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

Annex I: National Reports EU

Written by
Max Planck Institute for Innovation and Competition

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Annex I: National Reports EU

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1 INTRODUCTION

The national reports have been drafted with the support of the corresponding national intellectual property offices. The purpose of the reports was to collect information about the national rules implementing the SPC Regulations, the national practices and procedures. Particular attention has been dedicated to the questions whether the country concerned has adopted implementing rules, whether the national office competent for the grant of SPCs has published guidelines for examination of SPC applications, the scope of the SPC application's examination, the product definition, the calculation of the SPC duration, whether the SPC application is published and to other aspects not addressed by the SPC Regulations.

This Annex supplements Chapter 20 of the Study, where the information collected is summed up and some proposals or hypotheses for further harmonisation of the applicable law have been discussed.

The report includes countries whose NPOs conduct full examination of patents and countries that do not provide full examination, countries that cover large market and countries with a middle size market, countries that were founding members of the EU and countries that have more recent EU membership.

In addition, the content of these reports has been supplemented by information which the MPI extracted from a questionnaire for NPOs elaborated by the MPI and by the information received in a workshop organised by the MPI in collaboration with the German Patent and Trade Mark Office in March 2017.

2 DENMARK

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2.1 INTRODUCTION: THE SOURCES OF LAW

Denmark is an EPC Contracting State, as well as Member of the Strasbourg Convention, the PCT, the PLT and the TRIPS Agreement. Denmark also takes part in the enhanced cooperation in the area of the creation of unitary patent protection[1] and ratified the UPCA in 2014.

Patents are regulated under Patent Act No. 221 of 26 February 2017,[2] which Articles 91 and 103 are dedicated to SPCs.

The scope of protection of national patents[3] and the rights conferred by such patents[4] are regulated by provisions with similar wording to that of Article 69 EPC and Article 28 TRIPS Agreement respectively.

The requirements for patentability are the same as those of the EPC.[5] The same is true regarding the requirement of sufficiency of disclosure[6] and the possibility of amending the patent application.[7]

Denmark has made use of the option provided by Article 19 of Regulation 469/2009/EC and Article 18 of Regulation 1901/2006/EC to include in the national law special procedural provisions on SPCs through Order No. 25 of 18 January 2013 on

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1 See Regulation (EU) 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 L361/1.

2 The Ministry of Business and Growth, the Patent and Trademark Office, File No 16/00060.

3 Patent Act No 191, Section 39: 'The extent of the protection conferred by a patent shall be determined by the claims. For the interpretation of the claims the description may serve as a guideline'.

4 Patent Act No 221, Section 3:
(1) The exclusive right conferred by a patent shall imply that no one except the proprietor of the patent may without permission exploit the invention
(i) by making, offering, putting on the market or using a product which is the subject-matter of the patent, or by importing or stocking the product for such purposes, or
(ii) by using a process which is the subject-matter of the patent or by offering the process for use in this country, if the person offering the process knows, or it is obvious in the circumstances, that the process may not be used without the consent of the proprietor of the patent, or
(iii) by offering, putting on the market or using a product obtained by a process which is the subject-matter of the patent or by importing or stocking the product for such purposes.
(2) The exclusive right shall also imply that no one except the proprietor of the patent may without permission exploit the invention by supplying or offering to supply any person who is not entitled to exploit the invention with means for working it in this country, if these means relate to an essential element of the invention and the person supplying or offering to supply the means knows, or it is obvious in the circumstances, that they are suitable and intended for such use. This provision shall not apply when the means are staple commercial products, except when the person supplying or offering to supply the means induces the person supplied to commit the acts referred to in subsection 1.

5 Patent Act No 221, Sections 1 to 2.

6 Patent Act No 221, Section 8(2): '…The description shall be sufficiently clear to enable a person skilled in the art to carry out the invention…'

7 Patent Act No 221, Section 13: 'An application for a patent may not be amended in such a way that the patent is applied for in respect of subject-matter which was not disclosed in the application as filed'.

Patents and Supplementary Protection Certificates[8]. Chapters 16 and 17 of this Order are dedicated to SPCs.

2.2 INSTITUTIONAL ASPECTS

The patents and SPCs granting authority in Denmark is the Danish Patent and Trademark Office (hereinafter DKPTO), which is part of the Danish Ministry of Business and Growth (previously called Ministry of Economic and Business Affairs).[9]

The DKPTO is headed by a Director and the Board of Appeal for Patents and Trademarks.[10] The latter is in charge of the examination of appeals from the decisions of the DKPTO pursuant to the Patent Act and pursuant to the Designs Act, the Trade Marks Act, etc. The Board of Appeal consists of no more than 18 members, appointed for a term of five years. Two of the members, one of whom is the chairman, must possess the general qualifications for appointment to the office of high court judge, whereas the other members combined must possess the best possible expert knowledge on patents. They must be graduates from the Technical University of Denmark (Danmarks Tekniske Universitet) or another institute of higher education or have acquired the necessary expert knowledge in another way.[11] Considering the circumstances of each particular case, the chairman decides which and how many of the members of the Board are to participate in the examination of the case.[12]

The examiners of the DKPTO have a technical background and undertake substantive examination of patent applications. At the DKPTO, the technical examiners work in close collaboration with the legal department.[13]

In Denmark, applicants have the possibility of applying for a national patent before the DKPTO pursuant to national law or for a European patent before the EPO under the EPC rules. In addition, the DKPTO can act as receiving and designated office for patent applications internationally filed under the PCT procedure.[14]

2.3 FILING OF THE APPLICATION AND PUBLICATION

An application for an SPC and/or the extension of its duration (with regard to medicinal products for paediatric use) must be filed by the owner of the basic patent[15] before the DKPTO[16] in Danish or English[17] and upon fee payment.[18] The application

[8] The Patent and Trademark Office, Order No. 25 of 18 January 2013, http://www.dkpto.org/media/183780/the%20patent%20and%20trademark%20office%20order%202013%20no%20%2025.pdf.
[9] See: Order No126 of 19 February 2009 on Reference of Certain Rights to the Patent and Trademark Office.
[10] Patent Act No 221, Section 7(1).
[11] ibid, Section 7(2).
[12] ibid, Section 7(3).
[13] MPI's Questionnaire for National Patent Offices of the EU Member States, answer to questions No 52 and 54 by the DKPTO.
[14] Patent Act No 221, Section 28.
[15] MPI's Questionnaire for National Patent Offices of the EU Member States, answer to question No 3 by the DKPTO.
[16] Order No 25 of 18 January 2013 on Patents and Supplementary Protection Certificates, Section 70(1).
[17] Ibid, Section 71.
[18] Ibid, Section 70(4).

must contain all the prescribed information under Article 8 of the SPC Regulations,[19] including the following information:

i. The name and address of the applicant;[20]
ii. The name and address of the representative, if representation is required;
iii. The number of the basic patent and the title of the invention;
iv. The number and date of the first authorisation to place the product on the market in the EEA -when the marketing authorisation for the territory of Denmark was not the first one in the EEA-; and the number and date of the first marketing authorisation to place the product on the market in Denmark, accompanied by a copy of both authorisations.

The application must be filed within the timeframe indicated in Article 7 of the SPC Regulations. Such timeframe is calculated according to national provisions regulating the calculation of time limits in the patent grant procedure.

The number and the filing date of the SPC application, as well as the identity of the product, are published together with the information referred to in Article 9(2) of the SPC Regulations[21] namely:

i. The name and address of the applicant;
ii. The number of the basic patent and the title of the invention;
iii. The number and date of the first authorisation to place the product on the market in the EEA -when the marketing authorisation for the territory of Denmark was not the first one in the EEA-; and the number and date of the first marketing authorisation to place the product on the market in Denmark.

In addition, the SPC application must include information regarding the identity of the product covered by the marketing authorisation.[22]

The subject matter of the SPC is defined as the production definition. The DKPTO checks whether there is compliance between the indication of MA and the basic patent.

Practice regarding the definition of the product is that the applicant has to define the product on the application form. All product definitions are examined case-by-case and Danish NPO has not any rules or guidelines on the product definition. However, Danish NPO do not accept the wording of the claim as a product definition nor "as protected by the basic patent" in the wording of the product definition is accepted.

It is admissible to have product definition "compound y in all acceptable salts and derivatives", however, the wording of the claim must reflect the wording all acceptable salts and derivatives i.e. a product definition "compound Y and pharmaceutically acceptable salts and derivatives thereof" is acceptable as long as "acceptable salts and derivatives thereof" is reflected in the claims.

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19 Ibid, Section 70(2).

20 Order No 25 of 18 January 2013, Section 70(2):
If a certificate is applied for by several persons jointly, and they are not represented by an agent, the application shall, moreover, state whether any of the applicants shall be authorised to receive communications from the Patent and Trademark Office on behalf of all the applicants. If no recipient is stated, the applicant stated first shall receive communications from the Patent and Trademark Office on behalf of all the applicants…

21 Order No 25 of 18 January 2013, Section 70(5).

22 Order No 25 of 18 January 2013, Section 70(3).

There is no specific practise if it is process patent, however, where the method of production defines the nature of the product the method may be included in the product definition.

In the case of a biological product, DKPTO would admit a definition that include in some form possible future biosimlars if the basic patent is bio-product and biosimilar thereof.

In the case of second medical use is not accepted in the SPC product definition.

The SPC application is published once the formal examination is completed.

2.4 FORMAL EXAMINATION

If the applicant has not complied with the requirements prescribed under Article 8 of the SPC Regulations at the date of filing of the application, the DKPTO will notify him accordingly and invite him to correct the application within a specified time limit. If the applicant fails to correct the application within the given time limit, the application will be shelved. However, the examination and other processing of the application will be resumed if the applicant takes steps to correct the application within four months after the expiry of the specified time limit and pays the prescribed resumption fee.[23] If, after having received the applicant's reply, the DKPTO still has objections to the acceptance of the application, and if the applicant has had an opportunity to file observations on the objections, the application will be refused, unless the DKPTO feels called upon once more to invite the applicant to file observations or correct the application.[24] [25] The applicant must demonstrate through these observations that all the necessary information and facts that the DKPTO requires are provided in order for the DKPTO to start the substantive examination of the application.

2.5 SUBSTANTIVE EXAMINATION[26]

The DKPTO will examine the requirements under Article 3(a), (b) and (c) of Regulation 469/2009/EC or Article 3(1)(a), (b) and (c) of Regulation 1610/96/EC. However, it will not verify whether the condition of Article 3(d) of Regulation 469/2009/EC or Article 3(1)(d) of Regulation 1610/96/EC (i.e. that the authorisation to place the product on the market in Denmark is the first authorisation granted for that product in the EEA) is complied with. Therefore, the DKPTO may grant the SPC in absence of this condition. The examination is performed by an examiner and double-checked by a second examiner.

Danish guidelines are compliant with both the *Medeva* and *Neurim* case, however, there has not yet been final national practice regarding Eli Lilly.

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23 Similar to the right to further processing under Article 121 EPC.

24 Order No 25 of 18 January 2013 on Patents and Supplementary Protection Certificates, Section 74, in conjunction with Section 15(2) and (3) and Section 16 of Patent Act No 191 of 1 March 2016.

25 An application may be refused if no further arguments are provided or if the DKPTO believes that no further arguments can be provided.

26 Order No 25 of 18 January 2013, Article 73(1) and (2).

(a) *Examination of Medeva-requirement (specified in the claim[27])*

The Danish Patent Office understands Medeva in the sense that the fact that the product falls under the scope of protection of the basic patent is a necessary, but not sufficient condition to consider the product as being protected by the basic patent within the meaning of Art. 3(a). However, if the product is not specified in the claim of the patent, but the patent can be limited in such a way that the product of the SPC can be considered to be specified in the wording of the claims, the DKPTO would consider Art. 3(a) satisfied by the application for the certificate.

A product is considered to be specified in the wording of the claims when the product is described by a chemical name, a structural formula i.e. specifically mentioned or covered by a Markush formula. A product can in some cases be considered to be specified in the wording of the claims of the basic patent if the product is described by a functional term.

(b) *Implementation of Neurim (Art. 3(d) Reg. 469/2009)*[28]

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 authorization 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 authorization in the EU is the marketing authorization 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:

- scope of the basic patent;
- the marketing authorization;
- new therapeutic indication.

Regarding MA, more than one MA within the concept of "global MA" can be used for the purpose of SPC and thus one is able to receive a new SPC on a variation with regards to a new therapeutic indication.

2.6 THIRD PARTY OBSERVATIONS

Section 7 of the Public Administration Files Act No. 606 of 12 June 2013[29] enables "anyone" to apply for insight to a given administrative procedure.

The DKPTO always take third-party observations into account when examining an application.[30] When DKPTO's decision is final, the third-party is informed about the

[27] The MPI Questionnaire, answer to question 19.
[28] The MPI Questionnaire, answer to question 37.
[29] Public Administration Files Act No. 606 of 12 June 2013, https://www.retsinformation.dk/forms/r0710.aspx?id=152299 .

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.

2.7 GRANTING OR REJECTION OF THE SPC. APPEAL AND REVOCATION PROCEDURES

The grant of the SPC is published in the Danish Official Patent Gazette, including the information required pursuant to Article 11(1) of the SPC Regulations,[31] in addition to the number and date of filing of the SPC application, as well as the SPC registration number. The same applies to the publication of the grant of an extension of the SPC duration with regard to medicinal products for paediatric use (hereinafter paediatric extension).[32] There is no certain time for such publication set by law and the Danish Official Patent Gazette is updated weekly.

The DKPTO keeps a register of applications for SPCs and paediatric extensions, containing the information required for publication under Article 9(2) of the SPC Regulations. If the applicant or the holder is represented by an agent, the name or firm name and postal address of the agent will also be included in the register.[33] In addition, the SPC Register will include the information contained in the Patent Register regarding the basic patent.[34] [35]

The refusal of an application for an SPC or a paediatric extension will also be published, indicating the number and the filing date of the application, as well as the information referred to in Article 9(2) of the SPC Regulations including the identity of the product.[36]

The SPC applicant can appeal the decision of the DKPTO before the Danish Board of Appeal for Patents and Trademarks[37] not later than two months from the notification of the decision and upon fee payment.[38]

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30 See Order No 25 of 18 January 2013 on Patents and Supplementary Protection Certificates, Section 73(1).

31 The name and address of the SPC holder, the number of the basic patent, the title of the invention, the number and date of the first authorisation to place the product on the market in the EEA -when the marketing authorisation for the territory of Denmark was not the first one in the EEA-, the number and date of the first marketing authorisation to place the product on the market in Denmark and the duration of the SPC.

32 Order No 25 of 18 January 2013 on Patents and Supplementary Protection Certificates, Section 75(1).

33 ibid, Section 76(1).

34 ibid, Section 76(2) in conjunction with Section 42.

35 i.e. the date of the grant of the patent; the number of the application and the registration number of the patent; the classes of the patent; the name or firm name and postal address of the proprietor of the patent; if the proprietor of the patent is represented by an agent, the name or firm name and postal address of the agent; the name and postal address of the inventor; the title of the patent; the application's filing date, information as to where the application serving as a basis for claiming priority was filed and the date of filing and number of that application; the number of the parent application; the date on which the files of the application were made available to the public; if the patent comprises the deposit of a sample of biological material, information to that effect; and the cited documents.

36 Order No 25 of 18 January 2013, Section 75(3) in conjunction with Section 70(5).

37 Patent Act No 221, Sections 7(1) and 24(1).

38 Patent Act No 221, Section 25(1).

A request for re-examination of the SPC can be file by any person before the DKPTO, pursuant to the invalidity grounds indicated in Article 15(1) of the SPC Regulations and upon fee payment.[39] The request for re-examination must include:

i. The name or firm name and postal address of the person requesting the re-examination;
ii. The SPC registration number and the name or firm name of the SPC holder;
iii. The grounds within Article 15(1) of the SPC Regulations on which the request is based and a complete account of all the facts, evidence and arguments presented in support of those grounds;
iv. The name or firm name and postal address of the agent, if the person requesting the re-examination is represented by an agent;
v. In the case that licensees of the SPC holder are entered in the SPC Register, the request for re-examination must also include documentation to prove that such licensees have been notified that re-examination has been requested.[40]

If the request is based on the grounds stated in Article 15(1)(a) or (b) of the SPC Regulations, the DKPTO will notify the SPC holder of the request for re-examination and will give him the opportunity to file observations within a time limit of six months.

The DKPTO will then undertake the re-examination of the SPC on the basis of the materials and the grounds produced in connection with the request. The decision of the DKPTO, which may be to revoke the SPC or to maintain it unamended, will be notified to the parties.[41]

There is no standard hearing procedure before Danish NPO.

2.8 EFFECT ON THE SPC GRANTING PROCEDURE OF PENDING REVOCATION OR OPPOSITION PROCEDURES AGAINST THE PATENT[42]

If the SPC re-examination request is based on the grounds stated in Article 15(1)(c) of the SPC Regulations, a re-examination of the basic patent must be requested at the same time. In such a case, the re-examination of the SPC will be suspended until the re-examination of the basic patent has finished.[43]

If the SPC re-examination request is filed during the period prescribed for the filing of oppositions against the basic patent or if there is a pending opposition against the basic patent, the DKPTO will suspend the re-examination of the SPC until the opposition period has expired or a decision on the opposition request has been made.

The re-examination of the SPC will also be suspended until the DKPTO has come to a decision regarding the basic patent, when a previous request for re-examination or termination of the basic patent is still pending.

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39 Order No. 25 of 18 January 2013, Section 78(3).
40 ibid, Section 78(1).
41 ibid, Section 79.
42 ibid, Section 78(2), in conjunction with Section 80.
43 In case there is a pending re-examination of the basic patent during the SPC examination procedure, the DKPTO may suspend the examination of the SPC. However, the DKPTO does not suspend the examination automatically and the applicant can submit arguments in order for the examination to proceed.

The SPC will be revoked pursuant to Article 15(1)(c) of the SPC Regulations if the basic patent is revoked/declared invalid or if the basic patent is amended to such an extent that the product for which the SPC was granted is no longer protected by the basic patent.

2.9 CALCULATION OF THE PATENT AND SPC DURATION. CALCULATION OF TERMS. RELIEF BEFORE THE DKPTO

2.9.1 Calculation of the patent and SPC duration

According to Section 40 of the Danish Patent Act, '[a] granted patent may be maintained until 20 years have elapsed from the date of filing of the patent application...'

For the calculation of the SPC term, the DKPTO takes into account the date of signature of the first authorisation to place the product on market in the EEA, when such authorisation was granted by the Danish health authorities. However, if the first marketing authorisation was granted by the EMA, the relevant date for the calculation of the SPC term is the date of the notification to the applicant of the grant of the marketing authorisation.

2.9.2 Calculation of terms

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.

2.9.3 Relief before the DKPTO for missed deadlines[44]

If the non-observance of a time limit vis-à-vis the DKPTO prescribed in the SPC Regulations causes a loss of rights to an SPC applicant or proprietor who has taken all due care reasonably required, the DKPTO will re-establish his rights, upon request.

The request must be filed with the DKPTO within two months from the removal of the obstacle causing non-observance of the time limit, but at the latest, one year after the expiry of the time limit. The omitted act must be completed and the prescribed fee for re-establishment of rights must be paid within the same time limits.

Re-establishment of rights may also be granted when an SPC has lapsed under the provisions of Article 14(c) or (d) of the SPC Regulations.

The request for re-establishment of rights will be published in the Danish Official Patent Gazette.

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[44] Order No 25 of 18 January 2013, Section 85 in conjunction with Patent Act No 191, Section 72.

2.10 REPRESENTATION BEFORE THE DKPTO

The DKPTO may[45] invite the applicant to appoint an agent residing in the EEA to represent him in all matters relating to the application.[46] If an agent is appointed, a letter concerning the power of attorney must be filed,[47] unless the appointed agent is:

1) a lawyer or
2) a patent attorney/advisor who
   a) is employed in a company who for the last 3 years have served as an agent for IP-applications,
   b) declares that he or she is on the EPO professional advisor list,
   c) declares that he or she has worked with IP rights and served as an agent for applications for at least 3 years directly up to the to the current application, or
   d) is able to refer to a previous given power of attorney.

2.11 POST-GRANT AMENDMENT OF THE SPC DURATION

According to Section 82(1) of Order No 25 of 18 January 2013, any person can file a request for re-examination of the SPC duration before the DKPTO, upon fee payment. Section 78 of the same Order, which refers to the filing of a request for re-examination of the SPC, will apply in the case of a request for re-examination of the SPC duration, provided that a reference is made to the grounds of Article 13 of the SPC Regulations.

If the request for re-examination of the SPC duration is filed by another person than the SPC holder, the DKPTO will notify the SPC holder accordingly, giving him the opportunity to file observations within a time limit of two months.[48]

The DKPTO will decide whether the request for re-examination meets the requirements of Section 82 in conjunction with Section 78 of Order No 25 of 18 January 2013. If the request meets such requirements, the DKPTO will change the SPC duration, otherwise the request will be refused.[49]

Both the filing of the request and the DKPTO's decision will be published and entered in the SPC Register. The publication of the DKPTO's decision will state the name or firm name of the SPC holder, the number and filing date of the SPC application, the SPC registration number, the number of the basic patent, the title of the invention and the duration of the SPC. The publication of the filing of the request for re-examination will, in addition to the aforementioned, state the name or firm name of the person who requested the re-examination.[50]

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45 The DKPTO can only encourage the applicant to appoint an agent, but the applicant is free to choose whether or not to appoint one. In order to represent the applicant as an agent, the agent must reside in the EEA and be of legal age.
46 Patent Act No 221, Section 12.
47 Order No 25 of 18 January 2013, Section 102.
48 Order No 25 of 18 January 2013, Section 82(3).
49 ibid, Section 82(4).
50 ibid, Section 84.

The above-mentioned under this section applies mutatis mutandis to the amendment of the duration of a paediatric extension.51

2.12 PAYMENT OF FEES

The maintenance of the SPC is subject to a renewal fee, to be paid for each year commenced after the expiry of the term of the basic patent. The renewal fee falls due on the last day of the month in which the fee year begins and may not be paid earlier than three months before the due date. If the applicant fails to pay the renewal fee within the prescribed time limit, he has the possibility to pay it with surcharge within six months after its original due date.[52]

2.13 ENFORCEMENT OF THE SPC

A published SPC application grants provisional protection to the applicant, which entitles him to claim damages for infringement during the transition period. The applicant must make the files of the application available to the public (in Danish or English) before he can assert his right.[53] The national Maritime and Commercial Court is to decide whether or not the applicant should receive damages.

Once the SPC has been granted, any person who intentionally or grossly negligently infringes the exclusive right conferred by an SPC will be punished with a fine. In such a case the proceeding will be instituted by the injured party.

