of the NPOs (AT, DE, DK, FI, FR, HR, HU, IT, PL, RS, SE, UK) have confirmed that they have a uniform understanding of the date of the MA by interpreting Art. 7 and Art. 13 Reg. 469/2009 or Art. 3, Art. 7 and Art. 13 Reg. 1610/1996. At the same time, we found two different tendencies in the practice of the NPOs. Some NPOs (CZ,[1575] DK, ES, FI, FR, GR, IE, LT, LV, PL, RO, SE, SK, UK) differentiate between European and national MAs. In the case of a European MA, these NPOs apply *Seattle Genetics* to both Art. 7 and Art. 13 Reg. 469/2009 and consider the date of the notification as the critical date for the MA. By contrast, in the case of a national MA, these NPOs consider the critical date to be the date on which the decision to grant the MA is adopted.[1576] In UK, if the applicant can prove that the date on which the relevant national MA was granted is not the date on which it takes effect, then the NPO is prepared to consider this latter date for the purposes of Art. 13 of the SPC legislation. All national UK MAs in the UK take legal effect on the date when they are issued.

Other NPOs (AT, DE, HR, HU, IT, NL, PT) regard the day of notification as the relevant date, regardless of the procedure – European or national – under which the relevant MA was issued.

In Switzerland and Serbia, of course, only national MAs can be supplied in support of an application for a certificate. The critical date is the date on which the decision was adopted.

20.2.15 Post-grant amendment of the duration of the certificate

20.2.15.1 Art. 17(2) Reg. 1610/96 and related practice of the NPOs

According to Art. 17(2) Reg. 1610/96 the decision to grant the certificate shall be open to an appeal aimed at rectifying the duration of the certificate where the date of the first MA is determined incorrectly. Like all provisions of the SPC Regulations, this rule is applicable directly. However, the provision applies directly only to certificates

[1574] *Ibid.,* para. 35.

[1575] In the case of a national MA, the Czech NPO considers the date from which the SPC applicant is in fact able to enjoy the benefit of his/her MA by marketing his/her product.

[1576] The Swedish NPO pointed out that in the case of a national MA the date of grant is considered unless the applicant can prove that another day is the relevant day (e.g. the day of the notification).

for plant protection products and not to certificates for medicinal products. By Recital 17 Reg. 1610/96, indeed, Art. 17(2) 1610/96 is valid only for the interpretation of Art 17 Reg 1768/92 and therefore Reg. 469/2009, but it does not amend the provisions of the Medicinal Products Regulation. Nevertheless, the majority of the countries examined (CH, CZ, ES, FI, HR, HU, IE, IT, LU, LV, NL, PL, PT, RS, SK,[1577] UK) have not adopted rules implementing Art. 17(2) Reg. 1610/96 in their jurisdiction with respect to medicinal products.[1578]

The latter is the situation also in the UK, where the applicant may base an appeal on Art. 17(2) Reg. 1610/96, although the NPO has not established a bespoke formal procedure for such appeals. In practice, the UK IPO "does not impose any time limit with regard to the filing of such appeals; does accept appeals lodged either by the applicant or by a third party; and publishes (in the Patents Journal) the new expiry date of the SPC if the appeal results in a corrected date".[1579]

In France,[1580] Art. 17(2) Reg. 1610/96 is considered to be applicable directly. The French NPO also seems to apply the provision directly to applications for a certificate for a medicinal product.

In Germany Art. 17(2) Reg. 1610/96 has been implemented in Sec. 49a(4) German Patent Act; according to German practice, anyone can file a request, but it must be done before the expiry of an SPC.

In Sweden,[1581] issues regarding Art. 17(2) Reg. 1610/96 were addressed in several court decisions.[1582] According to the information provided by the Swedish NPO regarding those court decisions, a Swedish Patent and Market Court has stated that Art. 17(2) is an autonomous ground for an appeal aimed at rectifying the duration of the certificate. Nevertheless, the deadline for such appeal is subject to national law. According to Art. 26 of the Swedish Patents Act, the appeal against a Swedish NPO's final decision shall be submitted within two months of the date of the decision. The appellants in those court proceedings claimed that Art. 17(2) constitutes the ground for an appeal regardless of the time limit existing under national law. Basically, the argument was that appeal of a decision shall be admitted at any time. The court assessed the admissibility of an appeal lodged against a positive ("reconsidered/corrected") decision. The court reasoned that Art. 17(1) does not give a clear answer whether a ground for an appeal could be an incorrect duration of an SPC: "this is because the decision to grant an SPC is a positive decision and might therefore exclude the possibility to appeal on said grounds (since in some jurisdictions one may only appeal a negative decision)".[1583] Furthermore, the court held that Art. 17(2) constitutes a ground to "appeal a granted SPC solely based on the fact that the

[1577] In Slovakia the amendment to the Slovak Patent Act will take effect from 1 January 2018. This amendment will implement Art. 17(2) Reg. 1610/96 stating that the NPO at the request of the SPC owner or a third party shall amend the duration of the SPC if the date of the first MA to place the product on the market in the EU indicated in the application for a certificate is incorrect.

[1578] Answer to Q65 of MPI Questionnaire for the National Patent Offices of the EU Member States: "Has Art. 17(2) Reg. 1610/96/EC been implemented in your legislation? Is the appeal aimed at rectifying the duration of the certificate provided for under Art. 17(2) Reg. 1610/96/EC subject to deadlines? Do you see a practical need for providing the applicant with the right to amend at any time the duration of the certificate or for the Office to amend ex officio such duration?"

[1579] Fiona Warner et al, *United Kingdom* in Annex I of this Study, Chapter 13, Section 13.12.

[1580] Mathilde Junagade, Anais Collin, *France* in Annex I of this Study, Chapter 13, Section 13.1.1.

[1581] Joakim Sånglöf et al, *Sweden* in Annex I of this Study, Chapter 11, Section 11.9.

[1582] See cases of the Swedish Patent and Market Court: PMÄ 10959-16, 10962-16, 10963-16, 10969-16, 10971-16 cited in Joakim Sånglöf et al, *Sweden* in Annex I of this Study, Chapter 11, Section 11.10.

[1583] See Joakim Sånglöf et al, *Sweden* in Annex I of this Study, Chapter 11, Section 11.9.

duration is incorrect, no matter whether the decision to grant is a positive decision. However, the court stated that an appeal based on 17(2) is still subject to the same deadlines for appeals etc. as any other national Swedish matter."[1584] The court came to the same conclusion as the Swedish NPO, stating that the applicant has no right to ask to rectify the SPC duration at any time[1585] and the appeal was rejected. The court decision was then appealed. [1586]

20.2.15.2 Deadlines for the appeal aimed at rectifying the duration of the certificate provided for under Art. 17(2) Reg. 1610/96

In some of the countries examined, the appeal aimed at rectifying the duration of the certificate provided for under Art. 17(2) Reg. 1610/96 is not subject to deadlines (CZ, DE, DK, NL, PT, RO, SK, UK). Some of the NPOs require, however, that the SPC still be in force when the appeal is filed (CZ, DE, RO).

In other countries deadlines apply, but they differ in their term: France – four months; Lithuania and Luxembourg – three months; Austria and Sweden – two months. The NPOs of these states cannot rectify *ex officio* the SPC duration, and appeals filed by other parties are equally excluded if the deadline for lodging the appeal has expired, unless national law so provides.

This lacuna has obtained practical relevance in the aftermath of the CJEU's *Seattle Genetics* decision (C-471/14).[1587] According to this decision the date on which a European MA is to be considered as granted for the purposes of Art. 13 Reg. 469/2009 is the notification date. Consequently, many NPOs have had to change their practice of calculating the terms for pending and future SPCs. Furthermore, they have also received requests filed by certificate holders to amend the duration of already granted certificates. If the deadline to appeal the decision to grant the certificate provided under national law has passed, it is unclear whether or not such rectification could be exceptionally allowed. This question led to a referral to the CJEU (C-492/16, *Incyte Corporation*[1588]). The question was asked whether it is appropriate to rectify the date of expiry of an SPC, even if the SPC was granted before the *Seattle Genetics* ruling, and the time limit for appeal determined by national legislation has already expired. Moreover, the CJEU has been asked whether an NPO is entitled to rectify of its own motion the date of expiry of an SPC. The case is still pending.[1589] Despite that, there have been national decisions on this issue in the meantime.

The Swedish NPO is among the NPOs rejecting appeals to rectify the SPC terms if the general time limit provided under national law (two months) has expired.[1590] This has led to requests for a revision of the practice lodged before the Swedish Patent and Market Court as mentioned in the previous Chapter. In several decisions,[1591] the Patent and Market Court has confirmed the practice of the Swedish NPO. One of the

[1584] *Ibid*.
[1585] *Ibid*.
[1586] See Chapter 20, Section 20.2.15.2 of this Study.
[1587] See on this decision Chapter 9, Section 9.3.8.3.
[1588] Case C-492/16 *Incyte Corporation*, pending, December 2017.
[1589] *Ibid.*
[1590] Louise Jonshammar, 'Swedish Appeal Court opens towards re-examination of Swedish SPC terms', 9 October 2017, the SPC Blog, available at http://thespcblog.blogspot.de/2017/10/swedish-appeal-court-opens-towards-re.html (last accessed 13 December 2017). See also Chapter 20, Section 20.2.15.1.
[1591] Swedish Patent and Market Appeal Court, PMÖÄ 9632-16, PMÖÄ 9828-16, PMÖÄ 9838-16, PMÖÄ 9847-16, PMÖÄ 9824-16, PMÖÄ 9836-16, PMÖÄ 9845-16, PMÖÄ 9848-16. All issued on 4 October 2017.

main arguments was that a rectification of the duration of the SPC could affect third parties' interests. In the subsequent appeals, the Court of Appeal has adopted a differentiated approach: if the term of the SPC had not commenced at the time the request for rectification was filed, the request for rectification of the term can be admitted; if the SPC term had started to run (and therefore the patent had expired), the request shall be rejected, because the interest of third parties shall be taken into account.[1592] The Swedish NPO appealed these decisions of the Court of Appeal to the Supreme Court on 23 October 2017,[1593] but the Supreme Court has not granted leave to appeal.[1594]

[1592] Louise Jonshammar, 'Swedish Appeal Court opens towards re-examination of Swedish SPC terms', 9 October 2017, the SPC Blog, available at http://thespcblog.blogspot.de/2017/10/swedish-appeal-court-opens-towards-re.html (last accessed 13 December 2017).

[1593] Information provided by the Swedish NPO to the authors of the Study.

[1594] Re-examination/Rectification of the Duration of a Supplementary Protection Certificate at https://www.prv.se/en/about-us/news/re-examinationrectification-of-the-duration-of-a-supplementary-protection-certificate/ (last accessed 14 May 2018).

20.2.16 Payment of fees (EURO)

Country	Filing an SPC application	1st year	2nd year	3rd year	4th year	5th year	Request for extension of duration	Additional information
Austria	363	2,611	3,029	3,448	3,864	4,282	258	
Croatia*	Adm. fee 20 + coverage charges 400	1,500	2,000	2,400	2,800	3,200	330	In case of late payment (grace period 6 months), the specified amounts double
Czech Republic *	191	994	1,070	1,147	1,223	1,299	-	
Denmark *	403 Paed. ext. – 336	685	685	685	685	685	403 (re-establishment fee)	Fee for appeal: 537; fee for administrative re-examination: 2,012
Finland	500	900	900	900	900	900	500	Decision fee under section 71a of the Finnish Patents Act: 450 and annual fee for each year or part of it: 900
France	520	940	940	940	940	940	470	
Germany	300	2,650	2,940	3,290	3,650	4,120	100 (if filed with SPC request) 200 (if filed separately)	6th year (extension) – 4520
Greece	250	1,200	1,300	1,400	1,500	1,800		Filing fees for duration of the validity of an SPC for paediatric medicines 6 months extension – 1200

Hungary *	774	965	1,157	1,351	1,544	1,735	774	
Ireland	95	468	468	468	468	468	95	
Italy	404	1,011	1,011	1,011	1,011	1,011		
Latvia	120	550	550	550	550	550		
Lithuania	115	347	347	347	347	347		
Luxembourg	20 (soon 50)	410	420	430	440	450	250	
The Netherlands	544	1,800	2,000	2,200	2,400	1,300		
Poland*	129	1,401	1,401	1,401	1,401	1,401		Publication about granting: 21
Portugal	Online: 209.14 Paper: 418.29	731.98	784.28	836.56	888.86	914.14	679	
Romania *	500	1,000	1,100	1,200	1,300	1,400		
Slovak Republic	166	995.50	1,327.50	1,659.50	1,991.50	2,323.50	100	Maintenance fees for SPC during extended period: 829.50
Spain	517.21 (online: 439.63)	803.93	1,688.24	2,661.05	3,731.05	4,908.12	517.21 (online: 439.63) (Paediatric extension	There are no renewal fees. Only a single maintenance fee for the whole SPC duration

							application fee)	
Sweden	520.53	1,041	1,041	1,041	1,041	1,041	312	
Switzerland*	2,182.94	829.52	873.18	916.83	960.49	1,004.15		
UK*	276.54	663.7	774.32	884.94	995.55	1,106.17	219.84	The SPC maintenance fee is paid all together in one single payment when the SPC comes into force (for the full term of the SPC, up to 5 years). In case of late payment (6-month grace period), specified amounts increase by 50 per cent. Other than the £200 (approx. 227 EUR) application fee, no fee is payable to bring the paediatric extension into force in the UK.

*Non-euro currency states. The fees have been converted to euros based on the average exchange rate of 13 August 2017.

Table 20.2: SPC's fees in the EU Member States and Switzerland

20.3 FURTHER HARMONISATION AND UNIFICATION

20.3.1 Background, form and effects of secondary rule-making

20.3.1.1 Impact of the Unitary SPC

The question of whether the divergences call for further harmonisation measures must be evaluated, *inter alia*, in light of the envisaged establishment of a unitary SPC system. It is true that, on the one hand, harmonisation could become less urgent, as most SPC applications will be filed with the Unitary SPC Division.[1595] On the other hand, legislation establishing the unitary SPC system must include a uniform and, in principle, exhaustive system of procedural and substantive provisions for examining SPC applications and granting SPCs, including uniform implementing rules and guidelines. While those rules and guidelines do not extend to the national level *ipso iure*, there is a practical need to provide for application of those rules *mutatis mutandis* also for national SPC granting proceedings.

Providing for uniformity in this regard will bolster cooperation between national offices and the Unitary SPC Division. Particularly for small NPOs, the harmonisation of the legal framework could make it easier to establish cooperation with the Unitary SPC Division, especially in areas where, in view of growing technical complexity or for historical or structural reasons, such offices are not in a position, or are not willing, to perform a full examination. Examples of such arrangements already exist in patent law;[1596] they could be replicated with respect to SPCs.

Regarding the form and legal basis of such implementing and guiding rules, one must distinguish between the different ways in which the EU and its institutions can exercise their competences pursuant to Art. 288 TFEU, namely by adopting regulations, directives, decisions, recommendations and opinions. As far as binding regulations issued by the European Commission are concerned, the specific rules set forth in Arts. 290 and 291 TFEU for delegated acts and implementing regulations must be taken into account.

20.3.1.2 Notices and guidelines

As mentioned above,[1597] a striking difference between the SPC legislation and other fields of harmonised EU law is the absence of implementing rules and soft law that could support the uniform application of SPC Regulations by NPOs. Indeed, although neglected in the field of SPCs, guidelines and other soft law provisions have been adopted by the European Commission in several fields, not only with respect to regulations, but also directives.[1598]

From a legal perspective, notices fall within the scope of "recommendations and opinions" mentioned in Art. 288 TFEU. These instruments are not binding;[1599]

1595 On the different options for the institutional design of that office see below, Chapter 22, Section 22.2.

1596 See for instance the specific cooperation programme between the EPO and the Italian Patent Office as well as between the French INPI and the EPO for prior-art search with respect to French patent applications.

1597 See Chapter 3, Section 3.3.2.

1598 For instance concerning Art. 4 Dir. 98/44/EC.

1599 See Case C-226/11 *Expedia* [2012] EU:C:2012:795, para. 31.

nevertheless, the guidance offered by the Commission's notices can be of high practical importance.[1600] For instance, in the field of antitrust law the European Commission has issued a number of notices addressing the application of Arts. 101 and 102 TFEU. By doing so, it provides information to private actors and offers guidance to national authorities whose competences run parallel to those of the European Commission.[1601] Furthermore, the Commission has issued a notice on cooperation with national courts in enforcing EU competition rules,[1602] as well as a "Practical Guide" addressed to national courts on the quantification of antitrust harm.[1603] In particular the latter is essential in ensuring a consistent enforcement of the EU *acquis* throughout the EU.

As already mentioned, in the field of SPCs, the granting authorities in some Member States provide guidelines while others do not.[1604] In view of the fragmented picture thus presented at the national level, the issuance of common guidelines would be highly recommended, as they are able to perform two functions: on the one hand, they ensure that all examiners are provided with common criteria and guidance for the examination; on the other hand, they have a notice function for applicants, who can reasonably expect that the examiner will adjust his or her conduct and way of decision-making to such guidelines. From that point of view the enactment of guidelines is also useful and relevant for such offices where only one or two examiners are entrusted with SPC applications and their examination.

20.3.1.3 Binding rules

While soft law instruments such as notices or guidelines (in the parlance of Art. 288 TFEU: "recommendations and opinions") have the advantage of being flexible and unproblematic under primary law, they are weak in the sense that they are not legally

[1600] In a notice regarding the exclusion of essentially biological processes from protection under the Biotech Directive (Notice on certain articles of Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions [2016] OJ C 411/3), the European Commission advanced an interpretation which diverged from that of the EPO. In spite of the notice not being binding – and the EPO not being formally bound to EU legislation – the EPO later adopted the interpretation by the European Commission.

[1601] The effect of such notices was discussed in Case C-226/11 *Expedia* [2012] EU:C:2012:795. The case concerned the Commission Notice on agreements of minor importance that do not appreciably restrict competition under Art. 101 TFEU (*de minimis* notice). In the ruling, the CJEU pointed out that the notice was adopted by the European Commission to provide guidelines for private undertakings in relation to its enforcement approach to Art. 101 TFEU (*ibid.,* para. 28) and that therefore the notice was binding for the European Commission for reasons of legal certainty and legitimate expectations (*ibid*., para. 31). The notice provided "guidance" to the National Competition Authorities (NCAs) and national courts in their application of Art. 101 TFEU. However, national authorities were not bound to follow the thresholds included in the notice (*ibid*., para. 31). See also Case C-23/14 *Post Danmark* [2015] EU:C:2015:651, para. 52 (regarding the European Commission Guidance in relation to its enforcement priorities in applying Art. 102 TFEU); Case C-428/14 *DHL Express (Italy) Srl and DHL Global Forwarding (Italy) SpA v Autorità Garante della Concorrenza e del mercato* [2016] ECLI:EU:C:2016:27, para. 32 (concerning the leniency model adopted by the European Competition Network (ECN)).

[1602] Commission Notice on the co-operation between the Commission and the courts of the EU Member States in the application of Articles 81 and 82 EC [2004] OJ C 101/54.

[1603] European Commission, Commission Staff Working Document, Practical Guide Quantifying Harm in Actions for Damages Based on Breaches of Articles 101-102 of the Treaty on the Functioning of the European Union [2013] C-3440. The text of the Practical Guide is available at http://ec.europa.eu/competition/antitrust/ actionsdamages/quantification_guide_en.pdf (last accessed 23 August 2017). This soft law instrument aims to explain to national courts the methods relied on by economists to quantify damage in the case of private enforcement of competition law. The guidance paper complements Directive 2014/104/EU of the European Parliament and of the Council of 26 November 2014 on certain rules governing actions for damages under national law for infringements of the competition law provisions of the Member States and of the European Union (the Damages Directive) [2014] OJ L 349/1 .

[1604] *Supra*, 20.2.3.

binding. As a consequence, their enactment would not prevent NPOs (partially or completely) from disregarding their content. Of course, the national authorities cannot deviate from the SPC Regulations themselves,[1605] and flaws in that regard can in the future, at least to some extent, be brought before the UPC.[1606] Nevertheless, in practice the aim of providing for legal certainty by way of soft law could be thwarted if national authorities remain unwilling to comply. The establishment of truly uniform practices and procedures therefore needs a binding framework of administrative rules to organise and inform decision-making at the EU level as well as in NPOs.

The legal bases for such rules are set out in Art. 290 (implementing regulations) and Art. 291 (delegated acts) TFEU. It is not necessary for the purposes of this Study to discuss which of these instruments is more appropriate. Both provisions require that the power to adopt such acts must be conferred on the European Commission in the relevant act of secondary legislation, including the exact scope of the conferred competence. It is clear that no such conferral of competences exists at present. As pointed out in the introduction to this Chapter (20.1), the Commission's initial proposal to provide for an entitlement to issue implementing regulations was not included in the final version of Reg. 1768/92.[1607] However, the relevant competences can be anchored in the legislation establishing a unitary SPC system.

In view of the high degree of specialisation that characterises the area of SPCs it is assumed that administrative rule-making undertaken *de lege ferenda* will be supported and complemented by groups of experts, in particular from the NPOs, in accordance with the principles and procedures of comitology.[1608]

Within the framework of comitology procedures, it would be advisable to provide a smooth system to amend implementing rules in order to incorporate new CJEU case law in the practice of the offices. It is suggested that proposals for amendments could be submitted by any NPO as well as by the Unitary SPC Division. This would provide uniformity, also with regard to the timing of implementation of new CJEU case law.

Further, since implementing regulations will be needed in any case for the establishment of the Unitary SPC Division and for the grant of unitary SPCs, it is also advisable to adopt a single text with separate chapters dealing with national SPCs and proceedings regarding unitary SPCs, respectively.

20.3.1.4 Opinion of stakeholders

(a) *Allensbach Survey*

The Allensbach Survey includes the question of whether the practice and the procedures of the NPOs differ *significantly in terms of predictability, transparency and*

[1605] See also Case C-226/11 *Expedia* [2012] EU:C:2012:795, para. 38: "The national authority does not have to observe the Commission's Notice, but it needs to make sure that the agreement at stake does constitute an appreciable restraint of competition in the meaning of Article 101 TFEU."

[1606] Where SPCs are granted too generously by the NPOs, it will be possible to request invalidation before the UPC. However, where SPCs are denied by NPOs for inappropriate reasons, this will not be possible, because such cases remain within the national court system (including the option that questions are referred to the CJEU).

[1607] See Proposal for a Council Regulation (EEC) concerning the creation of a supplementary protection certificate for medicinal products (COM(90) 101 final – SYN 255) [1990] OJ C 114, Art. 14.

[1608] See Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers [2011] OJ L 55/13.

also in terms of *quality of the rights granted* (Q26b / item No. 10).[1609] A clear majority of all respondents confirm this statement (62 per cent). Further, the Survey asked whether one would expect positive effects from a further harmonisation of the SPC examination procedure (Q59). This is confirmed by an overwhelming majority of 88 per cent of all respondents. Both opinions (Q26b and Q59) are obviously correlated: most stakeholders who affirm Q26b also affirm the respective statement in Q59. Answering Q62, with regard to whether, in their experience as an SPC applicant, there were aspects of the national granting procedures that constituted a burden on applicants, and where harmonisation would make sense, several respondents mentioned in their comments the possibility to adopt common guidelines for the examination. For example:

> [H]armonised guidelines common to national offices would lead to smoother processing.[1610]
>
> If this question is asking about substantive examination procedures then harmonised guidelines common to national offices would lead to smoother processing.[1611]
>
> Yes, for example national specific examination standards and high variation in examination timelines. Harmonisation makes a lot of sense, maybe through general mandatory guidelines for examiners.[1612]

(b) *Interviews and MPI Stakeholder Seminar on 11 September 2017*

In the qualitative interviews and at the Stakeholder Seminar on 11 September 2017 the participants were asked whether they would consider it useful for the European Commission to enact guidelines for the examination of SPCs as legally non-binding soft law in order to assist the NPOs in the examination of SPC applications.

All the associations and organisations represented[1613] at the Seminar considered the enactment of soft law to assist the NPOs in the examination useful. A positive attitude towards guidelines was also confirmed in the qualitative interviews. One stakeholder, in particular, did not consider it problematic that in some respects a common understanding of the CJEU case law is difficult to find, considering that the process for adopting and drafting common provisions for examination will necessarily involve experts from the NPOs; the drafting of the guidelines could be an opportunity to find agreement among the NPOs. Stakeholders pointed out *flexibility* as a benefit of such guidelines. Indeed, they could be smoothly amended and adapted to new case law. The following comments were made in the submissions before, during and after the Stakeholder Seminar:

> "[T]o the extent that the case law may add difficulties to SPC examiners, [...] believes that guidelines would be useful to codify the existing case law and provide guidance to national examiners. These would have the advantage of being flexible and can be adapted to reflect developments and new case law."
>
> "[...] considers it very helpful if the Commission enacts examination guidelines for assisting the NPOs in the examination of SPC applications, particularly if it builds on the various national guidelines already in existence and involves SPC experts from NPOs."
>
> "[W]e consider that Guidelines for the examination as non-binding soft-law in order to assist the NPOs in assessing the SPC application could be a good option."

1609 The term "quality of rights granted" means – consistent with the understanding in patent law – the strength of the SPC rights granted, i.e. the probability that the SPC is valid and can withstand revocation proceedings.

1610 Annex III of this Study, p. 377.

1611 *Ibid.*

1612 *Ibid.* p. 376.

1613 See Chapter 1, Section 1.3.2.

> "Clarifications of the regulation have been obtained by the decisions of the CJEU in the agrochemical sector, with regard to the definition of the active ingredient (C11/13) and with regard to the marketing authorization for filing an SPC (C-229/09), e.g. one, which is functionally equivalent, is sufficient. Further, the CJEU confirmed the applicability of *Georgetown* (C-422/10), also for the agrochemical sector, taking the importance of combination products for this sector into account. These decisions can just be applied together with the existing regulation or further laid down in examination guidelines. [...] believes that a route to true harmonization is through the introduction of a unitary SPC having the same geographical scope as the unitary patent. By harmonizing the European system for obtaining both patents and SPCs, this unifies the variations between national systems and prevents fragmentation, and hence fosters innovation in agriculture."

20.3.1.5 Recommendation

Against this background, we suggest that the European Commission establish a working group to prepare a draft of common guidelines for the examination of SPC applications with direct participation of experts from national patent offices. This would ensure that the guidelines or notices formulated at the EU level would not only concern the grant of unitary SPCs, but would likewise guide and inform the granting activities of NPOs. These guidelines could be adopted without any amendment of the SPC Regulations. The adoption of guidelines and implementing rules within the framework of cooperation of national experts suggested above will be challenging where the current law, due to the interpretation of certain provisions by the CJEU, is so unclear that it is difficult to establish common ground among the offices,[1614] or where guidance from the CJEU is completely missing. This is true, for instance, for the *Medeva*-requirement[1615] or for the implementation of *Neurim.*[1616]

20.3.2 Proposals for further harmonisation

In the next section we identify some aspects of the practice where harmonisation or the adoption of optional rules could be meaningful. The proposals are of course only meant to serve only as examples.

20.3.2.1 Publication of the SPC application and the rights conferred by the application

(a) *Publication*

In the interest of legal certainty and in addition to Art. 9(2) 469/2009, publication of the SPC application containing all relevant and non-confidential documents should be made compulsory. A uniform deadline should be set down, for instance three months from the filing of an SPC application. Timely publication is necessary in order to allow third parties to file observations in the granting procedure and to define the rights arising from the published application.

[1614] The situation would be different if the meaning of particularly controversial articles, such as Art. 3(a) and Art. 3(d), were clarified so that a common understanding is prescribed by legislation.
[1615] Case C-322/10 *Medeva* [2011] ECR I-12051.
[1616] Case C-130/11 *Neurim Pharmaceuticals (1991)* [2012] EU:C:2012:489.

(b) *Rights conferred by the published SPC application*

(i) The issue

Earlier commentators of the SPC Regulations have noted that the SPC Regulations are silent about the rights conferred by an SPC application. This issue can become relevant in situations where the SPC application is filed shortly before the expiration date of the patent.

Regarding this specific aspect, national law is not directly applicable. Article 19 Reg. 469/2009 and Art. 18(1) Reg. 1610/96 only refer to the procedural provisions applicable to the basic patent. The question of which rights arise from the published SPC application is, however, an issue of substantive law. Article 5 SPC Regulations is not applicable either, because this provision regulates the rights granted by the certificate and not by the application for the certificate. Therefore, a lacuna exists in this regard.[1617] The UPC Preparatory Committee itself seems to agree with the opinion that "an application for a certificate does not give any rights to be decided by the UPC and subject to an opt-out, whereas the published application for a European patent gives such rights (Art. 67 EPC)".[1618]

(ii) Legislative options and recommendations

In order to fill the lacuna described above, three options exist for the EU legislature.

First, a provision that refers to the rights granted by the SPC application to the law applicable to the application for the basic patent could be included in the SPC Regulations. However, this option would not lead to harmonised practice. Some countries provide that published patent applications confer full rights on the applicant, including the right to an injunction.[1619] Other countries provide that on the basis of published patent applications only indemnification claims are available.[1620] Further, it is not clear which law would apply in the case of a unitary patent.

Second, it could be stipulated expressly in the SPC Regulations that the published application confers the right to claim indemnification, but not the right to exclude others or to request an injunction. Such rules with respect to patent applications are well known and already provided for in several patent legislations.[1621]

Third, a provision could be adopted pursuant to which the published application for a certificate grants the same rights as the basic patent. In order to protect the interests of the defendant, it should be possible in infringement proceedings to raise an

[1617] This was also highlighted by some of the speakers at the MPI Workshop on 20-21 March 2017. The minutes of this workshop are with the MPI.

[1618] See Responses to the Public Consultation on the Rules of Procedure of the UPC, p. 1, available at: https://www.unified-patent-court.org/sites/default/files/rop-digest.pdf (last accessed 13 December 2017).

[1619] This is the situation in Cyprus, France, Greece, Ireland, Italy, Monaco, Serbia and the United Kingdom. Under the respective jurisdictions the published application provisionally confers full protection rights like a granted patent. The judicial assertion of such rights, however, is only possible in Italy (see Alfred Keukenschrijver et al, *Patentgesetz* (8th edn, De Gruyter 2016); Art. II § 1 IntPatÜG, marginal note 4).

[1620] This is the situation in Austria, Belgium, Denmark, Finland, Germany, Luxembourg, the Netherlands, Poland, Portugal, Spain, Sweden, Switzerland and Liechtenstein. Under the respective jurisdictions the published application provides the applicant with the right to claim compensation that is reasonable in the given circumstances (for a more detailed outline see Alfred Keukenschrijver et al, *Patentgesetz* (8th edn, De Gruyter 2016); Art. II § 1 IntPatÜG, marginal note 4).

[1621] An example in this regard is Art. 33 of the German Patent Act. The same system has been adopted for EU Trade Marks; see Art. 11(2) EUTMR.

invalidity defence based on Art. 3 Reg. 469/2009, considering that the defendant cannot file an action for revocation of the SPC before the latter has been granted.

As the second and the third option would result in uniform provisions that are directly applicable to SPCs, they are both recommended to the legislature, without preference for one of them. Due to the supremacy of EU law set forth in Art. 20 UPCA, the provisions would apply in proceedings before the UPC, without an amendment of the UPCA being necessary.

If the lawmakers decide to fix a deadline within which the certificate must be either granted or rejected, it is obvious that provisions on rights granted by the application are of marginal relevance and likely not needed.

20.3.2.2 Substantive examination

As regards the question of whether offices should examine the requirements for granting an SPC as provided for by Art. 3 SPC Regulations, the legislature has three options:

First, national offices could be obliged to examine all substantive requirements fully. At the same time, guidelines could be adopted to support the offices in carrying out their tasks. Also, a department equipped with technical staff could be created at the Unitary SPC Division to examine, on request and on behalf of the NPOs, applications for a certificate. For instance, with the more complex certificates the Unitary SPC Division could provide an opinion on the question whether the product is "specified in the claim" and/or whether it represents a "core inventive advance".

Second, it could be left to the Member States to decide whether or not to conduct a substantive examination of the requirements of Art. 3 SPC Regulations including a possible core-inventive-advance test. Under the current legislation only the examination of Art. 3(c) and (d) is optional.[1622]

Third, the EU States could be granted discretion in deciding whether to maintain for their NPOs the status of an SPC examining office. If they choose just to keep a registration office, they could be required to provide that the national office must postpone the grant of an SPC until an examining office of another state has granted a certificate based on an identical request.[1623] Alternatively, non-examining offices could be allowed to entrust the Unitary SPC Division with the task of providing them with a preliminary view on the eligibility of the product for an SPC, and granting or refusing the application on the basis of this preliminary report. Such a cooperation model already exists, for instance, between the Italian Patent Office and the EPO regarding Italian national applications. Similar cooperation exists between the French NPO and the EPO concerning prior-art searches. The SPC legislation itself allows the EU Member States to entrust a body other than the NPO with the grant of the SPCs.[1624]

Each of the aforementioned options has shortcomings and advantages. One should be aware, however, that it is problematic to create an IP right based on directly applicable Union law, and further to make the examination of Art. 3 (a) and Art. 3 (b)

[1622] See Art. 10(5) SPC Regulations.
[1623] Of course, this option could theoretically open room for forum-shopping strategies, but to a limited extent.
[1624] Art. 9(1) Reg. 469/2009.

Reg. 469/2009 mandatory, without assisting the NPOs by offering support or guidance in the form of secondary legislation or soft law or other means.

20.3.2.3 Transparency and uniformity

(a) *Introduction*

This section deals with means for improving the transparency and uniformity of the SPC granting procedure as well as the quality of the granted rights. By "improving the quality of rights" we mean improving the probability that the SPC granted is consistent with the requirements laid down in the SPC Regulations and would withstand a revocation action.

(b) *Third-party observations*

Third-party participation is recognised as being instrumental in reducing mistakes in granting technical rights. The same could be true for SPCs since the examination has grown in complexity; some provisions – such as Art. 3(d) or Art. 13 – require a search for prior MAs that is not easily performed by all NPOs. We consider that the proposal made by a speaker at the MPI Workshop to provide reasons for the decision to grant the SPC when third-party observations were filed could increase the incentive for third parties to submit such observations. Reasoned decisions and third-party observations should be published together with the information concerning the grant of the certificate. Third-party submissions should further be accepted anonymously and irrespective of a need for such third party to demonstrate his or her specific legal interest.[1625]

The following comments were made by stakeholders that would welcome third-party observations:

> "For generic and biosimilar medicines producers it is of utmost importance to ensure the highest level of transparency in SPC granting procedures. Today some European countries are more transparent than others. Third party observations and oppositions should also be taken more substantially into account."[1626]

(c) *Oppositions*

(i) Options and opinions of NPOs and stakeholders

As mentioned, Art. 19 Reg. 469/2009 prohibits oppositions. *De lege ferenda* the question that was posed by the MPI is whether post-grant opposition against SPCs would improve the transparency of the SPC granting system and the quality of the rights granted.

The majority of NPOs answered this question **in the negative**. According to some NPOs, the main function of oppositions in the case of patents is to allow third parties to submit to the national office prior art that has not been found or considered by the

[1625] See e.g. Third-party submission in the PCT system. Administrative Instructions under the Patent Cooperation Treaty, Section 801(b)(i): http://www.wipo.int/pct/en/texts/ai/ai_index.html (last accessed 13 December 2017).

[1626] See Annex III of this Study, p. 406. Comment to Q76: "Do you have any further comments, questions or criticism regarding the current SPC regulations or case law or on other aspects regarding SPCs that have not been addressed in this survey and that are important to you?"

examiner. Since the examination of SPCs does not require assessment of prior art, oppositions would not improve the examination.

In this regard the following considerations submitted by one NPO are illustrative:

> "Opposition against granted SPCs would create a more simple and cheap instrument for third parties to attack an allegedly invalid SPC, which can be expected to be used relatively often, given the economic value of SPCs.
>
> Whether there will be any positive effects on the quality and transparency of the system is questionable. Compared to the situation with patents, hardly ever new evidence (prior art in the case of patents) will be provided by the opponents. It will be more likely limited to the legal assessment of known facts."

According to another NPO an opposition would be unlikely to have any positive impact on its practice since this office already offers options for third parties to challenge the grant or validity of an SPC (third-party observations, the ability to request a declaration of invalidity at the NPO (low-cost tribunal), and the ability to request a non-binding opinion on SPC validity). There could be a risk of increased uncertainty in the case of providing a formal opposition period after grant, particularly if that period were extended into the SPC term itself. Furthermore, some NPOs have stated that the creation of an opposition system would be burdensome. According to a minority of NPOs, an opposition system would provide third parties with a less expensive option to challenge an allegedly invalid SPC.

A question on the possibility to introduce oppositions against SPCs was included in the Allensbach Survey (Q59). A clear majority of all stakeholders participating in the survey would not expect a positive impact from oppositions (59 per cent); 41 per cent of the stakeholders are of the opposite opinion. The only subgroup strongly in favour of oppositions, are representative of generic companies (74 per cent in favour):

Opinions on the proposal to admit oppositions against SPCs in cases where the right was granted in violation of Art. 3 of the Regulations		
Share of the respondents expecting a positive impact of oppositions		
Total %	Representatives of originator companies %	Representatives of generic companies %
41	16	74

Table 20.3: Q59 of the Allensbach Survey

At the MPI Stakeholder Seminar on 11 September 2017 representatives of the generic industry also expressed their support for allowing opposition against SPCs.

(ii) Recommendation

In our opinion oppositions would also be useful in the field of SPCs for the following reasons:

- If the core-inventive-advance test is considered to be a requirement for the validity of an SPC in general (if based on Art. 3(a)) or only in the case when an SPC has already been granted (if based on Art. 3(c)), then the prior art can be relevant in assessing the eligibility of the product for an SPC.

- *Neurim* and *Forsgren* have added technological complexity to the examination. The same is true for *Medeva* and *Eli Lilly*, if these are intended as requiring that the patent includes an individual disclosure of the compound concerned.
- The function of an opposition is not only to provide new prior art but also to identify points of view that examiners could have missed or did not consider, or to object to the breadth of the claims if not supported by the disclosure: if the product description is considered relevant for determining the scope of the SPC, then a technical examination also becomes relevant in this regard.[1627]
- An opposition has the advantage of being less expensive and less formal than revocation proceedings. Taking into account the fact that a revocation action against SPCs granted on the basis of a European patent will be subject to the exclusive jurisdiction of the UPC and to the functional competence of the London bench of the Central Division of the UPC,[1628] it would be useful to allow a company that is interested in one or two national markets to conduct an opposition in those countries instead. The same is also true for generic companies interested in the whole internal market of the EU. Revocation proceedings will be likely more expensive before an international Court.

As a consequence, we suggest that the unitary SPC system should include the possibility to file oppositions against SPCs granted by the Unitary SPC Division (or Unitary SPC Office). For the same reason Member States should be given the option to introduce post-grant opposition proceedings against SPCs, leaving it to *their discretion* to assess whether it is appropriate or to make use of it.

(d) *Establishment of a common register for national marketing authorisations*

A common register for national MAs could provide an easy search tool for NPOs to retrieve granted MAs that are relevant to the proceedings. Such a register could also facilitate the examination of Art. 3(d) by the offices and might improve the position of the applicant (for instance, in the case of a paediatric extension request).

A general register of the active ingredients authorised in Europe at the national or European level with an indication of the date of the respective first authorisation could be established with the support of the EMA. The same measure is opportune for active substances of plant protection products, considered the absence of centralised MAs.

(e) *Mandatory deadline for a decision on the SPC application*

The absence of a provision obliging the NPO to make a decision on the SPC application within a specific deadline was a subject of discussion at the time when Reg. 1768/1992 was enacted. As Justice Jacob pointed out in *Draco*,[1629] a pending SPC application may confer a *de facto* monopoly on the patentee, unless generic competitors take the risk of entering the market before the final decision is made. French law provides that the application must be considered as rejected if the NPO is unable to grant the SPC within a specific timeframe. Some stakeholders have criticised

[1627] As explained, granted SPCs don't have claims, but a product definition. Currently it is unclear, whether this definition as allowed by the granting authority has any impact on the assessment of the scope of protection in infringement proceedings. See in this Chapter Section 20.3.2.4 and Chapter 14, Section 14.2.

[1628] Subject to the ratification of the UPCA by the UK and the pending Brexit negotiations.

[1629] *Draco AB's SPC Application* [1996] R.P.C. 417.

this provision. Other stakeholders would, by contrast, favour some measure that could ensure that all NPOs make a decision on the application within a fixed period of time.

Inter alia the following comments have been made:

> "Currently, in many cases a large number of SPC applications is filed for the same product at the same date in a large number of EU member states. However, unfortunately, some Patent Offices suffer from enormous backlogs. As a result thereof, in some EU member states, SPCs are granted very rapidly, whereas in particular in the UK and in Germany, in some cases SPCs are only granted shortly before expiry of the basic patent. Therefore, with respect to the SPC filings across Europe, it would be favorable if there would be a deadline for the Patent Offices to start examination of the SPC applications, e.g. at the latest 3 years after the filing date of the SPC application. In an ideal world, the parallel SPC applications would be examined simultaneously across Europe."[1630]
>
> "… the time factor is a burden – all patent offices should be required to grant (or deny) SPC applications within 12 months from filing."[1631]
>
> "The speed of handling SPC applications differs greatly: in some countries the authorities only take weeks to come to a decision (not) to grant, in others the authorities wait until the basic patent is about to expire. This brings protracted legal uncertainty for all parties."[1632]
>
> "The French law provides that the SPC is automatically deemed to be refused if the SPC is not issued within 12 months from filing. This raises issues for the SPC applicants that wish/need to delay grant of the SPC, for instance if the basic patent is undergoing opposition proceedings."[1633]
>
> "The speed in handling SPC applications differs greatly from state to state. A uniform method for handling such applications would be greatly desired. You have to go through multiple granting procedures with different time lines and sometimes different outcomes. A centralization would be favourable."[1634]
>
> "It sometimes takes years to get a first office action. Given the importance of SPCs management system should be installed, for instance 6 months to 1st office action months reply deadline, and 4 month window for next office action/allowance."[1635]

A prompt examination of SPC applications is also crucial for competitors, who cannot make reasonable dispositions until a decision on the application is made. In addressing this issue, one could simply provide a deadline by which the examination must have begun or a deadline by which the decision must be made. The appropriateness of imposing a deadline (for the start of the examination, for the decision or for both) and the way to implement it in proceedings before the NPOs and the Unitary SPC Division should therefore be discussed with the NPOs. For the sake of completeness, we should report that this issue was already the subject of a written question to the European Commission in 1993. The Commission provided at that time the following answer:

> "As regards the time-limit for approval of an application for a supplementary certificate by national industrial property offices, the Commission would emphasize that Regulation (EEC) No 1768/92 refers, in the absence of express provisions, to the procedural provisions applicable under national law to the basic patent (Article 18).
>
> As a general rule, the public authorities in the various Member States are not obliged to take decisions within fixed periods, even though, in the interests of sound management and administration, they would be expected to do so within a reasonable time."[1636]

(f) *The obligation to submit complete and true information*

Only in Germany is the obligation to state the truth expressly set forth in the Patent Act.[1637] In several other countries such obligation arises from general administrative or

[1630] Annex III, p. 374.
[1631] *Ibid.,* p. 374.
[1632] *Ibid.,* p. 374.
[1633] *Ibid.,* p. 376.
[1634] *Ibid*., p. 377.
[1635] *Ibid.,* p. 378.
[1636] [1993] OJ C 61/9.

criminal laws. However, it has not been reported that the violation of the obligation to state the truth results in the invalidity of the SPC granted or in the rejection of the SPC application, or in the non-enforceability of the right.

The EU legislature might consider the appropriateness of incorporating such obligation in the SPC Regulations and sanctioning possible violations. It must be noted, however, that introducing such a scheme would trigger complex issues regarding the substantiality and causality of the misrepresentation.[1638] Making false statements in application proceedings can also result in sanctions based on other legal grounds (e.g. antitrust law[1639]).

(g) *Revocation ex officio of SPCs where the basic patent is revoked*

Another measure mentioned by one NPO that is worth considering is to provide the NPOs with the power to remove from the register and to revoke SPCs in cases where the basic patent has been invalidated or limited, so that the product is no longer protected by a patent in force. The NPOs would have to inform the patent holder of its intention to revoke the SPC. The patent holder should be entitled to submit observations before the decision is made and to lodge an appeal against the decision. However, no obligation for offices should arise from such power, since this would mean extensive monitoring of the legal status of basic patents. Further, in the cases where the patent was limited in the revocation proceedings, the exercise of such power would require an examination of Art. 3(a) Reg. 469/2009.

20.3.2.4 Product description (or definition)

(a) *Premise*

The practice concerning product definition is not uniform. Before the discrepancies can be addressed, clarification is needed with regard to the basic issue of whether the product definition has the same legal effect as a patent claim, namely to limit the protection granted by the SPC, or whether it corresponds to the title of the invention in a patent application, meaning that it is only of informative value. This issue is addressed in Chapter 14, Section 14.2.

(b) *Post-grant amendment of the product definition*

In the judgment handed down by the Borgarting Court of Appeal in the *Pharmaq* case,[1640] the court – consistently with the decision of the EFTA Court[1641] – came to the conclusion that when the product definition is broader than the subject of the MA, the SPC is invalid under Art. 4 Reg. 469/2009. The court also held that it cannot redraft the SPC to limit the product definition to the product covered by the MA. It is not clear

[1637] Art. 124 German Patent Act.

[1638] In the US the non-statutory and equitable defence of unclean hands in the case of misrepresentation of material facts in procedures before the USPTO is subject to debate and controversy for the high litigation costs that it may incur. Recent reforms and the case law have narrowed its scope; see for a legal analysis T Leigh Anenson, Gideon Mark, 'Inequitable Conduct in Retrospective: Understanding Unclean Hands in Patent Remedies' [2013] 62 American University Law Review 1441-1527.

[1639] Case T 321/05 *Astra Zeneca v Commission* [2010] EU:T:2010:266.

[1640] Borgarting Court of Appeal, 19 December 2016, Pharmaq AS v Intervet International BV, Case No. 15-170539ASD-BORG/01 and 15-204605ASD-BORG/01.

[1641] EFTA Court, Case E-16/14 *Pharmaq AS v Intervet International*, Decision of 9 April 2015, BV [2015] EFTA Ct. Rep. 212

from the judgment whether the certificate holder has filed an auxiliary request to limit the product definition. According to our understanding, the judgment is based on the following assumptions:

- Art. 138(3) EPC and corresponding national provisions cannot be applied to SPCs in order to allow the applicant to limit the product definition or the court to declare the SPC partially invalid;
- the product definition is legally binding and affects the scope of the protection granted by the SPC;
- if the product definition goes beyond the product identified by the MA, the SPC is invalid under Art. 4 Reg. 469/2009.

If the product definition cannot extend the scope of the SPC because the latter remains limited to the product identified in the MA, the decision of the court of appeal could not be followed, and there was no need to provide for a right to amend the definition. An NPO observed in this regard:

> "Limitation of a product definition in an SPC appears only reasonable, if this definition is given in a claim format.
>
> If pursuant to Art. 4 of Reg. 469/2009/EC the product definition extends only to the product covered by the MA, then it is hard to imagine in which situations such a limitation could be useful."

Another NPO remarked:

> "It could be useful for example to allow a coincidence of the SPC with the basic patent in cases when the basic patent itself has been limited. But it should be made clear that such a limitation does not create a right to file for another SPC."

A slight majority of NPOs are of the opinion that post-grant amendment of the product definition is not necessary.

(c) *Stakeholders' opinion*

The Allensbach Survey includes two questions related to post-grant amendment of the product definition: the first one on the product definition after grant before the patent office, analogous to Art. 105a EPC (Q60); the second one on amending the product definition during revocation proceedings before the revocation judge, analogous to Art. 138(3) EPC (Q61).[1642] A relative majority of the stakeholders reject both proposals (48 and 46 per cent, respectively) of either a right of the SPC holder to amend the product definition after the grant before the patent office, analogous to Art. 105a EPC, or a right of the SPC holder to amend the product definition during revocation proceedings before the revocation judge, analogous to Art. 138(3) EPC. Only 36 per cent and 39 per cent, respectively, are in favour of the respective propositions.[1643]

Regarding amending the product definition after the grant of an SPC, some stakeholders are of the opinion that it would be opportune to allow not only amendments that limit the product description, but also amendments that extend it, as expressed, for instance, in the following comments:

[1642] See Annex III of this Study, pp. 43-44 and pp. 238-243.
[1643] *Ibid.*

"Regarding the statement, "Would you welcome a right of the SPC holder to amend the product definition after grant before the Patent Office, analogous to Art. 105a EPC?", we welcome the option for amendment, but this should also include broadening amendments, not only limitation as under Art. 105a EPC, because the right of the SPC is already constrained by the scope of the patent pending when the SPC application is filed."[1644]

"1. the question of amendments after filing the SPC application substantially differs between national offices; in some countries national provisions exist which exclude any amendment. 2.The product definition is very different on national [level]."[1645]

"Regarding the previous question of amendment of the product definition. There should be no definition of the product in the SPC application, because there is no basis for that in the Regulation and there is no need for it. The scope of protection is provided by Article 4, and not by any product definition. Thus, there is no need for a provision for amendment. Also, the practice of national patent offices to allow product definitions, without any legal basis, is a burden for applicants."[1646]

(d) *Recommendation*

If the product definition is to have the effect of defining the scope of the SPC protection, and if a product definition that is broader than the MA or broader than the basic patent has the consequence that the SPC is invalid, then it will be necessary to provide the SPC holder with the right to limit the scope of the SPC and to amend the definition post-grant before the NPO and in revocation proceedings before the competent court. If by contrast the scope of protection is defined by the MA, and the product definition, even if required for the purposes of the examination, can neither extend nor reduce the scope resulting from the basic patent and MA under Art. 4 Reg. 469/2009, there is no need for such procedural rights.

Since the legal function of the product definition is not clear from the case law, we are not in a position to make a recommendation.

20.3.2.5 Calculation of the patent and SPC duration. Calculation of terms. Relief before the national office

(a) *SPC and patent terms*

The majority of NPOs are in favour of a uniform rule for the calculation of the term of SPCs. Several NPOs consider Rule 131 EPC a suitable normative model. We agree with this suggestion. As far as patent terms are concerned, the regulation of this aspect is outside the scope of the SPC legislation. As far as European patents are concerned, a uniformly applicable rule is provided under Rule 131 EPC, but the NPOs require some clarification whether this provision also applies to the calculation of the patent term. Indeed, several NPOs apply national law to compute the term, as already mentioned, and one NPO considers Rule 131 not applicable to the term of granted European patents. This is not a question of Union law, but of international and national law. However, in view of the creation of unitary patent protection, the adoption of uniform criteria for computing the 20-year term in order to have the same expiration date Union-wide seems appropriate and needed.

[1644] See Annex III of this Study, p. 417.
[1645] *Ibid.,* p. 375.
[1646] *Ibid.,* p. 376.

(b) *Relief before a national office for missed deadlines*

Several NPOs acknowledge that harmonisation in line with Art. 11(1)(ii) and 11(2) PLT and Art. 121 EPC would have positive effects in providing a patentee with the right to request further processing with respect to the application for a certificate in cases where the applicant has failed to comply with a time limit set by the national office.

20.3.2.6 Correction of the term of the certificate

(a) *The issue*

As already mentioned, pursuant to Art. 17(2) Reg. 1610/96,

> the decision to grant the certificate shall be open to an appeal aimed at rectifying the duration of the certificate where the date of the first authorisation to place the product on the market in the Community, contained in the application for a certificate as provided in Article 8, is incorrect.

This article was introduced following an amendment by the Council to the Proposal for the Plant Protection Products Regulation. Its function is explained in the Commission's Common Position No. 30/95 of 1995:[1647]

> The Council has added a new Article 17(2). Since the duration of the certificate depends on the date of the first marketing authorisation in the Community as stated in the application for a certificate and since the authority referred to in Article 9 does not check whether that date is correct, the Council sees a need to stipulate that, should that date be incorrect, the decision to grant the certificate is opened to an appeal aimed at rectifying the duration of the certificate. As that decision is not covered by those referred to in paragraph 1 of the Article, it needs to be mentioned in a separate paragraph. The statement referred to in the second paragraph in Article 9 also relates to this new paragraph. The Commission has agreed to the new paragraph.

Reg. 469/2009 does not contain a corresponding provision. Nevertheless, this provision is relevant for SPCs filed for medicinal products pursuant to Art. 22 Reg. 469/2009.

This provision incorporates a problem that was already partly addressed in Section 20.2.14: the date of the term of the certificate may be rectified only on the basis of an appeal, but such an appeal is subject to the national procedural provisions, including the provisions that provide for a deadline for lodging such an appeal. As a consequence, it is neither possible for the NPO to rectify a term *ex officio*, nor for an appeal to be filed by any party once the deadline for lodging appeals has expired. If as a consequence of a change in the case law or of a diverging interpretation of the NPOs, SPCs with different terms are granted without a rectification being possible, the supplementary period of protection will "differ from one State to another, a consequence which the legislature quite clearly wished to avoid", as Advocate General Ruiz-Jarabo Colomer pointed out in the proceedings of case C-207/03.[1648]

This lacuna has gained practical relevance in the aftermath of the CJEU's *Seattle Genetics* decision. It has motivated a referral to the CJEU (C-492/16 – *Incyte*

[1647] Common Position (EC) No 30/95 adopted by the Council on 27 November 1995 with a view to adopting Regulation (EC) No . . ./95 of the European Parliament and of the Council concerning the creation of a supplementary protection certificate for plant protection [1995] OJ C 353/36.

[1648] Case C-207/03 *Novartis* [2005] ECR I-03209, Opinion of AG Colomer.

Corporation[1649]) asking whether an NPO is required to rectify, of its own motion, the date of expiry of an SPC.

(b) *Options*

There are three options for addressing the issues raised by referral C-492/16. The first is to leave the law as it is, in the interest of legal certainty, "a central principle of the legal order of the European Union, which prevents final non-reviewable decisions being reopened once the ruling on the question is known".[1650]

The second is to provide the NPOs, certificate holders and any third parties with an option to file a request aimed at rectifying the duration of the certificate where mistakes in the calculation, changes in the case law or other circumstances justify that amendment. The national offices would obtain the right to amend the duration of the certificate *ex officio*, after hearing the certificate holder. Any interested party would be entitled to lodge an appeal aimed at correcting the term at any time until the expiry of the certificate.

Since Art. 17 Reg. 1610/96 does not mandate a specific deadline for lodging an appeal, such a rule could be introduced through implementing provisions. An amendment to Reg. 1610/96 does not appear to be necessary. However, an amendment to Art. 17 Reg. 1610/96 as well as the introduction of a corresponding rule in Reg. 469/2009 would be the preferable solution. If a direct amendment to Art. 17 Reg. 1610/96 is adopted, the following wording would be advisable:

> Article 17 Reg. 1610/96
> Appeals
> 1. The decisions of the authority referred to in Article 9(1) or of the body referred to in Article 15(2) and 16(2) taken under this Regulation shall be open to the same appeals as those provided for in national law against similar decisions taken in respect of national patents.
> 2. The decision to grant the certificate shall be open at **any time** to an appeal aimed at rectifying the duration of the certificate where the date of the first authorisation to place the product on the market in the Community contained in the application for a certificate as provided for in Article 8 is incorrect.

A provision with identical wording should also be incorporated in Reg. 469/2009. While this option would provide the NPOs with the necessary flexibility, a shortcoming would be that it does not take into account the position of third parties and the legal certainty required with respect to the term of patent-based exclusivity.

A third approach could be a compromise between the two solutions mentioned above. The lawmakers could allow a rectification, but only if the request is filed prior to the expiration date of the patent. In this way, on the date the SPC term starts to run, competitors can securely assess the duration of the *sui generis* right. Extension of the term after this critical date in consequence of a rectification will not be possible. The Swedish case law reported in Section 20.2.15 of this Chapter seems to be oriented in this direction.[1651] The decisions concerned are based on principles of domestic administrative law. However, the proposition of differentiating between SPCs depending on whether or not their term has already started to run could make sense from the perspective of Union law as well.

[1649] Case C-492/16 *Incyte Corporation v Szellemi Tulajdon Nemzeti Hivatala* (pending).
[1650] Case C-207/03 *Novartis* [2005] ECR I-03209, Opinion of AG Colomer, para. 73.
[1651] PMÄ 10959-16, 10962-16, 10963-16, 10969-16, 10971-16. For details see *supra*, Section 2.14.2.

(c) *Opinion of the NPOs*

Question 65 of the MPI Questionnaire for the NPOs[1652] refers to two (not mutually exclusive) options to address the issues underlying the *Incyte* referral, namely (1) to provide the SPC owner with the right to amend, at any time, the duration of the certificate, and/or (2) to endow the NPO with the duty or the power to amend such duration *ex officio*. Not all NPOs expressed their opinion on the issue. A slight majority of the NPOs expressing their view saw a practical necessity for conferring on the NPOs the power to rectify *ex officio* the duration of SPCs at any time and/or the right for an applicant to appeal for a rectification of the duration of the SPC at any time (or emphasising "any time if the SPC is still in force"). Other NPOs were not in favour of the options proposed, due to the interests of third parties not being properly taken into account. One NPO finds an obligation of the national authorities to amend the duration *ex officio* problematic, since it would mean an extensive monitoring requirement.

(d) *Recommendation*

It is possible that the question leading to the *Incyte* referral is a temporary one, but it cannot be ruled out that the need to amend the duration of the certificate at the request of the SPC owner or by an NPO *ex officio* can arise again in the future. The question currently pending before the CJEU has not been decided before, since in Case C-207/03 (*Novartis*) the CJEU did not answer the second question referred by the High Court of England, which is whether a competent authority within the European Economic Area "is obliged to rectify any existing supplementary protection certificates, the duration of which has been erroneously calculated".

Against this background, taking into account the opinion of the NPOs, the approach taken by the Swedish Court of Appeal which excluded the possibility of changing the term of running SPCs[1653] seems to be a sensible compromise between opposing interests.

20.3.2.7 Surrender of the SPC

(a) *The issue*

Pursuant to Art. 14(b) Reg. 469/2009, the holder of an SPC has the option to surrender the SPC. SPC Regulations do not regulate the legal effect of the surrender. The question of whether the surrender of an SPC has an *ex tunc* or *ex nunc* effect has practical implications. If the surrender has retroactive effect, the holder of an SPC will no longer be able to enforce damage claims even against infringing activities that occurred before the surrender. However, the surrender could affect the application of Art. 3(c) SPC Regulations.

In this respect it must be clarified, first of all, whether the surrender is a matter of European or national law. If it is a matter of European law, then the CJEU must autonomously define the effect of the surrender. If it is governed by national law, then the provisions concerning patents will likely apply analogously. In this case, different

[1652] Q65 reads: "[…] Do you see a practical need for providing the applicant with the right to amend at any time the duration of the certificate or for the Office to amend ex officio such duration?"

[1653] PMÄ 10959-16, 10962-16, 10963-16, 10969-16, 10971-16. For details see *supra*, Section 2.14.2.

solutions will result from the applicable national law. In some countries (AT,[1654] DE,[1655] ES,[1656] IE,[1657] PL,[1658] and UK[1659]) the surrender leads to an expiry of the patent with *ex nunc* effect. In other countries (FR and NL) the surrender of the patent has *ex tunc* effect.

Thus far, the CJEU has been faced with the question of whether the legal effect of the surrender should be defined by the law governing the basic patent or autonomously by EU legislation.[1660] The Advocate General considered this to be a question of European law and recommended that a uniform answer be given on the basis of the rationale of the Regulation.[1661] The reasons for this conclusion were twofold. On the one hand, the legal effect of the surrender is a matter of substantive law. Therefore, Art. 18 Reg. 469/2009 is not applicable. On the other hand, it would contradict the purpose of the Regulation if an issue affecting the application of Art. 3(c) were subject to different national provisions.

In order to assess the practical relevance of the issue two scenarios are helpful:

Example 1
On the basis of an MA granted for product A, the patentee has obtained an SPC that expires on a specific date. If the surrender has retroactive effect, on the basis of the same MA the patentee could obtain a new SPC based on a different patent. First and second certificate could have different expiration dates if the basics patents have a different priority date.
Example 2
On the basis of an MA granted for product A, the patentee has obtained an SPC. On the basis of a further MA for a combination product A-B, with a later granting date than the MA for A, the applicant requested a second SPC for A-B. If the combination A-B does not represent a separate innovation within the meaning of the CJEU case law, the application for a certificate could fail. The applicant surrenders the SPC for A before the expiration date of A and requests an SPC for A-B. If the surrender has retroactive effect, one could argue that Art. 3(c) does not apply.

The Court of Justice has not yet answered the question of whether the surrender has retroactive effect and whether this issue should be governed by European or national law.

[1654] Pursuant to § 46(1) No. 3 Patents Act (1970) the patent expires if the patent holder surrenders it. The expiry of the patent has effect *ex nunc* (see Andreas Weiser, *Patentgesetz. Gebrauchsmustergesetz*. *Kurzkommentar* (3rd edn, MANZ 2016) § 46, p. 309; Peter Burgstaller, *Österreichisches Patentrecht*. *Kommentar* (Medien u. Recht 2012) § 46, p. 124).

[1655] Pursuant to § 20(1) No. 1 Patents Act (1980) in case of surrender the patent expires with *ex nunc* effect (BPatG, *Decision of 18 July 2012*, 4 Ni 3/12 [2012] BeckRS 21847; see also Georg Benkard, *Patentgesetz* (11th edn, C.H. Beck 2015) § 20 marginal note 2 *et seq*.

[1656] Pursuant to Art. 92(4) of Royal Decree 316/2017 the patent will expire according to Art. 108(1)(b) of Law 24/2015. The expiry of the patent has effect *ex nunc* (see Eva M Domínguez Pérez, *La caducidad de las patentes: nuevos planteamientos en la ley 24/2015, de 24 de julio, de patentes* in Alberto Bercovitz Rodríguez-Cano, Raúl Bercovitz Álvarez (eds), *La Nueva Ley de Patentes: Ley 24/2015, de 24 de julio* (Thomson Reuters 2015) p. 488.

[1657] Pursuant to Sec. 39(1) Patents Act (1992) in the case of surrender the expiry of the patent has *ex nunc* effect (Robert Clark et al, *Intellectual Property Law in Ireland* (4th edn, Bloomsbury Professional 2016) p. 133).

[1658] Pursuant to Art. 90(1)(ii) Industrial Property Act (Act of 30 June 2000) in the case of surrender the expiry of the patent has *ex nunc* effect (Piotr Kostański, *Die Schutzwirkung des Patents nach polnischem Recht* (Baden-Baden 2010) [also: Kraków, Jagiellonen Universität, Diss., 2009], pp. 238, 242).

[1659] Pursuant to Sec. 29(1) Patents Act (1977) in the case of surrender the expiry of the patent has *ex nunc* effect (see Sec. 29(3) Patents Act (1977); see also Paul G Cole Lucas & Co (eds), *CIPA Guide to the Patents Acts* (8th edn, London Sweet & Maxwell 2016) Sec. 29, recital 29.06, p. 477).

[1660] See question referred for a preliminary ruling: Case C-484/12 *Georgetown University* [2013] EU:C:2013:828, para. 25.5.

[1661] See Case C-484/12 *Georgetown University* [2013] EU:C:2013:828, Opinion of AG Jääskinen, para. 56.1.

(b) *Options and recommendations*

The SPC Regulations do not provide a general reference to the law governing the basic patent. References are specific and limited in scope. The only reference of potential relevance for determining the law applicable to surrenders is found in Art. 19 Reg. 469/2009 and Art. 18 Reg. 1610/96, which refer in matters of procedural law to the law applying to the basic patent. However, the effect of the surrender is a question of substantive law, meaning that Art. 19 Reg. 469/2009 and Art. 18 Reg. 1610/96 are not applicable.[1662]

This means that a lacuna exists in the SPC Regulations. One way to deal with this could be to introduce a new provision that addresses the effect of a surrender. We recommend that such a provision should provide for the surrender only with effect *ex nunc*. Consequently, it would not be possible to grant another SPC to the same applicant for the product that was the subject of the surrendered certificate. The surrender would not interfere with the application of Art. 3(c) SPC Regulations.

In our view, this solution would also be consistent with the purpose and function of Art. 3(c) SPC Regulations. The application of Art. 3(c) cannot be made dependent upon the choice of the applicant as to whether or not an SPC is surrendered after the grant. Further, the existence of the SPC could already have had a deterrent effect on competition which the surrender of the right would not eliminate. If the surrender could achieve the effect that Art. 3(c) would not be applicable to the product concerned, this would deprive Art. 3(c) of one of its functions.

As pointed out by Advocate General Jääskinen,[1663] the fact that in some legislations the surrender of the patent has retroactive effect is not relevant here because such retroactive effect does not imply that, for instance, the patent application for which the patent was granted would not be part of the prior art in relation to a subsequent application for the same subject matter. By contrast, in the field of SPCs, if the surrender affected the application of Art. 3(c), a competitor could not be confident that no second SPC could be granted for the respective product, or any other non-inventive combination including that product. It is true, however, that if the inventive-advance test were based on Art. 3(a) Reg. 469/2009 the issue discussed here would lose a part of its relevance.

(c) *Summary*

We suggest amending Art. 15 Reg. 469/2009 so that the surrender has effect only *ex nunc*. The same principle should apply to all other grounds for lapse of an SPC provided under Art. 14 Reg. 469/2009. The granting authority should be entitled to declare *ex officio* the existence of a reason for the expiry of the certificate. Such provisions could read as follows:

Article 14
Expiry of the certificate
1. The certificate shall lapse:
   (a) at the end of the period provided for in Article 13;
   (b) if the certificate holder surrenders it;
   (c) if the annual fee laid down in accordance with Article 12 is not paid in time;

[1662] *Ibid.,* para. 29.
[1663] *Ibid.,* para. 38.

(d) if and as long as the product covered by the certificate may no longer be placed on the market following the withdrawal of the appropriate authorisation or authorisations to place on the market in accordance with Directive 2001/83/EC or Directive 2001/82/EC.

2. **The authority referred to in Article 9(1) of this Regulation may decide on the lapse of the certificate either of its own motion or at the request of a third party.**
3. **The lapse of the certificate shall have effect only for the future.**

20.3.2.8 Revocation of SPCs

(a) *Premise*

Two issues can be identified with respect to the revocation of SPCs. The first is whether the revocation grounds provided under Art. 15 Reg. 469/2009 are exhaustive. The second issue concerns the effect of a decision revoking the SPC.

(b) *Exhaustive or non-exhaustive nature of the grounds for revocation*

It appears to be the predominant view that the grounds for revocation under the SPC legislation are not exhaustive. This result is supported by the case law as well as by a literal interpretation of Art. 15 Reg. 469/2009. Unlike Art. 138 EPC, Art. 15 Reg. 469/2009 does not state that the SPC shall be revoked *only on the grounds* listed in Art. 15. In the literature and in the case law the existence of potential unwritten revocation grounds has been considered in situations where:

- SPCs were granted in conflict with Art. 19 Reg. 1768/92;
- the patent has been cancelled;[1664]
- SPCs were granted in conflict with the purpose or spirit of the Regulation: this situation can occur when the SPC is granted without the consent of the MA holder and is enforced against the owner of the MA;[1665]
- Mismatch between the scope of the product definition and the scope of the basic patent or of the MA (Art. 4 Reg. 469/2009).

Other revocation grounds, to the best of our knowledge, have not been discussed so far. The first reason mentioned above is not relevant anymore. The third reason would become moot if the legislature decides to clarify whether or not the consent of the MA holder is necessary to comply with Art. 3 Reg. 469/2009. The cancellation of the patent occurs in some legal orders when the patentee has not paid the fees or has surrendered the patent. However, these situations seem to be covered by a literal or purposive reading of Art. 15(b) Reg. 469/2009. As far as situations where the product definition is broader than the MA or broader than the patent are concerned, it is questionable whether a revocation ground based on Art. 4 Reg. 469/2009 is needed. In the case that the product definition is broader that the patent, a revocation ground under Art. 3(a) Reg. 469/2009 in conjunction with Art. 15 Reg. 469/2009 applies. In the former case, where the product definition is broader than the MA, one could argue that not all products protected by the certificate are covered by a valid MA. Therefore, Art. 3(b) Reg. 469/2009 is not satisfied. Of course, this is based on the assumption that the scope of the certificate is defined by the product description and not only by the MA.[1666]

[1664] Marco Stief, Dirk Bühler, *Supplementary Protection Certificates* (Beck 2016) p. 52.
[1665] Gertjan Kuipers et al, 'Recent European developments regarding supplementary protection certificates (SPCs)' [2014] 13(5) Bio-science Law Review 178 et seqq.
[1666] See on this issue Chapter 14, Section 14.2.

As a consequence, a need to amend Art. 15 Reg. 469/2009 is not evident. If the lawmakers intend to address expressly the third-party MA issue, then it is questionable if other revocation grounds – not covered by Art. 15 Reg. 469/2009 – may become relevant in practice. In line with Art. 138(1) EPC[1667] the lawmakers could introduce the expression "*only on the grounds*" in Art. 15 Reg. 469/2009 and by doing so ensure that the list of revocation grounds is considered as exhaustive.

(c) *Effect of the SPC revocation*

(i) The issue

The effect of a court decision revoking an SPC is a matter of substantive law. Art. 19 Reg. 469/2009 and Art. 18 Reg. 1610/96 are not applicable. As in the case of surrender, the preliminary question to be answered is whether the effect is governed by national law or whether it is a question of European law. In the latter case, the question is whether the decision has retroactive effect and whether the principle of retroactive effect has some exceptions.

A reasonable approach would be, as in the case of surrender, to consider the question an issue of European law. If national patent law is applied, then the general principle recognised by all EU Member States is that a decision has retroactive effect.[1668] Some countries limit such retroactive effect in line with the provision of Art. 33 CPC or Art. 29 of the Proposal for a Council Regulation on the Community Patent of 1 August 2000.[1669] Other countries, by contrast, do not provide for a similar limitation.[1670] The UPCA does not address the issue at all.[1671]

(ii) The options

The absence of a rule determining the effect of a decision revoking an SPC obviously has not led to any uncertainty since the courts are likely to apply the provisions governing national patents.[1672] However, the question may have practical relevance for unitary SPCs. In consideration of the fact that the UPC will have to apply the SPC Regulations, it could be appropriate to fill this lacuna and provide for a uniform provision. An objection against this approach is, however, that SPCs are often challenged together with the basic patent. It would not be appropriate to provide for different regimes, one applying to the effect of the revocation of the patent and the other to revocation of the SPC. The UPC does not regulate the effect of a decision on the validity of the patent. Therefore, it is not clear whether the decision will have retroactive effect or exceptions will apply.

1667 The first sentence of Art. 138 EPC reads as follows: "Subject to Art. 139, a European patent may be revoked with effect for a Contracting State only on the grounds that […]".

1668 Such retroactive effect is also determined by the Strasbourg Convention.

1669 Proposal for a Council Regulation on the Community patent [2000] OJ C 337 E.

1670 In Germany the final decision eliminated the patent with retroactive effect, see Secs. 22, 21(3) Patent Act (see also Rüdiger Rogge, Helga Kober-Dehm in Georg Benkard, *PATENTGESETZ* (11th edn, C.H. Beck 2015) § 22 marginal note 87 et seq. with further references). Already existing licence agreements, however, remain unaffected by this retroactive effect (see Eike Ullmann, Hermann Deichfuß in Georg Benkard, PATENTGESETZ (11th edn, C.H. Beck 2015) § 15 marginal note 192; Rüdiger Rogge, Helga Kober-Dehm in Georg Benkard, PATENTGESETZ (11th edn, C.H. Beck 2015) § 22 Rn. 89 ff.). This is so because of the case law and not an express provision.

1671 Some provisions are included in the rules of procedure.

1672 In Germany the Federal Patent Court has allowed revocation (*ex tunc*) of the certificate on applicant's request by DPMA, if SPC invalid, see BPatG, *Trifloxystrobin,* 15 W (pat) 22/14 [2016] JurionRS 2016, 33025.

Against this background, lawmakers have two options: the first is to provide for an exhaustive regulation of the retroactive effect of the decision. A normative model is provided by the CPC. The provisions could read as follows:

> The retroactive effect of the revocation of the SPC as a result of opposition or revocation proceedings shall not affect:
> a) any decision on infringement which has acquired the authority of a final decision and has been enforced prior to the revocation decision;
> b) any contract concluded prior to the revocation decision, in so far as it has been performed before that decision; however, repayment, to an extent justified by the circumstances, of sums paid under the relevant contract, may be claimed on grounds of equity;
> c) the operation of Art. 3(c) Reg. 469/2009.

If such broader harmonisation is not acceptable because it could contradict the effect of the revocation of the basic patent, a second, lighter approach could be taken. The lawmakers could limit themselves to addressing the question whether the revocation of the SPC affects the application of Art. 3(c).[1673]

(iii) Conclusion

The SPC Regulations do not address the effects ensuing from revocation of an SPC. A lacuna also exists in the UPC system, as the UPCA does not address the effects of patent revocation. Against this background, it could be advisable to fill the gap by adopting a provision that resembles in its function and content Art. 33 CPC. If that solution is not acceptable, an SPC-specific clarification should address the relationship between the retroactive effect of the revocation decision and the operation of Art. 3(c) SPC Regulations.

[1673] Chapter 12, Section 12.1.4.

20.4 SUMMARY

- The Allensbach Survey, the qualitative interviews, the analysis of the NPOs' decisions and the data provided in Chapter 7 have confirmed the existence of discrepancies in the practice of the NPOs regarding the granting of SPCs and refusal of SPC applications. This is true, *inter alia*, for the intensity, scope and length of the examination and also for the understanding and implementing of the CJEU case law.
- A difference between the SPC Regulations and other fields of EU law such as competition law is the absence of soft law and implementing rules that could assist the national offices in applying the SPC Regulations. The enactment of soft law or implementing rules could improve the level of uniformity of national practice. It would improve the efficiency of the system if the Unitary SPC Division and the NPOs could operate under a uniform legal framework, including common implementing rules and guidelines for the examination that could apply – *mutatis mutandis* – to proceedings before both the Unitary SPC Division and the NPOs.
- We have provided some examples where further unification could increase the transparency of the SPC granting system, reduce the divergences in the practice of the NPOs, or which are meaningful for other reasons. With a view to improving transparency of the SPC granting procedure and the quality of the rights granted, the following suggestions are made: allocating to third parties the right to submit observations with the corresponding obligation of the NPOs to provide reasoning for the decision to grant the SPC; allowing oppositions; creating a common register of national MAs; stipulating a fixed time period within which offices must decide on the SPC application; and revocation *ex officio* of SPCs in case of revocation or limitation of the basic patent. Further proposals concern incorporating in the SPC Regulations provisions dealing with the calculation of terms and deadlines; regulating the effects of a surrender or revocation of an SPC; and defining the right conferred by the SPC application. The proposals also deal with the examination carried out by examining offices. Possible cooperation forms between NPOs and the future Unitary SPC Division were also adressed.

PART FOUR:

UNITARY PATENT PACKAGE AND SPCS

21 UNITARY PATENT PACKAGE AND SPCS: ISSUES *DE LEGE LATA*

21.1 INTRODUCTION

The entry into force of the UPCA will trigger the materialization of the whole Unitary Patent Package.[1674] The Patent Package consists of three main sources of law:

- Regulation (EU) No 1257/2012 of the European Parliament and of the Council of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection (hereinafter: Reg. 1257/2012);
- Regulation (EU) No 1260/2012 of 17 December 2012 of the European Parliament and of the Council implementing enhanced cooperation in the area of the creation of unitary patent protection with regard to the applicable translation arrangements (hereinafter: Reg. 1260/2012);
- The Agreement on the Unified Patent Court (UPCA).

On the basis of these primary sources of law, secondary provisions can be (and partly have been) adopted to implement the Unified Patent System. Two sets of rules are primarily relevant for our analysis:

- The Rules of Procedure of the Unified Patent Court (hereinafter: Rules of Procedure);[1675]
- The Rules relating to Unitary Patent Protection adopted by Decision of the Select Committee of the Administrative Council of 15 December 2015[1676] (hereinafter: Unitary Patent Protection Rules).

Regarding the nature of these different legal acts, Reg. 1257/2012 and Reg. 1260/2012 are an integral part of the Union legal order. The UPCA is a multilateral agreement concluded by the EU Member States (with the exception of Spain, Poland and Croatia) without the participation of the EU itself. Therefore, the treaty is not part of the Union legal order. However, the UPCA includes a dynamic reference to the whole system of Union law, including the fundamental rights and principles of the Union legal order.[1677]

Regarding the function of these different sources of law, Reg. 1257/2012 has established the European patent with unitary effect, while Reg. 1260/2012 deals with the language regime of the unitary patent.

The UPCA, by contrast, fulfils two different and complementary purposes to those of Reg. 1257/2012 and Reg. 1260/2012. On the one hand, it creates a court common to the Signatory Member States that will decide on the infringement and validity of European patents, the Unified Patent Court (UPC). On the other hand, it adopts substantive uniform provisions in some matters which under the EPC are governed by national law, e.g. the rights conferred by the patent and the limitations of such rights (Arts. 25-29 UPCA). The EPC, in this respect, refers to the law governing national

[1674] The UPCA will enter into force when 13 states, including UK, DE and FR, have deposited the instrument of ratification.
[1675] See 18th draft of Rules of Procedure of 19 October 2015, available at https://www.unified-patent-court.org/sites/default/files/UPC-Rules-of-Procedure.pdf (last accessed 18 October 2017).
[1676] SC/D 1/15 [2016] OJ EPO A39, 1.
[1677] See Art. 20 UPCA.

patents (Art. 2(2) and Art. 64 EPC), but the UPC, in accordance with Art. 149a EPC, will have to apply Arts. 25-29 UPCA to the European patent without unitary effect. To this extent the substantive provisions of the UPCA replace the national law governing national patents to which Art. 64(1) and (3) EPC refer. However, the law on infringement laid down in the UPCA is not exhaustive. For many aspects, such as accessory liability, the UPCA does not include any provisions.

The Rules of Procedure will be adopted by the Administrative Committee of the UPC.[1678] Pursuant to Art. 41(1) UPCA the Rules of Procedure lay down the details of the proceedings before the Court. On the one hand, they contain an exhaustive and self-sufficient procedural code for the UPC. On the other, they regulate some aspects that concern the status of the IP rights before a proceeding is initiated, such as the exercise of the option to remove European patents and SPCs from the exclusive competence of the UPC.

The Unitary Patent Protection Rules are relevant for filing a request for unitary effect. They regulate in more detail the tasks of the EPO in processing the requests for such unitary effect.

The Patent Package will have a significant impact on SPCs granted on the basis of European patents. This impact concerns both jurisdiction and applicable law. From a jurisdictional point of view, the SPCs granted by the NPOs will become subject to the jurisdiction of the UPC. With regard to the applicable law, the substantive provisions of the UPCA will apply to both European patents and SPCs.

The inclusion of SPCs in the unified patent system is undoubtedly consistent with the purpose of the UPCA, which is to create a common jurisdiction for the EU Member States that is specialised in patent law and that, ultimately, can replace the fragmented national systems of enforcement and revocation of European patents. The SPC, as a *sui generis* right, is strictly interrelated with the basic patent that was designated by the applicant for the granting procedure. The reasons that justify a specialised and unified jurisdiction over patents are therefore also valid for a specialised jurisdiction over SPCs. At the same time, however, the sources of law do not sufficiently take into account the complexity of Reg. 469/2009 and Reg. 1610/96. The interaction between the SPC legislation and the Patent Package has not been fully considered by the EU legislature. Consequently, the wording of the UPCA and of Reg. 1257/2009 raises several interpretative issues *de lege lata*.

The entry into force of the Patent Package also poses some questions *de lege ferenda*. While it will be possible to enforce several SPCs through a single action before the UPC, it is not possible under the prevailing opinion to obtain SPC protection in the participating EU States through a single procedure. The entry into force of the UPCA therefore again raises some of the recurrent issues concerning national rights in a common market. The questions are:

- How can it be avoided that an SPC applicant must undergo multiple procedures (with the risk of diverging decisions) in order to get SPC protection in the various EU Member States?
- How can a duplication of work among the NPOs be avoided?

[1678] See Art. 11 UPCA in conjunction with Art. 41 UPCA.

- How can the burden on competitors be reduced in clearing the way to the common market for a product covered by multiple national SPCs?

These questions are the subject of Chapter 22. This Chapter focuses on the questions *de lege lata* raised by the Patent Package.

21.2 ISSUES *DE LEGE LATA* CONCERNING THE INTERPLAY OF REG. 1257/2012 WITH REG. 469/2009 AND REG. 1610/96

21.2.1 The nature of unitary patents

The European patent with unitary effect is not a new title of protection that may be requested by and granted to the applicant on the basis of one patent application. Instead, the European patent with unitary effect is the result of two different attributes and presupposes the filing of two different requests. These two features are:

- A European patent granted by the EPO;
- A unitary effect registered by the EPO.

The two requests are, respectively:

- The application for a European patent filed under Art. 58 EPC;
- A request for unitary effect filed under Rule 5 of the Unitary Patent Protection Rules in conjunction with Art. 3(1) Reg. 1257/2012.

The request for unitary effect may be filed only by the proprietor of a granted European patent. The registration of the unitary effect is subject to the substantive requirements laid down in Rule 5(2) in conjunction with Art. 3(1) Reg. 1257/2012 and to the formal requirements laid down in Rule 6 in conformity with Art. 9 Reg. 1257/2012.

As to the former, the unitary effect is registered only where the European patent has been granted "with the same set of claims in respect of all the participating Member States".[1679] The latter stipulates that the request must be filed with the EPO within a deadline of one month after the publication of the mention of grant of the European patent.

The decision to reject a European patent application is subject to appeal before the Boards of Appeal of the EPO, but not before the UPC. In turn, the decision of the EPO to reject a request for unitary effect is subject to action before the UPC,[1680] but it is not clear whether it will be subject to appeal before the Boards of Appeal of the EPO.

When the opposition division of the EPO revokes a European patent for which unitary effect has been requested and registered, no appeal is possible before a court external to the European Patent Organisation. However, again, this decision just concerns the European patent. It does not touch on the unitary effect of a patent. Since the unitary effect requires the existence of a European patent, the collateral effect of the decision

[1679] Art. 3(1) Reg. 1257/2012.
[1680] Art. 32(1) UPCA. See also Rule 23 Unitary Patent Protection Rules.

to revoke a patent is that the unitary effect will likewise cease to exist *de jure* pursuant to Art. 3(3) Reg. 1257/2012.

21.2.2 Unitary effect. The applicable law

The concept of a unitary effect of the patent warrants some clarification. The pertinent provision in this regard is Art. 3(2) Reg. 1257/2012, according to which the unitary patent will have "a unitary character" and provide "uniform protection and shall have equal effect in all the participating Member States". As a consequence, the unitary patent may only be "limited, transferred or revoked, or lapse, in respect of all the participating Member States".[1681]

What really distinguishes a unitary right from a bundle of national rights is not the uniformity of protection or of the applicable law in each of the participating Member States. Classic European or national patents are also subject to a law that is largely uniform in all Member States, due to the fact that the *jus excludendi* is governed by provisions which are identical in their wording to Art. 28 TRIPS. With the coming into force of the UPCA, classic European patents will moreover be subject to a uniform law on infringement, as Arts. 25-30 UPCA apply to European patents both with and without unitary effect.

Rather than providing for legal uniformity, the distinctive feature of a unitary right is that it conflates the territories of the participating Member States to which the unitary effect applies into one *unified territory of protection*.[1682] The territorial boundaries of each contracting State do not apply.[1683]

21.2.3 The issues of Reg. 1257/2012 with respect to SPCs

The applicability of Reg. 1257/2012 to SPCs poses two interpretative challenges regarding the SPC legislation.

21.2.3.1 Can an SPC be granted by an NPO if the basic patent is a unitary patent?

The first question raised by the interaction of Reg. 1257/2012 with Reg. 469/2009 is a simple one: whether, on the basis of a European patent with unitary effect, the patent proprietor may request, and the NPO may grant, an SPC.

The answer to this question seems to be straightforward. The European patent that enjoys a unitary effect under Reg. 1257/2012 is a European patent. The unitary effect is only a contingent and optional feature, an accessory quality that the right receives upon a separate request filed by the applicant with the EPO. The registration of the unitary effect does not change the nature of the patent concerned, which remains a

[1681] Art. 3(2), second sentence Reg. 1257/2012.

[1682] See Rudolf Kraßer, *Patentrecht* (6th edn, Beck 2009) p. 97; Roberto Romandini, Alexander Klicznik, 'The Territoriality Principle and Transnational Use of Patented Inventions – The Wider Reach of a Unitary Patent and the Role of the CJEU' [2013] IIC 524.

[1683] See also Art. 142 EPC, according to which a group of Member States that has provided by a special agreement that a European patent granted for those states has *unitary character throughout their territories* may provide that a European patent may only be granted jointly in respect of all those states. Reg. 1257/2012, according to its sixth recital, constitutes a special agreement within the meaning of Art. 142 EPC.

European patent within the meaning of Art. 2 EPC. Indeed, an opposition pursuant to Art. 99 EPC is possible against such a patent with unitary effect, and a revocation of such a patent pronounced pursuant to Art. 100 EPC is equally admitted.

As explained in Chapter 9, the notion of basic patent in accordance with Recital 7 of Reg. 469/2009 includes both European and national patent.[1684] For this reason, it is submitted that the patent owner can designate a European patent with unitary effect as a basic patent for the purpose of the procedure for granting a certificate and obtain said certificate, as long as the further requirements under Art. 3 Reg. 469/2009 are met. This is also the opinion of all the NPOs that answered the MPI Questionnaire for NPOs.[1685] Speakers and participants at the MPI Workshop likewise agree[1686] with this conclusion.

The Explanatory Memorandum confirms this conclusion. Indeed, when commenting on Art. 2 of the Proposal for a Regulation on Medicinal Products, it states:

> This article determines the scope of the Proposal. It refers to any product that is the subject of both a system of protection by patent and a system of administrative authorisation prior to its being placed on the market. It is specified that the authorisation concerned is that provided for in Directives 65/65/EEC and 81/85/EEC, thereby making it clear that the proposal applies only to medicinal products for human and veterinary use. On the other hand, the text does not state under what kind of law patent protection is given and it follows from this that the proposal applies to all pharmaceutical products protected by patent in all of the Member States, whether this be a national patent, a European patent or, in due course, a Community patent.

If the Proposal for a Regulation on Medicinal Products was intended to apply to European patents and Community patents, it will *a fortiori* be applicable to a European patent that enjoys a unitary effect, which is a European patent within the meaning of Art. 2 EPC.

Also, Rule 16 of the Unitary Patent Protection Rules takes for granted that the issue of SPCs on the basis of a unitary patent is consistent with Art. 3 Reg. 469/2009 and Art. 3 Reg. 1610/96. This understanding has also been adopted by the German legislature. The German draft for a law amending the national patent act in consequence of the UPCA[1687] provides that the German Patent Office may grant an SPC on the basis of a unitary patent.[1688] Of course, neither national provisions implementing the Patent Package nor European secondary provisions implementing the unitary effect control the interpretation of Art. 3 Reg. 469/2009. Whether the grant of an SPC is possible depends only on an autonomous interpretation of Art. 3 Reg. 469/2009. However, the legislation referred to above provides evidence that the understanding of Art. 3 Reg. 469/2009 endorsed by this Study is widely shared by those actively involved in interpreting the UPCA and shaping the unitary system, and even by national lawmakers. However, for the sake of clarity, it is proposed that Art. 1(c) Reg. 469/2009 be reformulated as follows:

> "Patent" means a European patent granted under the provisions of the EPC that enjoys unitary effect by virtue of Regulation (EU) No 1257/2012, a European patent granted under the provisions of the EPC that does not enjoy unitary effect by virtue of Reg. 1257/2012, or a

[1684] Chapter 9, Section 9.4.
[1685] See Q72 of MPI Questionnaire for the NPOs, Annex VI of this Study.
[1686] Thus the analysis of Prof. Dr. Ansgar Ohly, MPI Workshop, 20-21 March 2017.
[1687] Bill 18/8827 has been approved by both the Federal Council and the Parliament, but is still to be signed by the President because a constitutional complaint is pending directed against the releated Bill 18/11137 implementing the UPCA.
[1688] Art. 1 Bill 18/8827.

national patent granted under the national law of the Member States.

"Basic patent" means a patent which protects a product as such, a process to obtain a product, or an application of a product, and which is designated by its holder for the purpose of the procedure for grant of a certificate.

21.2.3.2 … and with what legal effect?

The second question raised by the interaction of Reg. 1257/2012 with Reg. 469/2009 concerns the legal effect of the granted certificate. If a patent proprietor files an application for a certificate and designates for this purpose a European patent with unitary effect, and this application is filed at the French and German NPOs, assuming that each of these offices grants an SPC, what are the rights resulting from the titles of protection granted? Is the effect of the German SPC limited to Germany, or does this effect extend to France and other EU Members? Is such effect governed by national law or Union law in conjunction with the UPCA? Two interpretations are in principle possible.[1689]

(a) *First theory: Each SPC granted by an NPO grants the same rights as the basic patent*

According to Art. 5 Reg. 469/2009 an SPC grants the same right and is subject to the same obligations as the basic patent designated in the application for the certificate. The same principle is confirmed with a purely declaratory purpose by Art. 30 UPCA.[1690] Reg. 469/2009 also refers to the law governing the basic patent. In the case of a unitary patent, the relevant provisions are laid down in Arts. 3 and 5 Reg. 1257/2012. Art. 3 Reg. 1257/2012 reads as follows:

1. A European patent granted with the same set of claims in respect of all the participating Member States shall benefit from unitary effect in the participating Member States provided that its unitary effect has been registered in the Register for unitary patent protection.
   A European patent granted with different sets of claims for different participating Member States shall not benefit from unitary effect.
2. A European patent with unitary effect shall have a unitary character. It shall provide uniform protection and shall have equal effect in all the participating Member States. It may only be limited, transferred or revoked, or lapse, in respect of all the participating Member States.
   It may be licensed in respect of the whole or part of the territories of the participating Member States.

Article 5 reads as follows:

1. The European patent with unitary effect shall confer on its proprietor the right to prevent any third party from committing acts against which that patent provides protection throughout the territories of the participating Member States in which it has unitary effect, subject to applicable limitations.
2. The scope of that right and its limitations shall be uniform in all participating Member States in which the patent has unitary effect.
3. The acts against which the patent provides protection referred to in paragraph 1 and the applicable limitations shall be those defined by the law applied to European patents with unitary effect in the participating Member State whose national law is applicable to the European patent with unitary effect as an object of property in accordance with Article 7.
4. In its report referred to in Article 16(1), the Commission shall evaluate the functioning of the applicable limitations and shall, where necessary, make appropriate proposals.

[1689] Charlotte Weekes, 'Getting the end-game right – SPCs and unitary patents in Europe', available at https://www.pinsentmasons.com/PDF/2016/getting-the-end-game-right.pdf (last accessed 18 October 2017).

[1690] Art. 30 UPCA reads as follows: "A supplementary protection certificate shall confer the same rights as conferred by the patent and shall be subject to the same limitations and the same obligations".

The wording of Art. 5(3) Reg. 1257/2012 differs from the wording of Art. 7 Reg. 1257/2012. The latter refers to the law applicable to national patents. Art. 5(3) Reg. 1257/2012 by contrast refers to the "law applied to European patents with unitary effect in the participating Member State whose national law is applicable to the European patent with unitary effect as an object of property in accordance with Article 7". In this way, Art. 5(3) Reg. 1257/2012 refers indirectly, but clearly, only to the law on infringement laid down in the UPCA. This conclusion results from the following arguments:

Firstly, pursuant to Art. 18(2) Reg. 1257/2012 a European patent only has unitary effect in the participating Member States in which the UPC has exclusive jurisdiction pursuant to the UPCA. In turn, the UPC will only have exclusive jurisdiction over European patents with unitary effect for those EU Member States that have ratified the UPCA. Therefore, in each participating Member State in which the European patent will benefit from a unitary effect, the UPCA will necessarily be an integral part of the legal order of that state. Otherwise a unitary effect could not apply to that territory.

Secondly, provisions dealing with the infringement of a European patent that benefits from a unitary effect by virtue of Reg. 1257/2012 are laid down in Arts. 25-30 UPCA. Such provisions have a double effect. On the one hand, they dictate the law on infringement applicable to the patent subject to the jurisdiction of the UPC. On the other hand, they prevent the UPCA contracting states from adopting diverging rules that deal with the infringement of the unitary patent. As a result, Art. 5 Reg. 1257/2012 has the purpose and the effect to refer, indirectly, to Arts. 25-30 UPCA, and not to the rules governing national patents. Of course, for aspects relevant to the law on infringement that are not addressed in the UPCA, for instance, accessory liability, a lacuna exists. It will be the task of the UPC to fill this lacuna.

The combined effect of Art. 3 and Art. 5 Reg. 1257/2012 is that the rights conferred by Arts. 25 et seq. UPCA include the territory of the participating Member States as a "unified territory of protection". Therefore, one could argue that since the SPC legislation just refers to the law governing the patent, the SPC will have the same effect as the designated basic patent: it will consist of a unitary right with effect in the same territory in which the basic patent has effect. As Art. 3(c) Reg. 469/2009 excludes the grant of an SPC to the same patent proprietor when the product has already been the subject of a certificate, the system itself would prevent that a patent holder could get multiple unitary SPCs by filing requests in several or all countries in which the patent has unitary effect.[1691]

[1691] This provision does not apply when the product is the subject of an SPC application in Germany even if the same patent holder has already obtained on the basis of the same European patent an SPC in the UK, because the UK SPC – like the UK designation of the designated European patent – does not have effect in Germany. This situation would change if the patent designated for the purpose of the procedure were a unitary patent. After the first NPO has granted an SPC, Art. 3(c) Reg. 469/2009 would effectively prevent the grant of other SPCs by other NPOs. As a matter of law, an SPC with effect in the Member State concerned has already been issued to the patent proprietor. If despite that SPCs are granted, they would be invalid under Art. 3(c) Reg. 469/2009. The patent proprietor cannot circumvent this provision by partially transferring the patent, because the unitary effect can only be transferred as such for the whole territory to which it applies.

(b) *Second theory: SPCs based on unitary patents do not have the same effect as the basic patent*

According to the opposite view, an SPC granted by the NPOs remains a national *sui generis* right, even if the associated patent is a unitary patent.[1692] This theory is based on the following arguments:

- The granting authorities are NPOs. National authorities can only grant rights limited to the territory of the respective state.
- No provisions concerning a common register for SPCs with unitary effect, the granting authority or the judicial review of the decision on grant are laid down in Reg. 1257/2012 or elsewhere.[1693]
- A theory according to which Reg. 469/2009 already provides for SPCs with unitary effect would not be compatible with the requirement that an MA be granted in the country for which the SPC is requested. Indeed, in this case either one accepts that an SPC may be granted or is valid only when an MA exists in all Member States on the filing date, or one accepts that an SPC may be granted with effect in a territory where no MA was issued. Both options seem to conflict with the purpose and objective of the requirements provided for under Art. 3 Reg. 469/2009.

In essence this means that the introduction of a unitary SPC was not intended by the EU legislature. This view also appears to be shared by the European Commission;[1694] it is supported by the fact that Reg. 1257/2012 was directed to creating a unitary patent without making mention of SPCs.

(c) *Legal assessment*

The drafters of the UPCA have not adequately considered the interaction between SPC legislation and Reg. 1257/2012. As a consequence, Art. 30 UPCA and Art. 5 Reg. 469/2009, which refer both *sic et simpliciter* to the rights conferred by the basic patent, pose some interpretative challenges.

Both theories – that such provision only defines the substance of the rights, but not the territorial scope, and that such rule implies that Art. 3 and Art. 5 Reg. 1257/2012 in conjunction with Arts. 25-30 UPCA apply to the SPC granted on the basis of a unitary patent – are tenable, but both are equally exposed to objections. Such objections follow from the absence of an adequate legislative choice in drafting the applicable legal framework. An evident lacuna, as pointed out by Professor Ansgar Ohly at the MPI Workshop in March 2017, exists in the legal framework with respect to SPCs.