If the infringement has been committed intentionally and under aggravating circumstances, the penalty may increase to imprisonment of up to one year and six months, unless a heavier penalty is provided for by Section 299b[54] of the Penal Code.[55] Aggravating circumstances will be considered to exist in particular if a significant and obviously unlawful profit is intended by the infringement. In this case, proceedings will be instituted only at the request of the injured party unless the institution of proceedings is required in the interests of the public.[56]

51 ibid, Section 83.
52 ibid, Section 77.
53 Patent Act No 221, Section 60.
54 Imprisonment for up to six years, in case of patent infringement of a particularly serious nature.
55 Justitsmin, j nr 2016-730-0967.
56 Patent Act No 191, Section 91(3) in conjunction with Section 57.

3 FRANCE

Mathilde Junagade[*] *Anais Collin*[**]

3.1 INTRODUCTION: THE SOURCES OF LAW

France is an active member of all the relevant intellectual property agreements at the European and international level in the field of patents. It was a Contracting State of the EPC and founding member of the European Patent Organisation since 1973, a party of the PCT and the PLT, as well as a member of the TRIPS Agreement. Furthermore, France was a Contracting State of the Strasbourg Convention and ratified this Agreement on 27 February 1980. Finally, France is a Contracting State of the UPCA and takes part in the enhanced cooperation for the creation of unitary patent protection.[57]

Patent protection in France can be obtained therefore by filing a European patent application with the EPO or by filing a national patent application with the National Patent Office, the INPI. Provisions dealing with national patents are laid down in Book 6, Title I, of the Intellectual Property Code[58] (hereinafter IPC). European and national patents are subject to provisions and conditions that are largely uniform, since national patent law was aligned with the substantive provisions of the EPC.

The scope of protection of national patents[59] and the rights conferred by such patents[60] are regulated by provisions with wording similar to that of Article 69 EPC and Article 28 TRIPS Agreement respectively. The scope of protection of European patents is governed in national proceedings directly by Article 69 EPC; the rights conferred by the European patents are subject to the same provisions that apply to national patents.[61]

The requirements for patentability that apply to national patent applications (articles L.611-10 to L.611-19 IPC) are similar to those of Articles 52 to 57 EPC. The wording of the provision governing the requirement for a sufficient disclosure is also aligned with

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57 See Regulation (EU) 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 L361/1.

58 The IPC was created by the Law n° 92-957 of July, 1st, 1992, published in the OJ dated 3 July 1992

59 IPC, Article L613-2: 'L'étendue de la protection conférée par le brevet est déterminée par les revendications. Toutefois, la description et les dessins servent à interpréter les revendications. Si l'objet du brevet porte sur un procédé, la protection conférée par le brevet s'étend aux produits obtenus directement par ce procédé'.

60 IPC, Article L613-3:
Sont interdites, à défaut de consentement du propriétaire du brevet :
a) La fabrication, l'offre, la mise dans le commerce, l'utilisation, l'importation, l'exportation, le transbordement, ou la détention aux fins précitées du produit objet du brevet;
b) L'utilisation d'un procédé objet du brevet ou, lorsque le tiers sait ou lorsque les circonstances rendent évident que l'utilisation du procédé est interdite sans le consentement du propriétaire du brevet, l'offre de son utilisation sur le territoire français;
c) L'offre, la mise dans le commerce, l'utilisation, l'importation, l'exportation, le transbordement ou la détention aux fins précitées du produit obtenu directement par le procédé objet du brevet.

61 EPC, Article 64(1).

the corresponding provision of the EPC. The same holds true for the revocation grounds of the national patents. They are all consistent with Article 138 EPC[62].

In France, a system of national SPCs was introduced by the law n° 90-510 of 25 June 1990[63]. It was then replaced by the system of European SPCs when Regulation EEC/1768/92 came into force.

The IPC contains provisions in its Book 6 "Protection of Inventions and Technical Knowledge" designating, amongst provisions applicable to patents, those which are applicable also to SPCs. Those provisions (Articles L611-2 and R617-2) were first introduced for application to former national SPCs, and now apply to European SPCs under Regulations EEC/1768/92, EC/469/2009 and EC/1610/96. The IPC also contains a provision concerning procedural aspects of SPCs' fee payment (Article R617-1), and the following provisions concerning the examination's timeframe:

Article R617-2-1 IPC:

> The Institute shall decide on the application for a supplementary protection certificate within twelve months of the date of filing said application. If the Institute notifies the applicant of any deficiencies, this time limit shall be interrupted until the deficiencies are remedied pursuant to Reg. (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 and Reg. (EC) No. 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products.
> The provisions of the first paragraph of this Article shall be applicable to applications for an extension filed pursuant to the provisions of Article 36 of Reg. (EC) No. 1901/2006 of 12 December 2006 on medicinal products for paediatric use and amending Reg. (EC) No. 1768/92, Dir. 2001/20/EC, Dir. 2001/83/EC and Reg. (EC) No. 726/2004.

Article R617-2-2 IPC:

> In the absence of an express decision within the time limit referred to in Article R617-2-1, the application shall be deemed to be refused.

3.2 INSTITUTIONAL ASPECTS

The National Institute of Industrial Property (INPI) is a self-financing agency created in 1951, ruled by the IPC. It is placed under the supervision of the ministry

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62 Article L613-25 : Le brevet est déclaré nul par décision de justice :
a) Si son objet n'est pas brevetable aux termes des articles L. 611-10, L. 611-11 et L. 611-13 à L. 611-19;
b) S'il n'expose pas l'invention de façon suffisamment claire et complète pour qu'un homme du métier puisse l'exécuter ;
c) Si son objet s'étend au-delà du contenu de la demande telle qu'elle a été déposée ou, lorsque le brevet a été délivré sur la base d'une demande divisionnaire, si son objet s'étend au-delà du contenu de la demande initiale telle qu'elle a été déposée ;
d) Si, après limitation, l'étendue de la protection conférée par le brevet a été accrue.
Si les motifs de nullité n'affectent le brevet qu'en partie, la nullité est prononcée sous la forme d'une limitation correspondante des revendications.
Dans le cadre d'une action en nullité du brevet, son titulaire est habilité à limiter le brevet en modifiant les revendications ; le brevet ainsi limité constitue l'objet de l'action en nullité engagée.
La partie qui, lors d'une même instance, procède à plusieurs limitations de son brevet, de manière dilatoire ou abusive, peut être condamnée à une amende civile d'un montant maximum de 3 000 euros, sans préjudice de dommages et intérêts qui seraient réclamés.

63 Published in OJ n° 147, June 27, 1990

responsible for industry, except for what concerns the examination and issuance of titles.

The INPI employs around 780 persons and has several national local representations (23 sites) and international representations (11 sites).

The INPI is in charge of granting industrial property rights (including patents, trademarks, designs, supplementary protection certificates and geographical indications on manufactured goods), centralising and delivering information in the field of industrial property. It implements laws and regulations on industrial property and takes initiative for their adaptation to the needs of innovators and enterprises. It participates in the drafting of international agreements and the representation of France in the relevant international organisations.

Under the national patent procedure the INPI, a first administrative and preliminary technical examination is performed the main purposes of which are to withdraw patent applications related to matter excluded from patentability and to ask technical clarification before performing the interiorities search. After this first examination, INPI directs 80% patent applications to the EPO for the preliminary search report (PSR) and written opinion and performs internally 20% of the preliminary search report (PSR) and written opinion. Then, a second technical examination takes place: the applicant's observations or amendments in response to the PSR are examined by a technical patent examiner (qualified with a technical master degree) who draws up a definitive search report and grants the patent. The INPI has authority to grant patents if the novelty criterion is fulfilled. If the patent examiner considers that the inventive step is not certain, he mentions it on the definitive search report. The INPI cannot reject an application with the argument that the subject matter is not inventive, but it can do that with the argument that the subject matter is not novel or industrial applicable or is not a technical invention.

The INPI is also the national competent authority to grant SPCs according to Article 9(1) of the SPC Regulations.

3.3 FILING OF THE APPLICATION. PUBLICATION OF THE APPLICATION

In France, an SPC application can be filed at the INPI by the owner of the basic patent himself or by an authorised representative.[64] If the patent is owned by several entities, a common representative is entitled to file the SPC application.

The request form must be filled out according to the formal requirements stipulated under Article 8 of the SPC Regulations, including mandatorily the name of the product for which the grant of the SPC is sought, which must comply with the definition of Article 1(b) of Regulation EC/469/2009 ("the active ingredient or combination of active ingredients of a medicinal product") and in Article 1 of Regulation EC/1610/96 ("the active substance or combination of active substances of a plant protection product"). This product is either designated by its INN (International Non-proprietary Name), as mentioned in the summary of product characteristics of the marketing authorization or

[64] IPC, Article R. 612-2.

by a functional name where the product does not have an INN. References to an adjuvant or excipient are not permitted in the product identification.[65] The request can also contain information proving that the product is protected by the basic patent indicated by its proprietor for the purpose of obtaining the SPC.

The protection conferred by a certificate shall extend only to the product covered by the marketing authorisation and for any use of the product as a medicinal product or plant protection product that has been authorised before the expiry of the certificate.

According to the French practice, a wording such as "product X in any form protected by the basic patent" in the definition of the product is accepted. Furthermore, a wording such as "product X and its salts and esters" in the definition of the product is accepted, provided that designated forms are also protected by the basic patent. Nevertheless, a wording such as "product X and its mutants and variants" in the definition of the product is not accepted because the mutants and variants are not considered to be the same active ingredient as the product. Moreover, a wording such as "product X and biosimilar within the meaning of the article 10(4) of the Directive 2001/83/EC, as protected by the basic patent" is not accepted either.

The application must be filed within the timeframe indicated in Article 7 of both SPC Regulations: "within 6 months of the date on which the patent is granted or within 6 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". Where the patent owner files the SPC application after the expiry of the 6 month time period, he can ask a re-establishment of right with a legitimate reason.

Finally, the application should also include a proof of payment of the application fee.

If the application includes a request for paediatric extension, required documentation pursuant to Article 8(1) (d) of Regulation EC/469/2009 must also be included.

The SPC applications are published at the Bulletin Officiel de la propriété industrielle (BOPI) within four weeks of their filing. The SPC extensions are published within four weeks of their grant. They are also made available on the patent database on the INPI website.

3.4 FORMAL EXAMINATION

Upon reception of the application, the INPI examines that the application fee has been paid, that the patent is in force at the date of filing of the SPC application and that the application contains the necessary information for its publication according to Article 9(2) of the SPC Regulations.

In the event of a formal irregularity being observed or in case of a missing document, for example the marketing authorisation, this formal irregularity is notified to the applicant at the same time as the substantive irregularities. Irregularities may be rectified within two months (extendable once by the same time period), failing which the application is rejected.

[65] CA Paris, September 11th, 2013, Lantheus v/ INPI.

The French Office is required by law to grant or reject the SPC within one year of the request. However, the notification of an irregularity interrupts this time period until regularisation, at which point the time period is re-initialised.

3.5 SUBSTANTIVE EXAMINATION

The French Office examines ex officio all the substantive requirements for issuing the SPCs. The examination is carried out by three technical examiners with post-graduate qualifications in biology or chemistry. Legal aspects are handled by a legal expert, who also defends the decisions of the Office on SPCs in case of judicial appeal before the Court of Appeal.

The practice of the INPI is reflected in its guidelines for examination of SPC, updated in 2017, which are made available on the INPI website, both in French and in English.

The active ingredient for which the SPC application is filed shall be the substance identified as active substance in the MA, "qualitative and quantitative composition" rubric of the summary of the product characteristics. A SPC cannot be granted for a combination of two substances, where only one of them is identified as active substance in the MA.

The INPI considers a new salt as a new product if it's covered by the MA and by the basic patent, and if the MA is the first MA for this salt.

In accordance with CJEU 'Farmitalia' case law a definition such as "compound Y in all acceptable salt and esters" is accepted, provided that said "salts and esters" are protected by the basic patent.

A product definition such as 'compound y in all acceptable salts and derivatives", is not admitted because "derivatives" may cover several different products.

As regards, more specifically, the examination under Article 3(a) of Regulation EC/469/2009, the Office checks whether the product is specified in the wording of the claims in accordance with the Medeva[66] case law. In the event that the claims relate to a product defined under a functional formula implicitly covering the one requested for the SPC, the INPI ensures that these claims, interpreted in light of the description, necessarily and specifically target the product, conformant to Eli Lilly[67] case law. This may be the case if the product is identified in an example or as a preferred embodiment in the description, for example under its chemical name or its structural form.

If there is no mention and individual disclosure of the product in the patent specification so that the patent cannot be limited to such a product without violating the French provisions corresponding to art. 123 (2) EPC, it isn't still possible to get a SPC.

As for Markush formulae, the product is considered to meet the requirement of Article 3(a) of the SPC Regulations if it appears to be covered by the Markush formulae

66 Case C-322/10 *Medeva* [2011] ECR I-12051.
67 Case C-493/12 *Eli Lilly and Company* [2013].

identified in the claims, even if the product is not precisely identified in the wording of the claims or in the description.

In the case of SPCs filed for combinations of products such as "A + B", the SPC is refused if the applicant has already obtained an SPC on A in the same basic patent (regardless of whether the patent is subject to a limitation in the interval between the issuance of the first SPC and the second one's application or it is rejected) unless A + B constitutes a "totally separate innovation" compared to A. The INPI does not, in this case, undertake an analysis of what constitutes the "inventive step of the patent", but only engages in an interpretation of the claims in the light of the description.

The fact that both A + B and A are claimed independently in the basic patent can itself be considered to indicate that they are separate innovations.

Conversely, the fact that the patent claims only A and that the possible association of A with an ingredient such as B is merely evoked in the description does not allow for the conclusion that A + B constitutes the subject-matter of the invention[68].

Concerning the examination of Article 3(b) and (d) of the SPC Regulations, the French Office, in connection with the national health authorities (the ANSM or the ANSES), ensures that the marketing authorisation specified in the application is the first marketing authorisation for the product as a medicinal product, without regard to the medical use identified in the marketing authorisation and whether this MA was in force at the date of filing of the SPC application.

In exceptional cases, where the marketing authorisation is not the first for the product, but the applicant relies on the Neurim[69] case law of the CJEU, the French Office examines the medical use of the marketing authorisation and the patent, based on a strict interpretation of the notion of "new medical use". The criteria of the Neurim case law is considered satisfied if, on one hand, the patent is -strictly speaking- a patent for a "new medical use" and, on the other hand, if the new medical use identified in the marketing authorisation concerns the treatment of a different disease – falling in the scope of the protection of the basic patent.[70] A new dosage or a new form of the medicinal product or the treatment of a new population group is not considered as "new medical uses". The French office applies Neurim even if both MA are for a human use but the second MA, provided the 2d MA is for a new medical use.

Finally, the INPI verifies that the product has not already been subject to an SPC, as required by Article 3(c) of the SPC Regulations. In this regard, it is irrelevant whether the previous SPC was issued for the product obtained by another process,[71] or having a different degree of concentration, or different purity. Similarly, it is irrelevant that a first SPC has been issued for the racemate and that the second is required for an enantiomer.[72] Where two applications from the same applicant for the same product are pending before the INPI, the applicant shall be asked to choose one and the other one shall then be rejected by the Office.

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68 CA Paris: June 8th, 2012, Boerhinger v. INPI and May 30th, 2014 Syngenta v. INPI.
69 Case C-130/11 *Neurim Pharmaceuticals* [2012].
70 CA Paris, February 15th, 2013, Merck & Co v/ INPI.
71 CA Paris, April 12th, 2016, The Government of the USA v/ INPI. Cass.com, September 29th.2009, AETS v/ INPI.
72 CA Paris, June 9th, 2010, Syngenta Participations v/ INPI.

3.6 THIRD PARTY OBSERVATIONS

French Law does not allow third party observations. Where such observations are addressed to the Office, the Office transmits them to the applicant for information but does not take them into account in its examination.

3.7 EFFECT ON THE SPC GRANTING PROCEDURE OF PENDING REVOCATION OR OPPOSITION PROCEDURES AGAINST THE PATENT

The time frame of one year imposed by aforesaid article R.617-2 IPC on the French Office to grant or reject the SPC is regardless of any revocation or opposition procedure that may be pending against the basic patent. However, the Office may accept to delay the procedure within the constraints of this legal limit. According to Article R617-2-1 IPC and Article R617-2-2 IPC if the time frame is not respected, the SPC application is deemed to be rejected.

3.8 GRANTING OR REJECTION OF THE SPC. APPEAL PROCEDURE

Where the SPC application (or the paediatric extension) is regular, the INPI grants the SPC (or the paediatric extension) and notifies the SPC owner the decision by specifying the date and number of the Official Bulletin of Industrial Property in which the decision is to be published, according to Article 11(1) of the SPC Regulations. This grant is registered in the Patents National Register and all documents relating to the examination are made available on the INPI's website.

Where the SPC application (or the paediatric extension) is irregular, the INPI rejects the SPC application (or the paediatric extension) and notifies the applicant the rejection. This rejection decision is published in the Official Bulletin of Industrial Property, according to Article 11(2) of the SPC Regulations, registered in the National Patents Register, and all documents relating to the examination are made available on the INPI's website.

The right to request an oral hearing is not formally written in law. However, this may be granted at the request of the applicant if the Office considers it appropriate.

The possibility of appealing the INPI's decision on the grant or rejection of the SPC, within the meaning of Article of 18 Regulation EC/469/2009 and Article 17 of Regulation EC/1610/96 is provided by Article L.411-4 of the IPC. The appeal shall be filed within one month (three months for non-French resident appellants) from the notification or publication of the decision, before the Paris Court of Appeal, which is the sole national Court competent in the field of patents. The INPI submits observations to the Court during the appeal procedure in order to defend its decision.

3.9 CALCULATION OF THE PATENT AND SPC DURATION. CALCULATION OF TERMS. RELIEF BEFORE THE INPI

3.9.1 Calculation of the patent and SPC duration

Calculation of the patent duration:

According to Article L611-2 IPC, inventions shall be protected by patents, granted for a term of 20 years from the day the application is filed.

The patent expires on the day prior to the anniversary date of its application; for example, a patent filed on 21/02/1997 expires on 20/02/2017 at midnight.

As regards calculation of SPC duration, according to Article 13 of the SPC Regulations, the certificate takes effect at the end of the lawful term of the basic patent for a period equal to the elapsed period between the date on which the application for a basic patent was lodged and the date of the first authorisation to place the product on the market in the Community, reduced by a period of five years. The maximum duration of the certificate may not exceed five years.

In accordance with CJEU Seattle Genetics[73] case law, where the first marketing authorisation in the EU as referred to in Article 13 of the SPC Regulations is a European marketing authorisation, its "date" is considered to be the date of its notification; whereas the "date" of a French marketing authorisation is the date of the decision.

According to CJEU Merck[74] case law, in order to allow a possible paediatric extension, the INPI does not reject SPCs with negative duration, provided this negative duration is no longer than six months.[75]

3.9.2 Calculation of terms

The current method for calculation of SPC term applied by the INPI is as follows:

The term of the SPC is fixed corresponding to the less favourable of the two following calculations:

- Date of issue of the marketing authorisation (notification or granting according to Seattle's case) + 15 years.
- Date of the legal term of the patent (the day before the anniversary date of the patent) + 5 years.
  E.g.: an SPC is attached to a patent filed on November 29th, 1994, which reaches the end of its legal term on November 28th, 2014. The marketing authorisation corresponding to the SPC is granted on August 11th, 2004.
- Expiry of 5 years from the legal term of the patent: November 28th 2019.
- Expiry of 15 years from the date of issue of the marketing authorization: August 11th 2019.

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73 Case C-471/14 *Seattle Genetics Inc.* [2015].
74 Case C-555/13 *Merck Canada Inc*. [2014].
75 CA Paris, July 5th, 2013, Hoffmann-Laroche v/ INPI.

The SPC term is fixed on August 11th 2019.

3.9.3 Relief before the INPI for missed deadlines

Article L.612-16 IPC allows an applicant who has not complied with a time limit as regards the INPI to submit a request for reinstatement of his rights if he is able to give a legitimate reason and if the direct consequence of the hindrance has been refusal of his patent application or of a request or the loss of any other right or means of appeal.

The appeal must be submitted to the Office within two months of the hindrance ceasing to exist. The act that has not been carried out must be accomplished within that period. The appeal shall only be admissible within a period of one year from expiry of the time limit not complied with.

This provision applies to SPC.

Article R612-52 IPC also provides for the right of a patent -or SPC- applicant to request further processing with respect to the application in cases where he has failed to comply with a time limit fixed by the Office:

If a patent application is refused or is liable to be refused due to failure to comply with a time limit afforded by the National Institute of Industrial Property, the refusal shall not be pronounced or shall not have effect if the applicant submits a request to continue the procedure. The request shall be submitted in writing within a period of two months as from notification of the refusal decision. The act that has not been carried out shall be carried out within that time limit. A request shall be admissible only if accompanied by payment of the required fee.

3.10 REPRESENTATION BEFORE THE INPI

Pursuant to Article R. 612-2 of IPC, the election of a representative is only mandatory if the applicant is not an EU or EEA resident. A representative, where elected, must be a qualified patent attorney or a barrister.

3.11 POST-GRANT AMENDMENT OF THE SPC DURATION. POST-GRANT LIMITATION OR REVOCATION OF THE PATENT

3.11.1 Post-grant amendment of the SPC duration

With regard to appeals concerning the duration of the certificate, the INPI implements Article 17(2) of Regulation EC/1610/96, which allows the applicant to correct the duration of the certificate if, as a result of an error on his part, the date of the first marketing authorisation in the Community as contained in the SPC application appears to be incorrect. However, as for any appeal against a decision of the INPI, this appeal may be exercised:

- before the Paris Court of Appeal, within one month of the notification of the decision to issue the SPC

- before the INPI itself, provided that such appeal has been exercised within a period which allows the Office to amend its decision at the latest four months after its issue.

Where the duration of the certificate is incorrect because of the INPI itself, in particular in the light of the Seattle Genetics case law of the CJEU, it is also possible:

- for the SPC owner, to lodge an appeal before the Paris Court of Appeal within one month of notification of the SPC grant decision
- for the Office, to amend this expiry date, ex officio or on request; such amendment to be made within four months from the issuance of the grant decision, in accordance with the provisions applicable to French administrative decisions and in particular Articles L.242-1, L.242-3 and L.242-4 of the code of relations between the general public and the civil service.

In the event that these periods of appeal have expired, the owner nevertheless retains the possibility of having the date of notification of the marketing authorization entered in the National Patent Register for the purpose of informing third parties. However, the duration of the SPC may not be corrected if the periods of appeal are expired.