An understanding of the Patent Package in the sense that the bodies designated by the participating EU Member States pursuant to Art. 9 Reg. 469/2009 were not vested with the power to grant rights effective in the territory of other Member States, and

[1692] Michael Nieder, `Einheitspatent, SPC und UPC´ [2016] GRUR Int. 906, 909; see also the presentation of Prof. Dr. Ansgar Ohly, Georgia Roussou, 'SPCs and the EU Patent Package: National rights in an Europeanized Environment or Unitary SPCs?', MPI Workshop, 20-21 March 2017.

[1693] Prof. Dr. Ansgar Ohly, Georgia Roussou, 'SPCs and the EU Patent Package: National rights in an Europeanized Environment or Unitary SPCs'?, MPI Workshop, 20-21 March 2017.

[1694] European Commission, Call for Tender 479/PP/IMA/15/15153, Tender Specification, section 1.1.2. 1.

that the granted rights are national rights, is in our view the preferable one.[1695] Indeed, only such interpretation matches the intention and the expectation of the historical lawmakers and participating Member States. By enacting Reg. 1257/2012 the Member States did not agree upon the substantial limitation of their sovereignty which would follow from accepting the validity in their territory of SPCs granted by the national authority of another EU Member State.

If, therefore, it is accepted that SPCs granted by an NPO on the basis of a unitary patent are national rights, it must be determined what provisions shall apply to such an SPC. The "natural" solution of applying Art. 30 UPCA in conjunction with Arts. 25 et seq. UPCA[1696] is rendered somewhat doubtful by the fact that the latter provisions are applicable only if and to the extent that Art. 3 and Art. 5 Reg. 1257/2012 refer to them. As pointed out under the first theory presented above, this legal mechanism would result in the SPC having the same unitary effect as the basic patent on which it relies.

However, as the argument based on respect of the sovereignty of the EU Member States prevails, a teleological correction of the reference included in Art. 30 UPCA and Art. 5 Reg. 469/2009 to the law applicable to the patent shall be possible. As consequence, the UPC must apply Art. 5(3) Reg. 1257/2012 and Arts. 25-30 to the SPC, but with effect only in the territory for which the SPC concerned was granted.

Against this background, soft law, even if not binding on any court or authority, could provide the argument based on respect of the sovereignty of the Member States with the necessary strength and clarity. A communication of the European Commission in line, for instance, with what has already been done with respect to the interpretation of Art. 4 Dir. 98/44/EC[1697] could facilitate the task of the UPC.

21.2.4 SPCs as objects of property. Further issues of international private law

The SPC Regulations do not contain a general rule that determines the law applicable to SPCs in all matters that are not covered by the SPC Regulations themselves. As mentioned in Chapter 3,[1698] the references to the law governing the basic patent are specific and limited in scope. A provision such as that laid down in Art. 2(2) EPC with respect to European patents, according to which the SPC shall be subject to the same law and conditions as the basic patent unless the SPC Regulations provide otherwise, is missing in the SPC legislation. As a result, there is also no rule indicating which law shall apply to the SPCs as objects of property. It is likely that in all national systems the applicable law is the law governing the basic patent. The lack of a rule, however, creates some coordination problems with the Patent Package. Art. 7 Reg. 1257/2012 provides that a European patent with unitary effect

[1695] More in general, whether an IP right has regional (unitary) character or national character does not depend on the nature – regional or national – of the office granting it, but on the applicable law. See Reto M Hilty, Roberto Romandini, *Developing a common patent system: Lessons from the EU experience* in Elizabeth Siew-Kuan Ng, Graeme W Austin (Hg.), INTERNATIONAL INTELLECTUAL PROPERTY AND THE ASEAN WAY – PATHWAYS TO INTEROPERABILITY (Cambridge University Press 2017) p. 254.

[1696] As proposed for for instance by Michael Nieder, `Einheitspatent, SPC und UPC´ [2016] GRUR Int. 906, 909.

[1697] Commission Notice on certain articles of Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions, C/2016/6997, OJ C 411, 8. November 2016, pp. 3-14.

[1698] See above, Chapter 3, Section 3.3.2.8.

> as an object of property shall be treated in its entirety and in all the participating Member States as a national patent of the participating Member State in which that patent has unitary effect and in which, according to the European Patent Register:
> (a) the applicant had his residence or principal place of business on the date of filing of the application for the European patent; or
> (b) where point (a) does not apply, the applicant had a place of business on the date of filing of the application for the European patent.

It is unclear whether this provision also applies to the SPC that the holder has requested by designating a unitary patent as a basic patent. One author has rules out the applicability of such a rule to SPCs, since the latter are national and unitary rights.[1699] The reason why this provision may not apply, however, is not the nature – national or unitary – of the right granted on the basis of a unitary patent, but the absence of a reference to the law governing the basic patent for matters other than the rights,[1700] the scope of protection[1701] and the procedure.[1702] Of course, the absence of a rule ensuring that a uniform law applies to all SPCs granted on the basis of the same unitary patent makes transactions with patent portfolios and associated SPCs more complicated, since basic patents and SPCs can be subject to diverging conditions as objects of property. Therefore, it is recommended that the legislature address the lacunae identified above.

First, the SPC Regulations should include a general reference to the law governing the basic patent in the matters for which the Regulations do not contain any specific rules. Such a reference should also include the rules of private international law applicable under the law governing said patent.

Second, with respect to unitary SPCs granted on the basis of a unitary patent, the SPCs should be subject to the same law as that designated by Reg. 1257/2012.

Third, in the case that it remains possible to acquire national SPCs on the basis of a unitary patent, Art. 7 Reg. 1257/2012 should not apply to the SPCs that are granted on the basis of a unitary patent but that do not benefit from a unitary effect.

21.3 INTERACTION BETWEEN UPCA AND SPCS

Some minor interpretative issues that could require clarification also exist, according to the prevailing literature, with respect to the interaction between the UPCA and SPCs. Such doubts do not, however, concern the scope of competence of the UPC if one leaves out the problems created by the transitional period rules.

Indeed, pursuant to Art. 2(h) UPCA, "supplementary protection certificate" means a supplementary protection certificate granted under Reg. 469/2009 or under Reg. 1610/96. This definition includes SPCs granted for products protected by a national or a European patent. However, Art. 3 UPCA states that the Agreement applies only to SPCs issued for a product protected by a patent, whereas "patent" pursuant to Art. 2(g) UPCA denotes, for the purposes of the Agreement, only a European patent with or without unitary effect. Therefore, SPCs granted on the basis of national patents remain subject to the jurisdiction of national courts. The same holds true for SPCs granted on the basis of national designations of European patents that have effect for

[1699] Michael Nieder, `Einheitspatent, SPC und UPC´ [2016] GRUR Int. 906, 909.
[1700] Art. 5 Reg. 469/2009.
[1701] Art. 4 Reg. 469/2009.
[1702] Art. 18 Reg. 469/2009.

countries that have not signed or not ratified the UPCA. For instance, SPCs granted for products protected by the Polish or the Spanish fractions of European patents will be subject to the jurisdiction of the respective national courts.

The competence of the UPC is limited to the actions listed in Art. 32(2) UPCA. Pursuant to Art. 32(2) "the national courts shall remain competent for actions relating to patents and SPCs which do not come within the exclusive competence of the Court". The list of actions provided under Art. 32(1) UPCA includes actions concerning decisions of the EPO as well as "actions for damages or compensation" based on a published European patent application. By contrast, Art. 32 UPCA does not mention:

- actions against the decisions of the bodies mentioned by Art. 9 Reg. 469/2009 refusing the grant of an SPC on the basis of a European patent with or without unitary effect;
- actions based on a published SPC application.

As a consequence, national courts maintain jurisdiction over the appeals of decisions of the NPOs that reject an SPC application. If a competent body grants an SPC, however, a third party will be entitled to initiate a revocation action before the UPC.

Pending SPC applications will not be subject to the jurisdiction of the UPC. Whether a published SPC application pursuant to the SPC legislation or national law confers any right is unclear, as already pointed out in Chapter 20.[1703] Art. 5 Reg. 469/2009 and Art. 30 UPCA refer only to granted certificates. No other provision of the UPCA addresses the jurisdictional or legal status of SPC applications within the UPCA system.

So far, the scope of competence of the UPC with respect to SPCs is clear. Possible interpretative doubts concern minor details and the transitional period.

Pursuant to Art. 15(2) Reg. 469/2009, "any person may submit an application or bring an action for a declaration of invalidity of the certificate before the body responsible under national law for the revocation of the corresponding basic patent". If one considers the UPCA to be an integral part of the national law of the Member States since the latter have ratified the Agreement, the reference to national law laid down in Art. 15(2) Reg. 469/2009 will include the provisions that establish the concurring or exclusive jurisdiction of the UPC. However, under national law, the body responsible for the revocation of a European patent is, according to the English version of the EPC, also the EPO when an opposition is filed. Since, however, Art. 19(2) Reg. 469/2009 excludes opposition against SPCs, it is clear on the basis of a systematic interpretation that no parallel action against the grant of an SPC on the basis of a European patent can be initiated before the EPO. Further, since the EPO considers itself bound only by the EPC, the organs of the EPO would reject such oppositions since they are not provided for under Arts. 100 et seq. EPC.

The above-mentioned considerations also apply to the interpretation of Art. 19(1) Reg. 469/2009. According to this provision "in the absence of procedural provisions in this Regulation, the procedural provisions applicable under national law to the corresponding basic patent shall apply to the certificate, unless the national law lays down special procedural provisions for certificates". The wording of this provision

[1703] See Chapter 20, Section 20.3.2.1 (i).

seems to refer to the provisions applicable to the granted patent. But, as already explained, the provision can fulfil its purpose only if the expression "basic patent" is understood as referring to the granted basic patent and corresponding patent application. If interpreted in a literal sense, this provision would imply that the EPC provisions that apply to the European patent, such as that providing the right to amend the patent, will apply to the SPC as well. But such an interpretation is not acceptable, because the national granting office cannot apply the provisions laid down in the EPC when examining SPCs. Therefore, the reference must be understood as pointing to the national law that applies to national patents and patent applications, whether or not in the concrete case the basic patent designated for the purpose of the SPC procedure is a national or a European patent.

After the entry into force of the UPCA, such reference must be understood in the sense that

- up until the grant of the SPC the applicable law is the procedural law applicable to a national patent application filed at the same office that examines the SPC application;
- after the grant of the SPC the procedural law applicable to the granted SPC is, in the case of national patents or European patents that have opted out of the jurisdiction of the UPC, the law applicable to the national patent, and in the case of an SPC subject to the UPC, the provisions laid down in the UPCA and in the Rules of Procedure.

An amended wording of Art. 19 Reg. 469/2009 could clarify the references to the applicable law.

Another question discussed in the literature is whether or not an opt-out under Art. 83(3) UPCA can be declared for the SPC even if the basic patent is subject to the UPC jurisdiction. It is questionable whether the European Commission can address this issue by adopting soft law. Guidance has been provided in this regard by the Rules of Procedure. According to Rule 5(2) RoP it shall not possible to opt out supplementary protection certificates, whether granted by the authorities of a Contracting Member State or otherwise, based on a European patent with unitary effect. Such interpretative issues will have to be answered by the UPC.

21.4 INTERACTION BETWEEN EPC, UPCA AND SPC LEGISLATION

21.4.1 Premise

As already mentioned, the Patent Package will have an impact on "infringing act" rules and "extent of protection" rules that apply to European patents with or without unitary effect. Since there is some controversy in the literature on the law of infringement that applies to European patents with or without unitary effect under the UPCA, and since this issue is relevant for deciding on both validity (Art. 3(a) Reg. 469/2009) and infringement of SPCs (Arts. 25-29 UPCA), some brief comments on this topic are necessary. In this regard we have to distinguish between unitary patents (1.4.2), European patents subject to the competence of the UPC and litigated before the UPC (1.4.3), and European patents opted out of the competence of the UPC under Art.

83(3) UPCA or, even if not opted out, litigated before the national court under Art. 83(1) UPCA (1.4.4).

21.4.2 Unitary patents

As far as unitary patents are concerned, according to Art. 5(3) Reg. 1257/2012

> "the acts against which the patent provides protection referred to in paragraph 1 and the applicable limitations shall be those defined by the law applied to European patents with unitary effect in the participating Member State whose national law is applicable to the European patent with unitary effect as an object of property in accordance with Article 7. "

According to Art. 7 Reg. 1257/2012

> "a European patent with unitary effect as an object of property shall be treated in its entirety and in all the participating Member States as a national patent of the participating Member State in which that patent has unitary effect and in which, according to the European Patent Register:
> (a) the applicant had his residence or principal place of business on the date of filing of the application for the European patent; or
> (b) where point (a) does not apply, the applicant had a place of business on the date of filing of the application for the European patent."

A part of the literature draws from these two provisions the conclusion that the rights conferred by the patent and the limitations to such rights are those provided by the law that applies to the national patent of the state whose law applies to the unitary patent as object of property pursuant to Art. 7 Reg. 469/2009.[1704] We disagree with this conclusion[1705]. According to Art. 5(3) Reg. 1257/2012, the rights and the limitations to such rights are those defined by the law applied in the Member States concerned to the European patent with unitary effect, and not those defined by the law applied to national patents. In each participating Member State, such provisions will be the norms of the UPCA and the EPC that respectively regulate the rights and the scope of the patent. Indeed, the unitary effect pursuant to Art. 18 Reg. 1252/2012 may apply only to those EU Members that have ratified the UPCA and whose legal order includes Arts. 25-29 UPCA (and Art. 69 EPC). As a consequence, the rights conferred by the unitary patent and the limitations to those rights are governed by Arts. 25-29 UPCA in each Member State.

21.4.3 European patents without unitary effect

As far as European patents without unitary effect subject to the exclusive competence of the UPC are concerned, nothing will change for the scope of protection. Art. 69 EPC will continue to apply after the entry into force of the UPCA. With respect to the rights conferred by the patent, Arts. 25-28 UPCA apply instead of the national provisions to which Art. 2(2) EPC and Art. 64(1) EPC refer. This opinion is subject to a qualification in a part of the literature, according to which the UPC rules are applicable to the European patent without unitary effect only if they apply to national patents as well. This is inferred from the fact that the UPCA cannot amend the EPC, and from the plain wording of Art. 2(2) EPC, pursuant to which "the European patent shall, in each of the Contracting States for which it is granted, have the effect of and be subject to the

[1704] See for this opinion, for instance, Darren Smyth, 'Harmonisation by the back door - what will the Unified Patent Court Agreement do to the law of patent infringement?' 7 April 2013, available at http://ipkitten.blogspot.de/2013/04/harmonisation-by-back-door-what-will.html (last accessed 18 October 2017); Horst Vissel, `Die Ahndung der mittelbaren Verletzung Europäischer Patente nach dem Inkrafttreten des EPGÜ´ [2015] GRUR 619, 620.

[1705] See already above, Section 21.2.3.2.

same conditions as a national patent granted by that State, unless this Convention provides otherwise", as well as of Art. 64(2) EPC, pursuant to which

> a European patent shall, subject to the provisions of paragraph 2, confer on its proprietor from the date on which the mention of its grant is published in the European Patent Bulletin, in each Contracting State in respect of which it is granted, the same rights as would be conferred by a national patent granted in that State.

As a consequence, it is argued that the substantive provisions of the UPCA that define the rights and their limitations may apply to European patents only if they apply to national patents as well, because both national and European patents must be subject to the same condition and law of infringement under the EPC. This opinion is not convincing, because it does not consider the implications of Art. 149a(1) EPC and of the second sentence of Art. 2(2) EPC, according to which the European patent is subject to national law unless the EPC provides otherwise. One of the exceptions allowed by the exceptive proposition "unless the EPC provided otherwise" is laid down in Art. 149a(1) EPC, according to which the Contracting States have the right "to conclude special agreements on any matters concerning European patent applications or European patents which under this Convention are subject to and governed by national law". The UPCA is one such special agreement. In consequence, its provisions apply to European patents under Art. 2(2) EPC and Art. 149a(1) EPC in proceedings before the UPC, whether or not the Contracting States in implementing the UPCA decide to align national patent law with Arts. 25-29 UPCA.

21.4.4 European patents opted out or litigated before national courts after the entry into force of the UPCA

As concerns European patents opted out of the competence of the UPC under Art. 83(3) UPCA or European patents litigated before the national courts under Art. 83(1) UPCA, the scope of the patent will be governed by Art. 69 EPC in accordance with Art. 2(2) EPC, while the rights conferred by the patent and the applicable limitations are governed according to the predominant option[1706] by national law.

21.4.5 Implication for SPCs

The enter into force of the UPCA will have the following implications from the perspective of substantive law for SPCs:

- If the SPC is requested on the basis of a unitary patent or a European patent without unitary effect, but subject to the competence of the UPC, the question whether the product is protected by the basic patent pursuant to Art. 3(a) of the SPC legislation is governed by Art. 69 EPC and by the further criteria developed by the CJEU. Nothing will change also.
- If the SPC has been granted on the basis of a European patent with unitary effect or a European patent subject to the competence of the UPC, the scope of protection and the rights conferred by the SPCs will be governed by Arts. 25-30 UPC and Art. 69 EPC. However, for SPCs granted on the basis of European

[1706] UPC Preparatory Committee, Interpretative note - Consequences of the application of Article 83 UPCA (January 29, 2014), http://www.unified-patent-court.org/news/71-interpretative-note-consequences-of-the-application-of-article-83-upca [Accessed May 1, 2017]. See for a different opinion Roberto Romandini/Reto Hilty/Matthias Lamping, 'Stellungnahme zum Referentenentwurf eines Gesetzes zur Anpassung patentrechtlicher Vorschriften auf Grund der europäischen Patentreform' [2016] 65(6) GRUR Int. 554.

patents without unitary effect this is true only when they are enforced before the UPCA.

- If the SPC has been granted on the basis of a European patent opted out from the competence of the UPC or the SPC is litigated before the national courts under Art. 83(1) or (3) UPCA, then the national courts according to the prevalent view have to apply national law.
- As far as the revocation of SPCs is concerned, nothing will change. Art. 15 Reg. 469/2009 and Art. 3 Reg. 469/2009 will continue to apply under Art. 20 UPCA if the SPC is subject to a revocation action or counterclaim for revocation before the UPC.

21.5 SUMMARY

- It is possible for the NPOs to grant an SPC on the basis of a European patent with unitary effect because such an IP right remains a patent within the meaning of Art. 1(c) Reg. 469/2009 and a European patent within the meaning of Art. 2(1) EPC.
- An interpretation of Art. 30 UPCA and Art. 5 Reg. 469/2009 that gives precedence to concerns of sovereignty of the EU Member States leads to the conclusion that an SPC granted on the basis of an unitary patent confers the rights granted by Art. 30 UPCA only for the territory in which IP rights granted by the national authority concerned have effect. The territorial scope of an SPC issued on the basis of an unitary patent by a NPO is coextensive with the territorial scope of a national patent granted by the same NPO.
- Art. 7 Reg. 1257/2012 should not apply to SPCs that are granted on the basis of a unitary patent but that do not benefit from a unitary effect. A rule defining the law applicable to the SPCs as objects of property is appropriate.

22 ISSUES *DE LEGE FERENDA*: SPCS WITH UNITARY EFFECT

22.1 INTRODUCTION

22.1.1 The practical needs a unitary SPC is supposed to satisfy

The contributions at the MPI Workshop on 20-21 March 2017, the opinions of the stakeholders collected by the quantitative Allensbach Survey, the submissions of the industrial organisations to the MPI Seminar on 11 September 2017, and finally the qualitative interviews with companies have all confirmed that in the perception of the stakeholders a need for an SPC with unitary effect exists. The European Commission itself has pointed out that such an SPC with unitary effect is necessary for completing the Patent Package and ensuring a smooth functioning of the common market. Before we tackle the issue of how to achieve that result, it is important to identify exactly what the needs are that such a "unitary SPC" is supposed to satisfy.

Regional unitary rights are intended to meet two practical necessities[1707]:

- On the one hand, the purpose of the regional unitary right is to reproduce the conditions for acquiring a right valid in the whole region that are equivalent to the conditions existing under the relevant national IP systems. Accordingly, just as in the individual Member States domestic law provides the applicant with the opportunity to obtain protection for the whole national market through a single application and procedure, so the regional law intends to provide the applicant with the opportunity to obtain protection for the whole regional market through a single application and procedure.
- On the other hand, the creation of a unitary right should make it possible for the right holder to react through a single action against infringing acts that have occurred in one or several Member States or for the competitors to remove through a single action an IP right covering a specific product. Here as well, the purpose of the regional right is to reproduce at regional level standards of enforcement and defence that are equivalent to those existing – under national law – for the national markets.

Of course, unitary rights have further functions within the Union legal order.[1708] They constitute an instrument for preserving the integrity of the Union market and for implementing specific regional policies. However, from the perspective of the stakeholders the latter aspects represent rather peripheral concerns.[1709]

Now turning to the SPC with unitary effect and considering which practical needs, from the perspective of the stakeholders, such a title of protection should satisfy, it is clear that the second need mentioned – regional enforcement through a single proceeding

[1707] Reto M Hilty, Roberto Romandini, *Developing a common patent system: Lessons from the EU experience* in Elizabeth Siew-Kuan Ng, Graeme W Austin (eds.), INTERNATIONAL INTELLECTUAL PROPERTY AND THE ASEAN WAY – PATHWAYS TO INTEROPERABILITY (Cambridge University Press 2017) p. 254 et seqq.

[1708] *Ibid.,* p. 254.

[1709] It is equally obvious that the unitary or non-unitary character of a right is not a necessary condition for providing the applicant with a single procedure and single enforcement mechanism in a specific region. Such result can also be obtained through other systems than unitary rights. The European patent system offers an example of this. The European patent does not have unitary character under the EPC. Despite that, the EPC ensures that the applicant can obtain protection in multiple EPC Contracting States through a single application and granting procedure.

and regional revocation through a single action – is no longer relevant. In fact, with the entry into force of the UPCA, the stakeholders have the opportunity to enforce different national SPCs in one action before the UPC,[1710] just as competitors may remove the bundle of SPCs granted on the basis of the same European patents through a single action before the UPC.[1711]

The other practical necessity – to obtain an SPC through a single procedure – is by contrast more relevant than ever for SPC applicants. At the moment, it is not possible to obtain SPC protection in several Member States through a single procedure. Multiple applications and procedures are necessary for this purpose. Several patent agents need to be consulted, paid and entrusted with the filing of the national SPC applications. The different NPOs have to examine applications that are almost identical, (notwithstanding the fact that the underlying MA may vary between countries). This not only causes a duplication of work, but also creates room for diverging evaluations. As a result of these diverging evaluations, an SPC can be granted in one country, denied in another, or granted in all countries, but with a different product definition. As a consequence, the same product could be covered by SPC protection in one country, but not in another, although for both countries the same basic patent is in force, and equivalent MAs or the same European MA was supplied, and the same SPC application was filed. The creation of an SPC with unitary effect should offer relief in such situations. It can prevent diverging decisions on the grant of the SPC on the basis of the same set of facts. In this way it could also avoid a division of the common market into SPC-protected and SPC-free areas. Of course, this result will only be fully achieved upon the condition that a parallel protection through national and unitary SPCs for the same subject matter is prohibited. If an accumulation of unitary SPC and national SPCs for the same subject matter was possible, then the risk existing under the current system for diverging decisions will persist.[1712] Further, such double protection would create a heavier burden on competitors in clearing the way to the market of invalid rights.[1713] However, current SPC legislation already includes a prohibition of double protection in Art. 3(c) Reg. 469/2009.

The need that the unitary SPC should satisfy is therefore the creation of a procedural route to obtain protection in the whole region through a single procedure. It is clear that to satisfy this need, the unitary or non-unitary character of the right resulting

[1710] As we have seen, the UPC will apply uniform rules of infringement to the SPC granted on the basis of a European patent. The creation of an SPC with unitary effect would not imply significant qualitative differences for enforcement in this regard. Admittedly, in some technological fields – such as telecommunication – a practical qualitative difference exists between a bundle of rights and a unitary right. This is true even when both are enforceable and subject to uniform provisions and cover exactly the same territory. But in the field of chemistry and pharmacology, it is likely that for the patentee it does not imply any difference to have a bundle of European patents (or SPCs) or a unitary patent (or SPC), as long as the two categories of rights cover the same territory and can be enforced before the UPC. Possible differences can result from the fees and the translation costs that may be different in the case of an SPC with unitary effect and a bundle of SPCs.

[1711] It is true, however, that as long as SPCs remain national rights, their scope might differ, if and to the extent that they were granted on the basis of incongruent national MAs. Thus, while enforcement (and invalidation) in one single venue are possible, lack of unification could make such actions more complicated. However, the large majority of SPCs are granted on the basis of Union authorisations or national authorisations granted within the DP or MRP. National MAs granted within the contest of DP and MRP presents an uniform wording as the identification of the active substance(s) is concerned.

[1712] Although it may be mitigated if further harmonizing measures are put in place; see above, Chapter 20, Section 20.3.4.

[1713] The MPI is of the opinion that the current SPC Regulations already prohibit double protection under Art. 3(c), but this provision, in order to be effective, requires clarification regarding its scope; see Chapter 12 of this Study.

from the procedure is not crucial for the applicant, as enforcement before the UPC will be possible in both cases. However, the question whether the right thus created is a unitary title of protection or not is relevant from the perspective of EU lawmakers, as it determines the legal basis for such legislation. The creation of unitary rights is covered by Art. 118 TFEU, whereas this provision is not relevant for the creation or regulation of national rights.

Having this in mind, we will now turn to the question of how to create such SPCs with unitary effect. However, before we consider the introduction of a unitary SPC, and how to create it, we want to briefly address an alternative that could satisfy the same needs as an SPC with unitary effect, but would likely be less of a burden on the lawmaker.

22.1.2 An alternative option to unitary SPCs: The extension of the European patent with unitary effect

Unitary SPCs are not the only instrument conceivable for satisfying the practical needs identified in the previous section. An equivalent legal tool would be the extension of the unitary patent. Indeed the historical reasons that induced the EU lawmakers to create SPCs instead of introducing patent extensions have lost their weight nowadays. These reasons, as recalled in Part One, Chapter 3, Section 3.3.2.2 of this Study, were the existence of European patents alongside national patents and the wording of Art. 63 EPC 1973 that did not allow the extension of European patents in cases such as the delay due to product approval proceedings.[1714] These historical reasons for adopting SPCs are not relevant anymore because EPC has *medio tempore* undergone two significant reforms.

Firstly, since some States were of the opinion that the grant of SPCs on the basis of European patents could be in conflict with Art. 63 EPC 1973[1715], the provision was amended. The new wording of Art. 63 EPC entered into force in 1997[1716], that is, after the SPC Regulations became operative. The provision reads as follows:

> "The term of the European patent shall be 20 years from the date of filing of the application.
> (2) Nothing in the preceding paragraph shall limit the right of a Contracting State to extend the term of a European patent, or to grant corresponding protection which follows immediately on expiry of the term of the patent, under the same conditions as those applying to national patents:
> (a) in order to take account of a state of war or similar emergency conditions affecting that State;
> (b) if the subject-matter of the European patent is a product or a process for manufacturing a product or a use of a product which has to undergo an administrative authorisation procedure required by law before it can be put on the market in that State.
> (3) Paragraph 2 shall apply mutatis mutandis to European patents granted jointly for a group of Contracting States in accordance with Article 142.
> (4) A Contracting State which makes provision for extension of the term or corresponding protection under paragraph 2(b) may, in accordance with an agreement concluded with the Organisation, entrust to the European Patent Office tasks associated with implementation of the relevant provisions."

[1714] See the more extensive elaborations on this point in Chapter 3, Section 3.3.2.2.
[1715] See Chapter 3, Section 3.3.2.2, with references.
[1716] See Act Revising Article 63 EPC of 17 December 1991, entered into force on 4 July 1997 [1992] OJ EPO, 1 et seq.

Secondly, Art. 33(1)(b) EPC was amended by EPC 2000.[1717] The new wording reads as follows:

> "1) The Administrative Council shall be competent to amend:
> (…)
> (b) Parts II to VIII and Part X of this Convention, to bring them into line with an international treaty relating to patents or European Community legislation relating to patents;"

This provision has profound consequences for the relationship between EU law and the EPC. EU law can now be implemented in the EPC by the Administrative Council without a revision of the Treaty and ratification by the EPC Contracting States being necessary. Admittedly, unanimity of the EPC members is required for decisions made under Art. 33(1)(b) EPC. However, the majority of EPC states are EU members. In any event, Art. 63 EPC is no longer an obstacle to adopting a patent-extension model for European patents. Therefore, the EU legislature could also decide to introduce an extension of the European patent with unitary effect. The EPO could be entrusted under Art. 63 EPC with the task of receiving and examining the requests for extension of the unitary patents. Decisions taken by the EPO in performing this function could be the subject of an action before the UPC, provided that Art. 32 UPCA is correspondingly amended by the Administrative Committee under Art. 87(2) UPCA and an EU source of law so provides. The jurisdiction of the UPC is already provided for with respect to decisions taken by the EPO regarding a request for a unitary effect. No duplication of rights and no duplication of registers would become necessary. The introduction of unitary extension could be achieved by amending Reg. 1257/2012 where the Member States are obliged to amend the EPC in order to provide for the extension of the basic European patent to which the unitary effect is attached according to conditions that shall be laid down in the Reg. 1257/2012 itself first and reproduced in the EPC then. Against this option two objections are possible.

The first, legal, objection is based on the wording of Art. 63 EPC. According to this provision both the grant of an extension and an SPC are allowed. However, Art. 63 EPC does not seem to admit adopting extensions for European patents while allowing only SPCs for national patents and *vice versa*. According to Art. 63(3) EPC, indeed, Art. 63(2) applies *mutatis mutandis* to European patents granted jointly for a group of contracting states in accordance with Art. 142 EPC. Pursuant to Art. 63(2) EPC, Art. 63(1) EPC does not "limit the right of a Contracting State to extend the term of a European patent, or to grant corresponding protection which follows immediately on expiry of the term of the patent, under *the same conditions as those applying to national patents*". One could infer from this wording that the same conditions must apply to national and European patents; if for national patents only SPCs, but not extensions, are possible, the Contracting States are prevented from providing for the extension of a European patent. So the lawmakers could indeed only make an extension of the unitary patent possible by introducing the same mechanisms for national rights.

While this understanding of Art. 63 EPC may find a backing in the plain wording of the provision, we do not think that it would preclude the creation of a patent-extension model for two reasons:

[1717] Act Revising the Convention on the Grant of European Patents of 29 November 2000, entered into force on 13 December 2007 [2001] OJ EPO, Special Edition No. 1, p. 2 et seq.

- Article 63 EPC requires that the same conditions apply to both European and national patents; but the conditions for granting a patent extension or an SPC may be the same, even if the nature of the granted right is not. So if the lawmakers made the extension of the unitary patent dependent on conditions identical to those provided under Art. 3 Reg. 469/2009 and defined the scope of the extended patent in a corresponding way to Art. 4 Reg. 469/2009, Art. 63(3) EPC in our opinion would be satisfied.
- Even if one argues that Art. 63(2) EPC prohibits the extension of the unitary patent if the latter is not possible for national patents, the EU legislature could require in the Regulation establishing the extension and amending Reg. 1257/2012 that the Member States amend Art. 63(2) EPC. Since such amendment would be necessary to comply with Union law, it could be adopted by the Council pursuant to Art. 33 EPC.

The second objection is of a practical nature. If the EU legislature allows the extension of the unitary patent while maintaining the SPC for classic European patents and national patents, this would result in coexistence of two normative models within the same legal order. Such coexistence could lead to diverging case law with respect to the substantive provisions governing the two models. The complexity of the system would increase. Such objection would require a more detailed analysis of the form and the content of a patent-extension regime for unitary patents. Since the only option considered by the European Commission is the creation of unitary SPCs, we will not analyse this option further in this Study.

22.2 UNITARY SPCS: INSTITUTIONAL ISSUES

22.2.1 Premise

The question how to create an SPC with unitary effect concerns institutional issues (in Section 22.2) as well as substantive requirements (see under Section 22.3). The pertinent topics were identified for the MPI Workshop in Munich, for the MPI Questionnaire for the NPOs, and for the Allensbach Survey.

The institutional aspects can be divided into four subtopics. The first topic concerns the authority that should receive the application and grant the right. The second topic concerns the language of the application and of its prosecution. The third topic concerns the language of the title, and more precisely whether translations are necessary or not. The final topic concerns the system of judicial remedy for decisions concerning the grant or rejection of the application for a certificate.

It is submitted that these issues are interconnected to some extent insofar as opting for a specific authority may also imply certain consequences in regard to the other aspects mentioned above. They are therefore addressed, in turn, within the context of considering the possible options which have been identified regarding the authority that is to grant an SPC with unitary effect:

- National patent offices;
- The EMA;
- The EUIPO;
- The European Patent Office;

- A virtual authority consisting of national examiners under the institutional roof of an EU authority;
- The creation of an authority *ad hoc*.

Before outlining the respective advantages and shortcomings of those arrangements (Sections 22.2.2.2 – 22.2.2.6), some general remarks are in order as to the legal requirements that must be met, as a minimum, by any one of the options at the lawmakers' disposal in order for them to be compatible with primary EU law, as well as regarding some of the factual conditions that may be of relevance for the choice to be made (Section 22.2.2.1). Subsequent sections (22.2.3 and 22.2.4) present the findings of the survey among NPOs and stakeholders regarding the institutional issues. In Section 22.2.5 it is considered which legal steps are needed in order to implement the alternative institutional options. Section 22.2.6 provides a summary of the issues discussed.

22.2.2 The granting authority: The available options

22.2.2.1 General remarks

(a) *Requirements under primary law*

Granting unitary rights, such as unitary SPCs, falls within the competence of the EU. The conditions under which such tasks can be delegated to others are therefore a matter of primary law. The issue was explored in *Meroni*[1718] and subsequent case law, which established the general principle that it is not compatible with primary law to grant a wide margin of discretion to bodies entrusted with the respective tasks, as that would lead to a shift of responsibilities.[1719] Furthermore, full application of EU law with regard to judicial review and procedural guarantees must be ensured.[1720]

(b) *Decentralised agencies*

In practice, the grant of EU titles (unitary rights) is usually entrusted to decentralised agencies established for the purpose, such as the European Intellectual Property Office (EUIPO) or the Community Plant Variety Office (CPVO). Other examples of agencies adopting individual decisions with legal effect on third parties are the European

[1718] Joined Cases C-9/56 and C-10/56 *Meroni v Haute autorité* [1958] EU:C:1958:7 and EU:C:1958:8, as confirmed in Cases C-98/80 *Romano* [1981] ECR I-01241; C-301/02 P *Tralli v ECB* [2005] ECR I-4071 and C-270/12 *United Kingdom v Parliament and Council* [2014] EU:C:2014:18; see also Case C-146/13 *Spain v Council* [2015] EU:C:2015:298, para. 62 *et seq*.

[1719] This is emphasised in Case C-146/13 *Spain v Council* [2015] EU:C:2015:298, para. 84, with reference to Case C-9/56 *Meroni v Haute autorité* [1958] EU:C:1958:7, paras. 151, 152 and 154, and Case C-270/12 *United Kingdom v Parliament and Council* [2014] EU:C:2014:18, paras. 41 and 42.

[1720] The core issue arising in *Meroni* and subsequent cases is whether the distribution of tasks and competences between the institutions of the Union, as enshrined in Art. 13 TEU, might be jeopardised. It is understood that safeguarding the principles underpinning Art. 13 TEU is of utmost importance, as they come as close as possible to the classical model of division of powers ("checks and balances") in a nation state; Regina Kröll, *Das europäische Arzneimittelrecht* (Springer 2017) p. 76. Under those principles a distinction must be observed between institutional arrangements allowing for sub-legal provisions, such as general guidelines or implementing regulations, to be promulgated by a designated body, and decisions taken by such bodies in individual cases, on the basis of clear and precise provisions enacted by the EU legislature. In the first of these scenarios the question is triggered whether the delegation of regulatory tasks circumvents parliamentary control, while such concerns are absent in the second scenario. However, in both cases alike, guaranteeing that the rules promulgated or the decisions taken by the designated body are subject to full judicial review on the basis of EU law in all its relevant aspects is an indispensable requirement under primary law.

Medicines Agency (EMA), the European Aviation Safety Agency (EASA) and the European Chemicals Agency (ECHA).[1721] Since 2012, the European Commission has pursued a common approach with regard to these and other decentralised agencies, seeking to establish common structures and procedural guidelines. However, this is a matter of policy rather than being a consequence of binding rules in primary law concerning how and by whom such tasks must be carried out.

As decentralised agencies of different kinds were established in an ad hoc fashion where a need arose, there is still no clear definition as to which criteria exactly must be fulfilled for an institution to function as an agency. However, the following seem to be the most likely candidates for constituting minimum requirements. An agency must be

- a body governed by EU law (see above),
- set up (or mandated) by an act of secondary legislation,
- with a legal personality of its own,
- having financial and administrative autonomy.[1722]

Thus, the fulfilment of these criteria is an indispensable requirement for all the institutional options considered below.

(c) *Sub-legislative rule-making*

Regarding the delegation of regulatory powers within a system of unitary rights one must distinguish between implementing regulations and "delegated acts" (Arts. 290 and 291 TFEU respectively) that are issued by the Commission.

In principle, implementing regulations are confined to specifying certain (primarily procedural) details within the framework established by legislation. By contrast, delegated acts are defined as "non-legislative acts of general application that supplement or amend certain non-essential elements of a legislative act", meaning that delegated acts can go beyond mere implementing regulations, though without entailing substantial changes or amendment of the law.

For the purposes of this Study, it is not necessary to embark any further on the question of which kind of sub-legislative rule-making can and should be chosen in the respective institutional settings. However, the issue may be of interest where non-EU institutions such as the EPO are concerned (see below, 22.2.2.5).

(d) *Factual relevance of issues considered*

Regarding the factual background to be taken into account for the choice between the respective institutional arrangements it should already be highlighted at this point that the number of SPCs granted per annum is much lower than that of patents.[1723] This means in particular that the staff requirements should not be overestimated, both as regards the number of experts preparing and taking decisions and also in terms of the

[1721] See Analytical Fiche 1, 'Definition and classification of "European Regulatory Agency"', available at https://europa.eu/european-union/sites/europaeu/files/docs/body/fiche_1_sent_to_ep_cons_2010-12-15_en.pdf (last accessed 4 September 2017).

[1722] *Ibid.*

[1723] This point was highlighted by one NPO in response to the MPI Questionnaire for the NPOs as well as by several participants in the workshop organised by the MPI in March 2017.

infrastructural support to be provided within the offices. In a similar vein it should be emphasised that although language issues are certainly important for efficient prosecution, they do not have the same kind of paramount significance as in regard to patents, considering that the textual elements are usually comparatively brief. The same is true regarding the language of the title.

22.2.2.2 National patent offices

(a) *Primary law*

Under the current law NPOs can only grant SPCs with regard to their own territory. It is generally uncontested that this will not change after materialisation of the unitary patent system[1724]. To improve the situation legal arrangements could be put in place to ensure that once an SPC has been granted by a national office based on a unitary patent (and the required kind of market approval[1725]), it is mutually recognised by other offices in order to give it uniform legal effect in terms of scope. While that construction does not raise problems under primary law as long as it is based on pertinent secondary legislation, and while it might satisfy practical needs, it does not result in a genuinely unitary right matching the unitary nature of the basic patent.

(b) *Shortcomings and advantages*

Leaving it to the NPOs to grant SPCs with *de facto* (but not: *de jure*) unitary effect based on a system of mutual recognition would have the obvious advantage that no major change of the current system is required. To date, all national offices already provide the necessary expertise and infrastructure for granting such rights.

However, this model also has drawbacks. As pointed out above, such a scheme would not lead to a genuine unitary right; also, the process of mutual recognition might be slow and bureaucratic. Furthermore, given the complex issues arising in this context, the risk is high that divergent practices based on different interpretation of the legal rules would ensue, which might hamper the smoothness of the process even further. It is true that such divergences could be overcome, to some extent and in the longer run, if the system provides that appeals be directed to a common appeal body (see below, (e)). However, until then, applicants will most likely try to obtain the first SPC, triggering the process of mutual recognition, from the office where the most generous treatment is expected ("office shopping"). Such practices should be avoided in the interest of equal treatment and a fair balance.

(c) *Language of prosecution*

NPOs regularly apply their own national language in proceedings conducted before them. However, provided that the mandate for issuing (*de facto*) unitary SPCs is anchored in specific legislation, arrangements can be made to allow for filing requests in any official language of the participating states or, alternatively, either for following the language regime set forth in Reg. 1260/2012 or filing in the national language plus in English. Choosing between the two latter regimes would arguably yield appropriate results, as the other two solutions – prosecution in the official language of the national

[1724] See above, Chapter 21, Section 21.2.3.2.
[1725] See below, Chapter 22, Section 22.3.4.

office only, or filing in any language of participating states – would lead to inconvenience, either for the parties or for the office(s).

An option favoured by practice would be to provide for English as the sole language of filing and prosecution. That solution might raise an issue if (some) national offices were obliged on a constitutional basis to use the official national language in proceedings conducted before them. However, such concerns were not articulated during the consultation process.

(d) *Language of the title*

Similar to the language issues addressed under (c), national offices grant titles in their own language. If the model of national grant plus mutual recognition were chosen, a more appropriate solution would be to grant titles in the national language plus translation into English for information purposes.

(e) *Remedies*

All national systems have their own pattern of remedies, most frequently starting with internal review by appeal boards, with a further appeal to specialised or general administrative courts. As those courts operate under the obligations enshrined in primary EU law regarding liability and the duty to refer contentious issues to the CJEU, maintaining those proceedings would not pose a problem. On the other hand, a system of national remedies would hardly be able to achieve the goal pursued by the grant of unitary SPCs; furthermore, it would lead to a splitting of competences between the UPC, which deals with invalidity claims against SPCs, and the national courts, deciding on appeals against decisions taken in the grant procedure. To avoid such a split and to promote the development of a consistent body of case law concerning SPCs, the advisable solution would therefore be to allocate the competence for judicial review to the UPC, even in the case that the grant of the right should rest with national offices.[1726] This would raise an issue with regard to Art. 32 UPCA, which until now does not provide for such a competence. This aspect is addressed below (22.2.2.5).

22.2.2.3 The EMA

(a) *Primary law*

Mandating the EMA would not raise any problems under primary law. The EMA already operates as a decentralised agency under EU law, which guarantees that the requirements with regard to institutional control are fulfilled.

(b) *Shortcomings and advantages*

Though the EMA's field of activity is closely related to SPCs in that the issuance of an MA is a binding condition for granting an SPC for the relevant medicinal product, its specific expertise lies in issues of pharmacovigilance and related areas of human and

[1726] This also reflects the majority opinion among the national offices answering the respective question in the MPI Questionnaire for the NPOs.

veterinary health protection. The assessment is therefore completely different, in its objectives and the knowledge required, from that which is needed in respect of SPCs.

(c) *Language of the prosecution*

In the legal acts establishing the EMA no particular working language is indicated, meaning that by default, all official EU languages can be used for prosecution purposes. In practice, however, the usual working language at the EMA appears to be English.

Filing for centralised MAs at the EMA must be accompanied by annexes containing information needed for pan-European marketing purposes. Such information (summary of product characteristics and labelling, package leaflet) must be provided in English and in all EU languages including Norwegian and Icelandic.

(d) *Language of the title*

Regarding the language of the title, guidance can hardly be found in the current EMA system, which results in decisions being taken by the Commission itself. The language to be applied for titles granted by the EMA would have to be determined based on considerations of practicality and equity. Such considerations would most likely point towards English or to the language regime established by the EPC and Reg. 1260/2012.

(e) *Remedies*

Market approval based on centralised proceedings before the EMA is founded on statements and opinions rendered by the EMA and its committees. However, on a formal level, the decision is issued by the Commission. The consequences of this construction in regard to appeals have been unclear to some extent, in particular regarding the question whether the EMA (or EMEA, as it then was) can be named as a defendant in nullity claims.[1727] In any case, as is set forth in Art. 256 TFEU in conjunction with Art. 263 TFEU, claims challenging measures taken by the EMA or on its behalf by the Commission must be lodged at the General Court. Issues resulting therefrom are addressed below, in connection with the EUIPO (22.2.2.4 (e)).

22.2.2.4 The EUIPO

(a) *Primary law*

There are no problems under primary law.

(b) *Shortcomings and advantages*

To some extent, the EUIPO might seem to be the agency best suited for granting unitary SPCs. As marked by its recent name change from "OHIM" to "EUIPO", the Office's mandate already extends beyond trade marks and industrial designs. This is

[1727] See Case T-326/99 *Fern Olivieri v Commission and EMA* [2003] ECR II-6053, para. 50: opinions issued by the EMEA are mere preparatory acts that cannot be challenged on their own; Case T-133/03, *Schering-Plough v Commission and EMA* [2007] EU:T:2007:365, para. 14: the challenged measure is attributable to the Commission and can be challenged as such.

reflected not least in the activities of the Observatory on Infringements of Intellectual Property Rights, which cover IP rights in general. However, it is true that, at least for the time being, there is no specific expertise within the Office with regard to SPCs. Entrusting the EUIPO with the task would therefore involve recruitment and training efforts, even though the number of experts needed for the task may not be exceedingly high (see in this Chapter Section 22.2.2.1 (d)).

In order to avoid any such efforts, a combination could be envisaged by – formally – mandating the EUIPO, and delegating the actual workload to experts at the national level, as proposed in the model usually labelled as a "virtual office" (below, 22.2.2.6).[1728] Of course this would also mean that the issues raised by that model – regarding the legal status and payment of national experts participating in the virtual office – would have to be taken into account.

(c) *Language of prosecution*

The language regime governing proceedings before the EUIPO is set forth in Art. 145 EUTMR. The basic outlines of the system are as follows: The languages of the Office are English, French, German, Italian and Spanish. Applications can be filed with the Office in any official language of the EU. In the application the applicant must indicate a second language of the five languages of the Office, thereby agreeing to the use of that second language in *inter partes* proceedings (with the option for the parties in such proceedings to agree on the use of another official EU language). If the language of filing is not one of the five Office languages, the Office translates the filing document into the second language indicated. In *ex-parte* proceedings the Office uses the language of filing, even if that language is not one of the five Office languages, with the option for the Office to use the second language (i.e. one of the five Office languages) for sending written communications.[1729]

While this system is somewhat complex, it has its advantages for applicants. The EUIPO is used to dealing with the complexities of the system within its current fields of activity. It appears likely that this would not be different in regard to SPCs: it is true that the documents filed with regard to SPCs are more substantial than typical trade mark or design applications; on the other hand, as was pointed out before, they are by far not as large and comprehensive as in the case of patents (see above, 22.2.2.1 (d)).

(d) *Language of the title*

Pursuant to Art. 147 EUTMR, entries in the trade mark register as well as other information required to be published on the basis of the EUTMR or a legal act issued on its basis are published in all official EU languages. In case of doubt, the language of filing (if it is one of the five Office languages) or (if the filing was made in another language than those of the Office) the second language is decisive.

[1728] This option was introduced by Prof. Tilmann during the workshop arranged by the MPI in March 2017.

[1729] It has been clarified by the CJEU that the notion of "written communications" must be interpreted strictly, meaning that it does not extend to sending of procedural documents, i.e. "any document that is required or prescribed by the Community legislation for the purposes of processing an application for a Community trade mark or necessary for such processing, be they notifications, requests for correction, clarification or other documents. Contrary to the Office's submissions, all such documents must therefore be drawn up by it in the language used for filing the application." Case C-361/01 P *Kik v OHIM* [2003] ECR I-08283, para. 46.

(e) *Remedies*

Decisions on the grant of unitary rights issued by examiners in the EUIPO are subject to an internal appeal. Providing for such an internal review procedure before the matter is submitted, upon further appeal, to an external judicial body corresponds to the scheme observed at most NPOs as well as at the EPO. However, while such two-tiered appeal schemes are very common, they are not mandatory in the sense that a system only providing for "one tier" would be insufficient. Art. 47 of the EU Charter of Fundamental Rights, Art. 6 of the European Convention on Human Rights as well as Art. 41(4) TRIPS are clear in that they only require *judicial* control of decisions or potential violations of rights.

Whether or not the grant of SPCs should be subject to an internal review procedure within the EUIPO (or in a different framework, depending on the institutional choice made) is therefore no legal issue, but is primarily a matter of a cost/benefit analysis. On the one hand, internal appeals may unduly prolong the procedure. On the other hand, the overall effect may be beneficial where the parties accept the decision, which is usually rendered in relatively inexpensive and fast proceedings in comparison to litigating before a court. To carry out such an analysis one would have to estimate which proportion of cases is likely to be settled for good in appeal proceedings as compared to those that are going to be pursued through all instances. Given the high commercial values regularly at stake in the grant of SPCs, it seems rather likely that a high proportion of cases would actually go further than the appeal stage. If this is confirmed, it would be advisable to skip any kind of internal review,[1730] or to grant recourse to it only on an optional basis at the request of the parties.

More important than that is the question which judicial body is competent to hear complaints against decisions taken by the EUIPO. Pursuant to the scheme set forth in Art. 256 in conjunction with Art. 263 TFEU, such complaints would, as a matter of principle, have to be filed with the GCEU. The same applies to institutional arrangements involving other EU agencies such as the EMA or a virtual (or ad hoc) office; therefore the following remarks pertain to those options as well.

It is understood that as things stand now the GCEU does not have any expertise in considering the intricate issues raised by the grant of SPCs. Furthermore, involving the GCEU in the appeal scheme would lead to a split of competence between the UPC – having jurisdiction *inter alia* on invalidity claims against SPCs – and the General Court, which could result in inconsistent interpretations and legal uncertainty. It would therefore be preferable if appeals filed against decisions taken by the granting authority could be lodged at the UPC.[1731] This raises issues of primary law which are addressed below (22.2.2.5 (e)).

[1730] Other factors to be included in the analysis concern the respective costs of proceedings as well as the current lack of expertise in matters of SPC grants at the EUIPO; see above Section 22.2.2.4(b).

[1731] The position that appeals against decisions concerning the grant of SPCs should be directed to the UPC is practically unanimously endorsed by the NPOs responding to the relevant question.

22.2.2.5 The EPO

(a) *Primary law*

As the EPO is not an EU agency and is thus not subject to EU law, its suitability as the institution granting unitary rights might be questioned. The issue was already debated in the context of establishing the unitary patent system. Although the EPO does not engage in a formal act of granting unitary patents, it is substantially involved in the proceedings. Thus, the EPO must check the congruence of territorial and substantive scope when the filing documents contain a request for unitary effect.[1732] Furthermore, by keeping the register of patents with unitary effect and taking decisions pertaining to that register, the EPO also carries out administrative tasks under the EU Regulations.[1733] This means that, with regard to the unified patent system as established by Reg. 1257/2012, Reg. 1260/2012 and the UPCA, the specific conditions under primary law to be fulfilled in case of delegation of powers must be observed, thereby providing guidance for the circumstances to be considered here.

The issues arising in the context of the Patent Package were addressed in the judgment of the CJEU regarding the challenge by Spain concerning Reg. 1257/2012 (Case C-146/13). The point was raised, *inter alia*, by the government of Spain that when certain administrative tasks are delegated to the EPO the principles established in *Meroni*[1734] are disregarded. Spain furthermore argued that Art. 291(2) TFEU, which makes it a duty of the Commission (or, in certain cases, of the Council) to adopt delegated acts,[1735] had been violated by Art. 9(1) Reg. 1257/2012, which leaves a number of tasks to the EPO and a select committee.

In response the CJEU summarised that in *Meroni* and its successors it had been held that the delegation by an EU institution to a private entity of a discretionary power that implies a wide margin of discretion and is capable, according to the use which is made of it, of making possible the execution of actual economic policy is not compatible with the requirements of the TFEU.[1736] It further pointed out that, due to the fact that the EU itself is not a member of the EPC, it is clear and emerges from the contested provisions, i.e. Art. 9(1) and (2) Reg. 1257/2012, that it is not the EU but only the Member States that delegate the respective powers to the EPO.[1737] The CJEU does not comment any further on whether such a delegation of tasks by the Member States to the EPO in the context of granting unitary effect to European patents needs to be assessed under the same or similar criteria as those enunciated in *Meroni* and subsequent case law.

Similar lines of reasoning as those employed by the CJEU in *Spain v Council* could apply to measures taken for the grant of unitary SPCs. There, as well, it can be argued that instead of transferring powers directly from the EU to the EPO, the construction

[1732] Thomas Jaeger, 'All Back to Square One? - An Assessment of the Latest Proposals for a Patent and Court for the Internal Market and Possible Alternatives' [2012] IIC 286, 294; see Art. 3(1) Reg. 1257/2012.

[1733] Thomas Jaeger, 'All Back to Square One? - An Assessment of the Latest Proposals for a Patent and Court for the Internal Market and Possible Alternatives' [2012] IIC 286, 294; therein the collection and distribution of fees; see Art. 9(1) Reg. 1257/2012 and the text below.

[1734] Case C-9/56 *Meroni v Haute autorité* [1958] EU:C:1958:7

[1735] On the definition and substance of delegated acts, see above, Section 22.2.2.1 (c).

[1736] Case C-146/13 *Spain v Council* [2015] EU:C:2015:298, para. 84 with reference to Case C-9/56 *Meroni v Haute autorité* [1958] EU:C:1958:7, paras. 151, 152 and 154, and Case C-270/12 *United Kingdom v Parliament and Council* [2014] EU:C:2014:18, paras. 41 and 42.

[1737] Case C-146/13 *Spain v Council* [2015] EU:C:2015:298, paras. 85 and 86.

involves a delegation of administrative tasks by the Member States in a manner already provided for in the EPC. Under Art. 63(3) and (4) EPC, it is for a group of contracting states that have opted for a joint European patent under Art. 142 EPC to entrust the EPO, by virtue of an agreement, with tasks associated with the implementation of a system for term extension, as provided for in Art. 63(2)(b) EPC. Similar to what was pointed out above, it would then be for an act of EU legislation (such as, in the case of unitary patents, Reg. 1257/2012) to further expand on the kind and contents of the special agreement concluded within the framework of Art. 142 EPC.[1738]

It is true that it might be questioned whether the option in Art. 63(4) EPC to entrust the EPO with "tasks associated with implementation of the relevant provisions" (i.e. provisions allowing for a term extension) goes so far as to encompass the grant of the right as such, instead of merely checking prerequisites and carrying out administrative tasks with regard to registration. However, there does not seem to be a cogent reason why deciding on the grant itself should not likewise be considered as constituting "implementation" within the meaning of Art. 63(4) EPC. Given the background and purpose of the provision, it would rather seem highly plausible that it was meant precisely to include the option that Member States can leave it to the EPO to decide on the grant of a term extension under the pertinent law (which, in this case, is an act of EU legislation). In that light the difference between the situation under the Patent Package that was accepted by the CJEU as compliant with primary law and the arrangement to be considered here appears to be a matter of degree (or form) rather than substance.[1739] It is worth underlining that once the European patent has been opted in, it becomes a unitary patent and has to comply with EU law (for instance the unitary patent register has to comply with primary and secondary EU legislation).

Furthermore, irrespective of whether the delegation of powers occurs through the Member States or the EU itself, the ultimately decisive aspect is to ensure that the exercise of such powers fully remains under the control of EU law.[1740] Under that condition, it is neither completely unusual nor unprecedented that certain competences of the EU are delegated to external institutions.[1741] Thus, it has been decided in previous jurisprudence that integration of acts and decisions of an international body in the legal system of the EU is possible on condition that effective judicial control exists and that it is exercised by an independent court that is required to observe Union law (with the consequence of liability for failure to comply), and that it is authorised to refer a question to the Court of Justice for a preliminary ruling, where appropriate.[1742] Unlike the previous arrangement for the creation of a European Patent and Community Patent Court, which was found incompatible with primary law as the envisaged court remained outside the institutional and judicial framework of the EU,[1743] the UPCA has been designed so as to ensure full compliance with the pertinent requirements, *inter alia*, by ensuring supremacy of EU law in Art. 20 UPCA and by

[1738] This option was identified by Prof. Dr. Ansgar Ohly in the workshop arranged by the MPI in March 2017.
[1739] This opinion was endorsed by Prof. Dr. Ansgar Ohly in the workshop arranged by the MPI in March 2017.
[1740] This is also the essence of the *Meroni* doctrine as summarised by the CJEU in Case C-146/13 *Spain v Council* [2015] EU:C:2015:298, para. 84.
[1741] This was pointed out by the European Parliament in the proceedings by Spain against Reg. 1257/2012; see Case C-146/13 *Spain v Council* [2015] EU:C:2015:298, para. 64.
[1742] Joined Cases C-402/05 P and C-415/05 P *Kadi and Al Barakaat International Foundation v Council and Commission* [2008] ECR I-06351, paras. 284 and 285.
[1743] Opinion 1/09 of the Court on the Creation of a unified patent litigation system - European and Community Patents Court - Compatibility of the draft agreement with the Treaties [2011] EU:C:2011:123, para. 89.

stipulating that pursuant to Art. 32(1)(i) UPCA actions concerning decisions of the EPO in carrying out the tasks referred to in Art. 9 of Reg. 1257/2012 are included in the competence of the UPC. Provided that the necessary steps are undertaken to apply the same scheme to decisions concerning the grant of SPCs, mandating the EPO with the task would likewise appear compatible with primary law.

For clarification purposes it is added that, in regard to sub-legislative rule-making by the EPO, due consideration would have to be given to Art. 291(2) TFEU, which makes it necessary that certain regulatory tasks at the sub-legislative level are undertaken by the Commission or possibly the Council. In *Spain v Council* the CJEU refuted the argument made by Spain that Reg. 1257/2012 violated Art. 291(2), by pointing out *inter alia* that the provision only applies where the conditions for implementation must be uniform, and that it had not been sufficiently demonstrated by Spain that such uniformity was needed in regard to the tasks mandated in Art. 9 Reg. 1257/2012 to the EPO and the Select Committee.[1744] Regarding the granting procedures for unitary SPCs, however, it is obvious that the respective secondary legislation must guarantee uniform implementing conditions, and that it must therefore remain in the hands of the European Commission (for a general elaboration on secondary legislation and the potential contents of such rules see above, 20.3).

(b) *Shortcomings and advantages*

Although SPCs and patent protection are distinct fields of law, the fact that they are closely related has motivated most (or all) Member States to entrust their patent offices with the grant of SPCs. Under the same logic it appears appropriate to put the EPO in charge. This would also have the advantage that the register of unitary SPCs could be kept alongside the register of unitary patents.

It is true, however, that the expertise needed for the task of registering SPCs currently cannot readily be found at the EPO; competent staff would have to be recruited. On the other hand, as was pointed out before, the number of experts needed for the task is arguably rather limited. Furthermore, mandating the EPO would not necessarily preclude cooperation arrangements with national experts already working in these fields.[1745] However, unlike the situation in which a virtual office consisting of national experts is established as an EU institution, there is no way for the EU legislature to arrange for such a body to operate in the organisational framework of the EPO. Exploring the option and fixing the details of such an arrangement would be a matter for the negotiations between the Member States and the EPO in preparation of the contract to be concluded in accordance with Art. 63(4) EPC (below, 22.2.5.3).

(c) *Language of prosecution*

The EPO prosecution languages are English, French and German.

[1744] Case C-146/13 *Spain v Council* [2015] EU:C:2015:298, paras. 78-81.
[1745] This option was supported by several participants in the workshop organised by the MPI in March 2017.

(d) *Language of title*

Specific rules for patents with unitary effect are provided for in Reg. 1260/2012. These rules are aligned with the ones set in Art. 14(2) EPC, namely the title in one of the official languages of the EPO [and translation of the claims into the other languages].

(e) *Remedies*

As pointed out above, the fact that judicial control of administrative decisions concerning the unitary effect of European patents is exercised by the UPC is a crucial element in ensuring TFEU-compatibility of the Patent Package. The same applies *mutatis mutandis* to the institutional design for SPCs, as pointed out above under (a).[1746] The consequences of this are addressed below, 22.2. 5.3.

It might be an issue for further deliberation whether in the case of the EPO being tasked with the grant of unitary SPCs the decisions taken by the EPO in the granting process should be subject to an appeal filed with the EPO Boards of Appeal. There does not seem to be a reason *per se* why such a scheme should be legally unfeasible, given that judicial control will ultimately be exercised by the UPC. However, apart from the fact that providing for internal review is not mandatory and that its appropriateness in the case of SPCs depends on a cost/benefit analysis for which more data would be needed (see above, 22.2.2.4 (e)), involving the EPO Boards of Appeal appears particularly problematic, as they would have to apply EU law without being able to refer questions to the CJEU under Art. 267 TFEU.

22.2.2.6 Virtual authority and creation of an authority ad hoc

(a) *Primary law*

The creation of an authority ad hoc does not pose issues under primary law, as long as it is ensured that it is fully subject to EU law and to efficient judicial control. The same applies to a virtual authority, for example, consisting of a digital platform where applications are received and distributed to experts in the national offices.

(b) *Shortcomings and advantages*

A virtual authority has the obvious advantage that it does not require recruitment of staff or setting up of infrastructure at any given physical location. It suffices that those participating in the system – experts working in the national offices – are connected digitally, and that rules of procedure are established for organising their cooperation.[1747] Compared to the proposal building on the grant of rights by national offices (22.2.2.2), cooperation within the framework of a virtual office would prevent forum-shopping and eliminate the risk of inconsistent practices evolving in the

[1746] Similar to what was pointed out with regard to proceedings at the EUIPO it could be asked whether decisions concerning the grant of unitary SPCs should be amenable to the internal appeal procedure at the EPO. Given that such proceedings remain subject to judicial review by the UPC this should not pose particular problems under primary law. However, the decision requires a thorough cost/benefit analysis, and might therefore only be commendable in the form of a voluntary step at the discretion of the parties.

[1747] It is not to be ignored that in spite of its simplicity, implementing that model will need thorough considerations, *inter alia* concerning the legal status and equal payment of national experts staffing the virtual authority while at the same time remaining part of their respective national offices.

different Member States.[1748] Indeed, the creation of a virtual office would have the beneficial side-effect that it would "naturally" lead to greater harmonisation of national practice. It is true that a potential drawback could be that working together in a virtual environment is not able to produce the same kind of team spirit and common understanding of issues as emerges from physical proximity. On the other hand, digital communication renders distances in space basically meaningless. New technologies make it possible to conduct hearings and to cooperate on proceedings without being physically located in the same place. Some of the arguments in favour of the creation of a centralised structure at the time when existing offices such as the EPO were established could therefore be less stringent today.

Working models similar to the virtual office can already be observed under the EPC with respect to the Enlarged Board of Appeal, and under the UPCA with respect to the local and central divisions of national courts, where persons at different places have the opportunity to work both in a supranational and a national function, with largely harmonised provisions applying at both levels. There is prima facie no reason not to explore a similar model with respect to examiners specialised in SPC matters. Establishing a virtual office would ensure that NPOs are not deprived of resources and expertise; furthermore, the effect could be avoided that the workload is channelled towards lawyers established at the venue of the Office, thus creating a competitive advantage for such firms.

Regarding procedures it has been suggested that they could be organised in line with existing systems, such as committees operating within the EMA (CHMP and NRG).[1749]

(c) *Language of the prosecution*

It would be for the rules of procedure governing the cooperation within the virtual office to decide on the language(s) used.

(d) *Language of the title*

The language of the title would also have to be determined by the procedural rules (most likely those of EPC/Reg. 1260/2012).

(e) *Remedies*

For remedies against decisions taken by virtual offices or ad-hoc offices established as EU agencies, the scheme would be the same as that applying to decisions taken by already existing EU agencies such as the EUIPO or the EMA (see above, 22.2.2.4 (e)).

[1748] The option was presented by Georgia Roussou in the workshop organised by the MPI in March 2017. It found strong support by several participants.

[1749] ECPA, EFPIA and IFAH-Europe, 'SPCs in the Unitary Patent System', Joint Position Paper, Annex 1, available at http://www.ecpa.eu/sites/default/files/ECPA-EFPIA-IFAH%20Paper_SPCs%20in%20the%20unitary%20patent%20system_0.pdf (last accessed 18 October 2017). "CMHP" stands for Committee for Medicinal Products for Human Use; "NRG" means (invented) Name Review Group.

22.2.3 Survey conducted among NPOs and stakeholders

22.2.3.1 General remarks

Questions pertaining to the issues addressed above were included in the qualitative questionnaires distributed to NPOs and in the Allensbach Survey for the stakeholders.[1750] The answers received are summarised separately in the following sections (22.2.3.2 and 22.2.3.3).

While the questions posed to both groups were basically the same, their numbering in the MPI Questionnaire and in the Allensbach Survey was slightly different. For orientation purposes, the subject of the questions and their respective numbering are indicated below.

- Whether the understanding is correct that a patent with unitary effect can be the basis for a unitary SPC (MPI Questionnaire for the NPOs: Q72 (no corresponding question was posed to stakeholders);
- Whether there is a need for creation of a unitary SPC (MPI Questionnaire for the NPOs: Q73; Allensbach Survey: Q69);
- Which authority (national offices under a system of mutual recognition, EMA, EUIPO, EPO or a virtual office) should grant the title (MPI Questionnaire for the NPOs: Q74; Allensbach Survey: Q70);
- Which language should be applied for the prosecution in case of a system of mutual recognition (MPI Questionnaire for the NPOs: Q75; Allensbach Survey: Q71);
- Which language should be applied for the prosecution in case of a European authority granting the title (Allensbach Survey: Q72; no corresponding question was posed to NPOs);
- In which language the title should be granted and possibly translated (MPI Questionnaire for the NPOs: Q76; Allensbach Survey: Q73);
- Whether decisions by the granting body should be appealed to the UPC or an EU court (MPI Questionnaire for the NPOs: Q77; Allensbach Survey: Q74).

22.2.3.2 Summary of responses by NPOs

The MPI Questionnaire for the NPOs was answered by representatives from patent offices in 21 EU Member States and the Swiss Patent Office. Six of those patent offices did not answer Q72–77 (or, in one case, Q74–77), or restricted their answer to stating that this was a political decision. Others said that while all or most proposals seemed feasible in principle, the ultimate decision would depend on more comprehensive discussions regarding the details. In view of this, the following summary of answers must be read with caution. The clear majority of NPOs answering Q72 confirmed the understanding that a patent with unitary effect could form the basis for a unitary SPC. Most offices also agreed, in their answer to Q73, that creating such a right was a necessity. However, there was no complete unanimity: One office was expressly sceptical about the existence of such a need; another one expressed slight reservations by stating that such a need existed "on paper"; a third one suggested that one should consult the users, and a fourth office declared that unitary SPCs

[1750] For the wording of the questions, see Annex VI of this Study.

should only be introduced on an optional basis, whereas owners of unitary patents should retain the option to apply for national SPCs.

Regarding the granting authority, there was a large consensus among the offices responding to Q74 that no involvement of the EUIPO or the EMA was advisable because neither the EUIPO in particular, nor (to a somewhat lesser extent) the EMA currently has the expertise needed for the task. One office also added that proceedings at the EMA were costly and complicated and therefore not advisable. A few offices also pointed to the current lack of expertise at the EPO. In addition, two offices warned that the EPO was not an EU institution and that mandating it might therefore raise problems under EU law. Nevertheless, a slight majority of offices were positive about involving the EPO or at least did not expressly advise against it. At a more general level, some offices warned against the costs and efforts of creating new entities or setting up new infrastructure for the purpose of granting SPCs, which, as pointed out by one office, would lead to a doubling of work currently already undertaken at the national level. Presumably for that reason, a solution involving the national offices found the support of about 50 per cent of the offices (with one office pointing out that this would require harmonisation of proceedings), with a system of mutual recognition either being designated as the preferred option or one of the feasible options, or as an option to be realised in combination with a "virtual office". In contrast to that, one office stated that a solution should be "anything but" the grant of a title by national offices with subsequent recognition by others; in the same vein, other NPOs remained wary of the length of proceedings and the risk of "office shopping"; one office also pointed to the lack of a truly "unitary" effect of such rights. Finally, the suggestion of a virtual office – which is based on a Joint Position Paper by ECPA, EFPIA and IFAH-Europe[1751] – was expressly welcomed by two of the major offices and characterised as "interesting" or "feasible" by others. In that context it was also pointed out several times that a "virtual office" might operate in connection with NPOs, or that it could be integrated into the organisational structure of an existing EU institution.

Regarding the language of prosecution in a system of mutual recognition, seven of the twelve NPOs opted for "English only" as the language of prosecution, while three voted for the respective national language, one for the languages of the EPO, and another one for the language regime in Reg. 1260/2012. An equally clear picture also resulted from Q76 (language of the title; answered by thirteen offices): Nine NPOs opted for the national language plus translation into English, while two voted for the EPO languages and another two offices suggested that the title should be granted in the languages of all countries where the SPC would become effective. One office observed in this context that the language of the title is of only minor importance anyhow, as interested parties would rather consult the underlying documents – the basic patent and the MA – directly.

Regarding the preferred venue for appealing decisions of the granting authority (Q77), the majority clearly opted for such claims being directed to the UPC. The second alternative – appeals being directed to an EU court – found no express support

[1751] ECPA, EFPIA and IFAH-Europe, 'SPCs in the Unitary Patent System', Joint Position Paper, Annex 1, available at http://www.ecpa.eu/sites/default/files/ECPA-EFPIA-IFAH%20Paper_SPCs%20in%20the%20unitary%20patent%20system_0.pdf (last accessed 18 October 2017).

(however, three offices gave inconclusive answers by responding with "yes" instead of endorsing one of the alternatives presented).

22.2.3.3 Stakeholder survey: summary and comments

Regarding most of the questions posed in the Allensbach Survey, the opinions and preferences of stakeholders are typically rather clear-cut. Thus, three quarters (75 per cent) of all respondents confirmed a need for the creation of a unitary SPC, while only 14 per cent denied that need in Q69. As might be expected, the support is somewhat less strong among representatives of the generic companies compared to representatives of originator companies (81 per cent and 67 per cent, respectively); however, even among the generic companies the general attitude is clearly in favour of a unitary right.

Regarding the granting authority (Q70) the difference in opinions between the representatives of originators and generic companies is conspicuous. 71 per cent of the representatives of originator companies endorse the concept of a virtual office (which is not surprising in view of the fact that the proposal was advanced by the pertinent industry associations, ECPA, EFPIA and IFAH). By contrast, the concept of a virtual office is only favoured by 23 per cent of the representatives of generic companies, while the EMA and the EPO cut just as well (23 per cent and 26 per cent). Among the representatives of originator companies the EMA hardly finds any support at all (only one per cent), while the EPO scores at 21 per cent. Neither group considers the EUIPO and the national offices as particularly appealing (EUIPO: four per cent among representatives of originator companies, 13 per cent among representatives of generic companies; NPOs: three per cent of the representatives of originators and 16 per cent of the representatives of generic companies).

In a follow-up question for those who had opted for a system of mutual recognition, most respondents choose the option referring to the respective national language, few would prefer English (Q71; the total number of answers in this subgroup is so limited that we prefer not to present any percentage shares in this). Regarding prosecution within a European institution (including the virtual office that most stakeholders wish to see in charge) (Q72), two-thirds opt for the EPO languages (66 per cent), with "English only" being second (18 per cent). A similar picture results from the responses as to the language of the title (Q73): There is a clear preference for the EPO languages (63 per cent), with 21 per cent opting for English plus the national language if the title should be granted by a national office in a system of mutual recognition.

Regarding the judicial system (Q74), an overwhelming majority of 79 per cent would prefer if appeals were being directed to the UPC, while less than a tenth of that percentage (eight per cent) endorses the concept of involving an EU court such as the GCEU.

In addition to answering the questions in the Allensbach Survey, the stakeholders were encouraged to make individual comments. These comments echo the strong support given by a majority of originators to the concept of a virtual office. Several comments repeat *verbatim* the reasoning set forth in the proposal by the three industry associations (ECPA, EFPIA and IFAH). One comment even praises the "inventor" of that proposal as a "genius"; it also states that this kind of cooperative

endeavour with its lean organisational structure could become a model agency for the 21st century. Even in the less enthusiastic comments the aspect of minimising costs and recruitment efforts are evaluated positively. In contrast, comments expressly supporting the EUIPO, EMA or the EPO are less frequent and also less avid in their tone. Regarding the EPO, it is stated that it "can be a good choice provided that the specialised EPO's Examiners are devoted only to the SPC examination and not the EP patent prosecution". The EUIPO is even designated as a "true European agency"; some other respondent just stated that "a virtual office could be set under the roof of an EU body, the EUIPO". Of the EMA, it is said in one comment that "experts from EMA should participate" in the task; another comment wants to see cooperation between "the EMA (because the EMA knows best whether a full study program had been necessary for approval) and the EPO (or an NPO) to see whether the product is covered by the claims", making it "a common task". However, the EMA also got one decidedly negative comment, namely, that "EMA would NOT be a could [sic] alternative, since the SPC system is basically a particular part of the patent system. Giving the granting procedure to EMA bears the risk that too much emphasise [sic] is given to the regulatory part of the SPC system".

Comparatively few comments deal with other issues than the granting authority. However, some comments also address the appeal system, expressing the wish that the option to file such appeals with the UPC should at least be explored, or should be granted as an alternative to involving the GCEU. Apart from that, one commentator found it worthwhile to point out that language issues are not of much relevance in regard to SPCs.

22.2.4 Qualitative interviews. Stakeholder´s seminar

The qualitative interviews as well as the seminar with some stakeholders confirmed the results of the Allensbach Survey. The participants favour a virtual office with examiners from NPOs as granting authority and the UPC as the court competent to deal with appeals lodged against decisions of the granting authority. The institutional roof under which the virtual office is established does not matter for the stakeholders participating in the seminar.

22.2.5 Implementation of the different options

22.2.5.1 General considerations

A system for granting unitary rights like the SPC contemplated here can only be established on the basis of Art. 118 TFEU, that is, by a regulation of the European Parliament and the Council. In contrast, such a system cannot be brought into existence on the basis of an international agreement such as the UPCA. At most, what can be established by way of an agreement would be a system of mutual recognition following national grant, as considered above in Section 22.2.2.2. But even then, in order to minimise the risk of friction and bureaucratic delays, the agreement would have to be complemented by a harmonisation directive regulating the conditions and procedures for grant of the right and the conditions for subsequent recognition.

If, however, the creation of a unitary right is given preference over the "limping" solution presented by a system of mutual recognition, EU legislation in the form of a

regulation is a necessity. The options available for that purpose are to amend either Reg. 469/2009 and Reg. 1610/96, or Reg. 1257/2012 (the legislative objective of which would then have to be enhanced accordingly). Alternatively, a new regulation could be enacted. Which of the options is chosen is primarily a matter of political convenience. However, in case of amrnding Reg. 1257/2012 it would have to be checked whether such amendments would not contravene or go beyond the substance of the original decision on enhanced cooperation to create the unitary patent; see below.

Creating a new unitary IP title requires qualified majority according to Art. 118(1) while the language regime of the Unitary SPC will have to be adopted by unanimity pursuant to Art. 118(2) TFEU. It is true that languages are not as problematic in the SPC context as they proved to be for the unitary patent (see above, 22.2.2.1 (d)). Nevertheless, it may become necessary also for unitary SPCs to take advantage of the instrument of advanced cooperation in order to facilitate the acceptance of legislation setting up a workable language regime for unitary SPCs, corresponding to that enshrined in Reg. 1260/2012. It could be questioned whether it would suffice for that purpose to amend Reg. 1257/2012 and Reg. 1260/2012 accordingly, with the language regime to be installed for the unitary SPC being accepted unanimously by the Member States participating in enhanced cooperation based on the Council's decision of 10 March 2011.[1752] However, as that decision only aims at enabling enhanced cooperation for the purpose of creating a unitary patent,[1753] without mentioning SPCs in any form, it is advisable that the procedures set forth in Art. 20 (2) TEU and Art. 329 TFEU for the authorisation of enhanced cooperation are observed also for the creation of unitary SPCs, whether by amendment of Reg. 1257/2012 and Reg. 1260/2012 or by separate regulation.

Further aspects of the legislative measures necessary for bringing the unitary SPC system into existence depend on the institutional design chosen, namely, on the one hand, the grant of unitary SPCs being allocated to an EU agency (EUIPO, EMA, or a virtual authority), and on the other hand, the task being mandated to the EPO. In the following these options are considered separately.

22.2.5.2 Grant of unitary SPCs by an EU agency

As was pointed out before, tasking an EU institution – whether existing, *ad hoc* or "virtual" – with the grant of unitary SPCs is unproblematic in terms of primary law. However, the option implies that appeals must be directed to the GCEU, which for several reasons does not appear to be an optimal choice to the majority of the stakeholders consulted. It might therefore be considered whether, in the interest of coherence and legal certainty, legal measures can be installed that allow appeals to be lodged with the UPC. However, that option appears to be precluded by primary EU law. Article 265(1) TFEU sets forth that "[t]he General Court shall have jurisdiction to hear and determine at first instance actions or proceedings referred to in Articles 263 …, with the exception of those assigned to a specialised court set up under Article 257". Pursuant to Art. 263(1), second sentence, the CJEU "shall … review the legality of acts of bodies, offices or agencies of the Union intended to produce legal effects vis-à-vis third parties". Thus, given that the grant of an SPC by an institution established

[1752] Council decision 2011/167/EU of 10 March 2011 authorising enhanced cooperation in the area of the creation of unitary patent protection [2011] OJ L 76/53, p. 53.
[1753] See *ibid.,* para. 7.

or acting under EU law constitutes an "act" of that body, reviewing the legality of such grant falls within the competence of the GCEU.[1754]

It is also clear that the sole exception permitted by Art. 256 TFEU, namely, the establishment of a specialised court, is of no avail in the case presented here. The UPC was established by an international agreement between the Member States, and not, as required by Art. 257(2) TFEU, by way of a regulation that lays down "the rules on the organisation of the court and the extent of the jurisdiction conferred upon it". Furthermore, even if the UPC were considered to be a specialised court within the meaning of Art. 257 TFEU, the GCEU would remain charged with decisions upon (further) appeal. Thus, the aim of synchronising adjudicative jurisdiction on matters of validity and grant of unitary SPCs would be disrupted at least in the (further) appeal instance.

In view of the specific issues to be resolved here, these constraints appear unfortunate. As is pointed out above, the UPC is nearly unanimously – and correctly – considered as the court best placed to decide not only on matters of infringement and validity, but also on the grant or refusal of unitary SPCs. Engaging separate judicial bodies with those tasks makes the system less coherent and less secure. Furthermore, the example of EU trade mark (and Community design) courts deciding on counterclaims for invalidity in infringement proceedings demonstrates that the fact that the UPC corresponds in its legal position to a national court does not furnish a reason *per se* to deny its competence for reviewing and, eventually, vacating decisions taken by an EU agency with effect *erga omnes*.[1755] Lastly, the aspect that the organisational structure of the UPC was not set forth in an EU regulation but in an international agreement does not change the fact that it remains under the supremacy of EU law in all its elements (Art. 20 UPCA). Given the clear wording of the pertinent provisions and the fundamental importance of abiding by the exigencies of primary EU law, however, there is no way to include the UPC in the system if the granting authority is an EU agency other than amending the EU Treaty or by adopting a protocol of the Treaty excluding the competence of the GCEU for dealing with disputes relating to Unitary SPC to the benefit of the UPC.

22.2.5.3 Grant by the EPO

If the EPO should be charged with the grant of unitary SPCs, two elements must be considered. First, Member States participating in enhanced cooperation must conclude an agreement with the EPO – to be understood here as the European Patent **Organisation** – about the implementation (including the grant) of unitary SPCs, in accordance with Art. 63(4) EPC.[1756] Second, it must be ensured that competence to adjudicate on matters of grant of the unitary SPC is allocated to the UPC.

[1754] This is different from jurisdiction in regard to conflicts arising between private parties from a unitary right, where Art. 262 TFEU only provides an option, not a monopoly (see Opinion No. 1/09, para. 62).

[1755] This does not mean to suggest that the system considered here is fully comparable with the current situation of national "Community rights" courts vacating decisions of the EUIPO. While national EUTM (or CD) courts may order cancellation of rights granted by the EUIPO when counterclaims are raised in infringement proceedings, the courts cannot decide on isolated claims for invalidation or revocation, and in particular, they cannot review and eventually reverse decisions by which the grant of an EUTM (or CD) has been refused.

[1756] As is pointed out above (22.2.2.5 (b)), that contract could also address the participation of national experts in the granting process, in line with the suggestion to establish a "virtual office".

Regarding the agreement with the EPO, the regulation (or amendment of existing regulations) to be enacted for the purpose of establishing the unitary SPC system in accordance with what is set forth above (22.2.5.1) could oblige Member States to undertake the necessary steps. The main purpose of the agreement concluded must be that the EPO, while performing the tasks assigned to it, remains bound by EU law in its entirety, including secondary legislation. This could be achieved for instance by a clause corresponding to Rule 1(2) of the Rules Related to Unitary Patent Protection promulgated by the Select Committee.[1757] The entire provision reads:

> Rule 1 Subject matter
> (1) The participating Member States hereby entrust the European Patent Office with the tasks referred to in Article 9, paragraph 1, Regulation (EU) No 1257/2012. In carrying out these tasks, the European Patent Office shall apply the present Rules and shall be bound by decisions handed down by the Unified Patent Court in actions brought under Article 32, paragraph 1(i), Agreement on a Unified Patent Court.
> (2) In case of conflict between the provisions of the present Rules and Union law, including Regulation (EU) No 1257/2012 and Regulation (EU) No 1260/2012, *the provisions of Union law shall prevail*. (emphasis added).

It is important to note that irrespective of the prerogative of EU law thus established, engaging the EPO in the manner provided for in Art. 63(4) EPC does not change the legal character of the EPO acting as a non-EU entity. Not being a "body, office or authority" of the EU, the acts undertaken by the EPO in that context do not fall under Art. 263 TFEU and are thus not subject to the mandatory review scheme enunciated in Art. 256 TFEU.

This leads to the question which arrangements are needed in order to ensure jurisdiction of the UPC. The competence of the UPC is outlined in Art. 32 UPCA. *Inter alia* this includes

- actions for actual or threatened infringements of SPCs (Art. 32(1)(a) UPCA);
- actions for declarations of non-infringement of SPCs (Art. 32(1)(b) UPCA);
- actions for declaration of invalidity of SPCs (Art. 32(1)(d) UPCA);
- counterclaims for declaration of invalidity of SPCs (Art. 32(1)(e) UPCA).

Thus, the current list does not encompass actions concerning measures taken by the authority or authorities involved in SPC granting procedures. However, pursuant to Art. 32 (1)(i) UPCA the Court is also competent for "actions concerning decisions of the European Patent Office in carrying out the tasks referred to in Article 9 of Regulation (EU) No 1257/2012". Therefore, the UPCA cannot review decisions by the EPO on the grant of unitary SPCs only because, *and as long as*, Art. 9 Reg. 1257/2012[1758] (or a separate provision enacted for the purpose) does not allocate that task to the EPO.

Also of interest in this context is Art. 87(2) UPCA, stipulating that the "Administrative Committee may amend this Agreement to bring it into line with an international treaty relating to patents or Union law".

[1757] Rules relating to Regulation (EU) No 1257/2012 of the European Parliament and of the Council of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection and to Council Regulation (EU) No 1260/2012 of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection with regard to the applicable translation arrangements (consolidated draft); available at http://documents.epo.org/projects/babylon/eponet.nsf/0/658AE58124AC70DBC1257DB10028B3D4/$File/e_draft_rules_unitary_patent.pdf (last accessed 18 October 2017).

[1758] Submitting that the regulatory purpose of the Regulation is enhanced so that it encompasses the grant of unitary SPCs and provided the legal requirements set forth above (22.2.5.1), are met.

Furthermore, Art. 20 UPCA provides that "the Court shall apply Union law in its entirety and shall respect its primacy".

Based on these provisions, the following options for establishing jurisdiction of the UPC against decisions taken in SPC granting procedures could be envisaged:

- **Option 1**: change of Art. 32 UPCA by international agreement and subsequent ratification;
- **Option 2**: amendment of Art. 32 UPCA by the Administrative Council based on Art. 87(2) UPCA in conjunction with pertinent changes in EU law.

Option 1 presents the most traditional, but also the most cumbersome solution; it might take incalculable time to be implemented. Compared to that, option 2 is more easily put into effect. It requires an act of EU legislation (for the requirements see above, 22.2.5.1), by virtue of which the task to review decisions taken in the course of procedures concerning the grant of unitary SPCs is allocated to the UPC.

22.2.6 Conclusions

Due to mandatory provisions of primary law, entrusting an existing or virtual EU authority with the grant of unitary SPCs results in the GCEU being competent to decide on appeals against decisions taken in the granting process. It is therefore impossible for EU legislation[1759] in the current legal environment[1760] to install the system which, pursuant to the survey presented under 22.2.3, is favoured by a large majority of stakeholders, namely, the grant of the unitary SPC by a virtual (EU) office with appeals being directed to the UPC. This means that two alternative routes – grant by an EU authority with appeals filed to the GCEU and grant by a non-EU body (the EPO) with appeals lodged at the UPC – must be explored.

An EU granting authority with subsequent appeal to the GCEU presents the lowest legal hurdles – what is needed here are rather small amendments of existing regulations (or the enactment of a separate regulation). In contrast to that, entrusting the EPO with the task of granting unitary SPCs might require more complex legislation, which would include the obligation of Member States to conclude an agreement with the EPO within the meaning of Art. 63(4) EPC, and which would also secure, through an act of EU legislation, the jurisdiction of the UPC. The choice between these options is ultimately of a political nature, and does not require a recommendation in the context of a legal study.

22.3 UNITARY SPCS: SUBSTANTIVE ASPECTS

22.3.1 Introduction

The substantive requirements for unitary SPCs will remain those stipulated in the SPC Regulations, and more precisely in Art. 3 Reg. 469/2009 and Art. 3 Reg. 1610/96. In

[1759] However, arrangements for a virtual office could be set forth in the contract concluded with the EPO under Art. 63(4) EPC; see above, 22.2.2.5 (b).

[1760] Unless the EU Treaty is amended or a protocol of the Treaty is adopted which excludes the competence of the GCEU for dealing with disputes relating to Unitary SPC to the benefit of the UPC; see above, 22.2.5.2.

principle, the case law and the current understanding of such requirements will be applied to the unitary SPC. The unitary character of the IP right, however, will raise specific issues with respect to the basic patent that may be designated for applying for a unitary SPC, the requirement of an MA under Art. 3(b) Reg. 469/2009 and Reg. 1610/96 and the prohibition of multiple certificates under Art. 3(c) Reg. 469/2009 and Reg. 1610/96. These specific substantive issues may require an amendment of the law governing the conditions for granting SPCs, as explained in the next sections.

22.3.2 Preliminary issues

The assessment of the options with their advantages and shortcomings that the EU legislature has to consider in defining the technical aspects of unitary SPC protection is affected by two preliminary issues:

- Whether the unitary SPC is to have optional or mandatory character
- Whether it will be possible to combine in the territory covered by the unitary patent a territorially limited unitary SPC with one or more national SPCs.

Regarding the first aspect, the alternative options are to allow the holder of a unitary SPC to choose whether to apply for a unitary SPC or a bundle of national SPCs or to provide that once the owner of a European patent has registered a unitary effect under Art. 3 Reg. 1257/2012 this choice implies that only a unitary SPC will be possible. An aspect that could favour the latter solution is the purpose of the unitary patent protection to preserve the integrity of the common market. It would be consistent therefore that the SPC protection must be unitary, as is the basic patent designated for the application for a certificate. For the optional character of the unitary SPC one could invoke the fact that also the bundle of national SPCs would remain subject to the same substantive law and to the jurisdiction of the UPC. As a consequence, the differences between a bundle of SPCs and a unitary SPC after grant would be marginal from the perspective of the effects on the single market. Further, unitary rights are generally optional and not mandatory. In consequence, the owner of a unitary patent should also be entitled to decide whether or not to apply for a unitary SPC or a bundle of national SPCs.

On the second aspect, the options are to provide that the unitary SPC must be either granted or refused for the whole territory of protection covered by the unitary patent, or to provide the applicant with the option to request the unitary SPC only for a part of the territory covered by the unitary patent and to obtain national SPCs for the remainder of the territory. This would be relevant for situations where the application for a certificate satisfies the requirement of protection only for a part of the territory covered by the unitary patent. Such situation may occur with respect to the requirement under Art. 3(b) Reg. 469/2009.

It is clear that the two aspects are related. If the EU legislature opts for the mandatory character of the unitary SPC and excludes the possibility of granting partial SPCs on the basis of a unitary patent, this could have harsh effects on the applicant if he or his licensee has obtained MAs only for a part of the territory covered by the unitary patent. At the same time, one must wonder whether it may or should be a possible task of the SPC legislation to create incentives for the patent owner and their licensees to obtain MAs with effect in the whole territory of the EU. If this is the case, these harsh consequences would be consistent with a specific policy choice and would

be acceptable. At the same time, the question is related to the third-party issue: if the SPC is to be granted whether the holder of the MA is related to the patentee or not, whether the patentee (or his/her licensee) has invested or not to obtain the MA, and if the SPC is intended to be a reward for having disclosed the invention and not for having obtained the MA for a product incorporating the invention, one might equally ask why this reward should be denied to the holder of a unitary patent when the MA is granted only for part of the territory in which the patent has effect. This would result in an incentive to obtain a European patent without unitary effect.

22.3.3 Art. 3(a)

The European Commission and the industry have taken into consideration as the basis for granting an SPC with unitary effect only the unitary patent. At the Seventh Conference of Experts in Latvia on 26th September 2017 one representative of an NPO raised the issue whether also the owner of a classic European patent will be entitled to apply for a unitary SPC, and if not, what the reasons for this different treatment are. In this respect, we consider it necessary to distinguish between a European patent opted out and a European patent subject to the jurisdiction of the UPC.

For European patents that have opted out of the exclusive jurisdiction of the UPCA, the grant of a unitary SPC poses significant legal challenges. The law of infringement applicable to the basic patent and to the associated unitary SPC would be different, if one assumes that Art. 25-29 UPCA apply to the unitary SPC irrespective of the nature of the basic patent – with or without unitary effect – designated for the granting procedure. In some exceptional cases, the change of the law could lead to situations where the same activity would not infringe the basic patent designated for granting the SPC, or would infringe only in a part of the territories covered by the bundles of European patents, but it would infringe the unitary SPC in the whole territory of protection covered by the latter.

> **Scenario I**: A company located in Germany manufactures in Germany and supplies in the UK an active ingredient that is then used by the supplied UK-based company in a fixed combination product covered by a European patent in both Germany and the UK. This activity does not amount to a contributory infringement of the German fraction of the European patent under Section 10 German Patent Act, while it does amount to a contributory infringement of the UK designation of the European patent under Section 60(2) UK Patent act. If a unitary SPC is granted, the same activity performed in Germany would amount under Art. 30 UPCA and Art. 26 UPCA to a contributory infringement of the unitary SPC in the whole territory of protection, which includes Germany as well.[1761]
> **Scenario II**: A company manufactures and uses a compound covered by a third-party SPC in order to obtain some data relating to a fixed combination including that substance under Art. 10(b) Dir. 2001/83/EC. This activity would be allowed under Sec. 11(2b) German Patent Act, but it could infringe the SPC under Art. 27(d) UPCA.

As European patents are subject to the exclusive competence of the UPCA, the law applicable to the classic European patent and the unitary SPC would remain identical. The granting of an SPC would not pose legal challenges like those mentioned above. However, it seems reasonable to assume that one of the purposes of the unitary SPC is to create an incentive for requesting unitary patent protection, since the latter from the perspective of the EU legal order is the preferable form of protection. Indeed it is the form of protection more consistent with the purpose of preserving the unity of the

[1761] See the analysis with respect to unitary patents and European patents in Roberto Romandini R, Alexander Klicznik, 'The Territoriality Principle and Transnational Use of Patented Inventions - The Wider Reach of a Unitary Patent and the Role of the CJEU' [2013] IIC 524; Horst Vissel, `Die Ahndung der mittelbaren Verletzung Europäischer Patente nach dem Inkrafttreten des EPGÜ´ [2015] GRUR 619.

single market. This incentive would be undermined if both types of European patents – that is with and without unitary effect – equally qualified for grant of a unitary SPC and benefited from the associated advantages (the single granting procedure).

This argument is open to counterarguments. For instance, it is not clear what the real differences are, from the perspective of the functioning of the common market, between a bundle of European patents subject to the UPC and covering all the States that have ratified the UPC and a unitary patent covering the same territory. One could indeed argue that both are unitary and uniform rights if enforced before the UPC. However, since the activity of the European Commission focuses on the creation of a unitary SPC as accessory *sui generis* right to a unitary patent, we do not further analyse this option.

22.3.4 Art. 3(b)

22.3.4.1 The issues

SPCs rest on two pillars, the first pillar being the basic patent and the second pillar being the valid MA. Arts. 3(a) and (b) of the SPC Regulations require that both pillars stand in that EU Member State for which SPC protection is requested. As the CJEU has clarified, for the grant of an SPC in Member State A, the applicant cannot rely upon the MA granted for Member State B.[1762] The reference in Art. 13(1) of the SPC Regulation to the first MA *"in the Community"* constitutes a special requirement aiming at the harmonisation of the term of protection only.[1763] Hence, said rule shall not apply in relation to the granting requirement as set out in Art. 3(b) of the SPC Regulations. This mandatory consonance of territories of the basic patent and the relevant MA is a basic principle for the current legislation: we may call it the principle of territorial consonance. It is not only in line with the wording and the concept of the present SPC Regulations,[1764] but also corresponds to the SPC regime's spirit and purpose to provide for compensation for the reduction of effective patent protection following from the requirement for a MA.[1765]

The mandatory consonance of territories of the basic patent and the relevant MA poses a challenge for unitary SPCs. In most of the cases, the territory covered by the unitary patent will be narrower than the territory covered by the MA.[1766] In other cases, however, the territorial coverage of the MA will be narrower than the territorial

[1762] Case C-110/95 *Yamanouchi Pharmaceutical* [1997] ECR I-03251, para. 28.

[1763] According to the CJEU, the reference in Art. 13(1) of the SPC Regulation to the first MA "in the Community" constitutes a special requirement aiming at the harmonisation of the term of protection only; *ibid.,* para. 25: "By referring to the first marketing authorization in the Community, the regulation is designed to exclude the possibility that, in Member States in which there has been significant delay in the grant of authorisation to place a given product on the market, a certificate can still be granted even though that is no longer possible in the other Member States in which the authorisation in question has been granted before expiry of the deadline. The regulation is thus intended to prevent the grant of certificates whose duration varies from one Member State to another."

[1764] *Ibid.*, para. 24, points to the further provisions of Arts. 8(1) lit. a) (iv), lit. c), 9(2) lit. e), 11(1) lit. d) of the SPC Regulations, which underline that the reference to the first MA "in the Community" serves a purely temporal purpose and constitutes a special requirement to be applied to the calculation of the term of protection only (note: the aforementioned provisions refer to the SPC Regulations as in force, while the CJEU refers to the corresponding provisions of Regulation 1768/92).

[1765] For the corresponding purpose of the SPC regime see Chapter 2, Sections 2.1 and 2.2.

[1766] This is so, because the most applications for a certificate relies on an MA issued by the EMA. Since not all the EU Member States are participating to the enhanced cooperation establishing the unitary patent and since not all the EU Member States will have ratified the UPCA at the date on which the first generation of unitary patents will be granted, the MA supplied in support of the application for unitary certificate will cover a territory that is broader than the territory covered by the unitary patent.

coverage of the basic unitary patent. While the first scenario is typical for national granting proceedings, the second scenario is new and problematic. Such a scenario is possible when the applicant for a unitary certificate relies on national MAs obtained on the basis of an MRP or DP.[1767]

The problem that Art. 3(b) Reg. 469/2009 and Reg. 1619/92 poses with respect to national MAs is not unique to the unitary SPC. Rather, it is a general issue that concerns unitary EU IP rights when the subject matter of the application satisfies the requirements for protection only in a part of the unitary territory of protection. Indeed this situation occurs, for instance, with respect to Union trade mark law, when the sign protected by the Union trade mark is not distinctive in the whole territory of protection or has not been used in a part of this territory. With respect to the unitary patent this situation occurs when an old prior right exists only in some countries.