3.11.2 Post-grant limitation or revocation of the patent

According to Article L.613-24 IPC, at any point after the grant of the patent and until five years after its expiration, the patent owner may either file a request to limit the patent -through the amendment of the patent claims- or file a declaration of renunciation.

The INPI grants the limitation of the patent as long as the modified patent claims are clear and concise and the limitation does not extend the protection conferred by the patent and does not extend the content of the application as filed, otherwise the patent is partly void pursuant to Article L613-25.

It shall reject the request for limitation or renunciation if there are existing licences inscribed in the Patents Register and the owners of those rights have not given their consent to such limitation or revocation.

The amendment of the claims has retroactive effect on the protection conferred by the patent, which determines the protection conferred by the SPC to the extent that the limitation of the basic patent affects the product protected by the SPC.

Pursuant to Article 15 of Regulation EC/469/2009, revocation of the basic patent after the grant of the SPC and, in certain circumstances, its limitation, constitute a ground for invalidation of the SPC. However, since the INPI is not a competent body under French law to invalidate a patent, any request for invalidation of the SPC on this ground may only be referred to the Paris Court of First Instance, in accordance with Article 15 in fine of the Regulation.

3.12 SPECIFIC ISSUES CONCERNING EXTENSION PURSUANT TO ART. 36 OF REG. 1901/2006/EC

The INPI is also responsible for the issuance of SPC paediatric extensions under Regulation EC/1901/2006. The following documents must be attached to the application for the extension:

a copy of the statement indicating compliance of the marketing authorisation with an agreed completed pediatric investigation plan as referred to in article 36(1) of the Regulation EC/1901/2006; and the proof of marketing authorisation in all the Member States.

The applicant can file the application for an extension of the SPC term together with the SPC application or separately, no later than two years before the expiry of the SPC.

For the INPI to grant such extension, the application must meet the requirements of Article 8(1)(d) of Regulation EC/469/2009 in conjunction with Article 36 of Regulation EC/1901/2006. If the INPI detects an irregularity or deficiency in the documentation submitted by the applicant, the applicant is notified accordingly. Irregularities may be rectified within two months (extendable once by the same time period), failing which the prorogation application is rejected.

The extension of the SPC term is subject to revocation under circumstances as foreseen in Article 16(1) of Regulation EC/469/2009 (i.e. when it was granted contrary to the provisions of Article 36 of Regulation EC/1901/2006). However, since the INPI is not a competent body under French law for the revocation of the corresponding basic patent, any request for revocation of the extension of the duration on this ground may only be referred to the Paris Court of First Instance, in compliance with an Article 16(2) of Regulation EC/469/2009.

In the French practice it is possible to get the extension even if the pediatric studies were conducted by a third party.

3.13 PAYMENT OF FEES

According to article R.617-1 IPC, the filing fee for a supplementary protection certificate shall not cover the first annual fee. The payment of annual fees shall become due on the last day of the month of the anniversary date of the filing of the application for the basic patent. Overall payment of all annual fees may be accepted if made within the year preceding the entry into effect of the certificate.

Filing of SPC	520€
Filing of extension	470€
Annuities	940€

Table 3.1:

3.14 ENFORCEMENT OF THE SPC

According to Article L611-2 IPC, in conjunction with Articles 4 and 5 of the SPC Regulations, the SPC holder or the holder of an exclusive license can enforce his rights against third parties in the same terms as in relation to the basic patent, but limited to the product covered by the marketing authorisation.

According to article L613-5 IPC, the rights afforded by the patent or SPC do not extend to:

- the studies and tests required for the granting of a marketing authorisation for a medicinal product, as well as for the acts necessary for their realisation and for obtaining the authorisation;
- the acts necessary for obtaining the advertising visa referred to in Article L. 5122-9 of the Public Health Code;

A published SPC application entitles the holder to introduce infringement proceedings under Article L615-4 IPC. The court hearing an action for infringement on the basis of a patent or SPC application stays proceedings until the patent is granted.

4 GERMANY

Dr. Oliver Werner[*]

4.1 INTRODUCTION: THE SOURCES OF LAW

Germany has signed and ratified most European and international agreements in the patent field, including the Paris and Strasbourg Conventions, the EPC, the PCT and TRIPS. A notable exception is the PLT, which was signed in 2001 but not yet ratified, even though some PLT provisions have been incorporated into the German Patent Act in the meantime. Germany is also party to the enhanced cooperation for the creation of unitary patent protection and a Contracting Member State of the Agreement on a Unified Patent Court (UPCA), the ratification process for the latter currently being finalized.

Patent protection in Germany can therefore be obtained by filing a national patent application at the German Patent and Trade Mark Office (Deutsches Patent- und Markenamt; DPMA), or by filing a European patent application at the EPO with subsequent validation in Germany. Filing in both cases is also possible via the PCT route (national or regional phase entry respectively).

The provisions governing national patents and patent applications are laid down in the German Patent Act as published on 16 December 1980 (*Patentgesetz* PatG; BGBl. 1981 I page 1; last amended 17 July 2017, BGBl. 2017 I page 2541; unofficial consolidated English version at http://www.gesetze-im-internet.de/englisch_patg/englisch_patg.html). Provisions dealing with international applications and European patents are set out in the Act on International Patent Treaties of 21 June 1976 (*Gesetz über internationale Patentübereinkommen* IntPatÜbkG; BGBl. 1976 II page 649; last amended 17 July 2017, BGBl. 2017 I page 2541; unofficial consolidated German version at http://www.gesetze-im-internet.de/intpat_bkg/BJNR206499976.html).

Both Acts are largely harmonized with the EPC, in particular the provisions having regard to patentability (Articles 52 to 57 EPC vs. Sections 1 to 5 PatG), scope of protection (Article 69 EPC vs. Section 14 PatG), and revocation (Article 138 EPC vs. Section 22 PatG and Section 6 IntPatÜbkG) are consistent.

While Regulations (EC) no. 469/2009 and (EC) no. 1610/96 are directly applicable, German law on SPCs is governed by Sections 16a and 49a of the Patent Act.

By means of Article 1 no. 1 of the Act Amending the Patent Act and other Acts (*Gesetz zur Änderung des Patentgesetzes und anderer Gesetze*) of 23 March 1993, Sections 16a and 49a were included in the Patent Act with effect from 1 April 1993 (Section 16a last amended 19 October 2013; Section 49a last amended 31 July 2009).

Sections 16a and 49a read as follows:

[*] Dr. Oliver Werner - German Patent and Trade Mark Office (DPMA).

Section 16a
(1) An application for supplementary protection for the patent can be filed pursuant to the provisions set out in the Regulations of the European Communities concerning the creation of supplementary protection certificates, reference to which shall be made in the Federal Law Gazette, which supplementary protection shall follow immediately upon expiry of the patent in accordance with section 16. Annual renewal fees shall be paid for supplementary protection.
(2) Unless otherwise provided by the law of the European Communities, the provisions of this Act regarding the applicant's entitlement (sections 6 to 8), regarding the effect of the patent and the exceptions thereto (sections 9 to 12), regarding an order for use and the compulsory licence (sections 13 and 24), regarding the extent of protection (section 14), regarding licences and their registration (sections 15 and 30), regarding the lapse of the patent (section 20), regarding revocation (section 22), regarding the willingness to grant a licence (section 23), regarding representatives in Germany (section 25), regarding the Federal Patent Court and proceedings before the Federal Patent Court (sections 65 to 99), regarding proceedings before the Federal Court of Justice (sections 100 to 122a), regarding the re-establishment of rights (section 123), regarding the obligation to tell the truth (section 124), regarding electronic documents (section 125a), regarding the official language, notifications and judicial assistance (sections 126 to 128), regarding legal infringements (sections 139 to 141a, 142a and 142b), regarding the joinder of actions and arrogation of patent (sections 145 and 146) shall apply mutatis mutandis to supplementary protection.
(3) Licences and declarations made pursuant to section 23 which take effect for a patent shall also apply mutatis mutandis to supplementary protection.

Section 49a
(1) If the person registered as the proprietor of the patent applies for supplementary protection, the Patent Division shall examine whether the application complies with the relevant Regulation of the European Communities as well as with subsection (5) and section 16a.
(2) If the application meets these requirements, the Patent Division shall issue the supplementary protection certificate for the duration of its term. Otherwise, it shall invite the applicant to correct any deficiencies within a time limit of at least two months to be set by the Patent Division. If the deficiencies are not corrected, the Patent Division shall take a decision to refuse the application.
(3) If a Regulation of the European Communities provides for the extension of the term of a supplementary protection certificate, subsections (1) and (2) shall apply mutatis mutandis.
(4) The Patent Division shall take a decision on the requests provided for in Regulations of the European Communities to
1. correct the term of a supplementary protection certificate if the date included in the application for the certificate in respect of the first authorisation for placing the invention on the market is incorrect;
2. revoke the extension of the term of a supplementary protection certificate.
(5) Section 34 (6) shall apply. Sections 46 and 47 shall apply to the procedure before the Patent Division.

Supplementary provisions can be found in Sections 30(1), 81(1), first and third sentences, 142(1) of the Patent Act, Sections 19 to 21 of the Patent Ordinance (*Patentverordnung*), Sections 3(2), 5(2), 7(1) of the Patent Costs Act (*Patentkostengesetz*), Section 2 of the DPMA Ordinance (*DPMA-Verordnung*) and, for European patents, in Article II Section 6a of the Act on International Patent Treaties (*Gesetz über internationale Patentübereinkommen*).

In order to ensure consistent and expeditious examination of SPC applications by the patent divisions of the DPMA and to inform applicants on the application procedure and examination practice, the DPMA has issued "Examination Guidelines for SPCs" (current version as of 23 January 2015; German and English version available at the DPMA website https://www.dpma.de/docs/service/formulare/patent/p2799.pdf; ; https://www.dpma.de/docs/service/formulare_eng/patent_eng/p2799_1.pdf). The following statements in essence summarize the Guidelines, which in most cases contain more detailed information on the respective issues.

4.2 INSTITUTIONAL ASPECTS: THE GRANTING AUTHORITY

The German Patent and Trade Mark Office (DPMA) is the central federal authority in the field of industrial property protection in Germany. It operates within the portfolio of the Federal Ministry of Justice and Consumer Protection (BMJV). The office was originally founded in 1877 and currently employs about 2,500 staff in its headquarters in Munich and its Jena and Berlin branch offices. It is the statutory duty of the DPMA to grant and administer industrial property rights and to provide information to the public on industrial property rights effective in Germany. The DPMA is also an active partner in European and international industrial property systems.

The DPMA is the examining and granting authority for SPCs and paediatric extensions pursuant to Article 9(1) of Regulation (EC) no. 469/2009 (Section 49a Patent Act and Article II Section 6a of the Act on International Patent Treaties).

According to Section 49a(1) and (2) Patent Act, the relevant body within the DPMA is the Patent Division. The Patent Division is a panel consisting of at least three technically qualified members (chair, rapporteur, assessor) and optionally a legally qualified member (Section 27 Patent Act) which takes decisions *inter alia* on the grant of SPCs and paediatric extensions, the correction of term of an SPC, and the revocation of a paediatric extension. The composition of the Patent Division is governed by the IPC heading indicated in the basic patent on which the application for the certificate is based. The rapporteur usually is the patent examiner in charge of the respective IPC heading. Currently about 30 examiners (with varying frequency) are carrying out SPC examinations as members of patent divisions. About 10 additional persons act as chairs (mostly heads of Patent Departments and group leaders).

4.3 FILING OF THE APPLICATION

Applications for certificates must be filed in writing at the DPMA (cf. Art. 9 Regulations, Section 19 in conjunction with Section 4(2) nos. 1, 4 and 5 Patent Ordinance). They cannot be validly filed at a patent information centre because Sections 16a and 49a of the Patent Act do not contain a reference to Section 34(2) of the Patent Act. The form "*Antrag auf Erteilung eines ergänzenden Schutzzertifikats für Arzneimittel/Arzneimittel einschließl. Verlängerung der Laufzeit / Pflanzenschutzmittel*" (form P 2008; https://www.dpma.de/docs/service/formulare/patent/p2008.pdf) must be used for the application.

The DPMA will send an acknowledgement of receipt to the applicant indicating the file number and the date of receipt and will also enclose a copy of the request; the date of receipt is printed on the copy or is shown on the data bar printed onto the bottom of the fax document by the DPMA.

The necessary content of an application for a certificate, which is described in detail in the following sections, is based on Articles 6, 7, and 8 of the Regulations.

4.4 FORMAL EXAMINATION

In the procedure for the grant of a certificate it has to be initially examined whether all formal requirements of the request for the grant of a certificate are met.

Unless otherwise specified, staff of the upper grades of the civil service are responsible for the examination of the application as to (obvious) formal deficiencies, pursuant to the Administration Ordinance (*Wahrnehmungsverordnung*) (Section 1(3) in conjunction with (1) no.1 Administration Ordinance).

These staff can send a letter to the applicants inviting them to rectify the formal deficiency. In the case of extensive and complex deficiencies, the result of the preliminary formal examination will be forwarded to the patent division.

Within the scope of a substantive examination, the patent division must also examine compliance with formal requirements and object to existing deficiencies, if any.

The individual formal requirements of an application for a certificate are:

a) Name and address of the applicant and – if a representative is appointed – of the representative (Art. 8(1)(a)(i), (ii) of the Regulations)
b) Number and title of the basic patent in force at the date of the application (Art. 8(1)(a)(iii) of the Regulations)
c) Number and date of the authorisation(s) (Art. 8(1)(a)(iv) of the Regulations)
d) Copies of authorizations (Art. 8(1)(b) and (c) of the Regulations)
e) Title of the product for which protection is sought
f) Information explaining the protection provided by the basic patent for the product
g) Payment of application fee (Art. 8(2) Regulation (EC) no. 1610/96 and Art. 8(4) Regulation (EC) no. 469/2009 in conjunction with Section 2(1) Patent Costs Act)
h) Observance of time limits for lodging an application (Art. 7 of the Regulations)
i) Entitlement to file an application (Art. 6 of the Regulations)

Ad b)

Staff of the upper grades of the civil service will check whether the basic patent, indicated in the request, was in force in Germany at the time when the application for the certificate was filed.

Ad c) and d)

The application must also contain the number and the date of the first valid authorisation (national or central) to place the product on the market in Germany (hereinafter referred to as "authorisation"; form P 2008: field 8). Pursuant to applicable case law, the date of notification of the decision shall be considered the relevant date for all types of authorizations (CJEU C-471/14 *Seattle Genetics*).

If an authorisation for placing the product on the market was already granted in an EU or EEA member state before the first authorisation in Germany, the number and the date of the first authorisation in the EU or the EEA must be given (form P 2008: field 9). Furthermore, information regarding the identity of the authorised product and the

legal provision which governed the authorisation procedure must be stated (compare form P 2008: annexes 2 and 3 in field 12).

A copy of the authorisation to place the product on the market in Germany must be filed (form P 2008: annex 1 in field 12). For an authorisation for the identical product in a member state of the EU or EEA that was granted earlier than the German authorisation, only a copy of the notice publishing the authorisation in the appropriate official publication must be filed under Article 8(1)(c) of the Regulations (form P 2008: annex 4 in field 12).

Ad e) and f)

In the request form the applicant must indicate the product for which the grant of the SPC is sought (form P 2008: field 7).

The title of the product should be directed to the name of the active ingredient or combination of active ingredients resulting from the valid authorisation to place the product on the market. Combinations of active ingredients should be phrased as "component 1 with component 2". The German names of active ingredients/substances shall be indicated for medicinal products as well as for plant protection products.

The name of the active ingredient or names of the active ingredients in the German authorisation to place the medicinal product on the market is/are usually indicated in the section "*arzneilich wirksame Bestandteile*" or "*qualitative und quantitative Zusammensetzung*" according to the annex to the marketing authorisation and in a European authorisation at section "qualitative and quantitative composition" in annex I (Summary of product characteristics). If the name of the active substance of the plant protection product cannot be derived from the text of the authorisation, the text of the Register of Plant Protection Products (*Pflanzenschutzmittelverzeichnis,* published by the Federal Office of Consumer Protection and Food Safety) can be used alternatively.

Notably, an SPC can be granted for a product that covers the active ingredient as such as well as its various derived (chemical) forms (e.g. salts and esters) where only one of its possible forms is covered by the marketing authorisation provided that these forms are also protected by the basic patent (cf. CJEU C-392/97 *Farmitalia* and Federal Court of Justice, NJW 2000, p. 1723 et seqq. – *Idarubicin II*).

Since the product has to be protected by a basic patent that is in force at the time of filing the application for a certificate pursuant to Article 3(a) of Regulation (EC) no. 469/2009 or Article3(1)(a) of Regulation (EC) no. 1610/96, a seamless documentation explaining the correlation between the authorised product and the text passage in the patent specification must be furnished as annex to the request for the grant of an SPC (annex 6 in field 12) showing the protection afforded by the patent for this product (cf. Section 19(2) Patent Ordinance). Typically, it is useful and necessary to furnish copies of documents, namely

- from chemical or pharmaceutical standard publications showing the relationship between the chemical or the biological structure and the international non-proprietary name (INN) or the "common name",
- from official publications or documents clearly identifying the product covered by the authorisation (for plant protection products, for example, an excerpt

from the Register of Plant Protection Products published by the Federal Office of Consumer Protection and Food Safety),
- a copy of the relevant passages of the granted basic patent.

Ad g)

Where the application fee is not paid upon filing the application, the DPMA will set a time limit for payment of the fee. This time limit shall be at least two months (Art. 10(3) Regulations in conjunction with Section 49a(2), second sentence, Patent Act). If the time limit expires without response, the DPMA will reject the application (Art. 10(4) Regulations).

Ad h)

Article 7 of the Regulations prescribes periods for lodging an application for a certificate.

In this respect, two cases must be distinguished:

a) Where the basic patent is granted before the authorisation to place the product on the market, the period for lodging an application for a certificate is six months from the date of the authorisation in Germany.
b) Where the authorisation to place the product on the market in Germany is granted before the grant of the patent, the period for lodging an application for a certificate is six months from the date of the grant of the patent.

Pursuant to applicable case law (CJEU C-471/14 *Seattle Genetics* and CJEU C-127/00 *Hässle)*, with regard to case (a), the date of notification of the authorisation is considered the date from which the period starts.

According to the office's current practice with regard to case (b), the publication date of the grant in the German Patent Gazette or the European Patent Bulletin is considered the date from which the period starts. Usually, this date is printed on the first page of the patent specification following the INID code (45).

Compliance with these time limits is monitored through staff of the upper grades of the civil service.

Ad i)

Pursuant to Article 6 of the Regulations, only the holder/s of the basic patent or their successor/s in title can file an application for a certificate, because only this/these person/s has/have the right to the supplementary protection certificate.

Staff of the upper grades of the civil service also examine whether this formal requirement for an application for a certificate is met and in case of failure to meet this requirement, a deficiency letter is sent to the applicant.

In case of filing an application for an SPC extension, similar requirements are examined. Additional ones regard in particular:

a) Reference to a pending SPC application or granted certificate (Art. 8(2) and 8(3) of Regulation (EC) no. 469/2009)

b) Copy of the compliance statement (Article 8(1)(d)(i) of the Regulation (EC) no. 469/2009)
c) Proof of marketing authorisation in all member states (Article 8(1)(d)(ii) of Regulation (EC) no. 469/2009)
d) No Orphan Market Exclusivity or extended Regulatory Data Protection (Article 36(3) and (4) of Regulation (EC) No 1901/2006)

Ad j)

Where an application for a certificate is pending, an application for an extended duration shall include a reference to the pending application for a certificate (Art. 8(2) Regulation (EC) no. 469/2009).

Where a certificate has already been granted, the application for an extension of the duration of a certificate shall contain a copy of the decision of the certificate already granted (Art. 8(3) Regulation (EC) no. 469/2009).

Ad k) and l)

Pursuant to Article 8(1)(d)(i) of Regulation (EC) no. 469/2009, the request for an extension of the duration shall include a copy of the statement indicating compliance with an agreed completed paediatric investigation plan as referred to in Article 36(1) of Regulation (EC) No 1901/2006. The statement indicating compliance cannot be replaced by an opinion of the Paediatric Committee pursuant to Article 23(2) of Regulation (EC) No 1901/2006.

Pursuant to Article 8(1)(d)(ii) of Regulation (EC) no. 469/2009, proof shall be filed of possession of authorisations to place the product on the market in all other member states, as referred to in Article 36(3) of Regulation (EC) No 1901/2006.

If documents k) or l) are (partially) missing at the time of filing, the applicant is invited to file the documents within a fixed period set by the office. This period may be extended upon request until the time limit given in Art.7 (4) of Regulation (EC) no. 469/2009. If documents have not been issued by the respective authorities at the time of filing, the applicant has to prove that he has made every effort to obtain the documents and that he could have expected to receive the documents, if the procedure would have been completed by the respective authorities within the prescribed time limits. The documents have to be filed at latest at a time point, which allows a final decision before the expiry of the SPC.

No extension of the duration can be granted with documents missing at the time of grant.

Ad m)

The medicinal product shall not be designated as an orphan medicinal product pursuant to Regulation (EC) no. 141/2000 (cf. Art. 36(4), second sentence, Regulation (EC) No 1901/2006) and the applicant must not have applied for, nor obtained, a one-year extension of Regulatory Data Protection for the medicinal product concerned (cf. Art. 36(5) Regulation (EC) No 1901/2006).

If a corresponding self-declaration by the applicant is ticked on the form, this will be accepted by the DPMA.

4.5 SUBSTANTIVE EXAMINATION

Applications for a certificate should, if possible, be handled in such a way that an intermediate office action or the decision on grant will be provided within eight months after receipt of the request for grant of a certificate. The decision on the request for grant of a supplementary protection certificate shall be taken, if possible, before the expiry of the basic patent to avoid a delay in the certificate becoming effective.

Substantive examination at the DPMA includes an assessment of compliance with the requirements of Articles 3(a), 3(b), 3(c), and (to a limited extent) 3(d).

4.5.1 Article 3(a)

Pursuant to Article 3(a) of Regulation (EC) no. 469/2009 or Article 3(1)(a) of Regulation (EC) no. 1610/96, the product for which an application for the grant of a certificate is filed, must be protected by a basic patent in force at the date of filing the application for a certificate. That means that the basic patent must not have lapsed, withdrawn or declared invalid at the time of filing the application for the certificate. Even where the marketing authorisation has been granted only after the lapse of the basic patent, an application for a certificate cannot be filed. Usually, the staff of the upper grades of the civil service in charge of the matter will check whether the basic patent indicated in the application for the certificate was in force in Germany, at the time of filing the application for the certificate.