In these cases the lawmaker has several options: it can decide that the right may be granted, but it is void or without effect in the countries where the revocation ground exists; it can decide that the right must be refused and, if granted, is invalid, providing for the option to convert the refused application or the revoked granted right in a bundle of national applications under preservation of the priority date; or it can decide that the application is rejected *sic et simpliciter*, because the applicant has the power and the burden to choose the title of protection – national or unitary – for which to apply. Finally the lawmaker can even decide to give up the requirement or to accept that is satisfied only in a part of the territory. An example for the latter option is the requirement for genuine use in trade mark legislation.[1768]

The situation we are addressing is therefore not unique to the unitary SPC. In designing a regulation for it within the context of the SPC legislation the lawmaker has however several choices that reflect the complexity of the SPC as an accessory right.

First, the lawmaker has to decide what type of MA can be supplied in support of the unitary SPC application.

Second, if the legislature accepts national MAs, it must decide what territorial scope the MAs admitted must present to support the application.

Third, it must determine the critical date at which the application for a certificate must meet the requirement under Art. 3(b) and which event triggers the six-month deadline under Art. 7 Reg. 469/2009 for filing the SPC application.

[1767] For our analysis we do not consider the case of single national MAs. There is hardly a need for a unitary SPC in this case, since isolated national MAs may be requested only for one country. Furthermore, relying on national MAs may pose additional legal challenges, since in this case the product subject to the authorisation could be identified with different terms in the national documents issued by the national agencies. Finally, in the interviews with the stakeholders we have found no indication that there is an interest in a unitary SPC on the basis of MAs granted by national agencies outside the framework of the MRP or DP.

[1768] See Art. 15 Reg. 207/2009. It is not required that genuine use took place in all EU States in order to avoid the sanction for absence of genuine use provided in the Regulation. However, use in single member state may not be sufficient after the judgement of the CJEU in the case C-149/11, ECLI:EU:C:2012:816.

In considering the different options, we must take into account the current situation and its relevance for the grant of a unitary SPC, as illustrated in the following table with respect to medicinal products[1769]:

SUPPLEMENTARY PROTECTION CERTIFICATE				
Basic Patent	**Marketing authorisation (MA)**			
National Patent in Member State A	**NP**		**DCP/MRP**	**CP**
	Member State A	Member State B		
	(+)	*(-)*	*(+) if Member State A included*	*(+)*
Unitary Patent	**NP**	**DCP/MRP**		**CP**
	Member State A	Selected Member States	All Member States	
	unclear	*Unclear*	*(+)*	*(+)*

Table 22.1: Interaction of national patents and unitary patents with different types of MAs

In relation to plant protection products, the variety of choices is more limited. For this reason, in the following we will analyse the possible solutions that could be adopted for both categories of products separately.

22.3.4.2 Unitary SPCs for medicinal products and Art. 3(b)

(a) *Type and territorial scope of the MAs*

(i) Products authorised on the basis of centralised procedure

The first option is to grant unitary SPCs only for products which have been authorised on the basis of centralised procedure. In such a case, the territory covered by the MA would include the territory covered by the unitary patent.[1770]

The shortcoming of this scenario is that no unitary SPC would be available for the medicinal products that are not subject to the mandatory or optional use of the centralised procedure as provided for by Reg. 726/2004.

However, while existing medicinal products were predominantly authorised under national procedures, today the vast majority of MAs are granted under the centralised procedure. This is because, in addition to the list of indications according to which the conduct of centralised authorisation procedures is mandatory,[1771] the scope of the centralised procedure is already broad, as it can be optionally referred to when

[1769] The possibility of granting (national) SPCs on the basis of unitary patents is not illustrated in table 22.1; for details see Chapter 21, Section 21.2 above.
[1770] Dorothea von Renesse et al, `Supplementary Protection Certificates with Unitary Effect ("U-SPC") – A Proposal´ [2016] GRUR Int. 1129, 1131.
[1771] Art. 3(1) Reg. 726/2004.

- The medicinal product contains a new active substance which was not authorised in the Community on the date of entry into force of Reg. 726/2004; or
- the medicinal product constitutes a significant therapeutic, scientific or technical innovation; or
- the granting of a Union authorisation is in the interest of patients or animal health at Community level.

Now, under the current CJEU case law the grant of a certificate is possible, *inter alia*, with respect to three factual scenarios:

- an MA is issued for a medicinal product that includes an active substance never authorised before in the Union (that is a new active substance) protected by the basic patent;
- an MA exists for a medicinal product that include a combination of active ingredients as fixed combination products never authorised before and protected by the basic patent;
- an MA is given for a medicinal product that includes an active ingredient or a combination of active ingredients previously authorised in the past, but that is to be used for a new indication that is protected by the basic patent, provided that the MA concerned is the first that falls under the scope of said patent.

If one considers these three situations from the perspective of the rules governing the centralised procedure it follows that:

- New active substances will always be eligible for an assessment under the CP;
- Fixed combination products are eligible for an evaluation under the centralised procedure, provided that the combination of active ingredients was not previously authorised at national level and may be regarded as a new active substance. Further, if the medicinal product consists in a combination of active substances already authorised in the past at national level, such medicinal product could be eligible for the centralised procedure, provided that it represents a significant technical innovation or a centralised authorisation is in the interest of the patients (Art. 3(2)(b) Reg. 726/2004);
- New indications of active ingredients already authorised in the past will be eligible for the centralised procedure when they refer to a centrally authorised medicinal product, and the authorisation is requested by the MA holder itself as a II-type variation of the existing MA. Further, new indications of old active ingredients will be eligible for the centralised procedure if they are the subject of a hybrid abridged application under Art. 10(3) Dir. 2001/82 or Art. 10(3) Dir. 2001/83 filed by third parties, provided that the reference medicinal product was centrally authorised. Finally, new medical indications, even if they concerned an old active ingredient authorised before 2004 at national level, are eligible for the centralised procedure when the requirements under Art. 3(2)(b) Reg. 469/2009 are met.

In consequence, cases in which a medicinal product is not eligible for the CP, but the requested MA would be able to support an application for certificate, are possible, but not likely to be frequent.[1772]

One case could occur where a patent is granted for the new indication of an active ingredient authorised before 2004 at national level, and the indication concerned does not meet the conditions laid down in Art. 3(2)(b) Reg. 469/2009. In this case the medicinal product that employs the active ingredient for the patented indication will not be eligible for an evaluation under CP. Still, the patent concerned could successfully support the application for a certificate.[1773] Other situations are thinkable with respect to combinations products including old active ingredients.[1774]

Nevertheless, to foster the availability of unitary SPCs also in relation to products that are not subject to the centralised procedure, the EU legislature could consider further extending the scope of Reg. 726/2004. Such amendment should, however, be subject to a prior analysis taking into account the resulting burden for the EMA.

(ii) Products authorised in all territories of protection on the basis of national MAs

The second option could be to admit also national MAs for the purpose of the procedure for granting a unitary SPC, but to require that such MAs exist in the whole territory covered by the patent.

This option has some shortcomings. The authority entrusted with the grant of the unitary SPC would have to examine the content of documents drafted in the national languages of the national health agencies that have issued the MAs supplied with the application for a certificate.

(iii) National MAs issued for a part of the territory covered by the unitary patent

If the EU legislature accepts that national MAs may be the basis for a unitary SPC, then it will have to decide whether or not such MAs must exist in each Member State covered by the unitary patent designated for the purpose of the procedure. The latter option may not lead to admitting protection for the product in a country where no MA exists at the critical date, because this would contradict the very purpose of the SPC legislation. But under preservation of this principle, at least two variants are possible:

[1772] Before submitting an application for the grant of an MA, pharmaceutical companies must submit a so-called eligibility request for evaluation under the centralised procedure. The evaluation of such eligibility request is carried out by the EMA but its outcome is only communicated to the applicant. See EMA, 'European Medicines Agency pre-authorisation procedural advice for users of the centralised procedure', para. 2.2, EMA/821278/2015, 30 August 2017, available at http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004069.pdf (last accessed 31 october 2017).

[1773] Some NPOs apply *Neurim* not only to the factual scenario where the first MA was granted for the use of the active ingredient as medicinal product for a different species, but also when the previous MA concerned the use of the active ingredient for the same species.

[1774] According to the EMA, "old established products are generally not eligible for the centralised procedure, unless there is something significantly new, or unless there is 'Community Interest'". Presentation by George Wade, EMA, 'The Centralised Procedure', 1-2 February 2010, slide 10, available at http://www.ema.europa.eu/docs/en_GB/document_library/Presentation/2010/03/WC500074885.pdf (last accessed 17 July 2017).

Option I: The unitary SPC may be granted only for a part of the territory covered by the bundle of national MAs; in the remaining States national SPCs may be requested under the deadline of Art. 7 Reg. 469/2009 (grant of a partial SPC), once an MA with effect in those States is awarded;
Option II: The unitary SPC is granted for all territory covered by the unitary SPC, but it is effective or valid only in the part of the Union where an MA exists at the critical date; in the remaining countries the unitary SPC is not effective or not valid; third parties are entitled to an *inter partes* defence. The unitary grant for the whole territory covered by the unitary patent would prevent further SPCs from being granted (Art. 3(c) Reg. 469/2009) in the States where the SPC is ineffective.

The first option does not imply a relaxation of the principle of territorial consonance. Indeed, the unitary right is granted only in the territory where an MA exists. The second option, by contrast, means that a unitary SPC is granted also for States where the requirement under Art. 3(b) is not met at the critical date. However, the option of an EU unitary right that is granted for the EU, but not enforceable or not valid in the whole territory of protection is not without precedents. Examples exist in the Union trade mark system.[1775] Limitations to the unitary character of the granted right are also provided in the UPCA handling of prior-user rights[1776], as well as in the provisions concerning older national prior rights in the Luxembourg Agreement relating to Community patents.[1777]

The availability of a unitary SPC in situations where only national MAs are supplied, and these only for a part of the territory, in support of the application raises the further issue whether the legislature should introduce as an additional requirement in the SPC Regulation that the bundle of national MAs must have been obtained in a predefined minimum number of Member States in order to support the application for a unitary certificate. For instance, the grant of a unitary SPC could be made subject to the applicant having obtained at least three MAs at the critical date, or MAs for a group of participating Member States in which the combined number of patent applications in the year preceding the application for a unitary SPC amounts to two-thirds of all patent applications made in all participating Member States. Such a requirement would make sure that a substantial part of the internal European market is covered by MAs.

(b) *Critical date for assessing the existence of the requirements of protection*

Any system of IP rights needs a critical date on which the requirements for protection must be assessed. In patent law this critical date in Europe is the filing date or the priority date. Under the SPC legislation in force the critical date is the date on which the application for a certificate has been filed.[1778] This applies of course also to Art. 3(b) Reg. 469/2009.

Now, if a unitary SPC is to be possible only when the applicant has supplied a Union MA, there is no need and no reason to deviate from such principle. If national MAs are admitted, then the question – as already anticipated – the EU legislature has to deal with is whether to select other critical dates for assessing compliance with Art. 3(b)

[1775] So for instance, with respect to registered European Union trade marks (EUTMs), the CJEU has confirmed that while a sign may peacefully coexist with an EUTM in a part of the territory, it can still be infringing the same EUTM in another part of the Union (Case C-93/16 *Ornua (Kerrygold)* [2017] ECLI:EU:C:2017:571) In these situations the EUTM – despite its unitary character – is enforceable against said sign in one part of the Union but not in another. See also Case C-235/09 *DHL v Chronopost* [2011] ECLI:EU:C:2011:238.
[1776] Art. 28 UPCA.
[1777] Art. 36(1) in conjunction with Art. 56(1)(f) CPC.
[1778] Art. 3 Reg. 469/2009 refers to the date of the application.

Reg. 469/2009. Several options are conceivable, and some of them were mentioned at the MPI Workshop on 20 March 2017, in the literature or in the course of stakeholders' interviews:

- the expiration date of the six-month deadline for filing an SPC triggered by the first MA granted in one of the EU States covered by the unitary SPC
- the granting date of the SPC
- the expiration date of the basic unitary patent
- the date on which the unitary SPC is enforced

The latter option has been proposed in the literature[1779] and by several stakeholders[1780]. At the MPI Workshop on 21 March 2017 it has been observed, however, that this approach would require the judges of the UPC in infringement proceedings to examine and define the territorial validity of the right enforced. This is a task that is usually performed for registered rights by the granting authority.

(c) *Deadline for lodging the application for a certificate (Art. 7)*

In assessing the options, the EU legislature will have to take into account another aspect of the law, precisely the deadline for filing the application. The obvious option would be the date on which the first relevant MA is granted.[1781] But one could also argue that an application for a unitary SPC is meaningful only when the MA exists or is requested for a minimum number of jurisdictions, so one could fix the deadline with respect to the granting date of the second MA in the Union. This seems to be the approach suggested by one contribution in the literature.[1782]

(d) *The view of the NPOs and the stakeholders*

The question whether the unitary SPC should be granted only on the basis of a European MA was also put to the NPOs.[1783] Their answers were rather diverse. While over a third (eleven offices out of 27 asked) did not take a stand in this regard at all, seven NPOs were in favour of granting a unitary SPC only on the basis of a European MA, while five consider it feasible to grant the unitary SPC on the basis of a bundle of national SPCs.

The following comments made by the NPOs were relevant for our analysis:

> "This question should be examined in depth. A possible solution to this problem has recently been suggested for an SPC with unitary effect (Dorothea von Renesse et al., *Supplementary Protection Certificates with Unitary Effect ("U-SPC") a Proposal* [2016] GRUR Int. 1129). According to this proposal, a unitary SPC could be granted, even if there are not MAs in all member states covered by the unitary patent, but the resulting SPC would only be enforceable in states with an MA."

> "How can you have a unitary SPC based on a national MA? That would mean you would enjoy a monopoly (and deter generic competition) in countries where you don't have an MA, i.e. where the product is not on the market. One would think this goes against the basic principles of the current regulation.

[1779] Dorothea von Renesse et al, `Supplementary Protection Certificates with Unitary Effect ("U-SPC") – A Proposal´ [2016] GRUR Int. 1129, 1131.
[1780] *Ibid.*
[1781] Charlotte Weekes, `Getting the end-game right – SPCs and unitary patents in Europe´, available at https://www.pinsentmasons.com/PDF/2016/getting-the-end-game-right.pdf (last accessed 18 October 2017).
[1782] Dorothea von Renesse et al, `Supplementary Protection Certificates with Unitary Effect ("U-SPC") – A Proposal´ [2016] GRUR Int. 1129, 1131.
[1783] Q78 of the MPI Questionnaire for the NPOs, Annex VI of this Study.

> Apart from that, from a practical perspective, national MAs are written in the official national language (of which we have many in Europe). Hard to see how a centralised body could verify those or check national databases for their existence."
>
> "For granting an SPC the first MA (centralized or national) should always be taken into consideration, as it is now. However the existence of partly unitary SPCs should be taken also into consideration. According to SPC EU regulation, "the certificate shall confer the same rights as conferred by the basic patent and shall be subjected to the same limitations and the same obligations". As it is now, the regulation seems to indicate that an EU MA should be necessary."
>
> "Whilst we agree that the product which will be the subject of a unitary SPC should be authorised in all participating states, we see no reason why this should be limited to an EMA approval. A "bundle" of national MAs, or a combination of an EMA authorisation for some countries, and national authorisations in other should suffice. It is noted that the current SPC paediatric extension requires that a product be authorised in all MS, but does not limit this to EMA approval, so our suggestion is not without precedent."

Of the 145 Stakeholders that answered the questions concerning unitary SPCs the distribution of responses to Q75 on if a unitary SPC should be granted only when the product is covered by a European marketing authorisation granted by EMA is as follows:[1784]

- 31 per cent support the view that unitary SPCs should only be granted on the basis of MAs obtained within centralised procedures.
- 58 per cent support the view that unitary SPCs should also be granted on the basis of national MAs.
- 11 per cent had no opinion.

As to the comments and the submissions at the Stakeholder Seminar, the prevalent view was that making the issue of a unitary SPC dependent upon the existence of a European MA would lead to an unjustified unequal treatment of some companies and products. The following verbatim comment collected by the Allensbach Survey with respect to Q75 is in line with opinions collected by the MPI in qualitative interviews and at the Stakeholder Seminar:

> "To limit unitary SPCs to products authorised by the EMA would be doubly discriminatory. Firstly, only some medicinal products are permitted to seek authorisation via the EMA. Secondly, this authorisation route is not available for crop protection or veterinary products."[1785]

Also at the MPI Stakeholder Seminar representatives of the crop industry pointed out that the absence of an authorisation granted with effect for the whole EU market in the field of crop products calls for solutions that may accommodate this specific regulatory regime within the unitary SPC system. Otherwise the innovative industry of this field would refrain from applying for a unitary patent. Furthermore, it would also be excluded from the advantages of a unitary SPC, which would mean a discrimination.

(e) *Recommendation*

Some of the decisions the EU legislature has to make in designing a unitary SPC are of a policy and not a technical nature. This is true in particular of the question to what extent the principle of territorial consonance should be relaxed in order to accommodate national MAs as well in the unitary SPC system. These are policy issues because the lawmakers could pursue different objectives in refining the unitary SPC rules. On the one hand, they could be interested in creating incentives for the

[1784] Q75 of the Allensbach Survey, Annex III of this Study, pp. 274-275.
[1785] See Annex III of this Study, p. 414.

applicant to file and obtain MAs in the whole territory of protection. In this case it would be consistent to require – as in the case of paediatric extensions – that the applicant obtains an MA in all countries to which the unitary effect of the patent supplied for the procedure pertains. On the other hand, the lawmakers could have in mind as a main purpose to create incentives to apply for unitary patent protection, since this fosters the integration of the single market. In this case, flexibilities on the territorial scope of the granted unitary SPC would be appropriate. Finally the lawmaker could privilege the goal of preventing a heterogeneous development of the case law and practice in granting SPCs: in this case, there would be an interest in attracting a majority of applications toward the Unitary SPC Divisions, since they would then be subject to the uniform practice of that Division. Accordingly, it would be consistent with this goal to admit national MAs as basis for granting SPC even if they are valid only in a part of the territory covered by the unitary patent.

These policy aspects are at the discretion of the lawmakers, and are not dictated by primary law. As consequence we will only comment on the technical aspects – mentioning what are in our view the advantages and the shortcomings of the different options. The focus of the analysis lies on the approaches that, according to the information collected by the MPI, at the moment gain increased acceptance by the stakeholders.

(i) Unitary SPCs for centrally authorised medicinal products

The grant of unitary SPCs for products which have been authorised under centralised authorisation procedures is obvious and unproblematic. In this case, the situation is similar to that existing under national granting procedures, where only a (national or European) MA is supplied and this MA covers or includes the territory in which the basic patent is in force. Here there will be no problem for determining the deadline for lodging the application, which will remain the notification date of the MA. Only one document – the European MA – will be considered in examining Art. 3(b). The same holds true for determining what is the product covered by the granted SPC under Art. 4 Reg. 469/2009. The SmPC is available in several EU official languages, so that the examination of unitary certificate application should not present significantly higher burdens for the Unitary SPC Division than the examination of national certificate applications.

Modifications of the regulation scheme are not necessary. A corresponding rule could be implemented by introducing a new Art. 3(a) Reg. 469/2009 that could read as follows:

> Article 3(a)
> **Unitary Supplementary Protection Certificates**
> (1) If the basic patent referred to in Article 3(a) is a European patent with unitary effect pursuant to Article 3 Regulation 1257/2012, a unitary supplementary protection certificate shall be granted if a valid authorisation to place the product on the market as referred to in Article 3(b) has been granted in accordance with Regulation 726/2004.
> (2) …

In view of the fact the territory covered by the MA includes the territory to which the unitary patent applies, Art. 30 UPCA would not need to be amended or clarified in the present scenario.

(ii) Unitary SPCs for product authorised within the framework of DP or MRP

The granting of unitary SPCs on the basis of national MAs issued within the framework of the DP or MRP pose some technical and practical challenges. As pointed out by some NPOs, the examination of MAs drafted in 14 or 15 different languages could come to be a burden for the examiners concerned. One could argue that this exercise is to some extent already required in the system in force, when for instance an NPO has to examine a paediatric extension request or when the NPO has to examine an application with respect to which the first MA for the purposes of Art. 13 Reg. 469/2009 is a foreign MA. Admittedly, the examination required to check the compliance of an SPC application with Art. 3(b) Reg. 469/2009 is more complex. Further, under *Forsgren,*[1786] the NPO may be required to consider in detail the scientific part of the MA if the applicant requests the certificate for a product that was not identified as the active substance in the MA, and argues that such product has a therapeutic effect that falls under the therapeutic indication of the MA concerned. However, the national authorisations granted under the DP and MRP are drafted with identical content and structure. The establishment of a virtual office consisting of examiners from the different NPOs could make possible informal exchanges of information between examiners from different jurisdictions. A translation service can be provided when the analysis of a specific national MA becomes necessary. Alternatively, the lawmakers could require the applicant to file certified translations in English.

Another difficulty that could follow from accepting unitary SPCs on the basis of national MAs is that that the identification of the product in the national MA may not be uniform. As already mentioned, in our understanding of Art. 4 Reg. 469/2009 only the MA matters for defining the product covered by the SPC.[1787] The product description cannot extend or limit the scope of the SPC. According to what is reported in the literature, in some national MAs "the active substance is only described in terms of the active moiety, and not in the terms of the actual substance used, which may be a salt".[1788] In others, by contrast, the active substance is identified by referring to the active part of the compound, which can be shared by a several variants (salt, esters). However, while this may be true for purely national MAs,[1789] according to the statements of several stakeholders in the case of national MAs granted within the framework of the MRP and the DP this does not occur. Such MAs adopt the same wording in identifying the product and are uniform irrespective of the national authority that has granted the MA.

A corresponding legal provision to grant SPCs on the basis of national MAs obtained within MRP or DP could be implemented by introducing following additional paragraph in the Art. 3(a) SPC Regulation as already suggested above:

> Article 3(a)
> **Unitary Supplementary Protection Certificates**
> (1) …
> (2) Paragraph 1 shall apply mutatis mutandis if a valid authorisation to place the product on the market, as referred to in Article 3(b), has been granted in accordance with Chapter 4 of Directive 2001/82/EC or Directive 2001/83/EC.

[1786] Case C-631/13 *Forsgren* [2015] ECLI:EU:C:2015:13.
[1787] See Chapter 14, Section 14.5.
[1788] Paul G Cole Lucas & Co (eds), *CIPA Guide to the Patent Acts* (8th edn, Sweet & Maxwell 2016).
[1789] We have not collected evidence and conducted interviews on this point.

In addition, a reference to Art. 3(a)(2) would need to be included in the SPC Regulation to make clear that the authorisations referred to in Art. 3(b) include the MAs relied upon for the grant of a unitary SPC.

(iii) Unitary SPCs for products authorised by MRP and DP in part of the territory covered by the unitary patent

If the European Commission accepts that unitary SPCs should also be granted on the basis of national MAs issued within the framework of decentralised or mutual recognition procedures, then it will be confronted with the question whether or not the grant of a unitary SPC is possible when at the critical date MAs have been issued only in a part of the territory to which the unitary effect of the designated basic patent applies.

This decision has political character. As already mentioned, it will be the result of weighing complementary or conflicting goals, such as creating incentives for EU-wide MAs or increasing the attractiveness of unitary patent protection. According to our understanding, from a technical perspective, such option would imply only one additional burden for the examiners beyond those created by the admission of national MAs for granting unitary SPCs. The applicant will designate the countries for which the unitary SPC will be issued and in which a valid MA exists on the critical date. The limitation of the territorial scope could be included in a new paragraph of Art. 5(a) SPC Regulation:

> Article 5a
> **Territorial scope of unitary SPC**
> (1) In case of unitary supplementary protection certificates granted in accordance with Article 3(a)(2), the protection conferred by this certificate shall extend only to the territory of those Member States in which a valid authorisation to place the product on the market in accordance with Chapter 4 of either Directive 2001/82/EC or Directive 2001/83/EC has been granted at the time of **[critical date].**

It appears not mandatory for the functioning of the system in this regard to include an additional quantitative requirement for a certain minimum number of national MAs having been granted for the product in question at the critical date in order to grant the unitary SPC.[1790] In view of the principle of territorial consonance, it could also suffice to limit the territorial scope of a unitary SPC to those Member States that have actually granted MAs for the relevant product. While this concept may be in tension with Art. 30 UPCA, in order to avoid an amendment of the UPCA a corresponding provision should be included in the SPC Regulation. Such provision would apply in proceedings before the UPC pursuant to Art. 20 UPCA and Art. 288(2) TFEU.

(iv) Unitary SPCs with static or dynamic territorial coverage

Following the filing of an application for a certificate for or even the grant of a unitary SPC, additional MAs may be granted for the product in the remainder of the territory covered by the unitary patent. This scenario represents a challenge for the lawmaker but also for the applicants.

[1790] In the Allensbach Survey twelve participants underlined in general comments on Q62 that establishing a unitary SPC would already be beneficial for the reason that this would further harmonise the granting procedure. A single granting procedure was expressly considered as a potential benefit by these participants. See Annex III of this Study, pp. 373-378 and pp. 405-422.

Under the SPC legislation in force, in each of the countries where an MA is granted, the patent owner could apply for a national SPC under observance of the deadline of Art. 7 Reg. 469/2009. The duration of such SPC would still be based on the first MA granted in an EEA or EU State under Art. 13 Reg. 469/2009. But the 6-month deadline would start from the granting (or notification) date of the MA issued in the State concerned. In order to take account of this situation, the lawmaker has two methods that are technically equivalent.

The first is to provide that the unitary SPC has a static territorial coverage limited to the countries in which at the critical date an MA exists. At the same time, in the States where an MA is awarded after the critical date, a national application can be filed designating the same unitary patents. In this way the owner of the unitary patent can obtain a unitary SPC for the countries where an MA exists at the critical date, and a bundle of national SPCs for the countries where an MA is issued later. The granted SPCs will then anyway be subject to the jurisdiction of the UPC. This situation is not unique, since it could have occurred also under the UPCA with respect to unitary patents if Italy had refused to join the system of enhanced cooperation while ratifying the UPCA.[1791]

We may call this approach a combination of static unitary SPC and national SPCs with a different application date, but an identical expiration date, since they share the same basic patent and the same MA.

The second option is a more sophisticated one. It requires the creation of what we may call a unitary **SPC with dynamic territorial coverage**. The EU lawmaker could indeed provide that the owner of the unitary patent, instead of filing a national application for a certificate after the grant of the partial unitary SPC, could file a request for an extension of the territorial coverage of the unitary SPC itself. Such request could be filed up until the expiration date of the basic unitary patent. The territorial scope of the unitary right would grow and change with the time.

To implement such a solution, a new provision could be added providing for the possibility of an application for the territorial extension of a unitary SPC. A corresponding rule could be included as a new Art. 7a as follows:

> Article 7a
> **Application for territorial extension**
> "The holder of a unitary supplementary protection certificate granted in accordance with Article 3(a)(2) can apply for an extension of the territorial scope of protection pursuant to Article 4(2) within six months of the date on which an authorisation referred to in Articles 3(b) and 3(a)(2) to place the product on the market as a medicinal product was granted.

The second option discussed is not without problems. It would create a situation without exact precedents in the context of unitary titles of intellectual property protection[1792]. Indeed the extension of the unitary SPC is not really comparable with the extension of an international trade mark, as one speaker suggested at the MPI Seminar in Munich. The latter leads to a bundle of national rights, and does not lead to

[1791] In this case, the grant of a European patent could have led to a European patent with unitary effect for some countries, and to a bundle of European patents for others. The Italian fraction of the bundle would have been subject to the UPC jurisdiction together with the European patent with unitary effect granted for the EU Mamber States participating in the enhanced cooperation.

[1792] Some parallel is offered by the extension of Union trade marks and Community design to the territory of new Member States after the accessions in 2004, 2007 and 2013. However, this was the consequence of an act of state, and not of individual decisions.

the extension of the territorial coverage of a pre-existing unitary title of protection. The situation in which, at the granting date, third parties do not know what territory will ultimately be covered by the granted unitary right is unknown to national and European legislation.

However, one could adopt some precautions that could take into account the position of third parties. First, the law could require the applicant to designate immediately the countries for which the protection will be requested. The designation could be required at the filing date. Second, one could stipulate that such designation is effective only if at the filing date the request for an MA is pending for the countries designated. References to the pending MA application may be included in a public register for pending SPC applications or granted SPCs. Without going into the details of this option – details that must be left to experts from the NPOs – adequate precautions could ensure that the third parties are not rendered worse off under a unitary SPC with dynamic territorial coverage than under the current legislative framework or under a unitary SPC with static territorial coverage that can be combined with national SPCs. Indeed, also under the current legislation, if no unitary SPC is created, the applicant will be entitled to obtain a bundle of national SPCs that may cover in principle the same territory covered by the unitary patent. This will occur progressively, as soon the national MAs are issued in the EU States to which the unitary effect applies. Such SPCs will be then subject to the competence of the UPC. The only difference with respect to this situation is that the applicant will not obtain a unitary right, but a bundle of national SPCs. But since the bundle of national SPCs granted on the basis of the unitary patent can also be enforced and challenged before the UPC, the applicable law on infringement would remain the same. Therefore, for third parties it would not make a significant difference if, instead of granting a national SPC for an EU State where the MA has been issued, the Unitary SPC division or office grants a territorial extension of the unitary SPC already granted for other EU States.

The Unitary SPC Division will then examine the requirement for granting the extension of the unitary SPC – that is, same basic patent and MAs with identical wording granted within the DP or MRP procedure. A renewed examination of the general conditions for obtaining the certificate[1793] will in principle not be necessary. The unitary SPC division or office has already done this examination in the course of granting the unitary SPC. In this way, a uniform examination will be ensured for the territorial extensions.[1794]

22.3.4.3 Unitary SPCs for plant protection products and Art. 3(b)

In view of the different regulatory regime applicable to plant protection products, we recommend to adopt the model of a unitary SPC with dynamic territorial coverage.

As already explained, no counterpart to Reg. 726/2004 exists in the field of plant protection products. MAs for putting plant protection products on the market are granted within the framework of the so-called zonal authorisation system in

[1793] Art. 3(a) or Art. 3(c) for instance.

[1794] As the grant of the patent or of the SPC has retroactive effect, injunction will be possible in the territory covered by the unitary SPC on the basis of an extension only if the alleged infringing acts were performed after the grant of the extension and continued after that date. Indemnification claims for acts performed before the extension will be possible, provided that the applicable law provides for such claim. These issues, of course, may become relevant only in exceptional situations where the patent expires before the extension of the unitary SPC is granted. If the patent expires before the extension of the SPC is requested, as we will see, the extension of the unitary SPC will not be possible (just as it would not be possible to obtain a national SPC).

accordance with Arts. 28 et seqq. Reg. 1107/2009.[1795] According to this, MAs are granted by the competent national authorities of the Member States.[1796] Other Member States are then in principle obliged – subject to Art. 36(3) Reg. 1107/2009 – to accept the decision of the reference Member State on a mutual-recognition basis.[1797] One could raise the question whether the authorisation granted following the evaluation of active substances pursuant to Art. 4 et seq. Reg. 1107/2009 can be referred to as a legal basis for the grant of a unitary SPC.[1798] Still, this authorisation does not entitle its owner to place a specific plant protection product on the market. Its scope is limited to the use of the respective active substance as an ingredient of a plant protection product that in its turn requires formal approval prior to being put on the market. Therefore, the grant of an SPC cannot be justified on the basis of an active-substance authorisation. The option to provide for a central MA as a basis for a unitary SPC is not available for plant protection products. This aspect was also pointed out by several stakeholders in the Allensbach Survey as well as at the MPI Stakeholders Seminar on 11th September 2017. Therefore, a unitary SPC with dynamic territorial content would ensure an equal treatment for holders of European patents with unitary effect for plant protection products and medicinal products. It would ensure a uniform examination of the originally requested SPCs and later filed requests for extensions. Finally, it would not imply higher uncertainty for third parties. Under the legislation in force, third parties are already confronted with the possibility that the SPC obtained by the patentee in one State is followed by further SPCs in other Member States, until the basic patent is not expired.

22.3.5 Art. 3(c)

A specific issue with respect to unitary SPCs concerns the operation of Art. 3(c) Reg. 469/2009. This provision provides for a prohibition of double protection and an invalidity ground in the case that the applicant for a certificate has already received an SPC for the product for which a second SPC application is filed. If the product is covered by an older unitary SPC, this will prevent the grant of national or unitary SPCs. The question is whether a unitary SPC will be equally invalid in the converse case, that is, when an older *national SPC* in one or more countries has been granted for the same product to the same applicant. This factual scenario recalls the situation of older prior national rights and (the formerly envisaged) Community patents, in the case that an older national novelty-destroying patent application exists only in a part of the territory covered by the Community patent. Three options exist in this regard:

- The unitary SPC is invalid since the unitary character requires that in the whole of the territory of protection the requirements under Art. 3 Reg. 469/2009 are met.
- The unitary SPC is treated as invalid only in the country where the revocation ground – that is, the older national SPC – exists.
- The unitary SPC is invalid, but an option for conversion of the unitary SPC into a bundle of national SPC applications is provided.

[1795] See above, Chapter 4, Section 4.3.
[1796] Art. 28(1) Reg. 1107/2009.
[1797] Art. 40 Reg. 1107/2009.
[1798] This was suggested by some stakeholders in response to Q76, see Annex III of this Study, pp. 405-422.

Where senior national rights and unitary patents are concerned, no rules have been adopted under the Unitary Patent Package for the case that a revocation ground under Art. 139(3) EPC is given for the unitary patent in some of the territories covered by the unitary patent. As a consequence, the unitary patent is invalid pursuant to Art. 65(2) UPCA. By contrast, Art. 36(1) and Art. 56 Community Patent Convention limited the effect of the revocation of the Community patent to the countries where the revocation ground based on the older prior rights existed. The lawmakers could consider the latter models in the case that the same product is covered by a unitary SPC and in some countries by national SPCs with an earlier granting date. However, against this approach one could argue that a significant difference exists between the provisions implementing Art. 139(3) EPC in the community patent system and Art. 3(c) Reg. 469/2009: while the patentee has no way to predict or prevent the existence of an older prior right, except for a situation of self-collision, Art. 3(c) applies in consequence of the case law only to situations where the same entity has filed the applications concerning the same product.[1799] Therefore, it seems reasonable to accept that, just as a unitary SPC would prevent the grant of another (national or unitary) SPC for the same product to the same applicant, so a national SPC should prevent the grant of another SPC (unitary or national) with effect in the same Member State(s).

22.3.6 Art. 3(d)

Under Art. 3(d) of the SPC Regulations the MA on which the application for a certificate is based must be the first granted in the Member State concerned. This requirement may require some adaptation with respect to unitary SPCs. Indeed if the oldest relevant MA covering the product is a national MA and not a Union MA, situations are possible where the MA supplied in support of the certificate is the first MA in some countries, but not in other ones. An example can clarify the issue.

> **Example**: In support of the application for a certificate the applicant files a European MA granted for the compound A for a released formulation for indication B. A third party informs the Unitary SPC Division that in two EU countries some years before national MAs with effect in those countries were granted for a different formulation of the same active ingredient and for a similar indication. The virtual office comes to the conclusion that the MA supplied in support of the application is not the first MA in these two countries, but is the first one in the remaining countries in which the basic patent has unitary effect.

There are three approaches to regulate the operation of Art. 3(d) in situations such as that described in the example. First, the lawmaker could decide that the application must be rejected for the whole territory of protection; in the countries where this is still possible the applicant may file a national application. The lawmaker could provide the applicant with the right to convert the refused application or the revoked SPC into a national SPC application in line with the model of Art. 135 EPC.

The second option is similar to those identified with respect to 3(b) Reg. 469/2009: the applicant could be allowed to apply for a partial unitary SPC for the countries where the requirement of Art. 3(d) is satisfied by the MA or bundle of MAs supplied in support of the application. If one accepts a system where the applicant may obtain a

[1799] See Chapter 12, Section 12.1.2.

partial SPC and has to designate the countries for which protection is sought, this system could also apply to Art. 3(d) Reg. 469/2009.[1800]

With the growing importance of European MAs it is possible that the issue discussed in in this section will turn out to be marginal. Here the development of the case law could also be relevant. On the one side, if *Neurim* principles are confirmed and extended to new formulations, the cases where the first MA granted for the active ingredient will not be relevant under Art. 3(d) will become more and more. On the other side, if the older national MA cannot be disregarded under *Neurim*, irrespective of the solution adopted with respect to Art. 3(d), such older MA will continue to be relevant for the purposes of Art. 13 Reg. 469/2009.

22.3.7 Critical date

The critical date for assessing the existence of the requirements of protection under the current SPC legislation is the date on which the application for a certificate is lodged. A possible question for the legislature is whether a later date could be proposed for the unitary SPCs as far as Art. 3(b) Reg. 469/2009 is concerned. This would allow the examiner to take into consideration MAs granted after the filing date and to grant an SPC with a broader territorial scope.

We shall here distinguish three groups of MAs:

- national MAs granted before the filing date and supplied in support of the application,
- national MAs granted after the filing date but before the date on which a decision on issuing the SPC is made and
- national MAs granted after the issuance of the unitary SPCs.

The examiner can take into account the first group of national MAs in examining the application and defining the territorial scope of the right. He/she can take into account the third group in examining the request for a territorial extension of the granted unitary SPC. The question is whether the applicant shall be allowed to introduce in the proceedings for granting the SPC MAs granted after the filing date until the application for a unitary certificate is still pending. If the precautions suggested for the request of a territorial extension of the *granted* certificate are observed, then it should be possible in our view under the same condition of taking into account the MAs granted while the application for a certificate is pending. The applicant must then file a request for extending the scope of the pending application for a certificate.

As the critical date on which the requirements for protections must be met the examiner would take:

- for the application for the certificate the filing date of the application;
- for the request for extending the territorial scope of the application for a certificate the date on which such request was filed;
- for the request for extension of the territorial scope of the granted unitary SPC, the date on which the latter request was filed.

[1800] Unlike Art. 3(b) it is not possible that the application that in one country did not comply with Art. 3(d) Reg. 469/2009 can satisfy the same requirement later in another EU State. The withdrawal or the lapse of the older MA has no influence on Art. 3(d). As a consequence, with regard to Art. 3(d), there is no need for a unitary SPC with dynamic territorial scope.

22.3.8 Deadline for filing the application (Art. 7 Reg. 469/2009)

Regarding the application for the grant of a unitary SPC, Art. 7 of the SPC Regulation would need to clarify when the countdown for the application deadline is triggered in case of unitary SPCs applied for on the basis of a bundle of national MAs granted under DP or MRP. It seems appropriate to maintain the six-month application period commencing from the date of grant of the **first MA** in any participating Member State. As pointed out in the case law[1801], in the opinions of some Advocates General[1802] and in the literature[1803], this deadline serves the interest of third parties to be given timely notice of the chance that an exclusive right for a product could persist despite the expected expiration of the basic patent.

Such deadline allows the applicant to consider either following a mere national route for the grant of a bundle of national SPCs or applying for a unitary SPC so as to benefit from its harmonised granting procedures. A new second sentence could be added to Art. 7(1) SPC Regulation as follows:

> Article 7
> **Application for a certificate**
> (1) The application for a certificate shall be lodged within six months of the date on which the authorisation referred to in Article 3(b) to place the product on the market as a medicinal product was granted. In case of a unitary supplementary protection certificate applied for in accordance with Article 3(a)(2), the six-month period shall be calculated as of the first MA granted in accordance with the rules in Chapter 4 of either Directive 2001/82/EC or Directive 2001/83/EC and with effect for a participating Member State to which the unitary effect granted by the patent applies.

If one accepts the possibility that MAs granted after the filing date are taken into account in the examination, then a new provision will be needed in order to make possible a territorial extension of either the pending SPC application or, later, the granted unitary SPC. A corresponding rule could be included as a new Art. 7a as follows:

> Article 7a
> **Application for territorial extension**
> The holder of a unitary supplementary protection certificate granted in accordance with Article 3(a)(2) can apply for an extension of the territorial scope of protection pursuant to Article 4(2) within six months of the date on which an authorisation referred to in Articles 3(b) and 3(a)(2) to place the product on the market as a medicinal product was granted in an EU State to which the unitary effect of the basic patent applies.
> The application for the extension of the certificate shall be lodged within six months of the date on which the authorisation referred to paragraph 1 to place the product on the Market was granted in the EU State concerned.

Such a territorial extension would take into account the interest of the patent holder in continuously expanding the scope of its SPC and thereby realigning the territorial scope of the SPC on the one hand and of the MA(s) on the other. Potential concerns that such a solution might extend the protection over the term and the scope intended by the current SPC legislation would not be justified in our view. This is because the duration of the unitary SPC shall be calculated in accordance with Art. 13 SPC Regulation from the date on which the first MA to place the relevant product on the market in the Community was issued.

1801 Case C-482/07 *AHP Manufacturing* [2009] ECR I-7295, para. 28.
1802 Case C-130/11 *Neurim* [2012] EU:C:2012:489, Opinion of AG Trstenjak, para. 43.
1803 Charlotte Weekes, 'Getting the end-game right – SPCs and unitary patents in Europe', available at https://www.pinsentmasons.com/PDF/2016/getting-the-end-game-right.pdf (last accessed 18 October 2017).

The advantage of such an additional possibility for the grant of a unitary SPC is that in the interest of further establishing a single European market it would encourage the use of the unitary patent system. That is also the reason why only MAs granted within MRPs or DPs should be accepted as a basis for a unitary SPC. In this case, one Member State acting as a so-called reference Member State establishes an assessment report. The other Member States are then obliged to issue a decision in conformity with this assessment report.[1804]

22.3.9 Art. 13

As regards Art. 13 Reg. 469/2009, we do not see specific issues surrounding the application of this provision to unitary SPCs that would call for any adaptation. The first MA granted for the product in the EU/EEA will matter for calculating the duration of the SPCs, whether or not the latter have unitary or national character. In this way it is ensured that the unitary SPC granted for the EU States in which the unitary effect is registered and the national SPCs granted in the remaining EU States will expire on the same date if they are granted on the basis of the same European patent and MA.

22.4 FEES FOR UNITARY SPCS

In answering the MPI Questionnaire for the NPOs one NPO pointed out that an issue that needs to be discussed is the question of the fees for the unitary SPC and the distribution of these fees. Here, unlike the unitary patents, the SPC will require a legislation of this aspect in Union law. This is true even if the EPO is in the end entrusted with granting the SPC, since Art. 142 EPC does not apply directly to the unitary SPC. Therefore, it cannot serve as a basis for adopting provisions in this regard.

A discussion on the fine-tuning of the fees system has already taken place with respect to the unitary patents; *mutatis mutandis* the scheme adopted for unitary patents could be adopted for unitary SPC as well. Two differences should be taken into account.

On the one hand, the validation rate of the SPCs – that is the average number of countries for which protection is requested – is higher than the general validation rate of European patents. On the other hand, the value of an SPC is likewise higher than that of general patents (but not necessarily higher than the value of the basic patent, even if several patents may serve as basic patent, but only one SPC may be granted).[1805] Against this background, the fees could be fixed correspondingly higher and not refined on the basis of a top-four scheme.

22.5 EXAMINATION

Independent of institutional arrangements and substantive requirements, the creation of a centralised procedure and office for granting unitary SPCs must fulfil certain

[1804] For details on the mutual recognition and decentralised procedures see above, Chapter 4, Sections 4.2.2 and 4.2.3.

[1805] The SPC can however cover the years when a product is already established on the market and more profitable.

standards so as to lead to a higher quality of the rights granted in terms of legal certainty and validity. For this reason, substantive examination of all requirements must be mandatory, and the Guidelines for the examination that the Unitary SPC Division will need for its operation must be sufficiently detailed and precise. Furthermore, it is important that the same standards also apply to the NPOs. As already mentioned in Chapter 20, Section 20.3, it must be avoided that, in view of strict examination standards applied by the Unitary SPC Division, an incentive is created for stakeholders to resort to national routes in order to get protection for products that shall are intended to later become the object of an SPC. For this reason, in order to prevent any form of forum-shopping by the applicants, the substantive examination at national level and at the level of the common office must be as uniform as possible. As pointed out above (Chapter 20, Section 20.3), this objective can be achieved through notices and guidelines in the form of soft law or, where that does not appear to be sufficient, by way means of implementing regulations addressed to both the Unitary SPC Division as well as to the NPOs.

As remarked above (Chapter 22, Section 22.2.2.6 (b)), development of harmonised practice with regard to granting national and unitary SPCs is most likely to arise organically from the participation of experts from the Member States in the decision-making process on both levels, whether in the form of a virtual office established under EU law or by making corresponding arrangements in the organisational framework of the EPO.

Lastly, the establishment of a Unitary SPC Division could enable cooperation arrangements between NPOs and the Unitary SPC Division: as for instance some NPOs entrust the EPO with a preliminary examination of the patentability of inventions claimed in national patent application, so some NPOs could entrust the Unitary SPC Division with the function to assess the SPC eligibility of a product and to deliver a preliminary not binding opinion or even granting the SPC, an option that is in principle laid down in Art. 9 Reg. 469/2009. This would reduce the burden on small NPOs of the examination of SPC applications also in view of its growing complexity as consequence of the CJEU case law.

22.6 SUMMARY

22.6.1 General remarks

The information collected by the MPI confirms that in the view of the stakeholders a practical need for a unitary SPC exists. In order to satisfy the need mentioned above the EU legislature has two options: creating unitary SPCs as a *sui generis* right or extending the term of the unitary patent. The historical reasons that induced the EU lawmaker to reject the patent-extension model in favour of a *sui generis* right are not relevant any more, after Art. 63 EPC 1973 was amended and the process for incorporating Union law in the EPC has been simplified. However, since the European Commission focuses on unitary SPCs, only the latter are considered in the Study.

22.6.2 Institutional aspects

The task of granting a unitary SPC can be assigned to:

- An EU authority, whether already existing or created for the purpose, including the option of a "virtual office" consisting of national experts operating under a common institutional head on the basis of unitary procedural rules;
- The EPO, provided that the task is assigned to it by the Member States under Art. 63(3), (4) EPC. Whether or not that could include the model of a "virtual office" is an organisational matter to be addressed in negotiations with the EPO that cannot be pre-empted by EU legislation.

Depending on the institutional choice made, the following routes are available for appeals against decisions made in the course of the granting procedure:

- In case of an EU authority being in charge of the grant, appeals must be directed to the GCEU, with the possibility of directing further appeals on points of law to the CJEU;
- If the EPO is in charge of the granting procedure, decisions on appeals would be dealt with in the UPC system.

For implementing the respective institutional models, the following steps must be taken:

To charge an EU authority with the grant of unitary SPCs,

- it would be necessary and sufficient to amend existing legislation (the SPC Regulations or Reg. 2012/1257), or enact a separate regulation.
- Concerning the language regime, account must be taken of the unanimity requirement of Art. 118(2) TFEU, either among all Member States, or, if appropriate, among those participating in enhanced cooperation.

To charge the EPO with the grant of unitary SPCs,

- an agreement must be concluded between the respective Member States and the European Patent Organisation under Art. 36(4) EPC. The scope and contents of the delegation of powers this implies must be set forth in binding EU legislation.
- In order to extend the competence of the UPC to reviewing decisions taken in the grant of unitary SPCs, Art. 32 UPCA must be amended accordingly. For this purpose EU legislation must enacted, either by complementing Art. 9 Reg. 1257/2012; or by separate legislation. On that basis an amendmed of Art. 32 UPCA can be done by decision of the Administrative Council under Art. 87(2) UPCA.

Irrespective of the institutional model chosen, the provisions establishing the procedures and conditions for obtaining a unitary SPC must be complemented by secondary legislation in the form of implementing regulations and/or delegated acts to be issued by the European Commission.

22.6.3 Substantive aspects

Unitary SPCs and national SPCs will be subject to the same requirements for protection as laid down in Art. 3 Reg. 469/2009. The unitary character of the IP rights poses some challenges with respect to the conditions for grant laid down in Art. 3(b), (c) and (d) Reg. 469/2009.

A preliminary question that affects the assessment of the options at the disposal of the lawmaker is whether the SPC shall have optional or mandatory character. The regulation of this aspect will have an impact on the assessment of the options in designing the requirements under Art. 3(b), (c) and (d) Reg. 469/2009.

22.6.3.1 Art. 3(a) Reg. 469/2009

The European Commission has considered as the possible basic patent for requesting a unitary SPC only unitary patents. From a technical perspective, it would be feasible to extend the option to obtain a unitary SPC to classic European patents provided that:

- the patents present a uniform set of claims, and
- are subject to the substantive provisions of the UPCA and the exclusive competence of the UPC.

22.6.3.2 Art. 3(b) Reg. 469/2009

Under Art. 3(b) Reg. 469/2009 a valid authorisation for placing the product on the market must be granted in the territory of protection. In the case of the unitary SPC the territory of protection includes all EU States in which the basic European patent has unitary effect. In order to reconcile the operation of this requirement with the unitary character the lawmaker has several choices to make.

First, the lawmaker has to decide whether the application for a certificate may rely

- only on a European MA or
- also on a bundle of national MAs.

One thing that may weigh against the first and in favour of the latter solution is the fact that not all medicinal innovations are eligible for a Union authorisation and that in the field of plant protection products a European MA does not even exist at the moment. However, the need for allowing unitary SPCs on the basis of national MAs does not seem highly relevant for medicinal products, where the SPC application is based on the first MA for a new active ingredient. New active ingredients that have never before been authorised are anyway eligible for a Union authorisation.

If the legislature decides to admit national MAs for both medicinal and plant protection products, then it is confronted with a second choice:

- either it requires that the grant of the SPC is possible only if at the critical date a national MA has been granted in all countries in which the European patent has unitary effect, or
- it may admit the grant of an SPC even if at the critical date MAs were granted only for a part of the territory to which the unitary effect applies.

If the latter is the choice made by the EU legislature, then there will be several ways to implement it. The preferable option in our view is to grant a unitary SPC only for the territory in which at the critical date (i) the unitary patent is in force; (ii) an MA exists. This does not mean, however, that protection is excluded in those countries where at the critical date no valid MA has been granted.

On the one hand, the lawmakers can decide that in the countries where no MAs have been granted at the date an application for a unitary SPC is filed, the unitary patent can still be designated as basic patent once the MA is awarded in those countries, provided that the deadline of Art. 7 Reg. 469/2009 is respected and that the patent is still in force at the time the application for a certificate with effect in that country is filed. This solution combines a **unitary SPC with a static territorial scope** with national SPCs granted on the same unitary patent: the unitary SPC is granted by the Unitary SPC Division and the national SPCs are granted by the NPOs. The combination of unitary SPC and national SPCs may cover in principle the territory covered by the unitary patent if the MAs are granted before the expiration date of that patent and the application for the certificate is lodged before the deadline under Art. 7 Reg. 469/2009 expires.

On the other hand, the lawmaker could even experiment with a more sophisticated option, providing for a **unitary SPC with dynamic territorial scope**. In this approach, the owner of a unitary SPC may apply for territorial extension of the granted right once national MAs have been granted for EU States that are covered by the basic unitary patent and in which at the critical date a valid MA has yet to be granted. This solution does not seem to challenge fundamental principles of Union law such as the protection of legitimate expectations and legal certainty for third parties, nor does it create protection in situations where it would no longer be possible to obtain an SPC under the current legislation. This is true, at least, if specific precautions are adopted as discussed in Section 22.3.4.

22.6.3.3 Art. 3(c) Reg. 469/2009

Under Art. 3(c) Reg. 469/2009 if a unitary SPC has been granted for a product, this SPC will prevent the NPOs from granting further national SPCs, and the Unitary SPC Division or Office further unitary SPCs, for the same product if the SPC is requested by the same applicant. The same principle will apply in the converse case: if a national SPC has been granted for a product in country A, this national SPC prevents the grant of another SPC (unitary or national) with effect in the same Member State for the same product to the same entity. If the lawmaker allows the applicant to request a unitary SPC with a narrower territorial scope than the territorial scope of the basic unitary patent, then it will be possible for the applicant – by withdrawing the designation of the EU State in the application for a unitary certificate where the conflicting national SPC exists – to obtain a unitary SPC for the remaining countries covered by the unitary patent.

22.6.3.4 Critical date for assessing the requirements for protection

The critical date for assessing the requirements for protection is under the current legislation the date of the application. In the case of a unitary SPC, if the option for a partial unitary SPC with dynamic content is considered feasible, the date for assessing the requirement should remain the date on which the application is filed, while the date for assessing the requirement for the extension should be the date on which the request for extension is filed.

22.6.3.5 Art. 7 Reg. 469/2009

The deadline for lodging the application laid down in Art. 7 Reg. 469/2009 should also apply to the application for a unitary certificate. The event that triggers the deadline is the grant of the first MA in the territory of protection covered by the unitary patent.

The same deadline should apply to the request for extension of the territorial scope of the pending SPC application or of the granted unitary SPC.

If the grant of the European patent for which an unitary effect is then requested is later than the issue of the MAs in one or more countries, the date on which the European patent was granted and not the date on which the unitary effect was registered triggers the deadline under Art. 7 Reg. 469/2009. This happen, however, only for the countries where at the granting date of the patent an MA has already been granted.

22.6.3.6 Plant protection products and unitary SPC

The analysis carried out for medicinal products applies to plant protection products. In order to accommodate the regulatory regime of plant protection products it will be necessary to accept national MAs as a basis for the unitary SPC or to reform that regulatory system. At the moment Reg. 1107/2009 does not contemplate the grant of an authorisation to market the product in the whole EU, but only of authorisations with national effect. If the unitary SPC could be granted only if at the filing date an authorisation to place the product on the market with EU-wide effect is supplied in support for the application for a certificate, this would result in an unequal treatment of this technological field. The same may hold true if the lawmaker admits national MAs, but this would require the applicant to supply a bundle of MAs covering all countries in which the unitary patent is in force at the date on which the application for a certificate is lodged (Art. 7 Reg. 1610/96). Some products could have only a zonal, but not Community-wide relevance for the company concerned.

The model of a **unitary SPC with a dynamic territorial scope** could accommodate the specific features of the regulatory regime applicable to plant protection products. Legislative details need to be discussed with experts from NPOs and industry.

22.6.3.7 Art. 13 Reg. 469/2009

No changes dictated by the unitary character of the right are needed with respect to Art. 13 Reg. 469/2009.

PART FIVE:

COMPARATIVE INSIGHTS

23 REVIEW OF SELECTED EXTRA-EUROPEAN LEGISLATIONS (PTES AND SPCS)

23.1 INTRODUCTION: REFERENCE TO ANNEX II

One of the purposes of Reg. 469/2009, according to its Explanatory Memorandum,[1806] was to remove imbalance as compared to Japan and the USA. Japanese and American applicants could benefit under Japanese and USA law from a term extension of their patent rights when the introduction of the subject matter of the medicinal invention was subject to an approval procedure.[1807] Until 1993, by contrast, such an extension was not possible for applicants in Europe.

In the view of the European legislature, this imbalance was harmful to European industry. Indeed, European companies might have reduced their investment in the development of new chemical entities. In addition, there was a risk that research centres located in Europe might have been relocated to other jurisdictions.[1808] For this reason, the system of SPC protection was created in 1992. Originally, the reform only concerned medicinal products but, in 1996, a similar regulation was created for plant protection products. The intention of the European legislature was to create an instrument that would grant similar protection as the patent term extension (PTE) provided by USA and Japanese law.[1809]

After 25 years and the evolution of case law in Europe, Japan and the USA, it is important to assess whether the protection conferred by the SPC under EU legislation is still equivalent to that offered by PTEs in the two main competitor countries. The Study includes in Annex II reports that review the US and Japanese legislation and its application concerning PTEs. At the same time, as the PTE model has expanded to other jurisdictions as well, also these developments and peculiarities of PTE systems are revealed in this Chapter. Several countries – Korea as the first – have followed the US example. Others have done so due to contractual obligations under bilateral or multilateral treaties (Israel, Singapore, Canada, this is also planned in New Zealand). As a consequence, Annex II to this Study covers also further selected jurisdictions in which PTEs or SPCs are available (Australia, Canada, Israel, Japan, Korea, Singapore, the USA, Taiwan and New Zealand).

Such reports are useful for two purposes. On the one hand, the comparative insights help to identify possible critical points of the European legislation. On the other hand, they can give cause for supporting or opposing some of the proposals or options discussed in this Study. Following sections provide some information based on these reports, but cannot replace the consultation of the Annex II.[1810]

It is important to note that in three large pharmaceutical markets – China, India and Brazil – no SPC or PTE protection is available for pharmaceutical and plant protection

[1806] European Commission, Explanatory Memorandum to the Proposal for a Council Regulation (EEC), of 11 April 1990, concerning the creation of a supplementary protection certificate for medicinal products (COM(90) 101 final – SYN255), para. 6.
[1807] *Ibid.,* Recital 6.
[1808] Council Regulation (EEC) No. 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products [1992] OJ L 182/1, Recital 6.
[1809] Recital 7 Reg. 1610/96.
[1810] See full reports in Annex II of this Study.

products. In India, in addition, patent protection is not available for second medical indications and is strictly limited regarding new forms or formulations of known substances. Similar provisions have been adopted in other countries. Even Brazil is considering the introduction of exclusion from patent protection similar to that provided under Section 3d of the Indian Patent Act.[1811] As a result, in these countries medicinal products are or will soon become patent-free, while still being protected in Europe.

23.2 PATENT TERM EXTENSION OR SPC

In the majority of the countries reporting (**the USA**,[1812] **Japan**,[1813] **Australia**,[1814] **Israel**,[1815] **Korea**,[1816] **Singapore**,[1817] [1818] **Taiwan**[1819]), to compensate the reduced effective patent term caused by time-consuming marketing approval[1820] procedures a PTE model is provided. **Canada** is preparing to have protection under a *sui generis* right[1821] similar to that in the EU and it recently introduced SPC legislation according to the obligations under CETA.[18221823] This legislation received Royal Assent on

[1811] Roberto Romandini, 'Flexibilities Under TRIPS: An Analysis of the Proposal for Reforming Brazilian Patent Law' [2016] 15 J. Marshall Rev. Intell. Prop. L.

[1812] The USA provides two types of PTE – classic PTE and automatic patent term "adjustment". Adjustment applies if the USPTO does not meet certain deadlines provided for by the legislation. Each day of USPTO delay results in one additional day of patent term. PTEs are cumulative with the patent term adjustment. In John Thomas, *the USA* in Annex II of this Study, Chapter 8, Section 8.2.

[1813] In Japan, PTEs were introduced already in 1987, Patent Act No. 121, Art. 67(2); Order of Enforcement of the Patent Act, Art. 2. Cited in Yoshiyuki Tamura et al, *Japan* in Annex II of this Study, Chapter 4, Section 4.3.

[1814] The current PTE system of Australia was introduced in 1999 by amendments to the Intellectual Property Laws Amendment Act 1998, s. 3 and Sch. 1. Cited in Andrew F Christie, Benjamin Hopper, *Australia* in Annex II of this Study, Chapter 1, Section 1.1.

[1815] The PTE system of Israel was introduced in 1998 as a counterweight to the newly introduced *Bolar*-type exemption. The peculiarity of the PTE system in Israel was to link PTE terms and expirations with parallel PTE terms in other jurisdictions that already provided PTEs. As of 2006 Israel has a "two states" requirement which reflects the situation in Israel where only in very rare cases would registration of the medical product be applied for only in Israel, and not in any reference country. This system provides for an extension period based on a grant of a reference PTE in the US and/or in Europe instead of a theoretical extension of patent term. The system was introduced to foster generic competition in the Israeli market if it exists in any of the reference countries countries and to grant the shortest extension term granted in any of the reference countries. In Tal Band, Yair Ziv, *Israel* in Annex II of this Study, Chapter 3, Section 3.5.2.1.

[1816] In Korea, the PTE system was introduced after pressure and threats of economic sanctions by the USA in 1986 (PTE system in effect from 1987 July). Korea's PTE environment was calm until the patent-linkage system's introduction in 2015, when more than five hundred invalidation claims were filed until the end of 2016. In Jun-seok Park, *Korea* in Annex II of this Study, Chapter 5, Section 5.1.

[1817] In Singapore, the PTE was introduced in 2004 with the Patents (Amendment) Act 2004 (No 19 of 2004), partly as a consequence of the introduction of the US-Singapore Free Trade Agreement and also as a measure to strengthen the overall patent ecosystem and to encourage innovation and research development. In Elizabeth Siew-Kuan NG, *Singapore* in Annex II of this Study, Chapter 7, Section 7.1.

[1818] Section 36A of the Patents Act states three grounds for PTE: 1) unreasonable delay by the Registrar in granting patent; 2) where the patent was granted on the basis of any prescribed documents referred to in section 29(1)(d) relating to one corresponding application or related national phase application ((i) there was an unreasonable delay in the issue of the corresponding patent or related national phase patent (as the case may be); and (ii) the patent office that granted the corresponding patent or related national phase patent (as the case may be) has extended the term of the corresponding patent or related national phase patent (as the case may be) on the basis of such delay; 3) in the case of curtailment of the effective patent term as a result of the necessity of the MA. The Patents (Amendment) Act 2012 (No 15 of 2012, came into effect on 14th February 2014). Cited in Elizabeth Siew-Kuan NG, *Singapore* in Annex II of this Study, Chaper 7, Section 7.1.

[1819] Kung-Chung LIU, *Taiwan* in Annex II of this Study, Chaper 9, Section 9.1.

[1820] Also called market approval, market authorisation, regulatory approval, government approval, approval, MA.

[1821] In Canada called CSP – certificate of supplementary protection.

[1822] Giuseppina D'Agostino, Joseph F Turcotte, *Canada* in Annex II of this Study, Chaper 2, Section 2.1.

[1823] The Canada-European Union Comprehensive Economic and Trade Agreement (CETA), implemented on 31 October 2016 (Bill C-30). As per the joint Statement by the Prime Minister and the President of the

September 7, 2017.[1824]As of October 2017 **New Zealand**[1825] has neither PTE nor SPC systems in effect yet, but it intends to introduce supplementary protection by implementing obligations under the Trans-Pacific Partnership Agreement 2016 (TPP Agreement).[1826]

23.3 GRANTING AUTHORITY

In all the countries except **Canada**,[1827] the NPOs are entrusted with the task of examining applications and granting PTEs or SPCs.[1828] In **Canada** provisionally the Canadian Minister of Health is in charge of granting certificates for supplementary protection (CSPs).[1829]

23.4 SUBJECT MATTER ELIGIBLE FOR SPC/PTE

There are two different approaches regarding the subject matter of the PTE. On the one side, **the USA** provides PTE to almost all products that are subject to an approval procedure, which is the ground for PTE.[1830] On the other side, other countries provide a PTE to restricted categories of products. So for instance, **Korea** grants the PTE only to medicinal products and agrochemicals or raw materials of agrochemicals.[1831] In **New Zealand,** only pharmaceutical substances (for humans) and biologics are eligible for PTE;[1832] in **Canada** CSP eligible are substances and mixtures of substances for use in human beings as well as in animals;[1833] but in **Taiwan** PTE-eligible are inventions of pharmaceuticals (excluding veterinary drugs), agrochemicals, or the manufacturing process thereof.[1834] In **Taiwan** medical devices are not SPC eligible.[1835]

In **Australia**[1836] a PTE protection is available for patents disclosing and claiming a pharmaceutical substance as long as goods containing them are listed on the Australian Register of Therapeutic Goods.[1837] Not eligible for a PTE are inventions of a

European Commission on reaching a date for the provisional application of the CETA, 21 September 2017 is the set date to start provisional application; the CETA will enter into force when all the EU Member States will ratify it.

1824 Giuseppina D'Agostino, Joseph F Turcotte, *Canada* in Annex II of this Study, Chapter 2, Section 2.1.

1825 Before New Zealand adopted TRIPS it had PTE on the basis of "inadequate remuneration" under the Patents Act 1953. The extension in exceptional cases could even be 10 years. Under TRIPS the patent term of 16 years was extended to 20 years and thereby New Zealand abolished the PTE system. In Susy Frankel, Jessica C Lai, *New Zealand* in Annex II of this Study, Chapter 6, Section 6.3.

1826 New Zealand – Trans-Pacific Partnership Agreement 2016 (TPP Agreement). As pointed out, it is unlikely that it will come into force as the USA has withdrawn from signing it. In Susy Frankel, Jessica C Lai, *New Zealand* in Annex II of this Study, Chapter 6, Section 6.2.

1827 Giuseppina D'Agostino, Joseph F Turcotte, *Canada* in Annex II of this Study, Chapter 2, Section 2.4.

1828 Andrew F Christie, Benjamin Hopper, *Australia* in Annex II of this Study, Chapter 1, Section 1.4; Tal Band, Yair Ziv, *Israel* in Annex II of this Study, Chapter 3, Section 3.4; Yoshiyuki Tamura et al, *Japan* in Annex II of this Study, Chapter 4, Section 4.5.3; Jun-seok Park, *Korea* in Annex II, Chapter 5, Section 5.3.5.4; Susy Frankel, Jessica C Lai, *New Zealand* in Annex II of this Study, Chapter 6, Section 6.4; Elizabeth Siew-Kuan NG, *Singapore* in Annex II of this Study, Chapter 7, Section 7.4; John Thomas, *the USA* in Annex II of this Study, Chapter 8, Section 8.4; Kung-Chung LIU, *Taiwan* in Annex II of this Study, Chapter 9, Section 9.4.

1829 Giuseppina D'Agostino, Joseph F Turcotte, *Canada* in Annex II of this Study, Chapter 2, Section 2.4.

1830 John Thomas, *the USA* in Annex II of this Study, Chapter 8, Section 8.5.

1831 Jun-seok Park, *Korea* in Annex II of this Study, Chapter 5, Section 5.4.1.

1832 Susy Frankel, Jessica C Lai, *New Zealand* in Annex II of this Study, Chapter 6, Section 6.5.1.

1833 Giuseppina D'Agostino, Joseph F Turcotte, *Canada* in Annex II of this Study, Chapter 2, Section 2.5.1.

1834 Kung-Chung LIU, *Taiwan* in Annex II of this Study, Chapter 9, Section 9.2.

1835 *Ibid.*, Chapter 9, Section 9.5.1.1.

1836 PTE in Australia is called "extension of the term of the patent".

1837 Andrew F Christie, Benjamin Hopper, *Australia in* Annex II of this Study, Chapter 1, Section 1.5.1.

plant product, a medical device, or an implantable device through which a medical product is administered.[1838]

Singapore "does not deal specifically with PTEs for plant products *per se"*. Instead, "plant and animal products are broadly dealt with under the scope of what constitutes a pharmaceutical product".[1839] Moreover, there is no PTE protection for medical devices, substances used solely for diagnosis or testing and substances occurring naturally in any plant, animal or mineral.[1840]

It is worth mentioning that in **Canada,**[1841] **Israel**[1842] and the **USA**[1843] medical devices can also be the subject of PTE or SPC protection. Furthermore, in **Israel** a product is categorised as a medical product or a medical device depending on its primary mode of action. Since drug-coated implantable devices' primary function is their activity as a medical device these thus fall under the category "medical device".[1844] However, if the medical product in question is administered through a medical device but its main activity is its effect as a medical product, it falls under the category "medical product".[1845]

In **Korea** there has been no practical experience regarding medical devices yet and thus it is not clear if medical devices can be the subject of PTE protection. According to a part of the literature a medical device in combination with a drug could be PTE-eligible.[1846]

In **New Zealand**, medical devices as such would not qualify for a PTE.[1847]

23.5 PATENTS ELIGIBLE FOR PTE OR SPC PROTECTION

In the majority of the countries reported all categories of patents – product, process or use patents – are eligible for a PTE (**Israel,**[1848] **Korea,**[1849] **USA,**[1850] **and Taiwan**[1851]). However, in **Singapore**[1852] and **Australia**[1853] method (process) patents are not eligible for PTEs.

Taiwan admits new use claims if the new use is identified by the active ingredients and uses stated in the first MA. [1854]

1838 *Ibid.*
1839 Elizabeth Siew-Kuan NG, *Singapore* in Annex II of this Study, Chapter 7, Section 7.5.1.1.
1840 *Ibid.*
1841 However, the extended protection will only apply to the patented drug itself. Giuseppina D'Agostino, Joseph F Turcotte, *Canada* in Annex II of this Study, Chapter 2, Section 2.5.1.1.
1842 Tal Band, Yair Ziv, *Israel* in Annex II of this Study, Chapter 3, Section 3.2
1843 John Thomas, *the USA* in Annex II of this Study, Chapter 8, Section 8.5.
1844 *Ibid.*
1845 *Ibid.*
1846 Arne Markgraf, *Ergänzende Schutzzertifikate – Patent Term Extensions* (Nomos Baden-Baden 2015) p. 393. Cited in Jun-seok Park, *Korea* in Annex II of this Study, Chapter 5, Section 5.4. The author of the report comments that this opinion could not be plausible as it does not consider the changes introduced by the Presidential Decree of KPA 2013.
1847 Susy Frankel, Jessica C Lai, *New Zealand* in Annex II of this Study, Chapter 6, Section 6.5.1.1.
1848 Tal Band, Yair Ziv, *Israel* in Annex II of this Study, Chapter 3, Section 3.5.1.2.
1849 Jun-seok Park, *Korea* in Annex II of this Study, Chapter 5, Section 5.4.1.2.
1850 John Thomas, *the USA* in Annex II of this Study of this Study, Chapter 8, Section 8.5.1.2.
1851 Kung-Chung LIU, *Taiwan* in Annex II of this Study, Chapter 9, Section 9.5.1.2.
1852 Elizabeth Siew-Kuan NG, *Singapore* in Annex II of this Study, Chapter 7, Section 7.5.
1853 Andrew F Christie, Benjamin Hopper, *Australia* in Annex II of this Study, Chapter 1, Section 1.5.1.3.
1854 Kung-Chung LIU, *Taiwan* in Annex II of this Study, Chapter 9, Section 9.5.1.2.

In **Japan,** there is no requirement that the subject matter of PTE has to be a product, process or use. The eligibility for obtaining a PTE depends on the requirement of an MA for certain pharmaceuticals and regenerative medicine products or agricultural chemicals.[1855]

23.6 MEDICINAL PRODUCTS

23.6.1 Concept of active ingredient

As of 2012 **Korea** defines "medical products" as products produced with a new substance as an active ingredient.[1856] Thus, the new substance is defined as the substance whose chemical structure of the active part is new.[1857]

In **Japan**, according to the former practice the "product" was interpreted as an "active ingredient".[1858] First of all, this interpretation was important for analysing whether the requirement "first MA" was fulfilled.[1859] The term "active ingredient" came into consideration when there was an assessment of PTE issuance regarding certain products.[1860] This practice underwent a drastic change by virtue of the decisions of the Intellectual Property High Court and the Supreme Court in the *Pacific Capsules 30mg* and *Avastin* cases.[1861] Regarding the active ingredient the court in *Avastin* ruled that the PTE might be granted even if a pharmaceutical product approved by the first regulatory approval and a pharmaceutical product approved by the second regulatory approval had the same "active ingredient" and "effect/efficacy".[1862] The court further clarified that a PTE based on the second MA should be assessed depending on whether a pharmaceutical product approved by the second MA fell within the scope of the pharmaceutical product approved by the first MA.[1863]

In **Singapore,** the is no definition under the Patents Act of an "active ingredient", but the Health Products Act provides a definition of "active ingredient" as "any substance or compound that is usable in the manufacture of a health product as a pharmacologically active constituent", whereas the Medicines Act defines "ingredient" in relation to manufacture or preparation of a substance as "anything which is the sole active ingredient of that substance as manufactured or prepared". However, it is not clear whether "active ingredient" would have the same meaning under the Patents Act.[1864]

In **Israel,** the term "compound" is defined in the Patents Law as the active ingredient in a medical product, or salts, esters, hydrates or polymorphs of said ingredient. The definition of "compound" includes also salts, esters, hydrates and polymorphs;

[1855] Yoshiyuki Tamura et al, *Japan* in Annex II of this Study, Chapter 4, Section 4.4.1.
[1856] Article 7, Subparagraph 1 in Presidential Decree of KPA (No. 24491, April 3, 2013). Cited in Jun-seok Park, *Korea* in Annex II of this Study, Chapter 5, Section 5.4.1.3.
[1857] Jun-seok Park, *Korea* in Annex II of this Study, Chapter 5, Section 5.4.1.3.
[1858] Patent Act, Article 68-2. Cited in Yoshiyuki Tamura et al, *Japan* in Annex II of this Study, Chapter 4, Section 4.7.
[1859] *Ibid.*
[1860] *Ibid.*
[1861] *Ibid.*
[1862] *Ibid.*
[1863] Patent Act, Article 68-2. Cited in Yoshiyuki Tamuraet al, *Japan* in Annex II of this Study, Chapter 4, Section 4.4.3.4.
[1864] Elizabeth Siew-Kuan NG, *Singapore* in Annex II of this Study, Chapter 7, Section 7.5.1.2.

subsequently these derivatives would not be considered as a new or different compound.[1865]

In **the USA,** the concept is similar to that in Europe: the term "drug product" is defined as the "active ingredient [...] of a new drug [...] or a new animal drug or veterinary biological product [...] including any salt or ester of the active ingredient".[1866]

In **Taiwan,** "active ingredient" means ingredients of a pharmaceutical or agrochemical formula that have pharmacological action.[1867]

23.6.2 Combination of two active ingredients – a new product?

While in Europe an active ingredient and a combination of active ingredients are considered to be two different products, in the jurisdictions considered by the Annex II of this Study the situation is quite different and often less favourable to the applicant than in Europe.

In **Israel,** a combination of two substances would not be considered as a "new compound".[1868]

In **Australia,** it would not meet the requirement of being a "pharmaceutical substance" (unless the two substances interact to form a new substance)[1869] and in **Korea**[1870] it would not classify as a "medicinal product" if the product consists of two or more known (i.e. contained in a previously approved product) active substances.

In **the USA** – "if a patent claimed a composition comprising two ingredients, A and B, the patent was eligible for term extension if either A or B had not been previously marketed".[1871] As consequence, "where both ingredients had been subject to prior commercial marketing, the combination patent could not benefit from the term extension provisions of the Hatch-Waxman Act."[1872] This understanding is based on the interpretation that "even though a drug may contain two or more active ingredients [...], for the purpose of the patent term extension that drug is defined through reference to only one of those active ingredients; the other active ingredient [...] is merely 'in combination with this first active ingredient'"[1873]. Also, because of the rule that the patent may be extended only once, in the US it would not be possible

[1865] Tal Band, Yair Ziv, *Israel* in Annex II of this Study, Chapter 3, Section 3.5.1.3.
[1866] 35 U.S.C. §156. Cited in John Thomas, *the USA* in Annex II of this Study, Chapter 8, Section 8.5.1.1.
[1867] Examination Guidelines, 2-11-3. Cited in Kung-Chung LIU, *Taiwan* in Annex II of this Study, Chapter 9, Section 9.5.1.3.
[1868] *Novartis AG v The Registrar of Patents, Designs and Trademarks* (Published in Nevo.co.il, 26.2.2007) [Patent no. IL97219]. Cited in Tal Band, Yair Ziv, *Israel* in Annex II of this Study, Chapter 3, Section 3.5.1.3.
[1869] "A patent claiming the use of two known active substances in combination, which combination does not involve any chemical interaction between the two to produce a new pharmaceutical substance, would likely not meet the "pharmaceutical substance" requirement." Andrew F Christie, Benjamin Hopper, *Australia* in Annex II of this Study, Chapter 1, Section 1.5.1.3.
[1870] Article 7, Subparagraph 1 in Presidential Decree of KPA (No. 24491, April 3, 2013); Chun-won Kang, 'Whether or not the PTE is granted in case of new formulation patent including already authorised active ingredient' [2011] 8 IP Policy 76, 81. Cited in Jun-seok Park, *Korea* in Annex II of this Study, Chapter 5, Section 5.4.1.3.
[1871] John Thomas, *the USA* in Annex II of this Study, Chapter 8, Section 8.5.1.3.
[1872] *Ibid.,* 362 F.3d at 1341.
[1873] 246 F. Supp. 2d at 464-65. Cited in John Thomas, *the USA* in Annex II of this Study, Chapter 8, Section 8.5.1.3.

to obtain first an extension for A, and then an extension for A-B, unless B is protected by a different patent and was not authorised before.

A combination of two or more active ingredients is a new product in **Taiwan** and it has no impact if any of those ingredients has been approved before.[1874]

23.6.3 Combination of an active ingredient with an adjuvant – a new product?

In **Australia,** "a combination of an active ingredient with an adjuvant (or with a new adjuvant) provided the active ingredient, or the adjuvant, or the two together claimed as one invention and disclosed and claimed in the patent"[1875] would likely meet the requirement for ARTG entry.

In **Taiwan**, whether or not a combination of an active ingredient with an adjuvant constitutes a new active ingredient, is decided on a case-by-case basis.[1876] Other states which described such a combination (**Israel**,[1877] **Japan**[1878]) denied a possible formulation of an adjuvant and active ingredient as creating a new product.

23.6.4 Salts versus basic form of the substance – different ingredients?

In **Australia,** "it is possible to obtain a PTE in respect of two patents, one claiming the non-salt form of a pharmaceutical substance, and the other claiming a salt form or new formulation".[1879] Generally, a salt of a drug would likely meet the ARTG entry requirement.[1880]

In **the USA, Taiwan** and **Canada** salts, esters and other derivatives are treated as the same substance (active ingredient) and are not eligible for a second PTE.

The same applies in **Israel**, since the definition of compound as active ingredient in a medical product includes salts, esters, hydrates or polymorphs such derivatives would not be considered as a new compound.[1881]

In **Korea** there is the opinion that the scope of the extended patent also includes the active ingredient's substitutable salts.[1882]

1874 Kung-Chung LIU, *Taiwan* in Annex II of this Study, Chapter 9, Section 9.5.1.3.
1875 Andrew F Christie, Benjamin Hopper, *Australia* in Annex II of this Study, Chapter 1, Section 1.5.2.3.
1876 Kung-Chung LIU, *Taiwan* in Annex II of this Study, Chapter 9, Section 9.5.1.3.
1877 Tal Band, Yair Ziv, *Israel* in Annex II of this Study, Chapter 3, Section 3.5.1.3.
1878 Yoshiyuki Tamura et al, *Japan* in Annex II of this Study, Chapter 4, Section 4.4.
1879 Andrew F Christie, Benjamin Hopper, *Australia* in Annex II of this Study, Chapter 1, Section 1.5.1.3.
1880 *Ibid.* "In the series of disputes between Lundbeck and Alphapharm concerning a patent claiming an enantiomer of the racemate citalopram, namely, escitalopram, the relevant first inclusion on the ARTG of a good 'containing, or consisting of,' that pharmaceutical substance was the inclusion of Cipramil as the salt citalopram hydrobromide (i.e., the salt of the racemate): *H Lundbeck A/S v Alphapharm Pty Ltd* (2009) 177 FCR 151, [106]".
1881 Tal Band, Yair Ziv, *Israel* in Annex II of this Study, Chapter 3, Section 3.5.1.3.
1882 Jun-seok Park, *Korea* in Annex II of this Study, Chapter 5, Section 5.7.

23.7 REQUIREMENTS FOR SPC OR PTE

23.7.1 The product is protected by a basic patent in force

In Europe the product must be protected by a patent in force. A similar requirement is laid down in most of the jurisdictions subject to this Chapter.

23.7.1.1 Patent in force

In almost all of the states examined it is the same as in Europe – the rule is that the basic patent must be in force when the application for an SPC or PTE is submitted.

However, in some states (**Israel**,[1883] **USA**,[1884] **Taiwan**[1885]) if the patent is about to expire, the applicant has an option to file an interim extension request. In Israel, an interim extension is possible only when all the requirements for granting PTE are met prior to the expiry of the underlying basic patent. In the situation when the patent has expired in Israel and no PTE (or SPC) has been granted in the US and one more EU reference state, no interim extension request is possible.

In some reporting states, patent term is deemed to be extended until the moment when the PTE is granted or the application rejected. This applies if the PTE application has been submitted before the deadline but the patent term has expired during the PTE application's examination process.

So, for example, in **Australia**, if the application for a PTE was filed before the expiry of the basic patent but the extension was granted after the expiry, then the date on which the PTE takes effect is deemed to be the expiry date of the basic patent. In conclusion, the holder of a PTE can seek remedies for infringement of its PTE for the infringements occurring between the expiry of the basic patent and grant of a PTE.[1886] The same applies to PTE application in **Japan**[1887] and **Korea**[1888] – if the regulatory approval is obtained and PTE application is filed before the expiry of the basic patent, then the PTE can be registered even though the application's examination is conducted after the expiry of the basic patent.

23.7.1.2 Relation between patent and product

The **USA** case law has established that the term "claims a product" is not synonymous with "infringed by a product."[1889] According to USPTO, Manual of Patent Examining Procedure, a "patent is considered to claim the product at least in those situations where the patent claims the active ingredient *per se*, or claims a composition or

[1883] Tal Band, Yair Ziv, *Israel* in Annex II of this Study, Chapter 3, Section 3.10.
[1884] 35 U.S.C. §156(a)(1). Cited in John Thomas, *the USA* in Annex II of this Study, Chapter 5, Section 8.5.2.2. The request can be made during the period beginning six months and ending 15 days before the patent's expiration date. In accordance with 35 U.S.C. §156(d)(5)(B)(C) interim extension may be issued for a maximum of one year, but for a maximum of four times longer than the extension to which the applicant would be eligible (37 C.F.R. §1.760) and otherwise five years from the expiration of the original patent term (35 U.S.C. §156(d)(5)(E).
[1885] Kung-Chung LIU, *Taiwan* in Annex II of this Study, Chapter 8, Section 8.5.2.2.
[1886] Australian Patents Act, s. 79 sited in Andrew F Christie, Benjamin Hopper, *Australia* in Annex II of this Study, Chapter 1, Section 1.5.4.1.
[1887] Yoshiyuki Tamura et al, *Japan* in Annex II of this Study, Chapter 4, Section 4.5.2.
[1888] Jun-seok Park, *Korea* in Annex II of this Study, Chapter 5, Section 5.9. The PTE application must be filed no later than six months before the expiry of the basic patent.
[1889] John Thomas, *the USA* in Annex II of this Study, Chapter 8, Section 8.5.2.2.

formulation which contains the active ingredient(s) and reads on the composition or formulation approved for commercial marketing or use."[1890]

In **Israel,** there is the requirement that "the compound, its manufacturing process or its use or the medical product or its manufacturing process or the medical device which must be claimed in the basic patent".[1891] Furthermore, in the situation where a combination but not "a certain compound in and of itself" has been claimed, it will not be considered that the compound is claimed in the basic patent.[1892]

In **Australia,** the main criterion is the entry on the ARTG taking into account that a pharmaceutical substance or biologics must be claimed and disclosed, i.e. the pharmaceutical substance(s) (*per se* or when produced by a process that involves the use of recombinant DNA technology) must be "disclosed in the complete specification of the patent" and "fall within the scope of the claim or claims of that specification", and be included on the ARTG.[1893] The "pharmaceutical substance" must be claimed and not merely appear in a claim in combination with other integers or as a part of a method or process.[1894]

In **Singapore,** the substance must be the subject of the patent. The literature infers from this requirement that the substance must be protected by the patent.[1895]

In **New Zealand** it is required by the TPP Agreement Amendment Act "that one or more pharmaceutical substances *per se* or biologics have to be disclosed in the complete specification and be wholly within the scope of the claim or claims".[1896]

23.7.2 Valid authorisation to place the product on the market

In all the states examined there must be valid MA to place the product on the market in order to comply with the PTE or SPC granting requirements.

In **Australia**, the valid MA requirement is formulated as only those goods "containing, or consisting of" the substance which must be included in the ARTG.[1897] It is defined as the "ARTG entry requirement", as the MAs have been registered in the ARTG and thus the examination of this requirement involves the actual comparison of the pharmaceutical substance with the ingredients of the corresponding good registered on the ARTG.

In **Japan**, the criterion that the regulatory approval is necessary to work the patented invention is to be fulfilled[1898] i.e. the patented invention cannot be worked (exploited) before obtaining the regulatory approval.[1899] It is also possible to register two or more

[1890] USPTO, Manual of Patent Examining Procedure §2751 (9th edn November 2015). Cited in *ibid.*
[1891] Tal Band, Yair Ziv, *Israel* in Annex II of this Study, Chapter 3, Section 3.5.2.2.
[1892] *Ibid.,* Section 3.5.2.3. PTE application No. 142728 Biogen IDEC International GmbH (Published on the ILPTO website, 21 May 2015, 27 May 2015).
[1893] Andrew F Christie, Benjamin Hopper, *Australia* in Annex II of this Study, Chapter 1, Section 1.5.1.3.
[1894] *Ibid.*
[1895] Elizabeth Siew-Kuan NG, *Singapore* in Annex II of this Study, Chapter 7, Section 7.8.
[1896] TPP Agreement Amendment Act 2006, s 75, introducing 111D(1)(c). Cited in Susy Frankel, Jessica C Lai, *New Zealand* in Annex II of this Study, Chapter 6, Section 6.5.1.2.
[1897] Andrew F Christie, Benjamin Hopper, *Australia* in Annex II of this Study, Chapter 1, Section 1.5.1.2.
[1898] Yoshiyuki Tamura et al, *Japan* in Annex II of this Study, Chapter 4, Section 4.4.3.1. Patent Act No. 121, Article 67-3(3).
[1899] Yoshiyuki Tamura et al, *Japan* in Annex II of this Study, Chapter 4, Section 4.4.3.

PTEs on the basis of a single regulatory approval,[1900] although there is the requirement that the relevant approval has made it possible to work the patented invention for the first time. When there is "second regulatory approval", the leading criterion is the rule of "substantial identity".[1901] Consequently, a new PTE will be granted if the difference between those two products appears in a difference of active ingredients, because those products will not be considered as "substantially identical" within the meaning of the decision in the *Avastin* case based on the ground that the embodiments are different enough to prove that the second regulatory approval was necessary to work the patented invention.[1902]

In **Taiwan,** "any ingredients, processes or uses that are specified in the claims but not identified in the market authorization will not be covered by the term extension protection". Furthermore, there must be a correspondence between the patent claims and the active ingredients and uses.[1903]

23.7.3 The principle of one product – one PTE/SPC

In **the USA,** a product is required to be "new" to be eligible for PTE.[1904] As "new" means not previously approved for marketing, a single product can be subject to only one PTE.[1905]

In **Canada,** the "one product - one SPC/PTE" rule applies.[1906] The same applies for Korea.[1907]

In **Israel** a requirement for granting a PTE is that "no PTE was previously granted with respect to the basic patent or the compound". It follows that the principle "one PTE, one product, one patent" applies.[1908]

23.7.4 No prior extension of the patent term

The requirement for a grant of PTE or SPC in almost all reporting states is that the patent may not receive more than one PTE or SPC.

As pointed out by **Korea,** if more than one authorisation is given to the same active ingredient included in one patent, a PTE can be granted only for the first authorisation.[1909] This is the same as in the EU, **the USA** and **Japan**.

Furthermore in **Korea**, "if one patent covers multiple active ingredients and the respective authorisation is given for each active ingredient, only one of such multiple

[1900] *Ibid.*
[1901] *Ibid.*
[1902] *Ibid.*
[1903] Examination Guidelines, 2-11-5. Cited in Kung-Chung LIU, *Taiwan* in Annex II of this Study, Chapter 9, Section 9.5.2.
[1904] 35 U.S.C. §156(f)(2)(A). Cited in John Thomas, *the USA* in Annex II of this Study, Chapter 8, Section 8.5.2.6.
[1905] *Ibid.*
[1906] Giuseppina D'Agostino, Joseph F Turcotte, *Canada* in Annex II of this Study, Chapter 2, Section 2.5.2:"Para. 59 §106[1e]) no other CSP has been previously issued for the medicinal ingredient(s)".
[1907] Article 3(1) KIPO Regulation. In Jun-seok Park, Korea in Annex II of this Study, Chapter 5, Section 5.4.2.4.
[1908] Tal Band, Yair Ziv, *Israel* in Annex II of this Study, Chapter 3, Section 3.5.2.4.
[1909] Article 3(3) KIPO Regulation. Cited in Jun-seok Park, *Korea* in Annex II of this Study, Chapter 5, Section 5.4.2.4.

authorisations may be selected by the patentee for a PTE".[1910] On the other hand, if multiple patents are related to one authorisation, it is possible to get multiple PTEs by obtaining one respective PTE for each patent.[1911]

In **Japan**, the holder of the basic patent can file two or more applications for PTEs of the same patent, and a PTE may be granted to quite small elements of an invention according to the Supreme Court's decision in the *Avastin* case.[1912]

23.7.5 Second medical indication

In **Korea**[1913] and **Australia**[1914] second medical uses of known substances are not eligible for PTE.

As pointed out in the **New Zealand's** report, patents for reformulations of known pharmaceuticals and Swiss-type claims would not qualify for PTE.[1915] Two reasons account for this: on the one side, patent-term extensions are only available to pharmaceutical substances; on the other side "the application for extension would have to be with reference that substance's first marketing approval", a requirement that an application for an extension of a patent for the new use or reformulation of a known active ingredient cannot satisfy, unless the substance concerned was never authorised in New Zealand. [1916]

In **Israel,** second medical use patents may be considered as basic patents eligible for PTE, "as they relate to the use of a compound".[1917] However, if the compound of the basic patent was already issued an earlier MA, then the second MA – MA for second medical use is not to be considered as the first MA "enabling use of the compound" which is contained in the medicinal product.[1918]

In **Japan,** a patent for a second medical use and a prior patent relating to the compound can be extended if they fulfil the requirement of being "not substantially identical" and regulatory approval is obtained for each of them.[1919]

In **Taiwan** a "new therapeutic indication of an active ingredient" is PTE-eligible because the PTE covers only the same active ingredient and the same therapeutic indication.[1920]

23.8 SCOPE OF THE PROTECTION AND RIGHTS CONFERRED

Basically, in all states examined the SPC or PTE grants limited rights, firstly, in terms of the scope of the basic patent or the patent scope before extension, and secondly, in terms of the specific product authorised.

1910 *Ibid.*
1911 Article 3(2) KIPO Regulation. Cited in *ibid.*
1912 Yoshiyuki Tamura et al, *Japan* in Annex II of this Study, Chapter 4, Section 4.4.3.6.
1913 Jun-seok Park, *Korea* in Annex II of this Study, Chapter 5, Section 5.4.1.3.
1914 Andrew F Christie, Benjamin Hopper, *Australia* in Annex II of this Study, Chapter 1, Section 1.5.1.3.
1915 Susy Frankel, Jessica C Lai, *New Zealand* in Annex II of this Study, Chapter 6, Section 6.5.1.3.
1916 *Ibid.*
1917 Tal Band, Yair Ziv, *Israel* in Annex II of this Study, Chapter 3, Section 3.5.2.4.
1918 *Ibid.* Section 3.5.1.3.
1919 Yoshiyuki Tamura et al, *Japan* in Annex II of this Study, Chapter 4, Sections 4.4.3.6. and 4.4.3.4.
1920 Kung-Chung LIU, *Taiwan* in Annex II of this Study, Chapter 9, Section 9.5.2.

In **Japan,** the extended patent right is effective only against acts which exploit the patented invention for the product which is the subject of the MA, regarding the designated use which is specified in the disposition of the MA.[1921] However, recent Japanese case law shows that the scope of the extended patent should not be determined based solely on the product approved in the MA and its characteristics regarding dosage, quantity, administration, effect and efficacy defined defined in MA, but also comparing the alleged infringing product regarding the criteria "substantially identical", where, from the viewpoint of the person skilled in the art, technical features, functions and effects of the product subject to the MA must be compared and assessed.[1922]

In **Australia**, the patentee's rights during a PTE are "limited to therapeutic uses of the pharmaceutical substance *per se"*.[1923] For determining an infringement and thus the scope of protection afforded by a patent subject to PTE as well to PTE itself the doctrine of "purposive construction" of patent claims is applicable.[1924]

New Zealand also limits the scope of the extended patent to the therapeutic use(s) for which the MA was granted.[1925]

In **Israel,** the protection of an extended patent relates only to the medical product that contains the compound in so far as the compound, its manufacturing process or its use or the medical product or its manufacturing process are as it is claimed in the basic patent.[1926]

In **Singapore,** the protection conferred by a patent during a PTE pertains only to the substance which is an active ingredient of a pharmaceutical product and not to any other substance in the patent.[1927]

In **the USA,** the scope of the protection "is founded upon the claims of the patent", where the "broadest reasonable construction" of the claims in keeping with the decision of the US Supreme Court in *Markman v Westview Instruments, Inc* is applicable when interpreting claims.[1928] Furthermore, when a product patent is extended, the PTE is "limited to any use approved for that product" of the subject of the regulatory approval.[1929] When method of using patent has been extended, the rights of PTE holder are "limited to any use claimed by the patent and approved for the product" subjected to regulatory approval.[1930] When a patent is a method of

[1921] Yoshiyuki Tamura et al, *Japan* in Annex II of this Study, Chapter 4, Section 4.7.
[1922] Intellectual Property High Court, 20 January 2017, Case No. 2016 (Ne) 10046 – *Pharmaceutically Stable Preparation of Oxaliplatinum (Elplat)*. Cited in Yoshiyuki Tamura et al, *Japan* in Annex II of this Study, Chapter 4, Section 4.7.
[1923] Andrew F Christie, Benjamin Hopper, *Australia* in Annex II of this Study, Chapter 1, Section 1.5.3.
[1924] *PhotoCure ASA v Queen's University at Kingston* [2005] FCA 344, [158]. See also *Catnic Components Ltd v Hill & Smith Ltd* [1982] RPC 183, 242-3; *Populin v HB Nominees Pty Ltd* (1982) 59 FLR 37, 42-3. Cited in Andrew F Christie, Benjamin Hopper, *Australia* in Annex II of this Study, Chapter 1, Section 1.5.2.6.
[1925] TPP Agreement Amendment Act 2016, s 75, introducing s 111I. Cited in Susy Frankel, Jessica C Lai, *New Zealand* in Annex II of this Study, Chapter 6, Section 6.8.
[1926] Tal Band, Yair Ziv, *Israel* in Annex II of this Study, Chapter 3, Section 3.4.
[1927] Elizabeth Siew-Kuan NG, *Singapore* in Annex II of this Study, Chapter 7, Section 7.5.2.2.
[1928] 517 U.S. 370 (1996). Cited in John Thomas, *the USA* in Annex II of this Study, Chapter 8, Section 8.8.
[1929] §156(b)(1). Cited in *ibid,* Section 8.5.2.1.
[1930] §156(b)(2). Cited in *ibid*., Section 8.9.

manufacturing a product, rights during PTE are "limited to the method of manufacturing" of the approved product.[1931]

Taiwan stipulates that the scope of the PTE is limited only to the active ingredients and uses which are identified in the first MA: ingredient(s) and use(s) which are identified in the patent claim(s) but not specified in the MA will not be covered by PTE protection.[1932]

23.9 RIGHT TO OBTAIN AN SPC/PTE

In **Australia,** the patentee – the applicant of a PTE – is admitted to refer to a third - party's authorisation even if the holder of the MA does not agree to the grant of the PTE.[1933] The fact that the sponsor does not agree to the patentee seeking an EoTerm is not a ground on which an otherwise valid application for EoTerm can be refused.[1934] In other states (**Korea**,[1935] **USA**,[1936] **Japan**,[1937] **Taiwan**[1938]) there must be an established legal relationship (licence) between the patent holder and the MA holder.

In some states examined there are no clear provisions in their patent acts regarding the issue (see for instance **Singapore**,[1939] **Israel**[1940]). In **Israel,** however, based on the explanatory notes to the Bill and some statement of the case law, that "refer to PTE as compensation to patentees, who developed a new drug, but were precluded from marketing the new drug until completion of the authorization process", it is argued that the intention of the legislature was to prevent PTEs based on MAs obtained by third parties.[1941]

23.10 *BOLAR* EXEMPTIONS

The following section provides a concise overview of the relevant characteristics of *Bolar* exemption regarding not only the countries reported in Annex II, but also further countries from South America and Asia. The summary is based on a recent publication by Carlos Correa[1942] and on Annex II of this Study.