The patent division must perform an additional examination of the legal status or procedural status of the basic patent concerned by inspecting the respective patent registers (DPMAregister; European patent register).

At the time of the grant of the certificate, it should be considered and verified, with regard to the grounds of invalidity stated in Article 15(1)(b) of the Regulations that the basic patent has not lapsed before its lawful term expires. In that case, the application must be rejected.

However, if, after the regular expiry of the term of the patent, the basic patent is no longer in force at the date of the grant of the certificate, it is nevertheless possible to grant a certificate.

If the outcome of pending opposition, limitation or revocation proceedings, if any, in respect of the basic patent is known when the certificate is granted this shall also be taken into consideration. This may retroactively affect the scope of protection of the basic patent to such extent that the scope of protection no longer covers the authorised product. In that case, the application for the certificate shall be rejected due to non-compliance with the requirement of Article 3(a) of Regulation (EC) no. 469/2009 or Article 3(1)(a) of Regulation (EC) no. 1610/96, as the case may be. The same applies in case of the revocation of the basic patent. A certificate may be granted in spite of opposition, limitation and revocation proceedings if these proceedings have not yet been completed.

Where the product is protected by several patents (for example, product patent or process patent) the applicant himself may decide which patent to choose as the basic patent.

The basic patent, on which protection is based, may be a process patent, use patent or product patent (substance patent or product patent).

For the examination of the requirement of Article 3(a) of Regulation (EC) no. 469/2009 or Article 3(1)(a) of Regulation (EC) no. 1610/96, the extent of protection in accordance with Section 14 of the Patent Act shall be taken into consideration for German basic patents and the extent of protection in accordance with Article 69 of the European Patent Convention (EPC) in conjunction with the Protocol on the Interpretation of Article 69 of the EPC shall be taken into consideration for European patents taking effect in the territory of the Federal Republic of Germany.

In its decisions in the cases *Medeva* (CJEU C-322/10 *Medeva*) and *Georgetown* (CJEU C-484 *Georgetown*) the CJEU has clarified that a supplementary protection certificate in accordance with Article 3(a) of Regulation (EC) no. 469/2009 can be granted only for those active ingredients which are specified in the wording of the claims of the basic patent.

In order to fulfil this requirement it is not necessary for the active ingredient to be identified in the claims of the patent by a structural formula (CJEU C-493/12 *Eli Lily/Human Genome Sciences*). On condition that it is possible to reach the conclusion on the basis of the claims, interpreted *inter alia* in the light of the description of the invention, that the claims relate, implicitly but necessarily and specifically, to the active ingredient in question, it suffices where the active ingredient is covered by a functional or general structural formula in the claims.

It should be recalled that, in accordance with the case law cited at paragraph 34 of the mentioned judgment, an active ingredient which is not identified in the claims of a basic patent by means of a structural, or indeed a functional definition cannot, in any event, be considered to be protected within the meaning of Article 3(a) of Regulation (EC) no 469/2009 (CJEU C-493/12 *Eli Lily/Human Genome Sciences;* also Federal Patent Court 3 Ni 28/11 *Ranibizumab*, para. I.3.4.).

Due to the lack of clarity of the CJEU case law no further guidelines for the examination of the Article 3a requirement have been issued by the DPMA to date. Decisions are taken on a case by case basis by the respective patent divisions, applying national and CJEU case law.

4.5.2 Article 3(b)

Pursuant to Article 3(b) of Regulation (EC) no. 469/2009 or Article 3(1)(b) of Regulation (EC) no. 1610/96, as appropriate, an authorisation to place the product on the market, valid in Germany at the time of filing the application for a certificate, must have been granted for the product on which the application for the certificate is based.

The application for a supplementary protection certificate can validly be made only after a valid marketing authorisation has been issued (CJEU C-210/12 S*umitomo Chemical/DPMA*). This requirement has to be fulfilled at the filing date of the application and cannot be corrected after filing.

During examination of the furnished authorisations it must be confirmed that these authorisations were granted according to the European Directives mentioned in Article 3(b) of Regulation (EC) no. 469/2009 or Article 3(1)(b) of Regulation (EC) no. 1610/96 (Directive 65/65/EEC for medicinal products, meanwhile replaced by Directive 2001/83/EC; Directive 81/851/EEC for veterinary medicinal products, meanwhile replaced by Directive 2001/82/EC; Directive 91/414/EEC for plant protection products, meanwhile replaced by Regulation (EC) no. 1107/2009).

Provisional authorisations to place plant protection products on the market, which were granted pursuant to Article 8(1) of the Directive 91/414/EEC (implemented in Section 15c Plant Protection Act [*Pflanzenschutzgesetz*]), are recognised as valid first marketing authorisations (cf. CJEU C-229/09 *Lovells/Bayer*). However, this is not applicable to emergency authorisations to place a product on the market granted under Article 8(4) of the Directive 91/414/EEC (implemented in Section 11(2) Plant Protection Act; cf. CJEU C-210/12 *Sumitomo Chemical/DPMA*).

Pursuant to Article 13(3) of Regulation (EC) no. 1610/96, for the purposes of calculating the duration of the certificate, provisional marketing authorisations are taken into account as first authorisations to place a product on the market in the Community only if they are directly followed by a definitive authorisation concerning the same product. Where no definite marketing authorisation has been furnished, making it impossible to assess whether authorisations seamlessly followed each other, the provisional authorisation shall nevertheless be taken into account for calculating the duration of the certificate in order to take into account the CJEU case law (CJEU C-229/09 *Lovells/Bayer*).

The central marketing authorisations, available for medicinal products, granted pursuant to Regulation (EEC) no. 2309/93 or Regulation (EC) no. 726/2004, and hence also valid in Germany must be considered as first marketing authorisations pursuant to Article 3(b) of Regulation (EC) no. 469/2009.

Article 3(b) of Regulation (EC) no. 469/2009 or Article 3(1)(b) of Regulation (EC) no. 1610/96, as appropriate, stipulates as condition for obtaining a certificate that a valid authorisation to place the product on the market in Germany has been granted at the date of the filing the application. According to the office's current practice, this condition is interpreted to mean that the authorisation actually is in force at the date of filing the application for the certificate and, in particular, has not lost validity by revocation, withdrawal or expiry of the term of the authorisation.

With regard to the reason for the lapse of a certificate, mentioned in Article 14(d) of the Regulations, it must be ensured that the furnished authorisation to place the product on the market in Germany has not been revoked or withdrawn at the date of the grant of the certificate. Otherwise, the application must be rejected. However, the application will not be rejected for the reason that the duration of the authorisation expires after the date of filing the application.

4.5.3 Article 3(c)

Pursuant to Article 3(2), first sentence, of Regulation (EC) no. 1610/96 and recital 17 as well as Article 3(c) of Regulation (EC) no. 469/2009 or Article 3(1)(c) of Regulation (EC) no. 1610/96, a certificate for the identical product must not have already been

granted in Germany to the same applicant. If the same applicant applies for several certificates for the same product, he can only receive one certificate even though he possesses and indicates various patents as basic patents (Art. 3(2), first sentence, Regulation (EC) no. 1610/96 and recital 17).

However, where two or more applications concerning the same product and emanating from two or more holders of different basic patents are pending, one certificate for this product may be issued to each of these holders (Art. 3(2), second sentence, Regulation (EC) no. 1610/96) even though a certificate for that product has already been granted (see CJEU C- 482/07 *AHP Manufacturing*).

It is possible, on the basis of a patent which protects several different products, to obtain several supplementary protection certificates in relation to each of those different products, provided that each of those products is protected as such by that basic patent (CJEU C-484/12 *Georgetown University/Octrooicentrum Nederland*; CJEU C-443/12 *Actavis/Sanofi*).

For example, on the basis of this patent and the marketing authorisation for a medicinal product which is a combination of active ingredients, the holder of a basic patent may be granted a supplementary protection certificate for this combination of active ingredients as well as for one of those active ingredients which, individually, is also protected as such by the that patent (CJEU C-484/12 *Georgetown University/Octrooicentrum Nederland*).

In contrast, 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 an innovative active ingredient, this holder may not be granted a second supplementary protection certificate on the basis of that same patent but a subsequent marketing authorisation for a different medicinal product containing that active ingredient in combination with another active ingredient which is not protected as such by the patent (see CJEU C-443/12 *Actavis/Sanofi*; Federal Patent Court 3 Ni 5/13 *Telmisartan*).

For identification, the definitions of the product stated in Article 1 of the Regulations must be taken into account.

A search for certificates that have already been granted must be conducted at least in the special internal DPMA database of supplementary protection certificates for medicinal and plant protection products *(Fachdatenbank für Arzneimittel- und Pflanzenschutzmittelzertifikate [SPC]).* Alternatively, a search may be carried out in INPADOC and INPAFAM databases of STN.

According to the office's current practice, the date stated in the decision on grant by the patent division is deemed the day of the grant of the certificate.

4.5.4 Article 3(d)

Pursuant to Article 3(d) of Regulation (EC) no. 469/2009 or Article 3(1)(d) of Regulation (EC) no. 1610/96, a certificate shall be granted only if the furnished authorisation to place the product on the market in Germany is the first authorisation for this product in Germany.

The DPMA does not have the verification and search options required for a comprehensive verification of this condition. Since it is not possible in Germany to waive the verification of this condition, as laid down in Article 10(5) of the Regulations, verification has at least to be carried out as far as it is feasible. In view of the applicant's obligation to tell the truth it is generally assumed that the respective statements of the applicant are accurate.

However, if any evidence or information is found that challenges the statements of the applicant, it has to be considered and clarified during the course of the procedure. Information on an earlier first marketing authorisation of the product is available in the relevant authorisation lists (for example, Rote Liste®, website of the European Medicines Agency [EMA], website of the Federal Institute for Drugs and Medical Devices, website of Paul-Ehrlich-Institut, website of the Federal Office of Consumer Protection and Food Safety, Register of Plant Protection Products).

According to current case law, products containing identical active substances and which only differ with regard to the additional adjuvants or the content of active substances should be regarded as identical products within the meaning of the Regulations. Therefore the respective authorisations for these products shall be taken into account as first marketing authorisations.

According to the former office's practice, it was irrelevant for which use of a product the first marketing authorisation was granted (for example, medicinal product for human use or as a veterinary medicinal product; second medical uses; CJEU C-31/03 *Dostinex)*. However the CJEU (CJEU C-130/11 *Neurim*) stated that "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".

Pursuant to the *Neurim* judgment, Article 13(1) of Regulation (EC) no. 469/2009 must be construed as meaning that it relates to the authorisation of a product which falls within the scope of protection of the basic patent to which the application for the supplementary protection certificates refers.

For practical purposes, a "different application" according to *Neurim* is interpreted as a "new medical use" by the DPMA patent departments, which may be equal to a new group of patients that can be treated. In this regard it is possible that the DPMA may accept a new therapeutic indication in a type II variation as a new marketing authorisation for the purposes of Articles 3(b) and 3(d), if the new marketing authorisation required a full application in accordance with Article 8(3) of Directive 2001/83/EC.

4.6 PUBLICATION OF THE APPLICATION

Information regarding the supplementary protection certificates required under the provisions of the Regulations (Art. 9 and 11 Regulations and Art. 17 Regulation (EC) no. 469/2009 or Art. 16 Regulation (EC) no. 1610/96) or due to Section 16a of the

Patent Act in conjunction with the provisions mentioned therein, shall be published in part 7 of the Patent Gazette (*Patentblatt*; application, application for an extension, withdrawal, grant, rejection, revocation, rectification, invalidity and lapse). Since there is no separate register for supplementary protection certificates, they are also recorded in the Patent Register (Section 30(1) Patent Act). These entries have the same extent as the entries for patents or patent applications. Thus, publication is ensured (Section 32(5) Patent Act).

The product protected by the basic patent is published in the Patent Gazette using the INID code (95) when the application is published or the certificate is granted. The designation of the product need not be identical to the product identified by the authorisation.

After the conclusion of the formal examination, the applications or the requests are published in the Patent Gazette. A certificate document similar to the first publication of a patent application (*Offenlegungsschrift*) or to a patent grant is not issued.

Bibliographic and status information is available in an electronic version of the Patent Gazette online via the DPMAregister website (https://register.dpma.de/ DPMAregister/uebersicht). Part 7 of the Patent Gazette is dedicated to SPC information (https://register.dpma.de/DPMAregister/blattdownload/pat?lang=en). Online file inspection of documents is available via the DPMAregister website (https://register.dpma.de/DPMAregister/uebersicht). After searching for a specific file via the search interface https://register.dpma.de/DPMAregister/pat/einsteiger? lang=en) press the button "file inspection" at the bottom of the results page.

4.7 THIRD PARTY OBSERVATIONS

Section 16a does not explicitly refer to Section 43(3) German Patent Act, which deals with third party observations. But since the DPMA follows the principle of *ex officio* examination, third party observations have to be taken into account on a regular basis.

In the course of examination the applicant is provided with a copy of any observations that are filed by a third party and he is invited to comment on the observations. The patent division may use these observations, when asking the applicant to correct deficiencies of the application, but is not obliged to discuss it, when granting an SPC or SPC extension.

By filing observations, the third party does not become a party to the proceedings.

4.8 GRANT / REFUSAL PROCEDURE

4.8.1 Intermediate communication

If the application for a certificate does not meet the requirements of the Regulations and Section 16a of the Patent Act, the patent division shall invite the applicant, pursuant to Section 49a(2), second sentence, of the Patent Act, to correct any deficiencies within a time limit of at least two months to be set by it. The period may

be extended upon a request by the applicant stating the reasons. For reasons of legal certainty, this must be done in writing. Hence, an intermediate communication must be issued.

The number of intermediate communications is determined by the obligation to clarify the facts, to grant the right to be heard and the special circumstances of each individual case.

The intermediate communications must be drafted in a neutral and clear style. The formal and substantive deficiencies must be noted so concretely that the applicant is not left unclear as to what kind of deficiency has been noted.

The intermediate communications serve to prepare the grant of a certificate or the rejection of the application for a certificate pursuant to Section 49a of the Patent Act. In case that the rejection of the application for a certificate is intended, this possibility will be pointed out in the intermediate reply.

The intermediate communication can also be issued by the reporting examiner alone. In this case, this must be noted in the records.

4.8.2 Hearing

Pursuant to Section 49a(5), second sentence, of the Patent Act, Section 46 of the Patent Act (further examination, hearing, minutes) shall apply *mutatis mutandis* to the examination procedure for certificates before the patent division. The patent division may summon and hear the parties at any time, may examine witnesses, experts and parties and may undertake further examination as necessary to examine the matter.

Generally, a hearing can be expedient for conducting the procedure speedily. However, deficiencies regarding the application requirements and conditions for the grant of a certificate may as a rule be noted and rectified in the procedure conducted in writing.

The hearing is chaired by the head of the patent division; the hearing is not public. Third parties may only attend the hearing with the consent of the applicant.

The applicant shall be heard upon request (Section 46(1), second sentence, of the Patent Act shall apply *mutatis mutandis*). The request must be submitted in writing. If the request is not submitted in the requisite form, the request will be refused (Section 46 (1), fourth sentence, of the Patent Act shall apply *mutatis mutandis*). The decision to refuse the request is not independently contestable.

Minutes shall be drawn up of the hearings (and taking of evidence, if any) by a member of the patent division or a recording clerk. The minutes contain the essentials of the proceedings and the relevant statements made by the parties. Sections 160a, 162 and 163 of the Code of Civil Procedure shall apply *mutatis mutandis* (Section 49a(5), second sentence, Patent Act in conjunction with Section 46(2), second sentence, Patent Act). The following, *inter alia*, shall be included in the minutes: place, date, persons attending, course of the hearing, new circumstances and aspects as far as necessary to understand the course of the hearing or are conducive to the grant of the right to be heard and the relevant statements made by the parties. The latter comprises everything substantively altering the subject matter of the application (for

example, the product) or affecting the procedure, for example, all requests, amendments to requests and withdrawals of requests.

The provisions of the guidelines of the opposition proceedings shall apply *mutatis mutandis* to the minutes.

As a rule, the decision of the patent division on the application should be taken at the end of the hearing. The decision as well as the operative part of the decision taken shall be included in the minutes of the hearing.

When delivering the decision, it is sufficient to announce the operative part of the decision and to refer to the written statement of grounds (Section 49a(5), second sentence, Patent Act in conjunction with Section 47(1), second sentence, Patent Act). If the chair considers it appropriate, he may also give an oral statement on the essential contents of the grounds. Any inconsistencies between the written statement of grounds and the orally communicated grounds are non-prejudicial, but should be avoided, if possible.

The written statement of grounds shall be executed without delay and the complete decision shall be served in an execution copy.

The DPMA is bound by the decision delivered. Written pleadings received after the decision was delivered must not be taken into consideration – except later, in the case that an appeal is allowed.

4.8.3 Decision to grant the certificate

If the application for the certificate complies with the Regulations as well as Section 16a of the Patent Act, the patent division shall decide to grant the certificate for the duration of its term and, if appropriate, its extension pursuant to Section 49a of the Patent Act.

In analogy to opposition proceedings, the decision shall be taken in a session or in lieu of a session by way of a written procedure. If a session is held, the form P 2543 "*Sitzungsprotokoll*" (minutes of session) shall be completed.

The decision need not be reasoned if the single request or the main request of the applicant is granted. However, a decision shall be reasoned if it falls short of the request of the applicant, for example, if only a subsidiary request is allowed. A statement of grounds is required, in particular, where the certificate is granted according to the request, but an extension of the duration applied for, if any, is not granted.

The decision must be executed in writing and served on the applicant (Section 49a(5), second sentence, Patent Act in conjunction with Section 47 Patent Act).

The decision to grant a supplementary protection certificate shall contain: the product (active ingredient/substance or combination of active ingredients/substances) identified by the marketing authorisation pursuant to the Regulations, the name of the holder of the certificate, the file number of the basic patent, number and date of the above-mentioned marketing authorisation as well as the first authorisation to place

the product on the market in the Community as well as the duration of the certificate and the period of extension of the duration, if any.

Furthermore, a declaration instructing the applicant on the possibility to appeal shall be attached (Section 49a(5), second sentence, in conjunction with Section 47(2) Patent Act).

The grant is published in the Patent Gazette.

4.8.4 Decision to reject the application

The patent division shall reject the application for a certificate pursuant to Section 49a(2), third sentence, of the Patent Act, if the application does not comply with the Regulations as well as Section 16a of the Patent Act. The applicant shall be given sufficient opportunity to be heard.

In analogy to opposition proceedings, the decision shall be taken in a session or in lieu of a session by way of a written procedure. If a session is held, the form P 2543 shall be completed.

The decision to reject the certificate shall be reasoned, executed in writing and served on the applicant *ex officio*, pursuant to Section 49a(5), second sentence, in conjunction with Section 47(1) of the Patent Act. In accordance with Section 47(2) of the Patent Act, the written execution copy shall be accompanied by a declaration instructing the applicant about the possibility to appeal.

In case that decisions must be taken on several requests (main request and subsidiary requests) in an application for a certificate, one decision on all requests shall be taken in analogy to the patent examination procedure and the opposition proceedings. This decision shall contain the rejection of the main request and the subsidiary requests as well as, if appropriate, the grant pursuant to a subsidiary request.

4.9A. CALCULATION OF THE PATENT AND SPC DURATION

Pursuant to Section 16 of the Patent Act the patent term is 20 years beginning with the day following the application and ending on the same day as the application (Sections 186 and 188 German Civil Code). So e.g. a patent filed on 15 October 2015 ends on 15 October 2035. This calculation is in line with Rule 131 EPC.

The start date of an SPC in the example above would be 16 October 2035, the maximum expiry date (five years) 15 October 2040, with paediatric extension 15 April 2041.

Pursuant to Article 13 of the Regulations, the certificate takes effect at the end of the lawful term of the basic patent for a period equal to the period which elapsed between the date on which the application for a basic patent was lodged and the date of the first authorisation to place the product on the market in the Community, reduced by a period of five years. The maximum duration of the certificate may not exceed five years.

For calculating the duration, the period between the filing date of the basic patent and the date of issuance of the grant of the first marketing authorisation in the Community is calculated first. This period is reduced by a period of five years resulting in the residual period pursuant to Article 13(1) of the Regulations. Then the duration that may be granted for the certificate can be calculated, bearing in mind that the maximum duration is five years (Art. 13(2) Regulations). For the calculation, the years will always be determined first, then the months and at last the days. Years and months are to be understood as whole units regardless of the actual number of days. In contrast, the calculation at day level must be based on the actual number of days of the respective month. The beginning of the duration of the certificate is always the first day after the end of the lawful term of the basic patent.

In its *Merck* judgment the CJEU clarified that the grant of a certificate cannot be rejected by reason only of the fact that the duration determined in accordance with the calculation rules laid down in Article 13(1) of Regulation (EC) no. 469/2009 is not positive (CJEU C-125/10 *Merck*). The reason for this is a possible paediatric extension pursuant to Article 13(3) of Regulation (EC) no. 469/2009. The period of the paediatric extension 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 lodging the patent application and obtaining the first marketing authorisation (CJEU C-125/10 *Merck*).

All authorisations granted in the member states of the EU or in a state party to the Agreement on the European Economic Area, Norway, Iceland or Liechtenstein, are regarded as a first authorisation to place the product on the market in the Community. This also applies to Swiss authorisations due to their recognition in Liechtenstein. The transitional provisions of Articles 19 to 22 of Regulation (EC) no. 469/2009 or Articles 19 and 20 of Regulation (EC) no. 1610/96, as appropriate, apply to the first authorisations to place a product on the market in the Community in the new EU member states before their accession to the EU.

Provisional authorisations to place a product on the market as a plant protection product, granted under Article 8(1) of the Directive 91/414/EEC (implemented in Section 15c Plant Protection Act), are recognised as valid first authorisations within the meaning of Article 3(1)(b) of Regulation (EC) no. 1610/96 (CJEU C-229/09 *Lovells/Bayer*). To take account of this judgment, a certificate must be granted even where a definite authorisation has not yet been issued. In that case, the calculation of the duration must be based on the provisional marketing authorisation.

If a request for the extension of the period has been received together with the request for the grant of a certificate for a medicinal product, the former has to be considered for calculating the duration. The periods laid down in Article 13(1) and (2) of Regulation (EC) no. 469/2009 will be extended by six months in the case where Article 36 of the Regulation (EC) No 1901/2006 applies. The months are treated as whole units. If, for example, the certificate ends on 31 August it will be extended by six months to 28/29 February of the following year. However, the period laid down in Article 13(1) of Regulation (EC) no. 469/2009 may be extended only once.