The *Bolar* exemption[1943] to PTE and SPC is provided in all the states reported in Annex II of the Study (**Canada**,[1944] **Japan**,[1945] **Australia**,[1946] **New Zealand**,[1947] **Israel**,[1948]

1931 §156(b)(3). Cited in *ibid.*
1932 Kung-Chung LIU, *Taiwan* in Annex II of this Study, Chapter 9, Section 9.5.1.3.
1933 Andrew F Christie, Benjamin Hopper, *Australia* in Annex II of this Study, Chapter 1, Section 1.5.2.4.
1934 *Ibid.*
1935 Jun-seok Park, *Korea* in Annex II of this Study, Chapter 5, Section 5.5.
1936 John Thomas, *the USA* in Annex II of this Study, Chapter 8, Section 8.6.
1937 Yoshiyuki Tamura et al, *Japan* in Annex II of this Study, Chapter 4, Section 4.5.1.
1938 Kung-Chung LIU, *Taiwan* in Annex II of this Study, Chapter 9, Section 9.6.
1939 Elizabeth Siew-Kuan NG, *Singapore* in Annex II of this Study, Chapter 7, Section 7.6.
1940 Tal Band, Yair Ziv, *Israel* in Annex II of this Study, Chapter 3, Section 3.6.
1941 *Ibid.*
1942 Carlos Correa, *The Bolar Exemption: Legislative Models and Drafting Opinions* in Bryan Mercurio, Daria Kim (eds), CON-TEMPORATY ISSUES IN PHARMACEUTICAL PATENT LAW (Routlege 2017) p. 125.
1943 Called regulatory review exception in New Zealand.
1944 Giuseppina D'Agostino, Joseph F Turcotte, *Canada* in Annex II of this Study, Chapter 2, Section 2.10.
1945 Yoshiyuki Tamura et al, *Japan* in Annex II of this Study, Chapter 4, Section 4.8.2.
1946 Andrew F Christie, Benjamin Hopper, *Australia* in Annex II of this Study, Chapter 1, Section 1.5.6.1.
1947 Susy Frankel, Jessica C Lai, *New Zealand* in Annex II of this Study, Chapter 6, Section 6.12.
1948 Tal Band, Yair Ziv, *Israel in* Annex II of this Study, Chapter 3, Section 3.12.

Korea,[1949] **Singapore**,[1950] **the USA**[1951] and **Taiwan**[1952]). In some states the *Bolar* exemption is divided into a general exemption for research and experiments and a specific exemption for research for the purpose of obtaining an MA.

Differences may be observed regarding the product groups which are eligible for *Bolar* exemption. Few countries, such as **New Zealand** and **Canada***,* provide very broad *Bolar* exemption, covering all products subject to a regulatory approval. In **the USA,** the *Bolar* exemption includes pharmaceutical and medical devices[1953] and is also available to veterinary products.[1954] However, it applies only if approval is being sought from the US FDA. At the same time, there is no limitation to generic drugs but the exemption can also be applied to originator products.

In **Latin American** countries, the *Bolar* exemption for the most part has been introduced following FTAs with the USA. However, the *Bolar* exemption is often limited to the filing for an MA for a generic product and furthermore only for the domestic MA and not for an MA application in another country.

In **Asia**, some countries have a *Bolar*-type exemption which applies only in cases of MA application in their own jurisdiction (**Pakistan**, **Singapore**) while others also allow the respective acts if approval for the drug is sought in other jurisdictions (**India**, **Philippines**, **Israel**).

In **Israel** commercial exploitation of a patented invention excludes *Bolar* exemption.[1955]

In **the USA**, there is no rich case law on whether the *Bolar* exemption applies to third-party suppliers that supply products to generic companies or follow-on competitors.[1956] In *Proveris Scientific Corp. v InnovaSystems Inc*.[1957] the court decided that third-parties are not covered by the US version of the *Bolar* exemption.[1958]

In **New Zealand,** the "act for experimental purposes" is exempted from infringement.[1959] This is defined as an act for the purpose of reverse engineering; "determining the scope of the invention; determining the validity of the claims, and seeking an improvement of the invention" (new properties, uses etc.).[1960] In addition, commercial nature of the use does not impact the experimental use exception[1961] as long as the use is experimental and serves one of the purposes mentioned above.

In **Australia,** there is an exemption for acts for experimental purposes and for prior use as well.[1962]

[1949] Jun-seok Park, *Korea* in Annex II of this Study, Chapter 5, Section 5.11.
[1950] Elizabeth Siew-Kuan NG, *Singapore* in Annex II of this Study, Chapter 7, Section 7.11.
[1951] John Thomas, *the USA* in Annex II of this Study, Chapter 8, Section 8.12.
[1952] Kung-Chung LIU, *Taiwan* in Annex II of this Study, Chapter 9, Section 9.12.
[1953] *Eli Lilly and Co v Medtronic* (496 US 661, 1990).
[1954] Carlos *Correa*, *The Bolar Exemption: Legislative Models and Drafting Opinions* in Biran Mercurio, Daria Kim (eds), CONTEMPORATY ISSUES IN PHARMACEUTICAL PATENT LAW (Routlege 2017) pp. 125, 135.
[1955] Tal Band, Yair Ziv, *Israel* in Annex II of this Study, Chapter 3, Section 3.12.
[1956] John Thomas, *the USA* in Annex II of this Study, Chapter 9, Section 9.12.
[1957] 536 F.3d 1256 (Fed. Cir. 2008). Cited in *ibid.*
[1958] John Thomas, *the USA* in Annex II of this Study, Chapter 9, Section 9.12.
[1959] Susy Frankel, Jessica C Lai, *New Zealand* in Annex II of this Study, Chapter 6, Section 6.12.
[1960] *Ibid.*
[1961] Patents Act 2013, s 143. Cited in *ibid.*
[1962] Andrew F. Christie, Benjamin Hopper, *Australia* in Annex II of this Study, Chapter 1, Section 1.5.6.3.

There has been no court decision in **Japan** deciding whether it would be seen as indirect infringement if a third party manufactures and supplies compounds protected by an extended patent necessary for another party for experiments. However, Japanese scholars' prevailing opinion denies indirect infringement in such a case.[1963] In a case in which a person who manufactures and sells a product which is protected by the patented invention on order (assignment) by a person who has a prior-use right, the Japanese Supreme Court has decided that this does not constitute direct infringement because the manufacturer acts solely for the benefit of the prior-use right holder and thus should be regarded to have acted as an agent and to have the right to refer to the right of prior use.[1964]

In **Korea**[1965] and **Taiwan**[1966] a third party who supplies products necessarily related to research and trials can rely on the protection of the *Bolar* exemption.

The differences between the various normative models of *Bolar* exemption are similar to those identified within the EU.[1967] On closer look, however, the following criteria can be identified:[1968]

- **The covered product**: either all products subject to regulatory approval or only specific products such as pharmaceutical or veterinarian products.
- **Permitted acts**: all acts required to obtain the MA may be included or the acts can be limited, for example by excluding manufacture of the active ingredient. On the other hand, manufacture by third parties can also be allowed.
- **Pre-clinical and/or clinical trials**: the question whether the exemption applies to clinical or pre-clinical trials has not been stipulated by most national laws. In some jurisdictions, this has been clarified by case law.[1969]
- **Generic products and/or originator products**: numerous jurisdictions, including **the USA**, **Canada** and several EU Member States do not limit the *Bolar* exemption to generic drugs, while others provide for such a limitation.
- **Timing**: while most jurisdictions do not specify time before the expiry of the patent or SPC when the acts are exempted, **Mexico** does only exempt acts conducted within three years before the expiration of the patent.
- **Submission in foreign countries**: while some jurisdictions (e.g. **the USA**) limit the exemption to trials conducted for approval in their jurisdiction, many other countries (e.g. **Canada**, **Croatia**, **Brazil**, **Philippines**, **Israel**) do not contain such a limitation.

[1963] Yoshiyuki Tamura, *Chitekizaisanhou (Intellectual Property Law)* (5th edn, Yuhikaku 2010), p. 260. Cited in Yoshiyuki Tamura et al, *Japan* in Annex II of this Study, Chapter 4, Section 4.8.2.
[1964] Supreme Court, 17 October 1971, 23 Minshu 10, p. 1777 – *Globe-shaped Radio*. Cited in Yoshiyuki Tamura et al, *Japan* in Annex II of this Study, Chapter 4, Section 4.8.2.
[1965] Jun-seok Park, *Korea* in Annex II of this Study, Chapter 5, Section 5.11.
[1966] Kung-Chung LIU, *Taiwan* in Annex II of this Study, Chapter 9, Section 9.12.
[1967] *Supra* Section 14.4.3.3.
[1968] Carlos *Correa*, *The Bolar Exemption: Legislative Models and Drafting Opinions* in Biran Mercurio, Daria Kim (eds), CONTEMPORATY ISSUES IN PHARMACEUTICAL PATENT LAW (Routlege 2017) pp. 125, 139 et seq.
[1969] *Merck KGaA v Integra Lifesciences I, Ltd* (545 US 193, 202, 2005)

PART SIX:

SUMMARY AND RECOMMENDATIONS

24 SUMMARY

24.1 SCOPE AND METHODOLOGY

This Study examines the functioning of the system of supplementary protection certificates (SPCs) established in the EU by Regulation 1768/92 on SPCs for medicinal products (now: Regulation 469/2009) and Regulation 1610/96 on SPCs for plant protection products. The functioning of the Regulations is considered in the context of adjacent and relevant legislation governing medicinal products (Directive 2001/83 and Directive 2001/82) or plant protection products (Regulation 1107/2009). The analysis focuses on the following topics:

- the case law of the Court of Justice (CJEU) and its implementation at the national level;
- the practice of national patent offices (NPOs);
- the impact of the Agreement on the Unified Patent Court (UPCA) on the scope of the *Bolar* exemption and the options for creating a manufacturing waiver;
- the interaction between the SPC legislation and the unitary patent package;
- unitary SPCs.

The Study combines a legal analysis with a fact-finding process. The latter included a questionnaire-based inquiry among the NPOs, a workshop with SPC experts from the EU Member States, an online stakeholder survey, qualitative interviews, and a seminar with industrial associations.

24.2 BACKGROUND OF THE SPC REGULATIONS

24.2.1 The purposes of the SPC legislation

The case law of the CJEU has been significantly influenced by a teleological approach. Therefore, the Study has attempted to assess what the original aims of the SPC legislation were. The relevant benchmark for this inquiry is provided by the recitals of the SPC Regulations and the Explanatory Memoranda.

24.2.1.1 The Medicinal Products Regulation

The Medicinal Products Regulation was adopted on the basis of the provisions concerning the free movement of goods. Consistent with this legal basis, the primary justification for enacting the legislation was to improve the functioning of the common market.

A second major goal of the Medicinal Products Regulation was, and is, to offer adequate protection for pharmaceutical research. While this *telos* is clearly stated in principle, its pursuit by the EU legislation raises two questions, namely, first, what type of research the Regulation intends to foster, and second, which achievements the Regulation intends to reward.

The first issue is clearly answered by the Medicinal Products Regulation adopted by the Council and by the Explanatory Memorandum to the Proposal for a Council Regulation

(EEC), of 11 April 1990, concerning the creation of a supplementary protection certificate for medicinal products.

The lawmakers intended to foster research in "new medicinal products". In the terminology of the Explanatory Memorandum this expression means "new active ingredients", that is, active ingredients that were never authorised before for medicinal use in Europe. This purpose is clearly reflected in the wording of Reg. 1782/92: Art. 3(c) allows only one certificate per product; Art. 3(d) requires the MA supplied in support of the application to be the first MA chronologically given for that active ingredient.

The intended and combined effect of all these provisions was to limit SPC protection to patented compounds that were brought to the market for the first time as active substances of a medicinal product. In the understanding of the German government and as indicated by the European Commission itself, the number of certificates should on average match the number of new active substances authorised by the health agencies each year (approximately 50).

While the kind of research that the SPC is intended to foster appears to be clearly defined – research in new active ingredients – the specific achievement within this kind of research that the SPC is meant to reward is less clear.

There are two possible rationales for patent term extensions for products subject to an authorisation. On the one hand, one can create a patent term extension as a supplementary incentive for investments and research that lead to patentable inventions in fields subject to a heavy regulatory burden. On the other hand, one can introduce a patent extension to incentivise and reward investments that lead, *after a patentable invention is made*, to a marketable medicinal product. In the latter case, only the patentee that has directly or indirectly (licensee) made investments in developing a medicinal product, including the active ingredient, and obtained the relevant MA for it, could obtain a certificate. The Explanatory Memoranda and some provisions of the SPC Regulations offer arguments that the SPC legislation intended to award the certificate as compensation for the *patentee* that obtained an MA to exploit the patented invention or contributed to this result by licensing the patent. However, the wording of the SPC Regulations allows also the opposite interpretation.

A third goal of the Regulation is to put the European industry on an equal footing with US- and Japanese competitors. To this end, the SPC legislation was to ensure protection, in principle, equivalent to that which existed at the relevant time in the US and Japan, which already provided for patent term extensions. It was assumed that the SPC Regulation would contribute to preventing a relocation of research centres to jurisdictions that offered greater protection. It is questionable, however, whether the assumption by the historical lawmakers that the availability of SPCs and the conditions for their protection would have an impact on companies' decisions as to where research facilities are located, was ever backed up by reality.

Fourthly, the lawmakers intended to establish a balanced system. Products that have previously been the subject of a certificate are not eligible for SPC protection. The MA supplied in support of the application for a certificate must be the first MA granted for the active ingredient or active substance in the EU Member State concerned. Multiple SPCs for the same active ingredient based on the same or different MAs thereby

remain excluded. For each product, SPC protection will expire within a period of 15 years from the date of the first MA in the EU/EEA.

Finally, the Regulation was aimed at establishing a simple and transparent system for granting SPCs. That purpose rather demonstrates the intention of the lawmakers to avoid imposing too high burdens on the NPOs than reflecting the importance of SPCs and the complexity of issues involved in their grant.

24.2.1.2 The Plant Protection Products Regulation

The Plant Protection Products Regulation in several aspects parallels the provisions and the recitals of the Medicinal Products Regulation. Consequently, it reflects similar objectives and purposes to Reg. 1768/92, including the aim of refining a balanced system.

The Plant Protection Products Regulation also indicates as a purpose "to place European industry on the same competitive footing as its North American and Japanese counterparts". However, in the USA, plant protection products are not eligible for a patent extension.

24.2.2 The sources of law applicable to SPCs

The legal regime of SPCs is highly complex due to a number of rather unique features. First, unlike patents, SPCs have their basis not in national or conventional law, but in EU Regulations that are directly applicable in the Member States. Unlike EU trade marks or Community designs, however, SPCs are not EU titles of protection, but national rights administered by national institutions.

Second, SPCs are separate and autonomous *sui generis* rights. However, their existence and validity are contingent on the existence of a further title of protection – a patent – and the existence and validity of a further administrative act – the MA. Both the patent and the MA are issued pursuant to and governed by provisions that are external to the SPC Regulations, but relevant for their operation.

Third, SPCs are a peculiar feature of EU law. For a long time they were foreign to other legal systems, some of which opted for an extension of the patent term instead. Therefore, the status of SPCs in international IP law is not easy to ascertain. This made it necessary for this Study to identify the applicable sources of law and their interaction.

24.2.2.1 International law

SPCs constitute a *sui generis* right that is not directly addressed in the Paris Convention or TRIPS. Nevertheless, the obligations stipulated in those Conventions apply insofar as the principles of national treatment, non-discrimination and most-favoured-nation treatment are concerned. With regard to the limitations and exceptions, however, the obligations stipulated in Art. 30 TRIPS must be evaluated in consideration of the specific nature and legal structure of the SPC system and the objectives on which it is founded. Thus, limitations reflecting the hybrid character of the right, insofar as they exempt certain acts for which an MA is not needed, cannot as such be considered to violate Art. 28 or 30 TRIPS.

SPCs are subject to specific or generic provisions included in bilateral free-trade agreements. The effects of such bilateral commitments must be interpreted in good faith in accordance with Art. 31 VCLT. For the substantive issues considered in this Study, the legislative freedom enjoyed by the EU is not negatively affected by such agreements. However, regarding procedural issues, the EU has made a clear commitment to observe the PLT (Art. 147.1 CARIFORUM EPA). This commitment should pertain to SPCs as well.

24.2.2.2 Union law

Under primary Union law, SPCs fall under the scope of Art. 17(2) Charter of Fundamental Rights of the European Union.

Under secondary Union law, certificates for plant protection products, on the one hand, and certificates for medicinal products for human and veterinary uses, on the other hand, are subject to two separate Regulations. In drafting the Plant Protection Products Regulation, the lawmakers adopted some recitals and provisions that are not included in the Medicinal Products Regulation and deleted some statements that are by contrast provided in Reg. 1768/1992 and confirmed in Reg. 469/2009. According to Recital 17 Reg. 1610/96, some of these provisions and recitals added to the Plant Protection Products Regulation – namely Recitals 12, 13 and 14, and in Arts. 3(2), 4, 8(1)(c) and 17(2) – are valid, *mutatis mutandis*, for the interpretation of the Medicinal Products Regulation. Art. 22 Reg. 469/2009 confirms that the reference to Reg. 1768/92 should be construed as a reference to Reg. 469/2009. However, under EU case law, recitals cannot be relied upon to interpret a provision in a manner contrary to its wording. Therefore – irrespective of the policy assessment of the provisions concerned – the interest in clear and transparent legislation calls for a consolidated version of the Medicinal Products Regulation.

Lastly, some provisions of the Regulations are not fully coordinated with the existence of a European patent alongside national patents. With the coming into force of the Unified Patent System, that lack of coordination will also concern the UPCA.

24.3 LEGAL ANALYSIS OF THE SPC REGULATIONS

24.3.1 Active ingredient

(a) *Notion*

All systems of registered or unregistered IP rights need a set of rules to define the subject matter that is eligible for protection under the applicable law. For SPCs, the corresponding rule results from a combined reading of Arts. 1 and 2 Reg. 469/2009 and Arts. 1 and 2 Reg. 1610/96. From those provisions it follows that two things can *in abstracto* be eligible for an SPC: the active ingredient of a medicinal product subject to an administrative authorisation procedure under Dir. 2001/83/EC or Dir. 2001/82/EC; or the active substance of a plant protection product subject to an administrative procedure under Reg. 1107/2009. While the SPC legislation defines the concept of a medicinal product, it does not further specify the concept of an active ingredient. This has given reason for case law.

The first interpretative issue concerned the question whether the term "active ingredient" should be considered coextensive with the notion of "active substance" in Art. 3(a) Dir. 2001/83. The CJEU answered this question in the affirmative. This case law has not clarified, however, how to assess whether or not the product to which the certificate pertains is an "active ingredient" in the above-mentioned sense. Two approaches are possible: either the NPO has to make its own assessment, or the NPO has to conform to the evaluation of the regulatory authority as included in the submitted MA. The Study proposes adopting the second approach and defining the concept of active ingredient as the active substance identified in the MA. This is consistent with the purpose of allowing a certificate for a product that undergoes an authorisation procedure as the active substance of the medicinal product to which the MA submitted in support of the application refers. Furthermore, it complies with the purpose of establishing a simple and transparent system, where NPOs, applicants and third parties can assess on the basis of two documents only – the MA and the basic patent – which active ingredients may qualify for SPC protection. Finally, such a definition would match the division of work between the specialised agencies competent for issuing MAs and the NPOs competent for issuing SPCs.

(b) *Active substance versus its derivatives*

Most free bases can form salts with a wide range of acids – and so can exist in many different "forms" – but all will generate the same active moiety in the body – and so, generally, will have an identical effect, irrespective of the particular salt (or form) in which they are authorised. The existence of different variants of the same compound claimed by the patent poses a challenge for the SPC legislation. The case law and the recitals of the Plant Protection Products Regulation have clarified that the certificate is granted for all variants of the compound, provided that they are covered by the basic patent. At the same time, however, the legislation considers it possible that a derivative may separately qualify for SPC protection. While the wording of Recital 14 Reg. 1610/1996 refers to the existence of a patent separately covering the derivative, a part of the case law requires as a further condition that the salt or derivative represents a different substance. This approach is persuasive: the mere fact that a patent was granted for a salt does not imply that the latter has different pharmacological properties from the free base. It does not even imply that the derivative is inventive *vis-à-vis* the free base. The derivative may be the subject of a divisional patent application or a patent application filed before the publication of the earlier patent application for the free base. It is in our view consistent with the purposes of the legislation to grant an SPC only when the derivative has been considered a new active substance by the agency that has granted the MA submitted in support of the application for a certificate. The criteria governing the question whether a derivative of a substance may be considered as a new substance for the purpose of eligibility for an SPC should also govern the question of whether a derivative is the same product as the free base for assessing the scope of the certificate under Art. 4 Reg. 469/2009.

24.3.2 Concept of marketing authorisation (MA)

Although the applicable regulatory law provides for different types of MAs and although MAs are dynamic and not static documents, subject to variations and changes, the drafters of Reg. 469/2009 neglected to define the concept of marketing authorisation. A definition was likely considered to be superfluous in 1992 because

only the first MA was intended to be the basis for granting an SPC (Art. 3(d) Reg. 1768/92), and only one SPC per product could be granted (Art. 3(c) 1768/92). Therefore, only MAs based on a full dossier could be the basis for granting an SPC. However, the legal situation has become more complex in both regulatory law and SPC case law. On the one hand, new types of MAs have been provided for. On the other hand, the principle that only one certificate per product is possible and only the first MA for each active ingredient can support the grant of a certificate has been relativised by the case law (Chapter 11, Section 11.3.1). As a consequence of *Neurim*, even variations of existing MAs can become relevant for the operation of Art. 7, Art. 3 and Art. 13 Reg. 469/2009. Against this background, a definition of what types of MAs (or variations of MAs) can support the application for a certificate under Art. 3(b) and (d), and how to assess their chronological order, would be useful today even if it was superfluous in 1992.

24.3.3 Conditions for granting the certificate

24.3.3.1 Art. 3(a) Reg. 469/2009

Article 3 Reg. 469/2009 defines the requirements for protection that the subject matter eligible for an SPC must satisfy in order to be *in concreto* protectable by an SPC. The first requirement is that the product be protected by a basic patent in force. The provision was the subject of several preliminary rulings of the CJEU. Nevertheless, the CJEU has so far failed to deliver a clear test for applying Art. 3(a) Reg. 469/2009. We identify three reasons why this is the case.

First, the CJEU has ruled that the mere fact that a product falls under the scope of the basic patent is not sufficient for the product to be protected within the meaning of Art. 3(a) Reg. 469/2009. It has required that the product be "specified" or "identified" in the wording of the claim. We have called this approach the *Medeva*-requirement.

In *Eli Lilly* the Court maintained that it is not necessary for the claim to mention the product by its name or chemical structure in order to satisfy Art. 3(a) Reg. 469/2009. However, it has differentiated between products to which the claim refers specifically and necessarily, and products to which the claim does not specifically and necessarily refer. Whether an SPC falls under the first or second group must be assessed on the basis of national patent law. This law consists of the provisions that govern the extent of protection of the patent (Art. 69 EPC and corresponding provisions of national law).

The main problem with this approach is that on the basis of the law governing the basic patent, one can discern the following distinctions:

- products that fall under the scope of the patent versus products that do not fall under the scope of the patent;
- products that fall under the scope of the patent and are individually disclosed so that the patent could be limited specifically to them without violating Art. 123(2) EPC versus products that fall under the scope of the patent but are not individually disclosed in that patent, so that the patent cannot be limited to them without infringing Art. 123(2) EPC;
- products that fall under the literal scope of the patent versus products that fall under the scope of the patent only because of the equivalence doctrine (which

states that elements equivalent to the elements *specified* in the claim should be taken into account).

As a consequence, the distinction between a product that is "specified" (or "identified") in the wording of the claims and a product that is not "specified" (or "identified") in the wording of the claims can be based on the law governing the basic patent only if one of the three former concepts is intended. If something else is meant, the law governing the basic patent cannot be invoked as a basis for this distinction. Instead, the basis would be an SPC-specific criterion. But in this case, the CJEU must spell out the details of how to implement such a requirement.

The second problem of the case law is that the CJEU has not explained the actual purpose of the *Medeva*-requirement.

Third, the CJEU introduced in *Actavis I* the requirement that the product must embody the core inventive advance of the patent. While in *Actavis I* such requirement was based on Art. 3(c) Reg. 469/2009, *Actavis II* bases such requirement on Art. 3(a) as well. The interaction between *Actavis I* and *II* and *Medeva* is not clear.

As a result, the case law is open to several interpretations. According to the *first* possible understanding, a product is protected under the CJEU case law when it is *specified in the wording of the claim.* This is the only requirement that the product must satisfy to comply with Art. 3(a) Reg. 469/2009. The inventive-advance test is not relevant in the context of Art. 3(a) Reg. 469/2009. It only applies in the context of Art. 3(c) Reg. 469/2009.

According to the second possible understanding, a product is protected within the meaning of Art. 3(a) Reg. 469/2009 when two requirements are cumulatively satisfied:

- it is specified in the wording of the claim, and
- it embodies the core inventive advance of the patent.

In this view, the core-inventive-advance requirement elaborated in *Actavis I* and *II* constitutes an element for interpretation of Art. 3(a) Reg. 469/2009. As a consequence, it applies to all SPC applications whether or not the applicant has obtained an SPC on the basis of the same patent. The core inventive advance does not replace the *Medeva*-requirement, but supplements it.

According to the third understanding, the requirement that the product must embody the core inventive advance of the basic patent replaces the requirement "*specified in the wording of the claim*".

In all the possible readings of the CJEU case law mentioned above, the product must fall under the scope of protection of one patent claim in order to be considered protected. This is a common feature of all understandings of the case law on Art. 3(a) Reg. 469/2009.

The three possible interpretations described in the Study are reflected in the practice of the NPOs. In examining Art. 3(a) Reg. 469/2009 some of them apply the core-inventive-advance test, others apply the *Medeva*-requirement, and others apply both.

In reaction to this development, it must be considered whether legislative action is called for. The majority of stakeholders consulted during the Study opposed a reopening of the Regulation. Nevertheless, we believe that the better arguments speak in favour of legislative action (see the discussion in this Chapter, Section 24.5 and Chapter 10, Section 10.2.3.5). In this regard, the Study has identified three possible ways to clarify Art. 3(a) Reg. 469/2009. The proposed criteria have two features in common: they are based on notions that are not foreign to patent law and they have been applied or considered applicable in interpreting Art. 3 Reg. 469/2009 by national courts.

The *first approach* is to adopt a (direct) *infringement test*. The clarification could read as follows:

> The product is protected by the basic patent within the meaning of Art. 3(a) Reg. 469/2009 when it falls under the extent of protection of the basic patent according to the law applicable to said patent.

According to some NPOs and a part of the literature this approach has several shortcomings. It requires the NPOs to assess the scope of the basic patent. It could allow multiple SPCs covering overlapping combinations. It would not prevent the patentee from obtaining a patent for a product that is not individually disclosed in the patent. But these assumed shortcomings can be addressed by

- a recital that limits the category of products eligible for a certificate to the products that fall under the **literal scope** of the basic patent. The NPOs would be dispensed from taking into account elements that are equivalent to those specified in the claims.
- specific rules dealing with the problem of combinations.
- a rule addressing the question of third-party issues (see Recommendation No. 13);

The *second option* to be considered is a *disclosure test*:

> The product is protected by a basic patent in force if:
> It falls under the extent of protection of the basic patent pursuant to applicable provisions of the EPC and national patent acts and is, be it explicitly or implicitly, directly and unambiguously disclosed to the skilled person in said basic patent and in the patent application as filed.

This approach would be clear, because it is based on the concept of disclosure that underlies several institutions of European patent law (Art. 123(2), Art. 87 and Art. 54(2) EPC). However, it also has its shortcomings. On the one hand, it would significantly reduce the number of SPCs and would penalise basic research. A patent concerning a new class of antibodies would likely satisfy this requirement only if at least the active part of the specific antibody for which the certificate is requested is also disclosed. On the other hand, such criterion would not reduce the number of multiple SPCs for combinations covering the same active ingredient, assuming that this was one of the purposes of the CJEU case law. Indeed, it is sufficient that the patent application directed to a new class of compounds includes in the specification a list of known active ingredients (for instance, a list of diuretics) that may be combined with the compounds that are the subject of the invention. In this case a disclosure test would not prevent the grant of certificates for the combinations including a diuretic

disclosed by the patent. Art. 3(c) Reg. 469/2009 could be easily circumvented (Chapter 12).

The *third option* could be to adopt the *core-inventive-advance approach*:

> The product is protected by a basic patent in force if:
> It falls under the extent of protection of the basic patent pursuant to applicable provisions of the EPC and national patent acts and
> it embodies the core inventive advance of the patent.

Such a criterion would require guidance on how it should be applied to categories of patents other than product patents and products other than combinations.

Which solution should be chosen is driven by *policy* considerations. From a legal perspective, the core-inventive-advance test provides some advantages over the Art. 123 EPC-based disclosure and the (direct) infringement test. It is already a part of the system: it was adopted in *Actavis I* and *II*, even though not clearly based on Art. 3(a) Reg. 469/2009, and it has been applied by the NPOs. It could avoid multiple SPCs for the same ingredient in combination with other products unless a separate innovation exists. It would provide the NPOs and the courts with a uniform European criterion that could prevent a fragmentation of the internal market. It is likely that these objectives were also at the basis of the CJEU case law.

24.3.3.2 Art. 3(b) Reg. 469/2009

A discrepancy exists between the wording of Art. 3(b) and Art. 1(b) Reg. 469/2009 on the one hand, and the case law on the other. An MA granted for a combination including A-B does not allow the marketing of a medicinal product that only includes A; the single active ingredient A and a combination including A-B are not the same product under Art. 1(b) of the SPC legislation. Despite that, according to the case law, Art. 3(b) Reg. 469/2009 must be interpreted as allowing the grant of a certificate for "a combination of two active ingredients, corresponding to that specified in the wording of the claims of the basic patent relied on, where the medicinal product for which the marketing authorisation is submitted in support of the application for an SPC contains not only that combination of the two active ingredients but also other active ingredients". The same principle applies to monotherapy products.

All NPOs have adapted their practice to this case law. The implications of the latter for Art. 13 or Art. 7 Reg. 469/2009 and the extent to which it shall apply, however, have occasionally given rise to diverging decisions. One national court has considered the principle of *Medeva* applicable only to combinations, but not single active ingredients, which is in conflict with *Georgetown I*. Another court has considered the principle of *Medeva* applicable only to medicinal products that include various active ingredients with different indications such as multivaccines. For this reason, closing the gap between the wording of Art. 3(b) Reg. 469/2009 and the case law, and clarifying by some form of soft law the criteria for applying the principle formulated in *Medeva* could help national courts to deal with the validity of granted certificates.

24.3.3.3 Art. 3(d) Reg. 469/2009, Neurim and Abraxis

In *Neurim* the Court of Justice maintained that

> "Articles 3 and 4 of Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products must be interpreted as meaning that, in a case such as that in the main proceedings, the mere existence of an earlier marketing authorisation obtained for a veterinary medicinal product does not preclude the grant of a supplementary protection certificate for a different application of the same product for which a marketing authorisation has been granted, provided that the application is within the limits of the protection conferred by the basic patent relied upon for the purposes of the application for the supplementary protection certificate."

Further, the Court has maintained that "Article 13(1) of Regulation (EC) No 469/2009 must be interpreted as meaning that it refers to the marketing authorisation of a product which comes within the limits of the protection conferred by the basic patent relied upon for the purposes of the application for the supplementary protection certificate".

As explained in Chapter 11, Section 11.3.1, *Neurim* is interpreted in two different ways. The first interpretation is that the *Neurim* principles only apply to the specific situation where the first MA is for a veterinary medicinal product and the second MA is for a human drug. The second reading is that the *Neurim* principles apply when (i) the patent concerns a new indication of an old active ingredient, and (ii) even if an older MA for the treatment of the same species was granted. In both cases, *Neurim* would not be consistent with the wording of the SPC legislation. There is nothing in Art. 3(d) Reg. 469/2009 that suggests that the scope of the basic patent is of any relevance for determining what is the first MA for a specific product granted in a Member State.

However, if one were to understand *Neurim* as allowing the grant of a certificate only when the specific factual scenario of the referral proceedings occurs – that is, a first MA for a medicinal product for veterinary use, and a second MA for a medicinal product for human use – *Neurim* would on the one hand likely be irrelevant, because that situation is extremely rare, but on the other hand it could be justified as a possible reasonable interpretation of the SPC legislation that does not conflict with the principles of the SPC system. Indeed, the referral in *Neurim* was the effect of conflating two categories of products in the same legislation, namely veterinary medicines and human medicines. This conflation is unfortunate. While a previous MA granted for a medicinal product for human use significantly reduces the burden for obtaining a marketing authorisation for a medicinal product for veterinary use including the same active substance, the reverse is not true. A veterinary medicine cannot serve as a reference product for the authorisation of a human medicine under Art. 10 Dir. 2001/83.

A narrow understanding of *Neurim* in the sense suggested above is rejected by the majority of the NPOs. They understand *Neurim* as allowing protection when the patent covers a second medical indication and the MA granted is the first that falls under the scope of the basic patent. This reading of *Neurim* finds support in several passages of the judgment; however, it makes protection possible clearly beyond what was intended by the lawmakers.

Therefore, if the lawmakers consider still valid the arguments that induced the Commission in 1990 to propose a system directed to admit SPC protection only for active ingredients or combinations of active ingredients authorised for the first time, and to deny protection to new formulations or new uses of old active ingredients, then they must override the case law. If they share the arguments that led the CJEU to develop Art. 3(d) Reg. teleologically, they must codify the case law. The choice between the different options is of a matter of policy. The reason for having

certificates is the risk of market failure on the assumption that the ordinary patent term is not sufficient to make research in new active ingredients profitable. If the same risk is documented for new indications, the lawmakers should adopt *Neurim*. In the latter case, a distinction between a new formulation and a new indication of an old active ingredient is *prima facie* not justified, because:

- the time and the investments that may be needed to bring a new formulation on the market for an old indication is not necessarily less than the time and the investments needed to bring an old formulation on the market for a new indication;
- the distinction could be difficult to implement for the NPOs: a patent for a new formulation can include a claim for the a second medical use; it is sufficient to this purpose that the patent claim include a new technical feature. Such technical feature may also consist in a new formulation;
- from the point of view of primary and international law, a differentiation between new formulations and new indications could turn out to be problematic if the prohibition of discrimination under Art. 27 TRIPS or the principle of equal treatment applies to SPCs.

24.3.3.4 Art. 3(c) Reg. 469/2009

It was the intention of the lawmakers that Art. 3(c) should allow only one certificate per product. The number of SPCs should have matched the number of new active ingredients authorised each year (approximately 50).

An exception was only to be made in the case of co-pending applications. The provision was drafted on the assumption that the MA and the patent were in the same hands. It therefore not only implied one certificate per product, but also that one MA could only support one application for that product. The case law has narrowed the scope of the prohibition. The reasons provided are not fully convincing (Chapter 12). As a result of this development, the prohibition in Art. 3(c) Reg. 469/2009 only applies in the case that the *same patentee* has already obtained an SPC for the product.

This development does not imply that the prohibition of multiple SPCs for the same product has lost all relevance. Another development concerning the concept of a product pursuant to Art. 3(c) Reg. 469/2009 has limited the eligibility of combinations for an SPC. After *Actavis I* and *Actavis II*, if a patentee has already obtained an SPC for compound Y, Art. 3(c) Reg. 469/2009 prevents the grant of a further SPC to the same patentee for any combination including such compound, unless such combination represents a separate innovation. Furthermore, in *Neurim* the CJEU allowed the grant of an SPC on the basis of an MA that was not the first MA for the product concerned, since that MA was the first that fell under the scope of the patent designated for the SPC procedure. With respect to Art. 3(d) Reg. 469/2009, therefore, the examination of whether the product is covered by an earlier MA than the MA supplied in support of the application for a certificate must take account of the medical indication for which the MA was granted. As a consequence of *Neurim*, a product for indication A and a product for indication B are not the same product under Art. 3(d) Reg. 469/2009. However, *Neurim* does not address the question of whether this concept of a product formulated for Art. 3(d) Reg. 469/2009 also applies to Art. 3(c) Reg. 469/2009. If this is not the case, Art. 3(c) Reg. 469/2009 would limit the

applicability of *Neurim* to situations where on the basis of the first MA for the active ingredient either no SPC was granted or such SPC was granted to another applicant.

We recommend closing the gap between the wording of Art. 3(c) Reg. 469/2009 and the practice.

If the lawmakers agree with the reasoning that has induced the case law to relativise the prohibition, then they should codify this case law. If the lawmakers still agree with the reasoning that underlies the prohibition (Chapter 2 and 12), they should override this case law.

If the lawmakers are of the opinion that the case law should be codified, we recommend adopting some measures directed to ensuring the effectiveness of Art. 3(c) Reg. 469/2009. The lawmakers could provide that the prohibition applies in situations where

- the applicants are formally distinct, but related entities, and/or
- the designated patents even partly share the same inventorship.

Revocation and surrender of the SPC should not have any effect on the operation of Art. 3(c) Reg. 469/2009.

24.3.3.5 Third-party issue

The question of whether the SPC should reward each patentee or only the patentee that has directly or undirectly (through a licensee) contributed to developing a marketable product and obtaining an MA for it, has not been clearly answered in the case law of the CJEU.

It is the task of the lawmakers and not the courts to answer this question, because it defines the function of the SPCs and the purpose of the legislation.

The EU legislature has two options. The first is to allow the patentee to obtain an SPC for an authorised product whether or not he/she is the holder of the MA, and whether or not the holder of the MA agrees. The second is to require the consent of the MA holder. What option is to be preferred depends on whether the SPC should reward the investment and research that leads to a patentable invention or the investment and research that leads to a marketable product *after* an invention is made.

If the legislature intends to create a consent requirement, there are several options for refining it. As regards the procedure, the requirement might be introduced as:

- a condition for granting the certificate, or
- an opposition ground.

In both cases, the burden of proof for the MA holders' consent should lie on the patentee.

As regards the nature of the requirement, it can be defined as an absolute or relative condition for the validity of the certificate. In the latter case it could be invoked only by the MA holder and not by any party interested in removing the granted certificate.

Regarding the critical date at which the requirement must be met, the options are to require that both the consent and the contractual relationship on which it is based be established:

- at least by the time the MA is requested;
- by the time the application for a certificate is filed;
- or that they could even be established *ex post*, after the filing of the SPC application or the grant of the SPC (if the consent requirement is only an opposition ground).

If the policy of the requirement is to ensure that the SPC rewards only the patentee that has directly or indirectly contributed to developing a marketable product, an agreement between the parties involved should be reached at a relatively early stage of the product development.

24.3.4 Subject matter of protection (Art. 4 Reg. 469/2009)

With respect to the scope of protection conferred by the certificate under Art. 4 Reg. 469/2009, we focused on two issues:

- the status of the product description that the applicant includes in the application for a certificate and the NPOs require in the application forms for a certificate;
- whether the criteria for determining the scope of the certificate developed for small molecules may also apply to biological products.

The last question was addressed in Chapter 18.2 (see below, 25.3.11). As to the first question, a review of the case law undertaken by the Study leads to ambiguous conclusions. On the one hand, considering the language of the SPC legislation, the product definition is not a necessary feature of the application, and, if included, does not affect the scope of the certificate.

On the other hand, the product definition has become a necessary feature of the application for a certificate as a consequence of the case law. Indeed, following *Medeva*, the MA is not always sufficient to identify the product for which the certificate is applied (at least when the MA covers a combination). Furthermore, applicants and NPOs behave as if such definition will have an impact on the validity and scope of the certificate, once granted. The case law, at least in Germany, seems to attribute legal effect to the product definition.

For this reason, the legal status of the product definition or product description of the certificate is in our view unclear at the moment. One obvious approach for the legislature would be to remove this uncertainty.

The first option is to confirm that the patent and the MA are the only documents that are relevant for defining the scope of protection of a certificate. However, unless *Medeva* is rejected and *Forsgren* corrected, the mere submission of the MA is not sufficient to identify the product for which the certificate is sought. One could clarify that the product description has to be included in the application, but only has the function of identifying the substance among the active ingredient(s) contained in the MA that must undergo examination. It should not define to what extent and in which form(s) such active ingredient is then protected by the granted certificate.

The second option is to draw all necessary implications from creating a separate title of IP protection instead of extending the basic patent. One of these implications would be to provide that the certificate should have its own autonomous and self-sufficient definition of the subject matter protected like any other IP right. This definition should occur in the form of binding statements ("certificate claims"). If this model is chosen, the lawmakers should design an overarching legal infrastructure governing such certificate claims (Chapter 14).

24.3.5 Rights conferred by the SPC and their limitations (Art. 5 Reg. 469/2009)

24.3.5.1 Manufacturing waiver

Two general concepts for a manufacturing waiver must be distinguished: an export waiver and a stockpiling exemption.

From a legal perspective, manufacturing waivers in both forms are consistent with the purpose of the SPC Regulations to provide an extended period of time to compensate for the delay in the commercial exploitation of the invention that arises in consequence of the requirement for an MA under Directives 2001/82 and 2001/83. That rationale is satisfied if the exclusive rights granted by the SPC only extend to activities that are delayed by such requirement. The production of an active ingredient or of a medicinal product including the active ingredient for export or stockpiling purposes does not require an MA granted under Dir. 2001/82 or 2001/83. Therefore, allowing these activities after the expiration of the basic patent does not run counter to the legal objectives of the SPC system.

In spite of that, the stockpiling waiver appears more problematic than the export waiver, as it concerns the manufacturing of goods destined for the same market and for the same purposes as those covered by the MA. Therefore, the potential negative effects on the position of the SPC holder are more aggravating. The hurdles for introducing such a waiver must be higher than in the case of the export waiver.

Both forms of manufacturing waivers have the potential to level the playing field between EU-based generic companies and generic companies based in countries that do not offer an extension of the patent term in some form. However, in order to assess whether such legislation would have the desired effects or rather produce undesirable side-effects, economic and political factors must be taken into account which cannot be addressed in this Study.

As a corollary to the introduction of waivers in one or both forms, precautionary measures should be envisaged in order to ensure that generic manufacturers respect the terms of the limitation, without impeding activities permitted under the waiver in a disproportional manner.

24.3.5.2 Bolar exemption

The majority of the EU Member States provide for a *Bolar* exemption that is broader at least to some extent than the minimum standard laid down in Art. 10(6) Dir. 2001/83 or Art. 13(6) Dir. 2001/82. Countries that have recently amended their patent legislation – such as the UK and Ireland – have adopted an exemption that covers

activities aimed at generating data for MAs for innovative products, for product approval outside the EU or for health technology assessment.

With the UPCA coming into force, the national provisions implementing Art. 13(6) Dir. 2001/82/EC and Art. 10(6) Dir. 2001/83/EC will no longer apply to European patents with unitary effect or to those European patents without unitary effect that are enforced before the UPC. Instead, the exemption laid down in Art. 27(d) UPCA will apply that includes a dynamic reference to Art. 13(6) Dir. 2001/82/EC and Art. 10(6) Dir. 2001/83/EC.

The qualitative interviews, the Allensbach Survey and the contributions to the MPI Workshop of 20-21 March 2017 all suggest that the majority of the stakeholders consulted would favour or at least not oppose a broad *Bolar* exemption along the lines of the UK model.

24.3.6 Specific issues in health technology

24.3.6.1 Biological products

Biological products are eligible for patent protection under the EPC. They are also eligible for SPC protection under the same general conditions as any other substance. The regulatory framework draws a distinction between generics and biosimilars, but the implication of such distinction for the SPC legislation and for the scope of a certificate granted for a biological product are still to be addressed in the case law. Although differences in manufacturing processes may give rise to differences in the properties of a biosimilar product compared to the reference product, the fact that the EMA approves such biosimilars with the same INN as the original product shall be sufficient for them to be considered to fall within the scope of an SPC based on a marketing authorisation relating to that original product.

24.3.6.2 Nanomedicines

Nanomedicines may be the subject of a patentable invention under the EPC. However, the granted patents will likely be unable to support the application for a certificate for the active ingredient included in the nanomedicine. Three reasons account for this.

First, nanomedicines usually consist of a new formulation of an old active ingredient, for instance the combination of an old active ingredient with nanoparticles that serve as a carrier. Therefore, the MA submitted in support of the application for the certificate will in this case not be the first MA granted for the active ingredient within the meaning of Art. 3(d) Reg. 469/2009. This is true unless the Court of Justice extends the logic of the *Neurim* principles to new formulations.

Second, the patent covering the nanomedicine will in most cases not claim the active ingredient or its use as such, but a combination of a nanoparticle with an active substance. It is questionable, therefore, whether an application for a certificate for the active ingredient would satisfy Art. 3(a) Reg. 469/2009. Finally, if the CJEU should adopt the inventive-advance test, an application for a certificate could also fail on this requirement. Indeed, the drug-delivery system, or the combination of a nanoparticle with an active substance, but not the active constituent as such, will embody the technical advance of the patent.

Consequently, under the legislation in force, SPC protection will not be available for a significant part of the advanced nanomedicine. However, the Study does not offer any criticism or recommendation in this regard. Whether or not the SPC legislation should be extended to cover new formulations or drug-delivery systems of old active ingredients is a question of policy. Legislative decisions should therefore be taken, *inter alia*, on the basis of an economic assessment.

24.3.6.3 Antibiotics

Antibiotics are patentable under the EPC and are in principle eligible for a certificate under the SPC legislation. Despite that, IP-based schemes seem to be ineffective in providing sufficient incentives for developing new antimicrobial agents. The Study has addressed the question whether amendments of the SPC legislation could be a sensible approach to address the declining numbers of new antibiotics brought on the market. Two options were discussed: the grant of longer SPCs or the creation of transferable SPCs (wild-card SPCs).

24.3.6.4 Personalised medicines

Inventions concerning personalised medicines are patent-eligible under the EPC, usually in the form of a second medical indication. Second-medical-indication patents may be the basis for granting an SPC. In the practice of the majority of the NPOs this is true even if the patent concerns the second medical use of an active ingredient already authorised in the past as active substance of an human medicine. However, it is unclear whether patented changes to the administration of a medicinal product oriented to a specific subgroup (e.g. frequency of administration) that requires the amendment of the related MA could also be eligible for a certificate. One could argue, following a broad understanding of *Neurim*, if (i) these changes consist in a type-II variation in terms of Reg. 1234/2008, (ii) this variation is protected by a patent and (iii) the amended MA is the first permission that falls under the scope of protection of that patent, the grant of a certificate could be possible. However, the requirement of a new application formulated in *Neurim* could limit the SPC eligibility of inventions in this field. More precisely, if one understands *Neurim* as allowing an SPC only when the patent covers a new indication intended as a new illness, new regimens of administration of a known substance for a known indication will not be eligible for an SPC.

24.3.6.5 Medical devices

Medical devices are not eligible for SPC protection under the current SPC legislation and the practice of the NPOs. They are not medicinal products within the meaning of Art. 1(a) and Art. 2 Reg. 469/2009 and they are not authorised as a medicinal product within the meaning of Art. 3(b) Reg. 469/2009. A teleological approach cannot affect this result. The purpose of the SPC legislation is to foster research in new active substances and not in new medical devices.

It is unclear whether this conclusion is also valid for medical devices with ancillary active ingredients (drug/device combination) that are subject to a consultation procedure that requires clinical data. The German Federal Patent Court takes the view

in the referral decision of 18 July 2017 that SPCs may be available in this regard, but it referred the question to the CJEU for a preliminary ruling whether

> "Art. 2 Reg. 469/2009 is to be interpreted to mean that an authorisation according to Directive 93/42/EEC for a drug-device-combination in the sense of Art. 1(4) of Directive 93/42/EEC has to be considered as equivalent to an MA according to Directive 2001/83/EC if the drug component, in the course of the approval procedure according to Annex I, Section 7.4, Paragraph 1 of Dir. 93/42/EEC, was scrutinised for quality, safety and usefulness according to Directive 2001/83/EC by an authority for medicinal products of an EU Member State."

However, this question really matters only when the application for a certificate meets all the other requirements of the SPC legislation, including Art. 3(a) and Art. 3(d) Reg. 469/2009. Since such drug/medical device combinations usually involve old active ingredients, the application for a certificate could meet Art. 3(d) Reg. 469/2009 only when the principles stated in *Neurim* apply. The question whether *Neurim* also applies to the use of an old active ingredient as an ancillary substance integrated in a medical device was not addressed by the CJEU.