The beginning and the end of the term must be indicated in the decision to grant the certificate pursuant to Section 49a(2), first sentence, of the Patent Act.

4.9B. CALCULATION OF TERMS; RELIEF BEFORE THE DPMA FOR MISSED DEADLINES

Terms are calculated at the DPMA according to Section 222(1) of the German Civil Procedure Code with Section 187 et seqq. of the German Civil Code, which corresponds to Rule 131 EPC. The sole difference lies in Section 193 German Civil Code, which states that if a declaration of intent is to be made or an act of performance to be done on a particular day or within a period, and if the particular day or the last day of the period falls on a Sunday, a general holiday officially recognised at the place of the declaration or performance, or on a Saturday, the next day takes the place of this day.

In case of a paediatric extension, the latest date for filing the application for an extension of the duration is two years before expiry of the certificate. The period has to be calculated backwards. It ends at the beginning (0:00) of the day of the year before the previous year whose date is equivalent to the day when the certificate expires.

Example:

If the duration of the certificate ends on 14 September 2025, the application for an extension must have been lodged by 0:00 on 14 September 2023.

The re-establishment of rights for a failure to comply with a time limit, which cause a legal disadvantage (e.g. in respect of the six-month period for filing the application or in respect of the period for payment of the annual fee) is possible pursuant to Sections 16a(2) and 123 of the Patent Act under the conditions mentioned in these provisions.

Although Section 16a(2) of the Patent Act lacks a corresponding reference, further processing is possible in case of a failure to comply with a time limit fixed by the office due to legal similarity by applying Section 123a of the Patent Act *mutatis mutandis*.

It is noted that all substantive requirements, as specified in Article 3 of the Regulations, must be satisfied at the time of filing and no re-establishment of rights or further processing is possible in these cases.

For missing documents in an application for a paediatric extension according to Article 8(1)(d) of Regulation (EC) no. 469/2009 see section 4, letters k, l above.

4.10 APPEAL PROCEDURE

Pursuant to Section 73(1) of the Patent Act in conjunction with Section 16a(2) of the Patent Act, the decisions of the patent divisions may be appealed.

Appeals are possible against decisions by the DPMA regarding

a) a rejection of an SPC application,
b) a rejection of an application for the extension of the duration, (both Art.10 Reg. (EC) no. 469/2009),

c) a decision on the revocation of an extension of the duration (Art.16 Reg. (EC) no. 469/2009), or
d) a decision on the correction of the duration of an SPC (Art. 17(2) Reg. (EC) no. 1610/96).

The applicant for a certificate or the holder of the certificate shall be entitled to appeal.

The appeal shall be filed in writing with the DPMA within one month of service of the decision (Section 73(2), first sentence, Patent Act in conjunction with Section 16a(2) Patent Act). An appeal fee pursuant to the Patent Costs Act is due upon filing the appeal. If the appeal fee is not paid within the time limit for filing an appeal, the appeal is deemed not to have been filed (Sections 2, 3, 6 Patent Costs Act).

The patent division shall examine whether an appeal received is admissible (filing in the due form and within the prescribed time limit) and well-founded. If it regards the appeal as well-founded, it shall rectify the decision (Section 73(3) Patent Act in conjunction with Section 16a(2) Patent Act).

A decision can be rectified only if the grounds for the rejection outlined by the patent division do no longer exist, e.g. because the reasons provided in support of the appeal convinced the patent division of the other opinion or because the requested amendments have been made. If the decision is rectified, the patent division may order that the appeal fee be reimbursed (Section 73(3), second sentence, Patent Act).

Reimbursement of the appeal fee shall be ordered if, due to particular circumstances, it would not be equitable to retain the fee. This is the case, if an obvious error of the DPMA prompted the appellant to file an appeal.

If the decision is not rectified, the appeal shall be remitted to the Federal Patent Court within one month and without comment as to its merits (Section 73(3), third sentence, Patent Act), even if the submission of further documents has been announced.

Invalidity actions against granted SPCs can also be brought to the Federal Patent Court. Appeals against decisions by the Federal Patent Court are possible with the Federal Supreme Court (*Bundesgerichtshof*, BGH).

4.11 ARTICLE 17(2)

Pursuant to Article 17(2) and recital 17 of Regulation (EC) no. 1610/96 the decisions to grant the certificate are open to an appeal aimed at rectifying the duration of the certificate (of the certificate for a medicinal product extended by six months, if appropriate) if the date, which is indicated in the application for a certificate pursuant to Article 8 of the Regulations, of the first authorisation to place the product on the market in the Community is incorrect.

Section 49a(4) no. 1 of the Patent Act prescribes that, for Germany, the decision on the request to correct the duration of a supplementary protection certificate shall be taken by the patent division. The request may be filed any time before the expiry of the SPC and by any person. The proceedings may be conducted in an adversarial manner.

4.12 ENFORCEMENT OF THE SPC

The protection provided by an SPC may be enforced by action for infringement as if the SPC were a patent. Consequently infringement proceedings must be started at a Regional Court (*Landgericht*), with subsequent appeals possible to a Higher Regional Court (*Oberlandesgericht*) and the Federal Supreme Court (*Bundesgerichtshof*).

Typical venues for infringement proceedings are e.g. the Düsseldorf, Munich and Mannheim Regional Courts.

5 HUNGARY

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5.1 INTRODUCTION: THE SOURCES OF LAW

Hungary is an EPC Contracting State, as well as a Member of the TRIPS Agreement, the PCT and the PLT. Hungary takes part in the enhanced cooperation in the area of the creation of unitary patent protection[76] and has signed but not yet ratified the UPCA.

Although Hungary is not a Member of the Strasbourg Convention, the domestic provisions are consistent with the substantive provisions of the latter Convention, since they have been harmonised with the EPC.

Patents are regulated under Act No XXXIII of 1995 on the Protection of Inventions by Patents.[77] SPCs are referred to in Article 22/A of Act No XXXIII, which establishes the mandate of drafting specific legislation for the implementation of Article 19 of Regulation 469/2009/EC and Article 18 of Regulation 1610/96/EC. This mandate has been accomplished through Government Decree No 26 of 2004 (II. 26.) on the rules necessary for the implementation of the European Community Regulations concerning the supplementary protection for certain products.[78]

The scope of protection of national patents[79] and the rights conferred by such patents[80] [81] are regulated by provisions with similar wording to that of Article 69 EPC and Article 28 TRIPS Agreement respectively.

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[76] See Regulation (EU) 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 L361/1.

[77] Consolidated text (01.01.2017) available at: < https://www.sztnh.gov.hu/sites/default/files/patent_act_xxxiii_1995_en_20170617_ footnotes.pdf>.

[78] Consolidated text (08.05.2014) available at: <https://www.sztnh.gov.hu/English/jogforras/26_2004_Kr_SPC_EN.pdf>.

[79] Act No XXXIII, Article 24(1): 'The scope of protection conferred by a patent shall be determined by the claims. The claims shall be interpreted on the basis of the description and the drawings'.

[80] Act No XXXIII, Article 19:
(1) Patent protection shall afford the holder of the patent (patentee) the exclusive right to exploit the invention.
(2) On the basis of the exclusive right of exploitation, the patentee shall be entitled to prevent any person not having his consent
(a) from making, using, putting on the market or offering for sale a product which is the subject matter of the invention, or stocking or importing the product for such purposes;
(b) from using a process which is the subject matter of the invention or, where such other person knows, or it is obvious from the circumstances, that the process cannot be used without the consent of the patentee, from offering the process for use;
(c) from making, using, putting on the market, offering for sale or stocking or importing for such purposes a product obtained directly by a process which is the subject matter of the invention.

[81] Please note that the so-called Bolar exemption and the private use exemption are foreseen by this provision. The preparation for individual cases, in a pharmacy, of a medicine in accordance with a medical prescription, or acts concerning the medicine so prepared also constitute an exception to the rights conferred under Article 19 of Act No XXXIII.

The requirements for patentability are essentially the same as those of the EPC.[82] The same is true regarding the requirement of sufficiency of disclosure[83] and the possibility of amendment of the patent application.[84]

5.2 INSTITUTIONAL ASPECTS

The Hungarian Intellectual Property Office (hereinafter HIPO) is the government office for the protection of intellectual property and has competence in patent matters[85] and also proceeds in matters relating to SPCs provided for in Government Decree No 26 of 2004.[86] The HIPO covers its operational costs from its own incomes and is entitled to manage them independently and use them to cover its operational costs.

The incomes of the Office consist of the fees for administrative services, the maintenance and renewal fees, the fees and shares for administrative activities carried out by the Office on the basis of the international treaties administered by the WIPO, and shares from fees paid for the European Union or other regional industrial property protection with a unitary effect extending to the territory of Hungary; taking into account the tasks performed by the Office, the income from services provided by the Office, as well as other sources of income.[87]

Applicants have the possibility of applying for a national patent before the HIPO pursuant to Act No XXXIII or for a European patent before the EPO under the EPC rules. In addition, the HIPO can act as receiving office for patent applications filed under the PCT procedure.[88]

The examiners of the HIPO have a technical background[89] and perform substantive examination of patent applications at the request of the applicant, which must be filed either simultaneously with the filing of the patent application or, at the latest, within six months after the date of the official information on the performance of the novelty search.[90] An examination fee prescribed by specific legislation must be paid within two months from the filing of the request for substantive examination.[91]

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82 Act No XXXIII, Articles 1 to 6.

83 ibid, Article 60(1): 'A patent application shall disclose the invention in a manner sufficiently clear and detailed for it to be carried out by a person skilled in the art on the basis of the description and the drawings…'

84 ibid, Article 72:
(1) A patent application may not be amended in such a way that, by introducing new subject matter, it contains subject matter which extends beyond the content of the application at the date of filing.
(2) The applicant shall be entitled to amend the description, claims and drawings as laid down in paragraph (1) until the day on which the decision on the grant of the patent is delivered.

85 In accordance with the provisions of the Act on the General Rules of Public Administration Procedures and the Act on the General Rules of Electronic Administration and Trust Services. See Act No XXXIII, Article 45(1).

86 Act No XXXIII, Article 44, in conjunction with Decree No 26/2004, Article 2.

87 Act No XXXIII, Articles 115/D and 115/E.

88 ibid, Article 45(6).

89 MPI's Questionnaire for National Patent Offices of the EU Member States, answer to question No 54 by the HIPO.

90 Act No XXXIII, Articles 74 and 75.

91 ibid, Article 75(3).

5.3 FILING AND EXAMINATION OF THE SPC APPLICATION[92]

An SPC application must be filed by the patent holder[93] before the HIPO and in Hungarian language,[94] within six months of the date of grant of the marketing authorisation[95] referred to in Article 3(b) of Regulation 469/2009/EC or Article 3(1)(b) of Regulation 1610/96/EC, according to the requirements prescribed in Article 8 of the SPC Regulations. In particular, the application must contain:

i. An indication that an SPC is sought, together with the name of the product;[96]
ii. Information identifying the applicant;
iii. The registration number of the basic patent and the title of the invention;
iv. The number and date of the first authorisation to place the product on the market, as referred to in Article 3(b) of Regulation 469/2009/EC and Article 3(1)(b) of Regulation 1610/96/EC and, if this authorisation is not the first authorisation for placing the product on the market in the EEA, the number and date of that authorisation.

The SPC filing date will be the date on which the application is filed before the HIPO containing all the aforementioned documentation.[97]

A filing fee, determined by special legislation,[98] must be paid within two months of the SPC filing date. If the filing fee is not paid at the date of filing of the application, the HIPO will invite the applicant to rectify this irregularity within the given time limit. In the event of failure to rectify the irregularity, the application will be considered withdrawn.

Following the filing of an SPC application,[99] the HIPO examines whether the application meets the conditions laid down for according a filing date under Article 3(2) of Decree No 26/2004. Where the filing date cannot be accorded, the applicant will be invited to rectify the irregularities within 30 days of the notification of the irregularities to the applicant. If the irregularities are rectified within the time limit, the date of receipt of the rectification of irregularities will be accorded as the filing date. Otherwise, the application will be considered withdrawn.

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92 Decree No 26/2004, Articles 3 and 4.

93 MPI's Questionnaire for National Patent Offices of the EU Member States, answer to question No 3 by the HIPO.

94 Act No XXXIII, Article 52(1), in conjunction with 22/A(3) of the same Act and Article 5(3) of Decree No 26/2004.

95 If a European patent granted by EPO is designated as the basic patent of an SPC application, the SPC application may be lodged at the HIPO from the date of the national validation of the European patent in Hungary.

96 The product must be identified as an active substance in the annex to the marketing authorisation under qualitative and quantitative composition. The combinations of active ingredients should be phrased as "combination of component 1 and component 2". The name of the product given by the SPC applicant is an essential topic at the HIPO procedure because of the Article 3(9) of Decree No 26/2004, according to which the application may not be modified to the effect that the certificate extends to a product, to an authorisation to place a product on the market, or to a basic patent different from the ones designated at the date of filing of the application. Therefore only minor modifications of the product name can be carried out during the examination procedure, for example the modification of a combination product to a mono product is not allowable.

97 Decree No 26/2004, Article 3(2)

98 Decree No. 19/2005. (IV.12.) GKM on the Fees for Administrative Services in Industrial Property Procedures before the Hungarian Patent Office, Article 6(1): 'The fee for an application for the grant of a supplementary protection certificate and the fee for a request for the extension of the duration of a supplementary protection certificate is HUF 214 000 alike'.

99 The HIPO starts the examination of an SPC application on the filing date of the application. There is neither a time limit under national procedural law within which to complete the examination, nor a formalised procedure for the acceleration of the examination of the SPC applications.

If the application meets the conditions for according a filing date, the HIPO will publish in the Gazette of Patents and Trademarks[100] the information on the SPC application required under Article 9(2) of the SPC Regulations. A notification on the SPC application is also recorded, referring to its basic patent, in the Patent Register.

The HIPO will then examine whether the SPC application meets the substantive requirements of the SPC Regulations and the conditions lay down in Act No XXXIII and in Decree No 26/2004. Three patent examiners with a technical background are in charge of carrying out the examination of SPC applications.

During the substantive examination all of the requirements of Article 3 of Regulation 469/2009/EC and Article 3(1) of Regulation 1610/96/EC are verified, including confirming with the medicine regulatory authorities (e.g. through online databases), whether information provided by the applicant on the first marketing authorisation is correct. However, the HIPO only partially verifies whether the marketing authorisation provided by the applicant is indeed the first one. The HIPO checks the data available in International Patent Documentation database (INPADOC) and on the websites of some national patent offices to ascertain which marketing authorisations were submitted as being the first in other Member States, but does not carry out further verification.

If the application meets the substantive requirements of the SPC Regulations and the conditions laid down in Act No XXXIII and in Decree No 26/2004, the HIPO will grant an SPC for the subject of the application and a notification of the grant will be published in the Gazette of Patents and Trademarks, in accordance with Article 11 of the SPC Regulations. The grant of the SPC will also be recorded in the Patent Register, referring to its basic patent, and in the SPC Register.

If the application does not meet the above-mentioned substantive requirements, the applicant will be invited to rectify it or to submit his comments within a given time.[101] The application will be rejected if it still does not meet the prescribed requirements after rectification of the irregularities or the submission of comments. If the applicant fails to comply with the HIPO's invitation within the given time limit, the application will be considered withdrawn. The rejection or withdrawal of the SPC application will be published in the Gazette of Patents and Trademarks, in accordance with Article 11 of the SPC Regulations.

5.4 FILING AND EXAMINATION OF A REQUEST FOR PAEDIATRIC EXTENSION[102]

A request for extension of the SPC duration with regard to medicinal products addressed to the infant population (hereinafter paediatric extension) must be filed before the HIPO in accordance with the requirements of Article 8(1)(d) of Regulation 469/2009/EC in conjunction with Article 36 of Regulation 1901/2006/EC. A filing fee, determined by special legislation, must be paid within two months of the date of filing of the request for a paediatric extension.

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100 Act No XXXIII, Article 56.

101 The application may not be modified to the effect that the certificate extends to a product, to an authorisation to place a product on the market, or to a basic patent different from the ones designated at the filing of the application.

102 Decree No 26/2004, Articles 4/A and 4/B.

The request for a paediatric extension will be published in the Gazette of Patents and Trademarks, in accordance with Article 9(2) and (3) of Regulation 469/2009/EC.

The HIPO will then examine whether the request satisfies the requirements laid down in Regulation 469/2009/EC in conjunction with Regulation 1901/2006/EC, Act No XXXIII and Decree No 26/2004. If the request complies with these requirements, the HIPO will extend the SPC term as prescribed in Article 13(3) of Regulation 469/2009/EC.

Should the request not comply with the above-mentioned requirements, the HIPO will invite the applicant to rectify the irregularities or submit comments within a given time limit. The request will be rejected if it still does not meet the prescribed requirements after the applicant has been given the opportunity to rectify the application or submit his comments. If the applicant does not reply to the HIPO's invitation within the time limit, the request will be considered withdrawn.

The request for a paediatric extension can be filed simultaneously with the application for an SPC or in the course of the procedure for the grant of the SPC, in which case the HIPO will decide on the request for a paediatric extension in its final decision on the grant of the SPC.

If there is a pending procedure on the lapse or invalidity of the SPC when the application for a paediatric extension is filed, the procedure on the paediatric extension will be suspended until the decision on the lapse or invalidity of the SPC becomes final. Should the HIPO declare the SPC to be lapsed or invalid, the request for a paediatric extension will be considered withdrawn; otherwise the procedure on the paediatric extension will continue.

The HIPO will publish its decision on the grant or rejection of the paediatric extension in the Gazette of Patents and Trademarks, in accordance with Article 11 of the SPC Regulations. In addition, the extension of the SPC duration will be recorded in the SPC Register.

The HIPO will revoke the paediatric extension *ex officio*[103] should the basic patent be revoked after the grant of the paediatric extension.

5.5 THIRD PARTY OBSERVATIONS

During the SPC granting procedure, any third party may file an observation with the HIPO to the effect that the application does not comply with the requirements laid down in the SPC Regulations, in Act No XXXIII or in Decree No 26/2004. Such observation will be taken into consideration when the requirement objected to in the observation is examined. The HIPO will notify to the third party the outcome his observation.[104]

[103] MPI's Questionnaire for National Patent Offices of the EU Member States, answer to question No 70 by the HIPO.

[104] Act No XXXIII, Article 71, in conjunction with 22/A(3) of the same Act and Article 5(3) of Decree No 26/2004.

5.6 EFFECT ON THE SPC GRANTING PROCEDURE OF PENDING REVOCATION OR OPPOSITION PROCEDURES AGAINST THE PATENT

A pending revocation procedure against the basic patent does not have an impact on the SPC granting procedure before the HIPO.[105] The same applies when there is a pending opposition procedure against a European basic patent. However, there is no opposition procedure in the Hungarian national patent procedure.

5.7 GRANTING OR REJECTION OF THE SPC. JUDICIAL REVIEW[106]

A request for judicial review of the decisions of the HIPO can be filed by any party to the procedures before the HIPO; any person excluded from, or limited in, the inspection of files; or any person whose legal status as a party to the procedure has been denied.

The request must be filed before the HIPO within thirty days from the date of communication of the decision to the party concerned or to any other party to the procedure. This time limit begins on the date of the communication of the order refusing, or considering not to have been filed, a request for further processing or for *restitutio in integrum*, if that date is later than the date of communication of the HIPO's decision, and the request for further processing or *restitutio in integrum* was filed to prevent the consequences of an omission which served directly as a basis for the HIPO's decision.

The HIPO will forward the request for judicial review to the court within fifteen days, together with all the documents in the SPC's file. If the request for review raises legal questions of fundamental importance, the HIPO may make a written statement about such questions and forward it to the court within thirty days, together with the request for judicial review and all the documents in the SPC's file.

Any person having a legal interest in the outcome of the proceedings may intervene in favour of the party whose interests he or she shares, until such time as the court decision becomes final. The intervener can take any action, except settlement, admission of claims and waiver of rights. The intervener's acts will have effect only where they do not conflict with the acts of the party concerned. Any legal dispute between the intervener and the party concerned may not be decided in the course of the proceedings.[107]

Requests for judicial review are heard by the Budapest-Capital Regional Court (Fővárosi Törvényszék).[108] [109]

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105 MPI's Questionnaire for National Patent Offices of the EU Member States, answer to question No 59 by the HIPO.

106 Act No XXXIII, Article 85, in conjunction with 22/A(3) of the same Act and Article 5(3) of Decree No 26/2004.

107 Act No XXXIII, Article 93.

108 Act No XXXIII, Article 86, in conjunction with 22/A(3) of the same Act and Article 5(3) of Decree No 26/2004.

5.8 CALCULATION OF THE PATENT AND SPC DURATION. CALCULATION OF DEADLINES. RELIEF BEFORE THE HIPO

5.8.1 Calculation of the patent and SPC duration

Act No XXXIII prescribes that patent protection shall have a term of 20 years beginning on the filing date of the application. Performing the calculation yields an expiration date that corresponds to the filing date.[110] [111]

The SPC duration is calculated in accordance with Article 13 of the SPC Regulations.

The *date of the first authorisation* is understood – both in the case of national and centralised marketing authorisations – as the *date of the notification* to the applicant of the grant of the first authorisation to place the product on the market in the EEA.[112] [113]

The SPC expiration date in the case of the maximum term of 5 years shall correspond to the filing date of the basic patent. When a term of less than 5 years is calculated, the SPC expiration date shall correspond to the notification date of the grant of the first authorisation to place the product on the market in the EEA.

This also serves the purpose of fulfilling the principle enshrined in Recital 9 of Regulation 469/2009/EC stating that the holder of both a patent and a certificate should be able to enjoy an overall maximum of 15 years of exclusivity.

5.8.2 Calculation of terms

For the calculation of time limits, the HIPO applies similar criteria to that stated in Rule 131 EPC. Specifically, Article 65(2) of the Administrative Proceedings and Services Act states that where a time limit is defined in months or years, it shall expire on the day that corresponds to the starting day based on its number, or if this day is not available in the month when the time limit expires, on the last day of the month.[114]

5.8.3 Relief before the HIPO for missed deadlines [115]

In the event of failing to comply with a time limit vis-à-vis the HIPO, the applicant can either request further processing or restitutio in integrum.

A request for further processing must be submitted within two months from the date of notification of the decision taken by the HIPO because of the failure to comply with

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109 MPI's Questionnaire for National Patent Offices of the EU Member States, answer to question No 62 by the HIPO.

110 Act No XXXIII, Article 22.

111 MPI's Questionnaire for National Patent Offices of the EU Member States, answer to question No 44 by the HIPO.

112 Act CXL of 2004 on the General Rules of Administrative Proceedings and Services (Administrative Proceedings and Services Act), Article 73/A(3).

113 MPI's Questionnaire for National Patent Offices of the EU Member States, answer to question No 15 by the HIPO.

114 MPI's Questionnaire for National Patent Offices of the EU Member States, answer to question No 44 by the HIPO.

115 Act No XXXIII, Articles 48 and 49, in conjunction with 22/A(3) of the same Act and Article 5(3) of Decree No 26/2004.

a time limit. The omitted act must be completed simultaneously with the filing of the request. If the HIPO grants the request for further processing, the acts completed by the party in default will be considered to have been performed within the time limit not complied with and the decision taken because of the failure will be revoked in whole or in part or modified as necessary.

A request for *restitutio in integrum* must be filed before the HIPO within two months, but at the latest within twelve months, of the unobserved time limit or the last day of the time limit not complied with.[116] The omitted act must be carried out simultaneously with the filing of the request. The request must be accompanied by a statement on the grounds for the failure to comply with the time limit and proof that the failure did not occur due to the negligent behaviour of the applicant.

Should the HIPO grant *restitutio in integrum*, the acts carried out by the party in default will be considered to have been performed within the time limit not complied with; a hearing held on the date not complied with will be repeated where necessary. The decision taken as a result of the failure will be revoked in whole or in part, modified or maintained as necessary or dependent on the outcome of a new hearing.

Restitutio in integrum is excluded in the event of failure to comply with the time limit referred to in Article 7 of the SPC Regulations.[117]

5.9 REPRESENTATION BEFORE THE HIPO[118]

Applicants with their permanent residence or domicile outside the territory of the EEA must be represented by an authorised patent attorney or an attorney-at-law in all SPC matters within the competence of the HIPO.

According to Article 51(2) of Act No XXXIII:

> A power of attorney shall be made in writing. As to the validity of a power of attorney given to a patent attorney, an attorney-at-law, a patent attorneys' office, a patent attorneys' partnership or a law office – either in the country or abroad – the signature by the mandator shall be sufficient for it to be valid. The power of attorney may also be a general authorization, on the basis of which the representative can proceed in all patent cases under the competence of the Hungarian Intellectual Property Office, to which the mandator is a party. A power of attorney given to a law office, a patent attorneys' office or a patent attorneys' partnership shall be deemed to be a power of attorney given to any person who certifies that he/she works within the framework of the office or partnership.

5.10 POST-GRANT AMENDMENT OF THE SPC DURATION. POST-GRANT LIMITATION OR REVOCATION OF THE PATENT

General procedural rules under Hungarian law provide applicants with the possibility to request a post-grant amendment of the SPC duration. This issue has been recently

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116 Where the failure to comply became known to the party subsequently or the cause thereof was removed subsequently, the time limit will be reckoned from the date on which the failure to comply became known or the cause thereof was removed.

117 Decree No 26/2004, Article 5(3)(a).

118 Act No XXXIII, Article 51, in conjunction with 22/A(3) of the same Act and Article 5(3) of Decree No 26/2004.

referred by the Budapest-Capital Regional Court to the CJEU for a preliminary ruling in case C-492/16.[119] [120]

The post-grant amendment of the patent is expressly forbidden under Article 72(2) of Act No XXXIII, without prejudice to the possibility of surrendering claims or partially revoking the patent in cases of partial invalidity.[121]

5.11 PAYMENT OF FEES

The fee for an application for the grant of an SPC and the fee for a request for the extension of the duration of a supplementary protection certificate is HUF 235 400.

The maintenance of the SPC is subject to the payment of annual fees[122], which are due in advance on the same calendar day on which the filing of the application for the basic patent took place. The annual fee due prior to granting the SPC must be paid within a six-month grace period after the granting decision becomes final. If the last year of the duration of the SPC is an incomplete year, the annual fee must be paid proportionately together with the total amount of the annual fee for the last complete year.[123]

5.12 ENFORCEMENT OF THE SPC

Pursuant to Article 5 of the SPC Regulation 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. At the national level, Article 7(1) of Decree No 26/2004 states that the provisions of Chapters II to V[124] of Act No XXXIII apply *mutatis mutandis* to the rights and obligations resulting from an SPC, the exploitation licenses concerning SPCs, as well as compulsory licenses and infringement of SPCs. In addition, Article 13(1) of the SPC Regulations states that the certificate shall take effect at the end of the lawful term of the basic patent.

Based on a combined interpretation of these provisions, if the grant of the SPC takes place later than the expiry of the basic patent, the protection conferred by the SPC

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119 Incyte Corporation v Szellemi Tulajdon Nemzeti Hivatala (5.12.2016 OJEU C 454/17).

120 MPI's Questionnaire for National Patent Offices of the EU Member States, answer to question No 65 by the HIPO.

121 MPI's Questionnaire for National Patent Offices of the EU Member States, answer to question No 31 by the HIPO.

122 Decree No. 19/2005. (IV.12.) GKM on the Fees for Administrative Services in Industrial Property Procedures before the Hungarian Patent Office, Article 6:
(2) The amount of the maintenance fee of the certificate is
(a) HUF 293 700 for the first year;
(b) HUF 352 000 for the second year;
(c) HUF 411 400 for the third year;
(d) HUF 469 700 for the fourth year;
(e) HUF 528 000 for the fifth year;
(f) HUF 620 400 for the sixth year.
(3) If the last year of the duration of the certificate is an incomplete year, the amount of the maintenance fee shall be the result of multiplying the number of each commenced calendar month of the incomplete year by one twelfth of the maintenance fee indicated in paragraph (2) for the complete year having the same serial number as the incomplete year.

123 Decree No 26/2004, Article 7(2), in conjunction with Act No XXXIII, Article 22/A(4).

124 Concerning rights and obligations conferred by a patent, exploitation contracts, compulsory licenses and patent infringements.

shall take effect retroactively, without any temporary lapse. Thus, an SPC application confers the same rights as the basic patent between the expiry of the basic patent and the grant of the SPC, provided that it is granted.[125]

The Budapest-Capital Regional Court has exclusive competence in patent litigation matters and sits in a chamber consisting of three professional judges of whom two have technical university degrees or equivalent qualifications.[126]

In addition to civil remedies applicable in the case of infringement, the patentee can request the court, on conditions relating to provisional measures, to order precautionary measures in accordance with the provisions of the Act on Judicial Execution,[127] if he demonstrates circumstances likely to endanger the later satisfaction of his claim for damages or for the surrender of the enrichment obtained by infringement; compel the infringer to communicate or present his banking, financial or commercial documents with a view to ordering the precautionary measures; and order the lodging of security, if instead of demanding discontinuance of the patent infringement, the patentee consents to the continuation of the allegedly infringing activity by the infringer. The court may order the lodging of security even in the absence of a request of the patentee to this effect, provided that the patentee filed a request for the discontinuance of patent infringement, which the court does not allow.[128]

[125] For a detailed legal analysis see: Ficsor, M. (2006). Kiegészítő megjegyzések a kiegészítő oltalmi tanúsítványok joggyakorlatához. Iparjogvédelmi és Szerzői Jogi Szemle, 111(2), p. 71-77. Available at: https://www.sztnh.gov.hu/kiadv/ipsz/200604-pdf/06-ficsor-kiegeszito.pdf.

[126] Act No XXXIII, Article 104(1) in conjunction with Article 87.

[127] 1994. évi LIII. törvény. Available at: <https://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=99400053.TV&timeshift=fffffff4&txtreferer=00000001.TXT>

[128] Act No XXXIII, Article 104(5) and (6).

6 LITHUANIA

Dovilė Tebelškytė[*]

6.1 INTRODUCTION: THE SOURCES OF LAW

Lithuania is a member of the European Union and a contracting state to the European Patent Convention. Lithuania has also joined the Agreement on the Unified Patent Court.

The Patent Law of the Republic of Lithuania contains a provision (Article 37) on the supplementary protection certificates (SPCs), setting out the basic rules on paying the maintenance fees for SPC.

Detailed procedures applicable for applying for and granting SPCs are set out in the Rules on Granting Supplementary Protection Certificates, approved by the Director of the State Patent Bureau of the Republic of Lithuania.

6.2 INSTITUTIONAL ASPECTS

The State Patent Bureau is a governmental institution of public administration under the Ministry of Justice of the Republic of Lithuania. It is a budgetary institution, which is responsible for granting patents, registering trademarks, designs and topographies of semiconductor products in Lithuania, as well as for granting the SPCs.

There are five patent examiners in the State Patent Bureau, all of whom are of a technical background. Two of the patent examiners, holding a doctor degree in the field of chemistry, are currently *inter alia* responsible for handling SPC applications.

The State Patent Bureau does not carry out substantial examination of patent applications for novelty, inventive step or industrial applicability requirements. As there is no administrative procedure of opposition available, these aspects of patentability are only examined by courts in cases concerning invalidation of patents. Evaluation of the core inventive advance regarding the SPC application would be difficult in the light of the competence of the State Patent Bureau.

The State Patent Bureau does not have guidelines for the examination of SPCs.

6.3 FILING OF THE APPLICATION AND PUBLICATION

The requirements for content of the SPC application according to the Rules on Granting Supplementary Protection Certificates comply with and detail the requirements of Article 8 of Regulation 469/2009; the request is filed in a prescribed form, which *inter alia* includes the name of the product. Information on the application received is published once the application is granted the date of filing in the Official

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Gazette of the State Patent Bureau, which is available in electronic form every two weeks[129] and in the online patent database.[130] There is no SPC application file inspection available in the database.

Patent Law of the Republic of Lithuania does not establish a possibility to request the re-establishment of rights in case the SPC application is not filed within the time limit, prescribed by Article 7 of Regulation 469/2009.

6.4 FORMAL EXAMINATION. COPY OF THE MARKETING AUTHORISATION

Copy of the marketing authorisation is required by the State Patent Bureau, and failure of the applicant to provide it would result in rejection of the application, according to the Rules on Granting Supplementary Protection Certificates.

6.5 SUBSTANTIVE EXAMINATION

According to the Rules on Granting Supplementary Protection Certificates, the State Patent Bureau examines, in the scope of Article 3 of the Regulation 469/2009, whether the product, for which SPC protection is sought is covered by the basic patent indicated in the application, whether the product has not yet been the subject of an SPC, also if a copy of the first MA was furnished. The Rules establish that the State Patent Bureau does not check if the MA provided by the applicant is the first MA; the applicant is responsible for the truthfulness of the documents he/she provides with the application.

National law does not provide any additional regulation on cases where the MA is not valid at the date on which the SPC application is filed, in comparison with the Regulation 469/2009, and there were no such situations noticed in practice.

The State Patent Bureau follows the case law of EUCJ on Article 3 on a case by case basis, treating similar situations in a similar fashion as much as possible.

Concerning the practice following the EUCJ *Neurim* judgment, there has been an appeal brought to the Appeals Division of the State Patent Bureau, where the SPC application was based on a different dosage of the same medical product, which has already been granted an SPC. The examiner and Appeals Division have stated that different dosage does not constitute a different therapeutic application; therefore a second SPC was not issued.

6.6 THIRD PARTY OBSERVATIONS

Possibility to file third party observations is not established by national law. If the examiner received information from third parties, that is relevant to the examination process, he/she would consider it in the scope of the requirements of the examination.

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129 <http://www.vpb.lt/index.php?l=en&n=245>.
130 <http://www.vpb.lt/index.php?l=en&n=238>.

6.7 EFFECT ON THE SPC GRANTING PROCEDURE OF PENDING REVOCATION OR OPPOSITION PROCEDURES AGAINST THE PATENT

The issue is not regulated by national law, but the examiner would likely stay the SPC proceedings, in particular by the request of the applicant, if the case concerning the invalidation of the patent is brought in court (there is no opposition procedure available).

6.8 GRANTING OR REJECTION OF THE SPC. APPEAL AND REVOCATION PROCEDURES

There are no hearing proceedings before the examiner takes a decision to grant or reject an SPC, but the applicant may contact the examiner and provide necessary documents or explanations in the course of the examination.

There is a possibility to file an appeal to the Appeals Division of the State Patent Bureau, if the SPC application is rejected, within 3 months from the respective decision. The applicant may request a verbal hearing instead of written procedure in the Appeals Division, but it only takes place if there are enough arguments to show that the case is complex or important to practice of the Appeals Division.

The decision of the Appeals Division may be appealed to the Vilnius County Court, which has exclusive competence for industrial property cases. Vilnius County Court is also the first instance for hearing cases on patent and SPC invalidation.

6.9 CALCULATION OF THE PATENT AND SPC DURATION. CALCULATION OF DEADLINES. RELIEF BEFORE THE OFFICE

6.9.1 Calculation of the patent and SPC duration. Calculation of terms

Patent term lapses on the anniversary date of the application filing date. The SPC term is calculated according to the Article 13(1) of Regulation 469/2009; the last day of the SPC is the anniversary date of the grant of the MA, but the term of the SPC may not be longer than 5 years from the anniversary date of the lapse of the patent.

6.9.2 Relief before the office for missed deadlines

The Patent Law establishes a possibility to request the re-establishment of certain rights concerning patents. The State Patent Bureau does not allow for re-establishment of rights in case of failure to comply with time limits for filing an SPC application; re-establishment concerning the payment of maintenance fees could be possible *mutatis mutandis* applying the provisions applicable to patents, but there has not yet been such situations in practice.

6.10 REPRESENTATION BEFORE THE OFFICE

The applicant may be represented by the patent attorney of the Republic of Lithuania. Permanent residents or companies having a registered place of business in Lithuania or another member state of EEA or EPC may be represented by their employee; all other applicants must be represented by the patent attorney of the Republic of Lithuania, with exception of filing an application, paying a fee or receiving respective communications from the State Patent Bureau – these actions may be taken by the applicant himself.

6.11 POST-GRANT AMENDMENT OF THE SPC DURATION. POST-GRANT LIMITATION OR REVOCATION OF THE PATENT

6.11.1 Post-grant amendment of the SPC duration

The time limit to file an Appeal to the Appeals Division is 3 months from the relevant decision by the examiner. After that period the case could be brought in court. However, after relevant EUCJ decisions (e.g. C-471/14) the State Patent Bureau has allowed rectification of the duration of the certificates. The SPC holder should be allowed to amend the duration of certificate anytime, if it is being shortened.

6.11.2 Post-grant limitation or revocation of the patent

Patent may only be revoked by court; therefore the same procedure should to be applied in respect of the SPC.

6.12 SPECIFIC ISSUES CONCERNING EXTENSION PURSUANT TO ART. 36 OF REG. 1901/2006/EC

The applicant has to provide data and documents according to Article 8(d) of the Regulation 469/2009.

6.13 PAYMENT OF FEES

There are fees to be paid for filing an SPC application and maintenance fees. Filing fee is to be paid during the last 2 months of last year of the patent term. Maintenance fee for the next year is to be paid during the last 2 months of the preceding year of the SPC. After this term 50 percent higher maintenance fee may be paid in 6 months.

Amounts of the fees concerning SPCs are currently as follows:

Filing fee	115 Eur
Renewal fee SPC year 1	347 Eur
Renewal fee SPC year 2	347 Eur
Renewal fee SPC year 3	347 Eur
Renewal fee SPC year 4	347 Eur
Renewal fee SPC year 5	347 Eur

Table 6.1:

6.14 ENFORCEMENT OF THE SPC

Provisions of national law, applicable for enforcement of patent rights, are applicable for enforcement of SPC rights. National law does not regulate rights on a published SPC application.

7 POLAND

Wioleta Świerczyńska[*]

7.1 INTRODUCTION: THE SOURCES OF LAW

Poland signed the TRIPS agreement, has been Contracting State of the EPC since 2004 and is a Member of the PCT and PLT. Poland does take part in the enhanced cooperation in the area of the creation of unitary patent protection[131], but did not sign UPCA.

The sources of law that apply to national patents are: the Industrial Property Law[132] and the Regulation of the Prime Minister of 17 September 2001[133] on filing and processing of patent and utility model applications.

To SPCs concern Articles 751 to 7510 of the Industrial Property Law. To SPCs concerns also the Regulation of the Prime Minister[134], but it is available only in Polish.

In Poland the scope of protection of the patent is regulated by a provision[135] with similar wording to that included in Art. 69 EPC and the rights conferred by the patent by a provision[136] with wording consistent with Art. 28 TRIPS.

Polish legislator has not made use of the option under Art. 19 Regulation 469/2009 to include specific procedural provisions for SPC applications. Procedural provisions, i.e. litigation procedures, time limits, representatives, appeal procedure etc. are the same as for patents and are included in Title VI and Title VII of the Industrial Property Law.

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[*] Wioleta Świerczyńska – the Patent Office of the Republic of Poland.

[131] Regulation (EU) 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 L361/1.

[132] Act of 30 June 2000, Industrial Property Law as amended by act of 23 January 2004 and act of 29 June 2007. http://www.uprp.pl/akty-prawne/Lead03,13,1315,1b,index,pl,text/podstawowe-obowiazujace-akty-prawne/Lead03,50,262,1b,index,pl,text/

[133] Regulation of the Prime Minister of 17 September 2001 on filing and processing of patent and utility model applications. http://uprp.pl/akty-prawne/Lead03,13,1315,1b,index,pl,text/podstawowe-obowiazujace-akty-prawne/Lead03,50,262,1b,index,pl,text/

[134] Rozporządzenie Prezesa Rady Ministrów z dnia 9 września 2016 r. w sprawie składania i rozpatrywania wniosków o udzielenie dodatkowego prawa ochronnego dla produktów leczniczych i produktów ochrony roślin. http://uprp.pl/uprp/_gAllery/78/75/78758/dodatkowe_prawo_ochronne_dla_produktow_leczniczych_i_produktow_ochrony_roslin_poz._1482.pdf

[135] Art. 63 (2): The scope of the protection sought shall be determined by the claims contained in the patent specification. The patent specification and drawings may be used to interpret the claims.

[136] Art. 66: 1. The patent holder shall have the right to prevent any third party not having his consent from exploiting his invention for profit or for professional purposes by way of performing the acts consisting of:
(i) making, using, offering, putting on the market a product that is the subject matter of the invention, or importing the product for such purposes, or
(ii) employing a process that is the subject matter of the invention, as well as using, offering, putting on the market or importing for such purposes the product directly obtained by that process.
2. The patent holder shall have the right to authorise (license) another party to exploit his invention (license agreement).

7.2 INSTITUTIONAL ASPECTS

The Patent Office of the Republic of Poland is the authority that pursuant to Art. 9 Regulation 469/2009 is entrusted with examination.

In accordance with Title VIII Part I of the Industrial Property Law, Patent Office of the Republic of Poland is a central government agency responsible in industrial property matters. Patent Office is subordinated to the Council of Ministers. Supervision over the Patent Office's activities is exercised by a minister competent in economy.

The Patent Office of the Republic of Poland is an examining office. It undertakes substantive examination of patent applications with respect to all requirements of protection. Polish applicants can apply for national patents before the Patent Office of the Republic of Poland or, in accordance with Art. 40 of the Industrial Property Law, if they wish to seek patent protection in another country, they can do so after applying for protection with the Patent Office of the Republic of Poland.

Guidelines for the examination are included in "Poradnik wynalazcy"[137] edited by Andrzej Pyrża, Warszawa 2017, published by the Patent Office of the Republic of Poland. This handbook concerns examination procedures in all fields of industrial property, including SPCs. This handbook is available only in Polish and only in paper version.

Patent examiners have a technical background. Examiners entrusted with the examination of SPCs hold higher education degree in the field of chemistry, biology or biotechnology.

7.3 FILING OF THE APPLICATION AND PUBLICATION

The SPC application must be filed in Polish.

The information about the SPC application is published in Wiadomości Urzędu Patentowego (WUP)[138] just after finishing the formal procedure.

The SPC application can be filed by the patent holder or his/her representative.

The Office asks the SPC applicant about the product definition, which should be included in the title of the SPC application.

If the proposed definition is "compound in all acceptable salts and derivatives", the Office does not accept "all" in the definition if it is not present in the claims of the basic patent. The term "derivatives" is unclear so the kinds of derivatives have to be specified in the product definition, for example esters, solvates etc.

In the case of a process patent, the Office grants SPC for "Product obtained by a method in accordance with the patent no. ...".

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[137] Poradnik wynalazcy. Procedury zgłoszeniowe w systemie krajowym, europejskim, miedzynarodowym. Redakcja Andrzej Pyrża. Wydanie III-uzupełnione. Stan prawny na dzień 1 stycznia 2017 r.

[138] Wiadomości Urzędu Patentowego (WUP). http://portal.uprp.pl/wydawnictwa.html

In the case of second medical use, the use has to be indicated in the SPC product definition. The Office grants SPC for "The product for use...", where the use is specified in accordance with a content of the basic patent claim. If this kind of the product definition is inconvenient, the SPC is granted for "Product for use in accordance with the patent no. ...".

We have not had SPC applications that include in some form possible future biosimilars.

The SPC application must contain a copy of MA, which includes Summary of Product Characteristics for medicinal products or summary of data for plant protection products. If the MA to place the product on the market in Poland is not the first to place the product on the market of the European Union, the application must also contain the statement of the product's identity, the legal provision under which the MA was granted and a copy of the notice publishing the MA, if it was published.

The time limit for filing the SPC application is that indicated in Article 7 Reg. 469/2009. After expiry of the 6 month time limit, the SPC application cannot be accepted.

Regarding the centralised MA, the reference day is a day of notification. In the case of national MA, the reference day is a day of granting.

If exist two MAs with the same date, both of them are mentioned in the decision about granting SPC. The variations or extension of existing MAs can be used as a first MA in accordance with Art. 7 Reg. 469/2009. They are not considered as the same global MAs only in the case of the basic patents for a new medical application.

7.3.1 Formal examination

Patent Office of the Republic of Poland accepts the SPC application if it is complete. If the application is incomplete, also in the case of lacking the copy of the MA, or if the fee is not paid, the Patent Office invites the applicant in order to furnish it, within a fixed time limit and under pain of discontinuance of the proceedings, missing documents or information. If the deficiency is remedied within the time limit, the date of filing of the incomplete application is deemed to be the filing date. If the deficiency is not rectified on time, proceedings are discontinued.

If the SPC application is lack of the copy of the MA, the Office invite the applicant in order to furnish it based on Art. 42(1) in connection with Art. 75^3 of the Industrial Property Law. In accordance with the Art. 242(1) of the Industrial Property Law, the time limit is one month if the applicant has domicile or seat in Poland, or two months if the she/he has domicile or seat in another country. In reasonable cases, the Office can fix a longer time limit, but not longer than 3 months (Art. 242(2) of the Industrial Property Low). In accordance with Art. 242(3), the mentioned above time limits may be lengthen by two months.