If the drug/medical device combination includes (exceptionally) a new active ingredient, so that the EC Design Certificate submitted in support of the application for a certificate is the first "permission" to use the active ingredient for a medicinal purpose, the grant of a certificate is in our view consistent with the rationale of the SPC legislation, provided that the other requirements of Art. 3 Reg. 469/2009 are met. The argument that the CE Certificate as such is not an authorisation in legal terms would be a formal one with respect to the substance of the problem, that is, to ensure equal treatment. If the delay due to the regulatory work required by the applicable legislation to bring to the market a new active ingredient is to be compensated, it should not matter what the normative basis for this delay is, whether it is the consequence of a legislation that follows the new approach or a legislation that requires a formal MA. What is more significant is that the applicant cannot influence the qualification of the product as a medicinal product or as a medical device. The applicant cannot choose the applicable regulatory route unless it decides to change the means of administering the ancillary active substance. This is not the purpose and should not be the effect of the SPC legislation.

If the drug/device combination includes an old active ingredient, the assessment depends on whether or not the lawmakers intend to accept *Neurim* and generalise its logics. This is a policy issue that the Study cannot answer.

The same holds true for the question whether, under what conditions, and for which class of medical devices an SPC should be made available. The Study formulates some criteria to inform the exercise of legislative discretion in this respect. These criteria are based on the theory that the existence of SPCs in Europe is justified not by the mere existence of an approval procedure, but by the risk of a market failure.

24.3.7 Plant protection products

SPCs for plant protection products are provided by Reg. 1610/96. The motivation and the conditions for the introduction of an SPC for plant protection products are similar to those relating to medicinal products.

Stakeholders consulted during the preparation of the Study pointed out some differences between the sector of plant protection products and that of medicinal

products. Medicinal products are produced by companies, prescribed by doctors, used by patients and – usually – paid for by insurance companies. Plant protection products are produced by companies and bought, used and paid for by farmers. The public interests touched by SPCs for a plant protection product seem to be less relevant than the public interests affected by SPCs for human medicines. Further, there is a pressure to bring active substances to the market in combination products. It has been argued therefore that some limitation to the SPC eligibility of combinations, such as the inventive advance, should not apply to plant protection products. While differences between the market for and the interests involved in medicinal products and plant protection products exist, from a legal perspective we do not see a reason to differentiate between the two technical fields with respect to the question of whether or not the core inventive advance should apply. The lawmakers intended to create a balanced system in the field of plant protection products as well. Both Regulations share the same preconditions for granting the certificate.

24.3.8 National law and practice: options for further unification

The qualitative interviews and the Allensbach Survey, as well as the analysis of the NPOs' decisions and the data provided in Chapter 7, have confirmed the existence of discrepancies in the practice of the NPOs regarding the granting and refusal of SPCs. This is true *inter alia* for the severity, scope and length of the examination, as well as for the understanding of CJEU case law. Chapter 20 of this Study has reviewed some aspects of the national practice and national legislation implementing the SPC regime.

A difference between the SPC Regulations and other fields of EU law is the absence of soft law and implementing rules that could assist the national agencies in applying the Regulations. The enactment of soft law or implementing rules could improve the level of uniformity in national practice. It would improve the efficiency of the system if the Unitary SPC Division (see below) and the NPOs could operate under a uniform legal framework that could apply – *mutatis mutandis* – to proceedings before both the Unitary SPC Division and the NPOs.

The Study provides some examples where further unification could be meaningful. Some proposals are aimed at improving the transparency of the system and the quality of the rights granted under the SPC Regulations. Other options discussed are directed to increasing the uniformity of the system. Further proposals also deal with the examination and possible forms of cooperation between the examining offices and the prospective Unitary SPC Division. Such proposals are only meant to provide examples for issues that should be taken up for further discussion and in-depth research to be conducted with the cooperation of the NPOs and practitioners.

24.4 UNITARY PATENT PACKAGE AND SPCS

24.4.1 Issues *de lege lata*

The applicability of Reg. 1257/2012 to SPCs poses two interpretative challenges regarding the SPC legislation. The first question raised by the interaction of Reg. 1257/2012 with Reg. 469/2009 is whether, on the basis of a European patent with unitary effect, the patent proprietor may request, and the NPO may grant, an SPC. The European patent that enjoys a unitary effect under Reg. 1257/2012 is a European

patent granted under the EPC. The registration of the unitary effect does not change the nature of the patent concerned. As explained in Chapter 9, Section 9.4.2, the notion of basic patent within the meaning of Art. 1(c) Reg. 469/2009 in accordance with Recital 7 of Reg. 469/2009 includes both European and national patents. For this reason, it is possible for the NPOs to grant an SPC on the basis of a European patent with unitary effect, as long as the further requirements under Art. 3 Reg. 469/2009 are met.

The second question is what are the effect and the law applicable to the SPC granted by an NPO on the basis of an unitary patent. An interpretation that respects the sovereignty of the EU Member States leads to the conclusion that SPCs granted on the basis of a patent with unitary effect confer the rights provided under Art. 30 UPC only for the territory in which the rights issued by the national authority concerned have effect. The territorial scope of the certificate is coextensive with the territorial scope of a national patent granted by said authority.

24.4.2 Issues *de lege ferenda*: Unitary SPC

The information collected in the course of the Study confirms that, in the view of the stakeholders, a practical need exists for a unitary SPC that can be obtained through a single granting procedure. In order to satisfy the need mentioned above, the EU legislature has two options: creating unitary SPCs as a *sui generis* right or extending the term of the unitary patent. Since the European Commission focuses on unitary SPCs, only the latter are considered in this Study.

24.4.2.1 Institutional aspects

The task of granting a unitary SPC can be assigned to:

- an EU authority, whether already existing or created for the purpose, including the option of a "virtual office" consisting of national experts operating under a common institutional head on the basis of unitary procedural rules;
- the EPO, provided that the task is assigned to it by the Member States under Art. 63(3) and (4) EPC. Whether or not this could include the model of a "virtual office" is an organisational matter to be addressed in negotiations with the EPO and cannot be pre-empted by EU legislation.

Depending on the institutional choice made, the following routes are available for appeals against decisions made in the course of the granting procedure:

- if an EU authority is in charge of the grant, appeals must be directed to the GCEU, with the possibility of directing further appeals on points of law to the CJEU;
- if the EPO is in charge of the granting procedure, decisions on appeals would be dealt with in the UPC system.

Submitting that the establishment of the Unitary SPC is based on enhanced cooperation, a Council decision is necessary to authorize such legislation. Furthermore, the following steps must be taken for implementing the respective institutional models:

To charge an EU authority with the grant of unitary SPCs

- It would be necessary and sufficient to amend existing legislation (the SPC Regulations or Reg. 2012/1257), or enact separate regulation.
- Concerning the language regime, account must be taken of the unanimity requirement of Art. 118(2) TFEU, either among all Member States, or, if appropriate, among those participating in the enhanced cooperation.

To charge the EPO with the grant of unitary SPCs:

- An agreement must be concluded between the respective Member States and the European Patent Organisation under Art. 63(4) EPC. The scope and contents of the delegation of powers this implies must be set forth in binding EU legislation.
- In addition, EU legislation must provide a basis for allocating the competence to decide on appeals to the UPC. For instance, this could be achieved by stipulating that Member States are obliged to entrust the court that they have designated as the competent court under Art. 9(3) Reg. 2012/1257 with the task of deciding on appeals against decisions taken in the granting procedures of a unitary SPC.

Irrespective of the institutional model chosen, the provisions establishing the procedures and conditions for obtaining a unitary SPC must be complemented by secondary legislation in the form of implementing regulations and/or delegated acts to be issued by the European Commission.

24.4.2.2 Substantive aspects: medicinal products

The unitary SPC and national SPCs will be subject to the same requirements for protection as laid down in Art. 3 Reg. 469/2009. The unitary character of IP rights poses some challenges with respect to those requirements.

As a preliminary question it must be decided is whether the unitary SPC should be optional, so that the owner of an unitary patent can also choice to apply for a bundle of national SPCs. The regulation of this aspect will have an impact on the assessment of the options for designing the requirements under Art. 3(a)(b), (c) and (d) Reg. 469/2009.

(a) *Art. 3(a) Reg. 469/2009*

The European Commission has only considered unitary patents as the possible basic patent for requesting a unitary SPC. From a technical perspective, it would also be feasible to extend the option to obtain a unitary SPC to the owners of classic European patents provided that:

- the patents present a uniform set of claims, and
- are subject to the substantive provisions of the UPCA.

Should enhanced cooperation be chosen as a basis for establishing the future Unitary SPC, the lawmakers could also require the European patent to be in force in all participating Member States.

Whether or not the option to obtain a unitary SPC on the basis of a European patent should be given is a question of policy. If the lawmakers intend to increase the attractiveness of unitary patent protection for stakeholders, it is advisable to provide that only unitary patents can constitute the legal basis for unitary SPCs.

(b) *Art. 3(b) Reg. 469/2009*

Under Art. 3(b) Reg. 469/2009 a valid authorisation for placing a product on the market must be granted in the territory of protection. In the case of the unitary SPC, the territory of protection includes all EU States in which the basic European patent has unitary effect. In order to reconcile the operation of this requirement with the unitary character, the lawmakers have several options and choices to make.

First, the lawmakers must decide whether the application for a certificate may rely

- only on a European MA, or
- also on a bundle of national MAs.

An aspect weighing against the former and in favour of the latter solution is the fact that not all medicinal innovations are eligible for Union authorisation and that in the field of plant protection products a European MA does not even exist at the moment. However, the need to allow unitary SPCs on the basis of national MAs does not seem highly relevant for medicinal products, where the SPC application is based on the first MA for a new active ingredient. New active substances are eligible for Union authorisation anyway.

If the legislature decides to admit national MAs for both medicinal and plant protection products, then it is faced with a second choice:

- either it requires that the grant of the SPC be possible only if at the critical date a national MA has been granted in all countries in which the European patent has unitary effect, or
- it may admit the grant of an SPC even if at the critical date MAs were granted only for a part of the territory to which the unitary effect applies.

If the latter is the choice made by the EU legislature, it can be implemented in several ways. The preferable option, in our view, is to grant a unitary SPC only for the territory in which at the critical date (i) the unitary patent is in force; (ii) an MA exists. This does not mean, however, that protection is excluded in those countries where at the critical date no valid MA has been granted. The lawmakers have two possibilities to accommodate further MAs granted after the critical date.

On the one hand, the lawmakers can permit that in the countries where no MAs have been granted the unitary patent can be designated as the basic patent once the MA is awarded in those countries, provided that the deadline in Art. 7 Reg. 469/2009 is respected and that the patent is still in force at the time the application for a certificate with effect in that country is filed. This solution combines a **unitary SPC with a static territorial scope** with national SPCs granted for the same unitary patent: the unitary SPC is granted by the Unitary SPC Division and national SPCs are granted by the NPOs. The combination of the unitary SPC and national SPCs may, in principle, encompass the territory covered by the unitary patent if the MAs are

granted before the expiration date of the patent and the application for the certificate is filed before the deadline under Art. 7 Reg. 469/2009.

On the other hand, the lawmakers could even experiment with a more sophisticated option, providing for a **unitary SPC with dynamic territorial scope**. In this approach, the owner of a unitary SPC may apply for territorial extension of the granted right once national MAs have been granted for EU States that are covered by that unitary SPC and in which at the critical date a valid MA has yet to be granted. This solution is new in the landscape of EU unitary rights in IP, but it does not seem to challenge the fundamental principles of Union law, such as the protection of legitimate expectations and legal certainty for third parties, nor does it create protection in situations where it would no longer be possible to obtain an SPC under the current legislation. This is true, at least, if specific precautions are adopted, such as:

- the obligation to designate the countries for which the extension will or may be sought in the application for a certificate as filed (designation model);
- the provision that such designation is effective only when, at the date that the application for a certificate is filed in the countries designated, a request for an MA is pending and the application for a certificate refers to this pending request;
- the stipulation that the deadline under Art. 7 Reg. 469/2009 applies to the request for extension of the territorial scope of the unitary SPC to the Member State, and the stipulation that the event triggering the deadline for lodging the application is the grant or notification date of the additional MA(s);
- the provision that in the extended territory the injunction can be adopted only with respect to acts performed after publication of the decision of the Unitary Office granting the territorial extension of the unitary SPC.

The request for the territorial extension would be examined by the Unitary SPC Division.

(c) *Art. 3(c) Reg. 469/2009*

The purpose of the unified patent system is not only to improve enforcement, but also to provide a defence against "claims relating to patents that shall be revoked" (UPCA Preamble). It should indeed be possible through a single revocation action to clear the way to the market with respect to a specific patented invention.

Only a strict rule prohibiting the use of the same subject matter as the subject of both a unitary patent and a national patent is consistent with this purpose. This rule is absent in Union law, and it is left to the discretion of the EPC members under Art. 139 EPC to adopt such a prohibition in national law. Such a rule, however, arguably already exists under Art. 3(c) with respect to SPCs.

Under Art. 3(c) Reg. 469/2009, if a unitary SPC has been granted for a product, this SPC will prevent

- the NPOs from granting further national SPCs, and
- the Unitary SPC Division from granting further unitary SPCs for the same product if the SPC is requested by the same applicant.

The same principle will apply in the converse case: if a national SPC has been granted for a product in country A, this national SPC prevents the grant of another SPC (unitary or national) with effect in the same Member State for the same product to the same entity. If the lawmakers allow the applicant to request a unitary SPC with a narrower territorial scope than the territorial scope of the basic unitary patent, then it will be possible for the applicant – by withdrawing the designation of the EU State in the application for a unitary certificate where the conflicting national SPC exists – to obtain a unitary SPC for the remaining countries covered by the unitary patent.

(d) *Art. 3(d) Reg. 469/2009*

Under Art. 3(d) SPC Regulation, the MA on which the application for a certificate is based must be the first granted in the Member State concerned. This requirement may lead to some interpretative issues and requires some adaptation with respect to unitary SPCs. Indeed, if the oldest relevant MA covering the product is a national MA and not a Union MA, and this MA exists only in some Member States, situations are possible where the MA supplied in support of the certificate with unitary effect may be considered the first MA in some countries, but not in others.

The question is likely of limited practical importance for two reasons:

- if *Neurim* principles are confirmed and extended to new formulations of old ingredients, the cases where earlier national MAs granted for the active ingredient will not be relevant under Art. 3(d) will become more frequent.
- If an older national MA cannot be disregarded under *Neurim*, irrespective of the solution adopted with respect to Art. 3(d), the older MA will continue to be the relevant MA for the purposes of Art. 13 Reg. 469/2009.

(e) *Critical date for assessing the requirements*

Under the current legislation, the critical date for assessing the requirements for protection is the date of the application for a certificate. In the case of a unitary SPC, if the option for a partial unitary SPC with dynamic content is considered feasible, the date for assessing the requirement should remain the date on which the application is filed, while the date for assessing the requirements for the extension should be the date on which the request for a territorial extension of the pending application or of the granted unitary SPC is filed.

(f) *Deadline for filing the application (Art. 7)*

The deadline for lodging the application laid down in Art. 7 Reg. 469/2009 should also apply to the application for a unitary SPC. The event that triggers the deadline is the grant of the first MA in the territory of protection covered by the unitary patent. If the grant of the European patent for which a unitary effect is then requested is later than the issue of the MAs in one or more countries, the date on which the European patent was granted and not the date on which the unitary effect was registered triggers the deadline under Art. 7 Reg. 469/2009. This applies, however, only with regard to the countries where at the granting date of the patent an MA has already been issued.

(g) *Calculation of the duration of the certificate (Art. 13)*

The algorithm for calculating the duration of the certificate provided by Art. 13 SPC legislation shall apply to the unitary SPCs. The relevant MA will be the first national or Union authorisation granted in the EU/EEA to place the product on the market as a medicinal product.

24.4.2.3 Plant protection products and unitary SPCs

The analysis carried out for medicinal products also applies to plant protection products and the corresponding provisions of Reg. 1610/96. In order to accommodate the regulatory regime of plant protection products, it will be necessary to accept national MAs as a basis for the unitary SPC or to reform the regulatory system, because at the moment Reg. 1107/2009 does not contemplate the grant of an authorisation to market the product in the whole EU, but only of authorisations with national effect. Further, some products may only be meaningfully marketed in one or two zones established by Reg. 1107/2009, but not in the whole Union. If the unitary SPC could only be granted if at the filing date an authorisation to place the product on the market with EU-wide effect is supplied in support of the application for a certificate, this would result in a discrimination of this technological field. Similar concerns would arise if MAs are admitted as a basis for a unitary SPC, but the applicant is requested to supply a bundle of MAs covering all countries in which the unitary patent is in force at the date on which the application for a certificate is lodged (Art. 7 Reg. 1610/96). As some products may have only zonal, but not Community-wide relevance, such requests would be incompatible with commercial reality.

A **unitary SPC with a dynamic territorial scope** is the most appropriate model for accommodating the specific features of the regulatory regime applicable to plant protection products.

24.5 SOME FINAL CONSIDERATIONS

The responses to the Allensbach Survey, the discussion at the stakeholder seminar and the qualitative interviews have produced a relatively consistent assessment of the SPC legislation. The originators are of the opinion that the SPC system works. In the last 25 years, it has efficiently supported pharmaceutical and plant protection product innovation in Europe. The legislation is sufficiently flexible to accommodate new technical developments. It would be a misconception to assume that the legislation is unclear because of the number of referrals. It would be equally wrong to suggest that the lack of clarity causing those referrals results in uncertainty for the business community or makes legislative reform necessary. Several reasons were invoked for this stance.

First, in most cases, the stakeholders are in a position to assess whether a certificate will be granted, is valid, or is infringed by a specific product. The case law deals with pathological cases (mostly concerning combinations). Focusing on these pathological cases leads to a distorted perception of the practice.

Second, applicants in the field of SPCs tend to strive until the bitter end. This attitude often leads to intense litigation before the NPOs and the courts. And such litigation

may result in a number of referrals. But these requests for preliminary rulings are evidence not for the unclarity of the legislation or case law, but for the value of the SPC and the products covered by the MA.

Third, if some issues are still unclear, this unclarity has its origin in the case law and not in the secondary law itself. The wording of the SPC legislation could hardly be improved. As a consequence, it is the task of the courts (and not the legislature) to remove any residual unclarity.

Against this background, the majority of the stakeholders are of the opinion that an amendment to the legislation would not be useful, and could even be counterproductive. On the one hand, in the past years a development of the case law has taken place in the dialogue between NPOs, courts and the CJEU, which has resolved several issues. In the case of a reform, such case law could be lost. On the other hand, new provisions would make further referrals necessary and would lead to new case law. Finally, because of the nature of pharmaceutical innovation, new legislation could never satisfactorily or comprehensively provide answers to all the new factual scenarios that could emerge. The technology concerned is inherently dynamic. For this reason, an evolutionary approach is the best approach to take. The lawmakers should leave the task of adjusting the system to the case law, if adjustments are needed.

Some of the points made by the stakeholders consulted are persuasive. We could even add further arguments for the evolutionary approach advocated by the originator industry. The UPCA will have a significant impact on the SPC system. A single unified court, indeed, will decide in Europe on the validity and infringement of SPCs granted by national offices. The UPC will consist of specialist judges and will be in a position to develop a uniform approach in interpreting SPC Regulations. This will reduce the occasions for referrals to the CJEU. Further, it may be expected that the UPC, as a specialist court for patents and SPCs, will be able to develop clearer standards or tests by implementing the CJEU case law. So the clarification und unification of the practice that would be the intended goal of amending the law could more easily result from the UPC becoming operational.

However, while we do understand the position of the industry or a large part of it, the reasons in favour of a review of the legislation are relevant.

First, with resort to a teleological approach, the CJEU has progressively transformed the legislation. The SPC regime was intended to address the decline in the number of new active ingredients developed by the European industry. New formulations and new indications were to be excluded from SPC protection. Only one SPC per product was to be possible. And the grant of the certificate was to be based on the first MA granted in the Member State. The intended beneficiary should be a company that was both the owner of the basic patent and the holder of the relevant MA. The system was thus designed to allow only one certificate per product, one certificate per MA.

The impact of CJEU jurisprudence on this scheme has been radical. The CJEU has allowed multiple certificates for the same product, whether or not the applications were co-pending or filed within the deadline of six months from the filing date. It has allowed that the same MA may support multiple SPCs for the same or different products. It has even changed the definition of the first MA for an active ingredient in the Member State (Art. 3(d) SPC Regulation) or in the EU (Art. 13 SPC Regulation).

Such chronological order should not depend simply on the date of the MA, but also on the scope of the basic patent. In this way, it has also relaxed the principle that no certificate may still be in force after 15 years from the grant of the first MA for the product.

Second, the requirements laid down in Art. 3 Reg. 469/2009 are interrelated. A strict interpretation of Art. 3 Reg. 469/2009 could lead to severe results if not compensated by a more generous handling of Art. 3(b) Reg. 469/2009. In turn, a generous interpretation of Art. 3(a) Reg. 469/2009 could lead to problematic results if the use of third-party authorisations were allowed without any limitation. By contrast, a patent-holder-friendly interpretation of Art. 3(a) Reg. 469/2009 could hardly be balanced by a broad understanding of the concept of a product for the purposes of Art. 3(c) Reg. 469/2009. The latter provision can easily be circumvented. Again, the whole system of SPCs should be viewed in the broader context of incentives for pharmaceutical innovation (data exclusivity, trade secret protection). The case law has only had few occasions to offer a review of the different requirements – and even less chance to strike a balance between them in a structured and rational way. It is concerned with specific cases and specific provisions.

Third, some of the decisions that the CJEU was requested to take and some of the questions that are still open are a matter of policy. One could reasonably argue that it is up to the lawmakers, and not the courts, to decide whether patents granted for the immediate results of basic research may also be the basis for a supplementary period of protection. The lawmakers, and not the courts, should decide whether second medical indications or new formulations should benefit from SPC protection. The lawmakers and not the courts should determine whether and to what extent the use of third-party authorisations should be allowed.

An intermediate approach between the two discussed above could consist in leaving the law as it stands, but supplementing it with soft-law provisions. However, guidelines would not bind the courts and NPOs. Further, they require an agreement on how to understand and implement the case law of the CJEU.

25 RECOMMENDATIONS

25.1 INTRODUCTION

The next few sections sum up the recommendations of the Study. A number of options are available for many of the issues addressed in the analysis. In several cases, the choice among these options is driven by policy preferences. In these cases we are not able to formulate a specific recommendation.

As an introductory and general recommendation, we suggest closing the gap between written law and case law that has resulted from the last ten years of CJEU jurisprudence. For this purpose, the lawmakers have three options: they can codify this case law, override it or adopt it with amendments. The CJEU has never maintained that the teleological approach adopted in answering several requests for a preliminary ruling was mandated by principles of primary law or international commitments that would bind the lawmakers.

25.2 MEDICINAL PRODUCTS REGULATION (REG. 469/2009)

Recommendation No 1: Consolidated version of the Medicinal Products Regulation

We recommend adopting a consolidated version of the Medicinal Products Regulation. In such a version the provisions and recitals of the Plant Protection Products Regulation available pursuant to Recital 17 Reg. 1610/96 for the interpretation of Reg. 469/2009 should be adopted.

These provisions are, specifically, Art. 3(2), Art. 8(1)(c) and Art. 17(2) Reg. 1610/1996. The wording of Recital 9 Reg. 469/2009 is not in line with the wording of Recital 14 of the Plant Protection Products Regulation.

Recommendation No 2: Reference to national law

The reference to national law included in the SPC legislation should be coordinated with the existence of a European patent alongside national patents and with the future existence of the UPC alongside national courts.

A general reference to the law applicable to national patents and to applications for a national patent should be included for any matter concerning the application for a certificate or the granted certificate which is not addressed by the SPC Regulations. The provision could read as follows:

> The application for a certificate and the certificate shall, in each Member State, be subject to the same conditions and rules as an application for a national patent or a national patent granted by that State, unless this Regulation or the implementing rules adopted by the European Commission provide otherwise.

This provision would reflect the current practice in a number of States.

Recommendation No 3: Updated definition of the term "medicinal product"

For the reasons explained in Chapter 9, we suggest adopting the following definition of medicinal product in Art. 1(a) Reg. 469/2009:

> 'medicinal product' means any substance or combination of substances presented as having properties for treating or preventing disease in human beings or animals; or any substance or combination of substances which may be used in or administered to human beings or animals either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

This definition is consistent with the CJEU case law.

Recommendation No 4: Definition of the term "product"

For the reasons explained in Chapter 9, we propose defining "product" in Art. 1(b) Reg. 469/2009 as the active ingredient or combination of active ingredients identified as the active substance or the active substances of the medicinal product that is the subject of the MA submitted in support of the application for a certificate under Art. 8(1)(b) Reg. 469/2009.

This definition is likely not fully consistent with the principles stated by the CJEU in *Forsgren*.

Recommendation No 5: SPC eligibility of salts, esters or derivatives of an active substance

The existence of a patent covering the derivatives of an old active ingredient should only be a necessary, but not sufficient, requirement for considering the derivative eligible for a certificate. In addition to this, the salt or ester, or derivative, must be regarded as a different product, that is, a different active ingredient. The conditions under which a derivative should be considered a different product for the purposes of Art. 1(b), Art. 3(c) and Art. 3(d) Reg. 469/2009 should be defined by the lawmakers and not by the courts. While several options are possible (Chapter 9) we deem it consistent with the original intention of the lawmakers to consider the derivative eligible for a separate certificate only when the derivative itself has been qualified as a "new active substance" by the authority that has granted the MA submitted in support of the application for a certificate.

Recommendation No 6: Concept of MA

In view of the evolution of the regulatory framework and of the case law, it is appropriate to clarify forms and types of permission to place a medicinal product on the market which can support an application for a certificate under Art. 3(b) Reg. 469/2009, be relevant under Art. 3(d) Reg. 469/2009, trigger the commencement of the deadline under Art. 7 Reg. 469/2009, and define the initial day of the period of protection under Art. 13 Reg. 469/2009. In this context, the lawmakers should take into account that a marketing authorisation is not a static, but a dynamic document. Therefore, the status of variations of the MA for the application of Art. 3, Art. 4, Art. 7 or Art. 13 Reg. 469/2009 must be clarified.

The latter question is closely correlated with the issue to what extent a new indication or formulation of an old active ingredient should be eligible for an SPC. If the lawmakers are of the opinion that the logic of *Neurim* should be adopted and extended to any new indication or formulation, then it would only be consistent with this decision to consider type-II variations and extensions of an MA as separate MAs for the purposes of the SPC legislation.

Further, we suggest expressly stating that conditional MAs can support the application for a certificate.

Recommendation No 7: Clarification of Art. 3(a) Reg. 469/2009 and Reg. 1610/96

We recommend clarifying the requirement under Art. 3(a) according to which the product must be protected by the basic patent.

The Study has identified three options:

- infringement test;
- an Art. 123(2) EPC standard-disclosure test; and
- (core-) inventive-advance test.

The choice between these options is driven by policy considerations. It is also strictly connected to issues of how many SPCs per product should be possible, how many certificates the same MA should and may support, and whether or not the consent of the MA holder or a relationship between the patentee and the MA holder is needed for granting a valid certificate.

From a legal perspective, the core inventive advance presents the advantage of already being part of the system as developed by the CJEU. It may likely fulfil many, if not all, of the purposes that the CJEU may have intended to pursue with the "specified in the claim" requirement. From an incentive perspective, it can potentially reward "basic" and "advanced" research, since it does not require an individual disclosure of the product for which the certificate is requested.

Recommendation No 8: Art. 3(a) and process patents

Irrespective of the approach taken to Art. 3(a) Reg. 469/2009, we recommend clarifying by soft law or other instruments that when the basic patent protects the process for manufacturing the product, a certificate can only be granted if the product is the product directly obtained by that process within the meaning of Art. 28(1)(b) TRIPS.

It is unclear whether this clarification would be consistent with *Queensland*.

Recommendation No 9: Art. 3(b) Reg. 469/2009

Following the teleological interpretation of the CJEU, the current meaning of Art. 3(b) Reg. 469/2009 is that a product is covered by the MA if the MA is granted for a medicinal product that contains the active ingredient as a single active ingredient or in combination with other active ingredients. This interpretation is not consistent with the

wording of Art. 1(b) and Art. 3(b) Reg. 469/2009. It also departs from the principles informing the regulatory framework. We recommend closing the gap between the wording of the provision and the case law.

In amending Art. 3(b) Reg. 469/2009, the lawmakers should clarify that the relevant rule applies to all applications for a certificate, whether the latter concerns vaccines including active ingredients with different medical indications, combinations or monotherapy products. Further, they should clarify that the principle laid down in *Medeva* applies to determining the first MA for the purposes of Art. 3(d) Reg. 469/2009, as well as determining the relevant MA for calculating the deadline under Art. 7 Reg. 469/2009 and the duration of the certificate under Art. 13 Reg. 469/2009.

Recommendation No 10: Closing the gap between the wording of Art. 3(d) Reg. 469/2009 and the case law (*Neurim* and *Abraxis*)

We recommend closing the gap between the case law and the written law with respect to Art. 3(d) reg. 469/2009. We have identified two options.

If the lawmakers agree with the reasons that induced the drafters of Reg. 1768/92 to admit SPCs not for any patented medicine, but only for active ingredients authorised for the first time, they should re-establish the principles enshrined in the plain wording of Art. 3(d) Reg. 469/2009. The SPC shall be granted only on the basis of the first MA for the active ingredient concerned in the Member State. The duration of the SPC shall be calculated on the basis of the first MA in the EU/EEA. The scope of the basic patent shall not matter for determining the first MA for a specific active ingredient in the Member State and in the EU/EEA. In implementing this option, however, we recommend differentiating between medicinal products for veterinary use and medicinal product for human use (see below). The issue of an MA for a veterinary drug does not reduce the burden and the work that must be done to obtain an MA for a human medicine.

If the lawmakers agree with *Neurim* or, more precisely, with the understanding of *Neurim* adopted by the majority of NPOs and the case law, they should codify this case law and amend Art. 3(d) and Art. 13 Reg. 469/2009. In doing so, they should clarify:

- whether the owner of a previous certificate may obtain a second certificate for the same active ingredient for a new indication (that is, they should clarify the impact of *Neurim* on Art. 3(c) Reg. 469/2009);
- whether the logic of the logic of *Neurim* applies only to new indications or also to new formulations.

The choice between the different options is one of policy. If the lawmakers decide to adopt *Neurim*, a distinction between new indications and new formulations of an old active ingredient is not opportune and not recommended.

If the lawmakers intend to correct *Neurim* and to re-establish the principles laid down in Art. 3(d) Reg. 469/2009, we suggest drawing a distinction between veterinary products and human medicines. Such a distinction could be implemented in two ways:

- splitting up the Medicinal Products Regulation into two Regulations: one for humane medicines and the other veterinary products;

- adopting a legal fiction with respect to the definition of a product in Art. 1(b) Reg. 469/2009, specifying that an active ingredient or combination of active ingredients contained in a medicinal product authorised for human use and an active ingredient or combination of active ingredients contained in a medicinal product for veterinary use shall be treated as *different products* for the purposes of Art. 3, Art. 7 and Art. 13 Reg. 469/2009.

Recommendation No 11: Closing the gap between the wording of Art. 3(c) Reg. 469/2009 and the case law (*AHP*; *Biogen*)

We recommend closing the gap between case law and codified law with respect to Art. 3(c) Reg. 469/2009.

In deciding whether and to what extent the case law admitting multiple SPCs for the same product should be confirmed or overridden, we recommend taking into account the interaction between *Neurim* and *Biogen*. *Biogen* has allowed more than one SPC for the same product on the assumption (made by the Advocate General) that all SPCs would expire on the same date because the relevant MA under Art. 13 would be the same. This assumption was problematic at that time – different filing dates of the basic patents can determine different expiration dates of the corresponding SPCs – but is clearly not valid nowadays. Under the general understanding of *Neurim*, the answer to the question of what is the first MA for an active ingredient may change according to the scope of the patent designated for the procedure.

If the lawmakers are of the opinion that the case law should be codified and the prohibition of Art. 3(c) Reg. 469/2009 should apply only in case the same entity applies for a second SPC, we recommend adopting some measures directed to ensuring the effectiveness of Art. 3(c) Reg. 469/2009 (Chapter 12). The lawmakers should provide that the prohibition of Art. 3(c) Reg. 469/2009 applies in situations where

- the applicants are formally distinct, but related entities, and/or
- the designated patents even partly share the same inventorship.

Recommendation No 12: Art. 3(c) Reg. 469/2009 and surrender/revocation of the certificate

We recommend clarifying that the surrender or the revocation of a certificate does not affect the operation of Art. 3(c) of the SPC Regulations.

Recommendation No 13: Entitlement to SPC and third-party MA issue

We recommend clarifying whether any patentee or only the patentee that has contributed directly or indirectly to the development of a marketable medicinal product and to the obtaining of an MA should be entitled to an SPC.

We identify two options for a legislative clarification:

- The patentee can obtain a certificate based on the MA granted to a third party whether or not the MA holder agrees;

- The patentee can obtain a certificate based on the MA of a third party only when the latter agrees or is contractually obliged to agree since it is a licensee, a member of the same group, or a party to the same development contract (consent requirement).

Recommendation No 14: Clarifying the status of the product description and its impact on the scope under Art. 4 Reg. 469/2009

We recommend clarifying whether a product description has to be included in the SPC application and what the legal effects on the scope of the certificate are.

Recommendation No 15: Biological products – soft law clarifying the scope

We recommend a clarification, according to which the scope of a biological SPC extends to all products having the same INN as the product covered by the MA submitted in support of the application, irrespective of differences in the manufacturing process between the biosimilar and the original product, provided that the basic patent protects the product as such, its use or the process for obtaining it.

Recommendation No 16: Drug/medical device combinations

We recommend allowing the grant of a certificate for a "new active ingredient" that is used as medicinal product in drug/medical device combinations, provided that all the requirements under Art. 3 Reg. 469/2009 are met and that the EC Design Certificate submitted in support of the application for a certificate is the first "permission" to use the active ingredient as a medicinal product, so that in order to market the drug/device combination the applicant had to generate data as evidence of the safety, efficacy and usefulness of that substance.

The question whether the same provision shall apply when the drug/medical device combination includes an "old active ingredient" is complex. If the lawmakers intends to adopt *Neurim*, then there is no reason to deny an SPC only because the first relevant "permission" to use, for a medicinal purpose, the active ingredient that falls under the scope of the basic patent was issued under Reg. 2017/745 and not under Dir. 2001/83. However, whether or to what extent the *Neurim* logic should be adopted is a policy issue.

25.3 MANUFACTURING WAIVER AND BOLAR EXEMPTION

Recommendation No 17: Manufacturing waiver – policy options to be considered

Different terms of protection lead, at least theoretically, to asymmetry at the level of international competition, with unclear economic consequences. We are not in a position to recommend or to advise against the creation of a manufacturing waiver. The following recommendations therefore list the policy options that the legislators could consider if a decision is made to implement such a waiver.

First, as to **the scope of the waiver**, the lawmakers could introduce a manufacturing waiver for export and/or for stockpiling purposes.

Second, as to **the design and the degree of freedom left to the EU States**, a choice can be made between the creation of, on the one hand, an option to introduce a waiver that is left to the discretion of the national legislatures or, on the other hand, a directly applicable, mandatory provision.

Third, as regards **the degree of freedom left to IP holders**, the legal options include incentive mechanisms that do not impose any obligation upon the IP holder, different degrees of compulsory licences, and a limitation to the rights of the IP holder in the form of an exemption. Regarding the last option, the limitation of the SPC right could apply without any other formalities or conditions, or by contrast be subject to formalities or conditions with which the party must comply before starting, or during, manufacturing (such as notification or compensation obligations).

Fourth, if a waiver is introduced, the legislators should consider introducing **precautionary measures** to safeguard the rights and interests of the originators (such as a differentiated distribution of the burden of proof for infringement, labelling obligations, or information requirements).

Recommendation No 18: *Bolar* exemption – defining a unitary scope of the exemption

We recommend the adoption of a uniform exemption that applies to national and European patents with or without unitary effect. In order to match the decision of the majority of the EU Members in implementing Art. 10(6) Dir. 2001/83/EC and Art. 13(6) Dir. 2001/82/EC, the exemption should be broader than the standard minimum provided for under Art. 27(d) UPCA, and could extend to:

- activities directed to generating data for MAs for any medicinal products (generics, biosimilars or innovative drugs);
- activities directed to obtaining data for product approval outside the EU/EEA; and
- activities directed to generating data for health technology assessments.

In order to implement the recommendations, a differentiated approach is needed:

- For the exemption of acts necessary or useful for obtaining regulatory approval as innovative products, that is, pursuance of any MA that may be granted under Dir. 2001/82/EC and Dir. 2001/83/EC, it is sufficient and necessary to amend the two Directives.
- For the exemption of acts necessary or useful for obtaining regulatory approval outside the EU, it is advisable to enact a separate piece of legislation. This would probably have to be in the form of a harmonisation directive, possibly complemented by a parallel amendment to Reg. 2012/1257. Changes in Reg. 2012/1257 would be immediately binding on the UPC due to Art. 20 UPCA. EU legislation in the form of a directive could be implemented in the UPCA under the simplified procedure pursuant to Art. 87(2) UPCA.

Recommendation No. 19: *Bolar* exemption and plant protection products

We recommend creating a *Bolar* exemption for plant protection products by creating an exemption under Union law. If the provision concerned is directly applicable in the Union legal order, by virtue of Art. 20 UPCA it will also directly apply in proceedings before the UPC.

Recommendation No 20: *Bolar* exemption and experimental use – third-party suppliers

The legislators should clarify that the *Bolar* exemption as well as the experimental use exemption cover the supply of patented substance(s) by third-party suppliers, if the supplied party uses or intends to use the substance(s) in activities covered by the relevant exemptions. The suppliers should be subject to a duty of diligence as regards compliance by downstream users. For instance, it must be ensured by stipulation in the contract that the supplied substances may be used only for an exempted purpose. Examples of such duty of diligence are already provided, *mutatis mutandis*, by the case law of the CJEU, for instance, concerning Art. 110(1) of Regulation 6/2002. For the *Bolar* exemption, the extension to third-party suppliers can be set forth in Art. 10(6) Dir. 2004/27/EC. For experimental use, the extension to third-party suppliers must be set forth in a separate act of legislation.

25.4 PLANT PROTECTION PRODUCTS REGULATION

Previous Recommendations, if not specifically related to medicinal products, apply to the corresponding provisions governing plant protection products. In addition, the following recommendations are made:

Recommendation No 21: Plant protection products – updating the reference to the regulatory framework

We recommend updating the references to Dir. 91/414 in Art. 2, Art. 3(1)(b) and Art. 8(1)(b) Reg. 1610/1996, since the Directive has been repealed and replaced by Reg. 1107/2009. The amendment is due for reasons of transparency even if any reference to the Directive under the current legislation already operates as a reference to the Regulation (see Art. 83(2) Reg. 1107/2009).

Recommendation No 22: Plant protection products – provisional MAs

With respect to the question of the relevant MA, the lawmakers may amend Reg. 1610/96 so that the wording also refers to the provisional MA in Art. 30(1) Reg. 1107/2009 (Art. 8(1) Dir. 91/414). Since Art. 28(1) Reg. 1107/2009, as opposed to the repealed Art. 48(1) Dir. 91/414, refers generally to authorisations granted "in accordance with this Regulation", a reference to the latter is sufficient to encompass both ordinary and provisional MAs. Such a reference would not include the emergency MA, since the latter is expressly classified as a "derogation" under Reg. 1007/2009.

Nevertheless, to increase transparency, one could make the reference explicit in either of the following two ways:

Article 3 (1):
(b) a valid authorisation to place the product on the market as a plant protection product has been granted in accordance with Article 28(1) of Regulation 1107/2009, Article 30(1) of Regulation 1107/2009 or an equivalent provision of national law.

or:

(b) a valid authorisation to place the product on the market as a plant protection product has been granted in accordance with Article 28(1) of Regulation 1107/2009 or an equivalent provision of EU or national law.

The first option would simply codify the case law (Case C-229/09). The second option would provide additional flexibility for future evolutions of the regulatory framework.

Recommendation No 23: Art. 13(3) Reg. 1610/96

To ensure coherence with the decision of the Court of Justice C-229/09 (*Hogan Lovells International* [2010] ECR I-11335), we recommend amending Art. 13(3) Reg. 1610/96/EC and clarifying that for the purposes of calculating the duration of the certificate, account shall be taken of the first marketing authorisation, including provisional marketing authorisations, even if the definitive marketing authorisation is not available at the date of grant.

25.5 NATIONAL PRACTICE AND FURTHER HARMONISATION

Recommendation No 24: Guidelines for the examination

We consider it opportune to adopt guidelines providing the NPOs with common criteria for the examination. The issue of guidelines does not require amendment of the SPC Regulations. The Commission is already entitled under Art. 288 TFEU to adopt "recommendations and opinions" that may inform, without binding effect, the interpretation of Union law.

Recommendation No 25: Further unification of the SPC framework

This Study provides some examples where further unification of substantive or procedural aspects of the SPC framework is meaningful. Furthermore, we have identified some measures that in our view would improve the efficiency and transparency of the system. In this regard, we have suggested:

- A provision that mandates the publication of SPC applications by a uniform deadline.
- A provision stipulating that the published application grants the same rights as the basic patent (with the possibility of an invalidity defence in infringement proceedings) *or* confers at least indemnification claims.
- An amendment to Art. 19 Reg. 469/2009 to allow the Member State to admit opposition against certificates granted by NPOs (optional opposition) and the provision of an opposition system in the Unitary SPC regime.
- The establishment of a common register for national marketing authorisations.
- The imposition of a common deadline for decisions on the grant or the refusal of an SPC application.
- An obligation to make truthful statements in proceedings before NPOs;

- a provision empowering (but not obliging) the NPOs to revoke the SPC *ex officio* in case of invalidation of the basic patent.
- If the product description is given legal effect on the scope of the certificate and its validity, a provision that provides the SPC holder with the right to limit or correct the product description of the granted certificate in *ex parte* or *inter partes* proceedings.
- The adoption of a uniform rule for calculating the duration of the certificate (in line for instance with Art. 121 EPC) or a clarification that the Euratom Regulation applies.
- A provision amending Art. 15 Reg. 469/2009 and specifying that surrender of the SPC has effect only *ex nunc*. The same principle should apply to all other grounds for the lapse of an SPC provided under Art. 14 Reg. 469/2009. Such provisions could read as follows:

1. The certificate shall lapse:
(a) at the end of the period provided for in Article 13;
(b) if the certificate holder surrenders it;
(c) if the annual fee laid down in accordance with Article 12 is not paid on time;
(d) if and as long as the product covered by the certificate may no longer be placed on the market following the withdrawal of the appropriate authorisation or authorisations to place on the market in accordance with Directive 2001/83/EC or Directive 2001/82/EC.
2. The authority referred to in Article 9(1) of this Regulation may decide on the lapse of the certificate either of its own motion or at the request of a third party.
3. The lapse of the certificate shall have effect only for the future.

- Clarification of the exhaustive or non-exhaustive nature of the list of revocation grounds provided by Art. 15 Reg. 469/2009.
- A provision addressing the effect of a revocation of the SPC in line with the following model:

The retroactive effect of the revocation of the SPC as a result of opposition or revocation proceedings shall not affect:
a) any decision on infringement which has acquired the authority of a final decision and has been enforced prior to the revocation decision;
b) any contract concluded prior to the revocation decision, in so far as it has been performed before that decision; however, repayment, to an extent justified by the circumstances, of sums paid under the relevant contract, may be claimed on grounds of equity;
c) the operation of Art. 3(c) Reg. 469/2009.

Further unification, if considered appropriate, could also be reached by way of implementing rules. To this purpose, a provision granting the European Commission the power to adopt rules for the application of the Regulations could be introduced in the SPC legislation itself in line with the wording of Art. 14 of the Proposal for a Council Regulation (EEC) of 11 April 1990 that reads as follows:

1. Detailed rules for the application of this Regulation, in so far as they are necessary, shall be laid down by an implementing regulation.
2. The implementing regulation shall be adopted by the Commission.

25.6 PATENT PACKAGE AND SPC LEGISLATION. UNITARY SPC.

Recommendation No 26: Interaction between Unitary Patent Regulation and SPC legislation

We recommend clarifying that the SPC granted on the basis of a unitary SPC by an NPO is subject to Art. 30 UPCA only with respect to the rights granted by the

certificate, but does not benefit from a unitary effect under the law applicable to the basic patent.

Recommendation No 27: Creation of a unitary SPC system

We recommend establishing a system for granting unitary SPCs.

Recommendation No 28: Institutional aspects

For this purpose, it is necessary that a decision is taken on the institutional design of such a system. There are basically three options: First, a system of mutual recognition of SPCs granted by one national office could be established; second, an EU authority, whether existing, to be created, or "virtual" in the sense that experts from the national offices cooperate on a common digital platform, can be charged with the task of granting unitary SPCs; third, that task could be allocated to the EPO. We do not consider the first option to be an appropriate solution, as it does not lead to a genuinely unitary right. Thus, the choice must be made between an EU authority and the EPO. This is a matter of policy that is up to the legislature. However, one important aspect to consider is that if an EU authority is put in charge, appeals must be directed to the General Court, whereas in the case of the EPO being mandated, it would be possible to direct appeals to the UPC, thus consolidating jurisdiction for the grant of (unitary) SPCs as well as for infringement and validity in the same forum.

As the purpose of the legislation is to create a unitary title, account must be taken of Art. 218 TFEU, including the unanimity requirement of Art. 218(2) TFEU with regard to languages. This may require that the prerequisites of enhanced cooperation have to be observed anew. Apart from that, the legislative and organisational steps to be taken depend on the model chosen.

- If competence to grant unitary SPCs is assigned to an EU authority it is possible to either introduce changes in Reg. 1257/2012 (or Reg. 469/2009 and Reg. 1610/1996) or enact a separate act.
- If the EPO is charged with the task, Member States must conclude a pertinent agreement with the European Patent Organisation. The conditions for the grant of SPCs as well as other relevant details concerning the activity must be set forth in an act of EU legislation. Furthermore, relevant steps by the Member States as well as by EU legislation must be taken in order to ensure that competence to decide on appeals concerning the grant of unitary SPCs is vested in the UPC.

In addition to creating a unitary SPC system, we recommend that guidelines in the form of soft law as well as implementing regulations (to be issued by the European Commission) be developed in order to bolster the evolution of consistent and transparent practice in the Unitary SPC Division and the national offices (see Recommendations 25 and 26).

Recommendation No 29: Substantive provisions – Art. 3(b)

The creation of a unitary SPC with dynamic territorial scope is technically feasible. Whether it is really necessary for medicinal products is less clear. In most cases, and

in any event in all cases where a new active ingredient is involved, European MAs will be available.

By contrast, we recommend adopting for plant protection products the model of a unitary patent with dynamic territorial scope.

Recommendation No 30: Substantive provisions – Art. 3(c)

We recommend maintaining the prohibition of double protection in the unitary SPC system, because it is consistent with the rationale for having a unified patent and SPC system. Article 3(c) shall prevent

- national NPOs from granting a national SPC, when a unitary SPC has been granted for the same product with effect for that State;
- the Unitary SPC Division from granting a valid unitary SPC when a national certificate has been granted for the same product with effect in at least one EU Member State participating in the enhanced cooperation.

The options considered with respect to Art. 3(c) Reg. 469/2009 when it applied to applications for a national certificate are valid also in the case it shall apply to application for a unitary certificate.

Recommendation No 31: Substantive provisions – Art. 3(d)

We do not recommend taking any action to adapt Art. 3(d) to the specific features of a unitary right.

Recommendation No 32: Duration of the unitary SPC – Art. 13

We recommend maintaining unchanged Art. 13 and the principle laid down therein that the duration of the certificate shall be determined on the basis of the first MA – national or European – for the active ingredient concerned in the EU/EEA. No relaxation of this principle is recommended.

Recommendation No 33: Procedural aspects – function of the granting office in appeal procedures

We recommend providing that, in the procedure introduced by an appeal lodged by the applicant for a certificate with unitary effect against a decision of the Unitary SPC Division to reject such application, the granting authority is party to the proceedings.

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