In accordance with the Polish legislation, based on Art. 244-245 and 248, the applicant has also the possibility to ask about re-examination or lodge a complaint to the administrative court.

7.4 SUBSTANTIVE EXAMINATION

Although in the Polish legislation is no deadline within which the SPC application should be granted or rejected, in practice we try to grant or reject the SPC application two years before the expiration date of the basic patent.

The Patent Office of the Republic of Poland examines all requirements under Art. 3 Regulation 469/2009. After publication about filling the SPC application, the principle of *ex officio* applied to the examination procedure.

Guidelines for the examination of the SPC applications are included in the handbook under the title "Poradnik wynalazcy" mentioned above. This publication also contains information about the Patent Office practice in terms of the CEJU case law on Art. 3 a.

In accordance with Polish examining guidelines, SPC can be granted relating to only these active ingredients which are specified in the wording of the claims of the basic patent. On the same condition, SPC can be granted relating to the combination of the active ingredient. If the basic patent protects different combinations of the active ingredients, each of these combinations involves separate SPC. SPC can protect derivatives of the active ingredient, such as salts or esters, if they are specified in the wording of the claims of the basic patent.

In the case of a process patent SPC can be granted only for product obtained by a method protected by this patent, what has to be clearly indicated in the decision.
SPC can be granted for the active ingredient X, if the basic patent protects composition containing this active ingredient X for use as a drug.

SPC cannot be granted for the active ingredient X, if the basic patent protects composition of the active ingredients X + Y.

If the basic patent protects active ingredient X, but medicinal product includes active ingredients X + Y, the SPC can be granted only for active ingredient X.

Another SPCs cannot be granted for the same active ingredient in the case where the basic patent protects a new dosage form or a new medical indication. The exception is a situation where the basic patent protects new medical use of the active ingredient which has not been protected as such by a patent (C-130/11 Neurim). In accordance with Art. 4 of the Regulation 469/2009, if the active ingredient was earlier protected by a patent, this protection included also all applications of this ingredient, even the later. If the SPC is granted for second medical use, this fact has to be clearly indicated in the decision.

SPC cannot be granted for medical devices.

In the Polish Patent Office the judgement C-322/10 Medeva is applied strictly. SPC can be granted only relating to active ingredients which are specified in the wording of the claims of the basic patent. SPC can be also granted relating to a combination of two active ingredients, corresponding to that specified in the wording of the claims of the basic patent, where the medicinal product for which the MA is submitted contains not only that combination of the two active ingredients but also other active ingredients.

At this moment in time the Office still does not have established practice concerning the judgement C-493/12 Eli Lilly. SPC applications, for which this judgement could be applied, are at the very beginning of the examination.

The Patent Office position on the judgement C-130/11 Neurim is that SPC for a new medical use can be granted only in a situation where the active ingredient has not been previously protected by a patent.

The MA must be in force at the date on which the SPC application is field.

7.5 THIRD PARTY OBSERVATIONS

Third parties can send their comments which are taken into consideration in the course of examining of the application. The legal basis for this right is Art. 44 (1) of the Industrial Property Law. The observations can be also filed anonymously. During examining proceedings we do not quote third party observations in the official letters sent to SPC applicants. If the Patent Office decides to grant an SPC despite third party observation opposing the grant, the decision is not provided with reasons.

The Patent Office does not inform the applicant about the third part observations.

7.6 EFFECT ON THE SPC GRANTING PROCEDURE OF PENDING REVOCATION OR OPPOSITION PROCEDURES AGAINST THE PATENT

In the jurisdiction of Poland we can suspend the SPC granting procedure in the case of pending revocation or opposition procedures against the patent. It can be done only at applicant's request. In real terms, we usually stop the examining procedure and wait for the result of the revocation or opposition procedure.

7.7 GRANTING OR REJECTION OF THE SPC. APPEAL AND REVOCATION PROCEDURES

In the jurisdiction of Poland is no deadline prescribed by law when the Office must grant or reject the SPC.

All decisions of the Patent Office can be appealed.

Decisions about grant or rejection of the SPC of the Patent Office are liable to a party's request for re-examination of the matter within the meaning of the Code of Administrative Procedure[139] (Art. 244-245 of the Industrial Property Law) and decisions are subject to complaint lodged to the administrative court (Art. 248 of the Industrial Property Law).

[139] Journal of Laws 1960 No. 30, item 168, Act of 14 June 1960, Code of Administrative Procedure.

Since June 2017, if the applicant does not agree with the decision of the Patent Office, she/he has two options. The first option is a request for re-examination by the Office at first and next, if the applicant still does not agree with decision, it can be a subject to complaint lodged to the administrative court. In the second option, the applicant can resign from re-examination of decision and lodge the complaint to the administrative court.

Before June 2017, applicants did not have such a choice, and always had to ask for re-examination at first.

7.8 CALCULATION OF THE PATENT AND SPC DURATION. CALCULATION OF DEADLINES. RELIEF BEFORE THE OFFICE

7.8.1 Calculation of the patent and SPC duration

The term of a patent is 20 years counted from the date of filing of the patent application with the Patent Office.

For example, if the patent application was filed 1 July 2001, the ending day is 1 July 2021. Yes, in terms calculating we apply the same rules as included in Rule 131 EPC.

Calculation of the SPC duration is based on the application date of the patent application and on the date of the first MA. The SPC enters into effect as of the last day in which the patent is in force. For example, for a patent filed on 15 October 2015, the expiry date of the basic patent is 15 October 2035, the start date of the SPC is 15 October 2035, the maximum expiry date of the SPC is 15 October 2040.

The Patent Office does not grant SPC for negative protection period, but waits for a potential application for paediatric extension.

7.8.2 Calculation of terms

In accordance with the Art. 242 of the Industrial Property Law, in the course of proceedings the Patent Office fixes one month time limit, where the party has its domicile or seat in Poland, or two months' time limit, where the party has its domicile or seat in another country. When reasonable, the Patent Office fixes a time limit longer, however of no more than three months. Any act may be performed within two months after the expiry of a fixed time limit, if before its expiry the Patent Office is notified in writing by the party on the reasons of non-observance of that limit.

An application shall be deemed to have been filed at the date at which it has been received by the Patent Office.

In the course of proceedings the fixed terms start at the date on which an act is served to the party. The deadline is considered to be met if the post stamp has been made not later than the deadline set.

If a period is measured in days or commences with a certain event, the calculation of the period shall not include the date on which the event occurred. The deadline shall be deemed to have expired at the end of the last of the number of days calculated. If

the deadline falls on a public holiday or Saturday, the deadline shall be deemed to be the next business day. Deadlines which are set in months shall expire at the end of the day in the last month which corresponds to the first day of the period, and if there is no such day in the last month on the last day of that month.

7.8.3 Relief before the office for missed deadlines

The Industrial Property Law (Art. 243) includes provisions for re-establishment of rights similar to those included in Art. 122 EPC. They also apply to SPC applications. It refers to the terms not complied with during the procedure of examining the application. The term for lodging an application shall not be restorable.

7.9 REPRESENTATION BEFORE THE OFFICE

In proceedings before the Patent Office in matters relating to patents and SPCs, patent attorney or a person providing cross-border activity may act as a representative. This obligation to use a professional representative does not apply to parties in proceedings before the Patent Office, who have a domicile or seat in the territory of the EU, EFTA Member State – party to the agreement on the European Economic Area or the Swiss Confederation.

A natural person may also be represented by a joint right holder or spouse, parents, siblings, descendants of the party or persons in the relation-by-adoption with the party.

7.10 POST-GRANT AMENDMENT OF THE SPC DURATION. POST-GRANT LIMITATION OR REVOCATION OF THE PATENT

7.10.1 Post-grant amendment of the SPC duration

Art. 17(2) Regulation 1610/96 has not been implemented in our legislation. The duration of the certificate can be rectified at the request of the applicant within two months from a day on which the party has received the decision of a grant of an SPC. Later, the duration of the certificate can be rectified in accordance with Art. 155 of the Code of Administrative Procedure. According to this provision "a final decision by which a party has acquired rights can at any time with the consent of the party be revoked or amended by the public administration body which issued it, or the higher body, if other regulations do not forbid such revocation or amendment and if this is in the public interest or the proper interests of the party; and Article 154 § 2[140] shall apply accordingly."

Yes, Art. 17(2) Regulation 1610/96 has been applied directly.

[140] Art. 154: § 1. A final decision by which no party has acquired any right may be revoked or amended at any time by the public administration body which issued it or by the higher body, if this in public interest or the proper interests of the party.
§ 2. In the situation referred to in § 1 the proper body shall issue a decision in the matter of revocation or amendment of the current decision.
§ 3. In cases pertaining to the duties of local government, local government bodies shall have jurisdiction to amend or revoke the decision referred to in § 1 and Article 155.

7.10.2 Post-grant limitation of the patent

A patent may be declared invalid in whole or in part at the request of any person having a legitimate interest therein before the Boards Hearing in Litigious Cases of the Polish Patent Office. Patent could be invalidated as a consequence of filing of opposition, which is claimed by the right holder to be unjustified. (Art. 89, 246 and 255 of the Industrial Property Law).

After grant the patent can be limited only in the case where patent claims contain at least two independent claims. In such a case the limitation is done by removing one or more independent claims. The patent cannot be limited by changing the content of the independent claim. Consequently, the patent which includes only one independent claim cannot be limited.

7.10.3 Specific issues concerning extension pursuant to Art. 36 of Reg. 1901/2006/EC

In Poland it is possible to apply for an extension of the SPC term, pursuant to Art. 8(1)(d) of Regulation 469/2009 in conjunction with Art. 36 Regulation 1901/2006. The documentation required by the aforementioned provisions can be partially filed after the filing of the request for extension within the time limit provided the Polish Patent Office.

7.10.4 Payment of fees

SPC applicant pays application fee and fee for publication of granting SPC. The SPC holder must also pay annual fees for every entered year of SPC protection.

The fees* are the following:

Application fee: 129 EUR

Fee for every following year: 1401 EUR

7.10.5 Enforcement of the SPC application

The SPC owner can enforce his or her SPC the same way as the basic patent but limited to the product covered by the marketing authorisation.

*Approximate fees in Euros.

8 PORTUGAL

Inês Cristóvão da Silva[*]

8.1 INTRODUCTION: THE SOURCES OF LAW

Portugal has signed and ratified almost all relevant European and International agreements in the field of patents. Portugal is a contracting state of the European Patent Convention (EPC) since 1992, as well as a member of the Patent Cooperation Treaty (PCT), the Strasbourg Convention, the Paris Convention and the TRIPS Agreement. Furthermore, Portugal has signed and ratified the Agreement on a Unified Patent Court (UPCA) and takes part in the enhanced cooperation in the area of the creation of unitary patent protection[141]. An exception is the Patent Law Treaty (PLT), which has signed in 2000 but not yet ratified.

Patent protection in Portugal can be obtained by filing a national patent application at the National Institute of Industrial Property (hereinafter INPI), or by filing a European patent application at the EPO with subsequent validation in Portugal. In both cases, filing is also possible via the PCT route (national or regional phase entry respectively).

In Portugal, patents are regulated under the Industrial Property Code (CPI) approved by Decree-law 36/2003 and amended by Decree-law 318/2007, Decree-law 360/2007, Decree-law 143/2008 and law 16/2008, in which Articles 115, 115-A and 116 are dedicated to SPCs.

The scope of protection of national patents[142] and the rights conferred by such patents[143] are regulated by provisions with similar wording to that of Article 69 EPC and Article 28 TRIPS Agreement respectively.

The Industrial Property Code is harmonized with the EPC, in particular the provisions regarding patentability[144] and sufficiency of disclosure.[145]

Portugal did not make use of the option provided by Article 19 of Regulation (EC) nº469/2009 and Article 18 of Regulation (EC) nº 1610/96 to include in the Portuguese law some special procedural provisions on SPCs.

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[*] Inês Cristóvão da Silva - Head of Patent and Utility Model Department of the Portuguese NPO.

[141] See Regulation (EU) 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 L361/1.

[142] Article 97(1) CPI "1 The extent of the protection conferred by a patent shall be determined by the content of the claims and the description and drawings shall serve to interpret them".

[143] Article 101 CPI.

[144] Article 55 CPI.

[145] Article 62 (4) "The description shall give a brief, clear indication, with no reservations or omissions, of everything making up the 108 Industrial Property Code invention and contain a detailed explanation of at least one way of making the invention, so that any person skilled in the art may carry it out."

8.2 INSTITUTIONAL ASPECTS

The National Institute of Industrial Property (INPI) was created under the aegis of the Ministry of Foreign Trade on 28th July, 1976, by Decree-Law nº. 632, as a reform to the old Department of Industrial Property and currently has 108 employees. INPI is now an Autonomous Government Institution, with legal personality as well as administrative and financial autonomy, and independent assets. It functions under the supervision and guidance of the Minister of Justice, with regards to the definition of specific policies relating to industrial property, and the overseeing of their implementation.

The Department of Patents and Utility Models (DPMU) has 20 examiners, with licentiate, master and doctoral degrees in several scientific areas, such as Chemical Engineering, Physics, Biological Engineering, Mechanical Engineering, Civil Engineering, Environmental Engineering, among others. These examiners are organized in clusters which are: Chemistry and Biotechnology (CQB), Technological Physics (CFT), Structures and Construction (CEC) and Industry and Mechanics (CIM).

INPI is also the examining and granting authority for SPCs and paediatric extensions according to article 9(1) of SPC Regulation.

Examination of SPCs and paediatric extensions are done by 2 senior examiners of the CQB cluster, so that they can be aware of the entire subject matter concerning this area and, therefore, obtain an improvement in the procedure implemented. The background of these examiners is chemistry and biotechnology and the examiners have only technical training. However, when is necessary, the legal department gives support to the examiners[146].

8.3 FILING OF THE APPLICATION AND PUBLICATION

In Portugal, an SPC and/or the extension must be filled by the owner of the basic patent or by an authorized representative before the INPI, in Portuguese, within the legal time limit (defined in Article 7 of the SPC Regulations) and upon fee payment[147].

Applications for SPCs shall include an application form containing all the prescribed information under Article 8 of the SPC Regulations, including: the name and address of the applicant (and of the representative); the patent number and title of the invention; the number and date of the first market authorization in Portugal, if this is not the first marketing authorization in the European economic area, the name and date of that authorization and a copy of both authorizations; and a summary of product characteristics in Portuguese.

In addition, the SPC application must include information regarding the name of the product for which the grant of the SPC is sought, which must comply with the definition of Article 1 of Regulation EC/1610/96 ("the active substance or combination of active substances of a plant protection product") and in Article 1(b) of Regulation

[146] MPI's Questionnaire for National Patent Offices of the EU Member States, answer to question Nº 52 and 54 by the INPI.

[147] MPI's Questionnaire for National Patent Offices of the EU Member States, answer to question Nº 52 and 54 by the INPI.

EC/469/2009 ("the active ingredient or combination of active ingredients of medicinal product").

If the application includes a request for pediatric extension, required documentation pursuant to article 8(1) of Regulation (CE) 469/2009 must also be included.

8.4 FORMAL AND SUBSTANTIVE EXAMINATION

INPI examines *ex officio* all the substantive requirements provided under for Article 3 of Regulation (EC) 469/2009 or Article 3 of Regulation (EC) 1610/96. The examination is performed by examiners who belong, as mentioned above, to the CQB cluster. The decision of granting or rejecting a SPC is validated by the Head of Department and by the Director.

8.4.1 Article 3(a)

According to Article 3(a), the product for which an application for the grant of a certificate is filed, must be protected by a basic patent in force at the date of that application. That means that the basic patent must not have lapsed, withdrawn or declared invalid at the time of filing the application for the certificate and that the product is specified in the wording of the claims of the basic patent in accordance with the Medeva and Georgetown case law.

When the product is a combination of two substances and only one of them is specified in the claims the SPC cannot be granted.

Regarding Markush formulae, the product is considered to meet the requirement of Article 3(a) of the SPC Regulations if it appears to be covered by the Markush formulae identified in the claims, even if the product is not precisely identified in the wording of the claims or in the description.

8.4.2 Article 3 (b)

As regards the assessment of Article 3(b), the marketing authorization has been granted and still in force at the date of filling of the SPC application, and, in particular, has not lost validity by revocation, withdrawal or expiry of the term of the authorization.

INPI recognizes provisional authorizations to place a product on the market as a plant protection product, granted under Article 8(1) of the Directive 91/414/EEC (implemented in Section 15c Plant Protection Act), as valid first authorizations within the meaning of Article 3(1)(b) of Regulation (EC) no. 1610/96 (CJEU C-229/09 *Lovells/Bayer*).

8.4.3 Article 3 (c)

INPI interprets the requirement of Article 3 (c) in the light of Article 3(2) of Regulation 1610/96 and recital 17. Therefore, in Portugal it cannot be granted a certificate for the same product to the same applicant. However, INPI will grant a SPC to different holders of a basic patent that protects the same product.

The examiners who study the SPC conduct a search for certificates that have already have been filed.

8.4.4 Article 3 (d)

Pursuant to Article 3(d) a certificate shall be granted only if the furnished authorization to place the product on the market is the first authorization for this product in the market. INPI does not verify this condition; however the applicant must be truthful on its claims, so it is generally assumed that the statements of the applicant are accurate.

8.5 THIRD PARTY OBSERVATIONS

INPI accepts third parties observations during the SPC granting procedure and the examiners can take these observations into account when examining an application, however these observations only play an informative role in the examination procedure. In this case INPI informs the applicant that third parties observations were filed and sends a copy of it to the applicant.

These observations should be filed through a front man, because the third party must fill out a form with its personal data in order to present the observations.

The Portuguese law provides that if no decision has been issued on an application and it is necessary to clarify the procedure, additional expositions may be accepted.

8.6 GRANTING OR REJECTION OF THE SPC. APPEAL AND REVOCATION PROCEDURES

If the SPC application (or the paediatric extension) fulfils the conditions set forth in the SPC regulations, INPI grants the SPC (or the paediatric extension) and publishes the request and the decision of granting it in the Industrial Property Bulletin. This publication includes the information required pursuant to Article 11 (1) of the SPC Regulations, in addition to the number and date of filing of the SPC application.

INPI, also, notifies the SPC owner the decision by specifying the date and the number of the Industrial Property Bulletin in which the decision will be published.

If the SPC application (or the paediatric extension) does not fulfil the conditions set forth in the SPC regulations, INPI gives two months to the applicant for the correction of the irregularities found in the examination. If the applicant does not comply with the notification, INPI refuses the SPC (or the paediatric extension) and notifies the applicant to inform of the rejection. This rejection decision is also published in the Industrial Property Bulletin, according to Article 11(2) of the SPC Regulations.

The Portuguese law does not provide the applicant the right to request a hearing before the examiner who takes a decision to grant or reject a SPC, but the applicant

can contact or have meetings with the examiner and to provide the necessary documents or explanations during the examination.[148]

Pursuant to Article 23º of CPI it is possible to change the final decision, within two months of publication of a decision. The request will be submitted to a higher authority (it is understood to be the immediate superior of the person who actually signed the decision to be altered) along with all the known facts that justify reversal of the decision made.

Furthermore, the decision regarding the grant or rejection of the SPC can be appealed before the Portuguese courts (*Tribunal da Propriedade Intelectual* or *Tribunal Arbitral*) within 2 months from its communication.

8.7 EFFECT ON THE SPC GRANTING PROCEDURE OF PENDING REVOCATION OR OPPOSITION PROCEDURES AGAINST THE PATENT

If revocation or opposition procedures against the basic patent are pending the examiner informs the applicant that the study of the SPC is stayed for the duration of such procedures or until the continuity of the study is requested by the applicant.

8.8 CALCULATION OF THE PATENT AND SPC DURATION. CALCULATION OF THE TERMS. RELIEF BEFORE THE INPI

8.8.1 Calculation of the patent and SPC duration

According to Article 99 of CPI "the duration of a patent is 20 years from date of application". The patent expires on the anniversary date of the application's filling date; for example, a patent filed on 10.10.2005 expires on 10.10.2025. This calculation is in line with Rule 131 EPC.

Regarding the calculation of SPC duration, according to Article 13 of the SPC Regulations, the certificate takes effect at the end of the lawful term of the basic patent for a period equal to the elapsed period between the date on which the application for a basic patent was lodged and the date of the first authorization to place the product on the market in the Community, reduced by a period of five years. The maximum duration of the certificate may not exceed five years.

The SPC enters into effect on the following day of the last day in which the patent is in force. For example, for a patent filled on 10 October 2005, the expiry date of the basic patent is 10 October 2025, so the starting date of the SPC is 11 October 2025 and the maximum expiry date of the SPC is 10 October 2030.

Since the CJUE decision, regarding the Seattle Generics case, INPI considers that the notification date is the MA's date used for the calculation of the SPC duration. In the case of a centralized MA (granted by the European Commission) the notification date

[148] INPI answer to the MPI Questionnaire's Question 55.

is easily detected in the EU Official Journal but in the case of a national MA it is more difficult to know the correct date and in this case the examiners ask the applicant to provide them with the necessary proof in order to establish the correct date.

Furthermore, INPI grants SPC for negative protection period to allow a possible paediatric extension, in accordance with CJEU *Merck* decision.

INPI recognizes provisional authorizations to place a product on the market as a plant protection product, granted under Article 8(1) of the Directive 91/414/EEC (implemented in Section 15c Plant Protection Act), as valid first authorizations within the meaning of Article 3(1)(b) of Regulation (EC) no. 1610/96 (CJEU C-229/09 *Lovells/Bayer*). In this case, the calculation of the duration is based on the provisional marketing authorization.

8.8.2 Calculation of terms

For the calculation of terms, INPI applies the following rules defined in Portuguese law[149]:

- the day on which the event from which the period starts to run, it is not included in the count;
- the fixed term is suspended on Saturdays, Sundays and holidays, except for periods of more than 6 month;
- the end of the period coinciding with the day on which the service before which the act is to be performed is not open to the public or does not work during the normal period, shall be transferred to the next working day.

8.8.3 Relief before the INPI

Article 8 of CPI allows an applicant who, in spite of all the attention required by the circumstances, have failed to respect a time limit, non-compliance with which may result on loss of a right or affect its validity, and the cause is not directly imputable to them, can submit before INPI a justified request for re-establishment of rights within two months of the cessation of the circumstance that prevented compliance with the time limit, but at the latest within one year of the end of the time limit missed. This provision is for all industrial property rights, including SPCs.

8.9 REPRESENTATION BEFORE THE INPI

Pursuant to Article 9 of CPI "those who have an interest in the legal acts have the legitimacy to perform them before the INPI" so the election of a representative is not necessary.

If an interested party or owner of the right is established or domiciled in a foreign country shall indicate an address in Portugal or an e-mail.

[149] MPI's Questionnaire for National Patent Offices of the EU Member States, answer to question Nº 45 by the INPI.

8.10 POST-GRANT AMENDMENT OF THE SPC DURATION. POST-GRANT LIMITATION OR REVOCATION OF THE PATENT

8.10.1 Post-grant amendment of the SPC duration

After the decision of the CJEU (C-471/14), INPI has allowed rectifications of the duration of the granted certificates, based on the application of Article 17, paragraph 2 of Regulation 1610/96, when the conditions set forth in this article are met and when such amendment is requested by the holder, his agent or other interested parties by means of a substantiated request, in which the date of the notification and a proof of such date must be provided. INPI considers that this rectification can be promoted at any time, taking into account the exceptional nature of article 17(2) Reg. 1610/96/EC and the absence of an express time limit.[150]

8.10.2 Post-grant limitation or revocation of the patent

According to Article 101(5), the patent owner may ask the INPI, on payment of a fee, to limit the scope of protection of the invention by altering the claims. If the examination shows that the request for limitation can be granted, the INPI shall promote the publication of a notice of this alteration.

Article 15 of Regulation EC/469/2009 defines that revocation of the basic patent after the grant of the SPC and, in certain circumstances, its limitation, constitutes a ground for the invalidation of the SPC. However, since INPI is not a competent body under Portuguese law to invalidate a patent, any request for the invalidation of the SPC on these grounds may only be referred to the Portuguese Court, in accordance with Article 15 *in fine* of the Regulation. However, INPI will publish "*CCP S/EFEITOS-CADUCID.DA PAT.BASE*" that according to Article 15 of the SPC regulations states that the SPC has no effects when the basic patent was revoked or invalidated.

8.11 SPECIFIC ISSUES CONCERNING EXTENSION PURSUANT TO ART. 36 OF REG. 1901/2006/EC

As mentioned in section 3 above, INPI is also responsible for the issuance of SPC paediatric extensions. The SPC owner or applicant has the possibility to apply for a six-month extension of the SPC term in the case of medicinal products for paediatric use.

A request for an extension may be submitted to INPI at the time of submission of a request for a SPC, while it is pending or, if a certificate has already been granted, up to two years before it expires.

According to Art. 8(1)(d) of Reg. 469/2009/EC, the following documents must be attached to the application: copy of the certification of compliance with an approved, completed paediatric research plan and, in the case of the procedures set forth in

[150] MPI's Questionnaire for National Patent Offices of the EU Member States, answer to question Nº 65 by the INPI.

Decree-Law 176/2006 of 30 August and a proof of marketing authorisations for all European Union Member States.

If the required documents are (partially) not filed with the request the examiner sends a notification to the applicant in order for him/her to send the missing information, within two months. However, there are some cases in which a request for an extension is granted with some of documents still missing but the applicant has to send evidence of its existence as for example that MAs have been requested in all member states but they have not yet been issued in all of them. In these cases, the applicant can deliver the missing information after the granting of the SPC.

INPI does not revoke the paediatric extension if the patent/SPC is revoked. We only inform that the basic patent/SPC was revoked so the extension cannot enter into force.[151]

[151] MPI's Questionnaire for National Patent Offices of the EU Member States, answer to question Nº 69 by the INPI.

8.12 PAYMENT OF FEES

There are fees for filling an SPC application and SPC extension application and also maintenance fees for granted SPCs which are[152]:

SPC	online	paper
SPC application	209,14€	418,29€
1st annuity	731,98€	731,98€
2nd annuity	784,28€	784,28€
3th annuity	836,56€	836,56€
4th annuity	888,86€	888,86€
5th annuity	941,14€	941,14€
Extension	679,70 €	679,70€

Table 8.1:

8.13 ENFORCEMENT OF THE SPC

According to Articles 4 and 5 of the SPC Regulations, the SPC owner can enforce his exclusivity rights against third parties in the same way as in relation to the basic patent, but limited to the product covered by the marketing authorization.

According to Article 102 of CPI the following acts are exempted from the exclusive rights:

a) Acts performed in private and not for commercial purposes;
b) The preparation of medicinal products performed at the time and for individual cases on the basis of a doctor's prescription at pharmaceutical laboratories or acts relating to the medicinal products prepared in this way;
c) Acts performed exclusively for trial or experimental purposes, including experiments for the preparation of the administrative 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;
d) Use on board ships from other countries belonging to the Union or WTO of a patented invention in the hull, machinery, rigging, gear or other accessories of the ship, if they temporarily or accidentally enter the waters of the country, provided that said invention is used exclusively to serve the ship's need;
e) The use of a patented invention in the construction or operation of aircraft or land vehicles of other countries belonging to the Union or WTO or their accessories, if they temporarily or accidentally enter national territory;
f) The acts set forth in Article 27 of the Convention of 7 December 1944 concerning international civil aviation if they have regard to aircraft from another state to which the provisions of said article apply.

[152] MPI's Questionnaire for National Patent Offices of the EU Member States, answer to question Nº 71 by the INPI.

9 ROMANIA

Mirela Georgescu[*] *María Victoria Rivas Llanos*[**]

9.1 INTRODUCTION: THE SOURCES OF LAW

Romania is a Contracting State of the EPC since 2003, as well as a Member of the PCT and the PLT. In addition, it takes part in the enhanced cooperation in the area of the creation of unitary patent protection[153] and has signed but not yet ratified the UPCA.

Romania has signed the TRIPS Agreement, but it is not a Member of the Strasbourg Convention. However, the domestic provisions are consistent with the substantive provisions of the latter Convention, since they have been harmonised with the EPC.

In Romania, patents are regulated under Patent Law No 64/1991,[154] as republished in 2014, and its Implementing Regulations, as republished in 2008.[155]

The scope of protection of national patents[156] and the rights conferred by such patents[157] are regulated by provisions with similar wording to that of Article 69 EPC and Article 28 TRIPS Agreement respectively.

The requirements for patentability are the same as those of the EPC.[158] The same is true regarding the requirement of sufficiency of disclosure[159] and the possibility of amending the patent application.[160]

Although Article 30(3) of Law 64/1991 foresees the possibility of granting an SPC for medicaments and plant protection products,[161] the Romanian legislator has not made use of the option provided by Article 19 of Regulation 469/2009/EC and Article 18 of

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153 See Regulation (EU) 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 L361/1.

154 Official Gazette of Romania, Part I, No 613/19 August 2014.

155 Official Gazette of Romania, Part I, No 456/18.VI.2008.

156 Law 64/1991, Article 31(3): 'The extent of the protection conferred by the patent or the patent application shall be determined by the content of the claims. At the same time, the invention description and drawings shall be used to interpret the claims'.

157 Law 64/1991, Article 31:
(1) The patent shall confer on its owner an exclusive right of exploitation throughout its entire duration.
(2) It is prohibited to perform, without the owner's consent, the following acts:
a) manufacturing, using, offering for sale, selling or importing for the purpose of using, offering for sale or selling, where the subject-matter of the patent is a product;
b) using the process and using, offering for sale, selling or importing for those purposes the product directly obtained by the patented process, where the subject-matter of the patent is a process.

158 Law 64/1991, Articles 6 to 12.

159 Law 64/1991, Article 17(1): 'The invention shall be disclosed in the patent application in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art'.

160 Law 64/1991, Article 26(5): 'At the request of OSIM or on his own initiative, the applicant or his successor in title may, until such time as a decision is made, modify the patent application, provided that the disclosure of the invention does not extend beyond the content of the patent application on the filing date'.

161 This possibility was introduced only after the amendment of Law No 64/1991 in 2007. See Official Gazette of Romania, Part I, no. 851/ 12 December 2007.

Regulation 1901/2006/EC to include in the national law special procedural provisions on SPCs. Nonetheless, the State Office for Inventions and Trademarks (hereinafter OSIM) has enacted guidelines both for applicants and for the examination of SPC applications, under Instruction No 146 of 28 December 2006.[162]

9.2 INSTITUTIONAL ASPECTS

OSIM is a specialised body of the central public administration, subordinated to the Ministry of Economy,[163] with legal personality and authority in the field of industrial property protection within the territory of Romania.[164]

Applicants have the option to apply for national patents before the OSIM pursuant to the national law[165] or for European patents before the EPO under the EPC rules. The OSIM can also act as receiving office for patent applications internationally filed by Romanian applicants under the PCT procedure.[166]

The OSIM is an examining office. It undertakes a substantive examination of patent applications with respect to all requirements for protection.[167] The examination takes place upon request and is subject to fee payment.[168]

The examiners involved in the examination of SPC applications have a technical background in the field of Chemistry, Biochemistry or Pharmacy.[169]

9.3 FILING OF THE APPLICATION AND PUBLICATION

The patent owner or his successor in title[170] must file the SPC application before the OSIM in Romanian language.[171]

The SPC application must contain an application form designed according to the formal requirements stipulated under Article 8 of the SPC Regulations, including the following information:

i. The name and address of the applicant and his representative -when representation is required-;[172]

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162 Instruction Concerning the Supplementary Protection Certificate for Medicaments and the Supplementary Protection Certificate for Plant Protection Products, issued by the Director General of the State Office for Inventions and Trademarks and Based on Art. 6(3) of the Government Decision No. 573/07.09.1998 Concerning the Organisation and Functioning of the State Office for Inventions and Trademarks, published in the Romanian Official Gazette no.345 of 11 September 1998.

163 Government Decision No. 63 of 23 February 2017 for the modification of Government Decision No. 573/1998 concerning organisation and functioning of the OSIM.

164 Law 64/1991, Article 65.

165 Law 64/1991, Article 66(b).

166 Law 64/1991, Article 66(d).

167 MPI's Questionnaire for National Patent Offices of the EU Member States, answer to question No 52 by the OSIM.

168 Law 64/1991, Article 24(1), in conjunction with its Implementing Regulations, Article 42(1).

169 MPI's Questionnaire for National Patent Offices of the EU Member States, answer to question No 54 by the OSIM.

170 Instruction No 146/28.12.2006, Article 2(7) and (8). The SPC application can be filed by the registered licensee; MPI's Questionnaire for National Patent Offices of the EU Member States, answer to questions No 3 and 4 by the OSIM.

171 Instruction No 146/28.12.2006, Article 2(1).

172 See heading 15.2.7.6 below.

ii. The number of the basic patent and the title of the invention;
iii. The number and date of the first authorisation to place the product on the market in Romania, the number and date of the first authorisation to place the product on the market in the EEA -if the marketing authorisation for the territory of Romania was not the first one in the EEA-;
iv. The product[173] identified by the marketing authorisation for which the grant of the SPC is requested, and the Regulation[174] based on which the SPC is requested).[175]
v. The SPC application form must be accompanied by a copy of the authorisation to place the product on the market in Romania[176] valid on the date of filing of the SPC application and it must indicate the product's name, the authorisation's number and date, a summary of the product characteristics and the authorisation's validity term.[177] If the authorisation to place the product on the market in Romania is not the first one in the EEA, the application must also be accompanied by the latter, indicating the product's name and the legal provision under which the authorisation was granted, together with a copy of the notice publishing the authorisation in an official gazette.[178]

The time limit for filing the application is that indicated in Article 7 of the SPC Regulations,179 calculated according to national law. If the first marketing authorisation in the EEA is granted before the basic patent and the latter is a European patent, the six-month time limit provided for in Article 7(2) of the SPC Regulations is calculated from the date on which the translation into Romanian of the European patent specification was filed before the OSIM.180

9.4 FORMAL EXAMINATION. COPY OF THE MARKETING AUTHORISATION

The OSIM will consider the application and will enter the certificate application in the Register, if the information requested in the application form is completed. If the OSIM finds any deficiency in relation to said information, it will give the applicant the opportunity to rectify it within one month from the OSIM's notification of the deficiency.[181] If the deficiency is remedied within the time limit, the date of reception of the rectified application will be considered the date of filing. If the deficiency is not rectified on time, the application will be considered not to have been filed.[182]

If a copy of the first authorisation to place the product on the market in Romania and/or, as the case may be, a copy of the first marketing authorisation to place the

173 Both the INN and the chemical formula of the product - active substance or combination of active substances. In addition to information regarding the protection of the product by the basic patent (claims, description). See Instruction 146/28.12.2006, Article 2(5).
174 Regulation 469/2009/EC or Regulation 1901/2006/EC.
175 Instruction No 146/28.12.2006, Article 2(4)(a).
176 If the marketing authorisation holder and the applicant are not the same person and the applicant is unable to provide a copy of the marketing authorisation, the OSIM will search for the marketing authorisation in the Official Journal of the European Union and/or in the European Commission Register.
177 Instruction No 146/28.12.2006, Article 2(4)(b).
178 In absence of an official publication, the applicant must present a document proving the grant of the marketing authorisation, the date of grant, the identity of the authorised product and the EEA Member State where it was granted. Instruction No 146/28.12.2006, Article 2(4)(c). MPI's Questionnaire for National Patent Offices of the EU Member States, answer to question No 5 by the OSIM.
179 Instruction No 146/28.12.2006, Article 2(2).
180 Instruction No 146/28.12.2006, Article 2(3).
181 Instruction No 146/28.12.2006, Article 3(2) or/and 3(4).
182 Instruction No 146/28.12.2006, Article 3(1)-(3).

product in the territory of the EEA (should it be earlier than the marketing authorisation granted in Romania) have not been filed or the application fees[183] have not been paid, the OSIM will invite the applicant by a written notification to submit the missing documents and pay the corresponding fees within the time limit of one month. If the applicant does not comply with such invitation within the given time limit, the application will be considered withdrawn.[184]

The OSIM will then examine whether the application was filed on time and it included all the required information and documentation. In addition, the OSIM will examine whether the basic patent was in force on the date of the application for an SPC and that the SPC applicant is the same person as the holder of the basic patent or his successor in title (in the latter case, a document proving succession must be submitted together with the SPC application).[185] If the OSIM finds any deficiency in this regard, it will inform the applicant accordingly and invite him to remedy such deficiency within 60 days from the date of the notification. If the applicant fails to comply with said invitation within the time limit, the application will be rejected.[186] After the date of filing of the SPC application, the OSIM will not allow the applicant to change neither the basic patent nor the product covered by the SPC.[187]

Once the above-mentioned requirements have been met, the OSIM will publish the SPC application in the Official Industrial Property Bulletin, mentioning at least the SPC application number and date; the applicant's identification data; the number of the basic patent; the title of the invention; the name of the product for which the SPC is requested; the number, date and authority of the first marketing authorisation granted in Romania; and, where appropriate, the number, date and country of the first authorisation to place the product on the market in the EEA.[188]

9.5 SUBSTANTIVE EXAMINATION

Subsequently, the OSIM will examine whether the requirements of Article 3, letters (a), (b) and (c) of Regulation 469/2009/EC or Article 3(1), letters (a),(b) and (c) of Regulation 1610/96/EC have been met (i.e. that the product for which the SPC is requested is protected by the basic patent, the authorisation to place the product on the market in Romania is valid and the product has not already been the subject of an SPC in Romania).[189]

The OSIM will not examine whether the requirement of Article 3(d) of Regulation 469/2009/EC or Article 3(1)(d) of Regulation 1610/96/EC (i.e. that the authorisation to place the product on the market in Romania is the first authorisation granted for that product in the EEA) is met. However, the OSIM is able to check in the national authorisation whether it is the first one or it is a re-authorisation. If the marketing authorisation has been granted by the EMA through the centralised procedure, the

183 The fees for filing and examining the SPC application, and for issuing the SPC. See Instruction No 146/28.12.2006, Article 6(1).
184 Instruction No 146/28.12.2006, Article 3(4) and (5).
185 Indstruction No 146/28.12.2006, Article 4(1).
186 Instruction No 146/28.12.2006, Article 4(2).
187 Instruction No 146/28.12.2006, Article 4(3).
188 Instruction No 146/28.12.2006, Article 4(4), and SPC Regulations, Article 9(2).
189 Instruction No 146/28.12.2006, Article 4(5).

OSIM checks in the Patent Register of the European Patents the authorisation granted in other Member States with regard to the SPC application and to the basic patent.

The OSIM's SPC Examination Staff is composed by five examiners with technical background and a jurist which carries out the formal examination of SPC applications. The decision on the grant or rejection of the SPC application is taken by the SPC Examination Board composed by three members, the President of the Board, the examiner of the SPC application and the jurist. The OSIM will publish its decision in the Official Industrial Property Bulletin[190] within one month from the date of expiry of the time limit to file an appeal against said decision[191] or within one month from the communication of the decision of the Board of Appeal. If the SPC is granted, a copy of the authorisation to place the product on the market in Romania will be made available to the public at the OSIM's premises.[192]

9.6 THIRD PARTY OBSERVATIONS

Third parties have the possibility of filing observations before the OSIM during the SPC granting procedure; however these observations play only an informative role in the examination procedure.[193]

If the OSIM receives a third party observation arguing that the SPC application does not satisfy the requirements of Article 3 of the SPC Regulations and decides anyway to grant the SPC, the OSIM does not provide in the decision to grant with reasons why the third party observations were not taken into account. The same approach is in case of a decision of rejection.

Within the examination proceedings, there is only a dialog between the applicant and the OSIM. Third parties cannot participate in this dialog and have no right to hear of the manner in which their observations have been taken into account. Nor does their observation give them the status of party in the proceedings.

9.7 EFFECT ON THE SPC GRANTING PROCEDURE OF PENDING REVOCATION OR OPPOSITION PROCEDURES AGAINST THE PATENT

According to the OSIM's answer to question No 59 of the MPI's Questionnaire for National Patent Offices of the EU Member States, the OSIM will usually suspend the SPC examination procedure if a revocation proceeding against the patent is pending.

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190 The mention of the decision to grant shall contain the following information: the identification data of the SPC holder and, when appropriate, of his patent attorney; the number of the basic patent and the title of the invention; the name of the product for which the authorisation was issued; the number, date and authority that issued the marketing authorisation for the territory of Romania; the number, date and Member State that issued the first marketing authorisation for the EEA; and the date on which the SPC protection starts and the SPC duration. See Instruction No 146/28.12.2006, Article 4(10).

191 See Instruction No 146/28.12.2006, Article 9(2).

192 See Instruction No 146/28.12.2006, Article 4(9).

193 MPI's Questionnaire for National Patent Offices of the EU Member States, answer to question No 57 by the OSIM.

The OSIM follow the same approach in case of a pending opposition procedure against the patent, considering the opposition of the basic patent as a prejudicial cause, because the patent can be revoked or altered in such a way that the product is no longer protected by the basic patent. In case of a European patent for example, the OSIM will suspend the SPC analysis until the EPO comes to a final decision.

9.8 GRANTING OR REJECTION OF THE SPC. APPEAL AND REVOCATION PROCEDURES

The decision of the OSIM's Examination Board regarding the grant or rejection of the SPC can be appealed before the OSIM within three months from its communication to the applicant.[194]

Within six months from the date of publication of the mention to grant, any person may apply for the revocation of the SPC pursuant to the invalidity grounds indicated in Article 15 of the SPC Regulations.[195]

9.9 CALCULATION OF THE PATENT AND SPC DURATION. CALCULATION OF DEADLINES. RELIEF BEFORE THE OSIM

9.9.1 Calculation of the patent and SPC duration

The patent term is of 20 years as from the filing date of the patent application, meaning that the date of filing counts as day one of the 20-year period.[196] [197]

According to the practice of the OSIM, the date of the first marketing authorisation in the EEA as referred to in Article 13 of the SPC Regulations for the calculation of the SPC term is the date of grant of the marketing authorisation written down in the respective national marketing authorisation,[198] which must be indicated by the applicant in the SPC application. In case of a European MA, OSIM applies *Seattle Genetics* to art. 13 Reg. 469/2009, considering the date of the notification as the relevant date of the MA for calculation of duration of the SPC.[199]

9.9.2 Calculation of terms

Regarding the general calculation of time limits, Article 3 of Law 64/1991's Implementing Regulations states that:

> (1) The time limits shall be expressed in days, months or years.

194 Instruction No 146/28.12.2006, Article 9(2).
195 Instruction No 146/28.12.2006, Article 9(3).
196 Law 64/1991, Article 30(1).
197 MPI's Questionnaire for National Patent Offices of the EU Member States, answer to question No 44 by the OSIM.
198 In Romania, a marketing authorisation issued by the National Agency of Medicines and Medical Devices takes effect on the date of grant. MPI's Questionnaire for National Patent Offices of the EU Member States, answer to question No 15 by the OSIM.
199 MPI's Questionnaire for National Patent Offices of the EU Member States, answer to question No 13 by the OSIM.

(2) The time limit expressed in days shall not contain either the day when the period started or the day when the period ended.
(3) The time limit expressed in months or years shall expire in the relevant subsequent day of the month or year corresponding to the starting day.
(4) The time limit starting on the dates of 29, 30 or 31 of the month and expiring in a month not having a day with the same number shall be deemed to end on the last day of the month; the time limit which expires on a statutory holiday or when the office is closed for the public shall be extended until the end of the first working day that follows.

9.9.3 Relief before the OSIM for missed deadlines

With similar wording to Article 12 PLT and Article 122 EPC, Law 64/1991[200] foresees the possibility for the applicant or patent owner to have his rights re-established when, for legitimate grounds, he was unable to observe a time limit in the proceeding before the OSIM resulting on the loss of a right in respect of the patent application or the patent. The request for re-establishment of rights must be filed before the OSIM within two months of the removal of the cause of non-compliance, but at the latest within one year of expiry of the unobserved time limit. Such a request is subject to fee payment.

If the loss of rights was due to delayed payment of the SPC maintenance fees, the applicant must file the request for re-establishment of rights within six months of the date of publication of the loss of rights in the Official Industrial Property Bulletin.[201]

Law 64/1991's provisions regulating re-establishment of rights are also applicable to SPCs.[202]

9.10 REPRESENTATION BEFORE THE OSIM

Representation[203] is compulsory in proceedings before the OSIM when the applicant, assignor or patent owner has his domicile or registered office outside the territory of Romania, with exception of the filing of the patent application with the purpose of being accorded a filing date, the payment of a fee, the submission of a copy of the previous application and the issuance of a notification by the OSIM with respect of one of these procedures.[204]

9.11 POST-GRANT AMENDMENT OF THE SPC DURATION. POST-GRANT LIMITATION OR REVOCATION OF THE PATENT

9.11.1 Post-grant amendment of the SPC duration

Article 17(2) of Regulation 1610/96/EC has been used in the Romanian appeal procedures, opening the possibility for the applicant to file an appeal against the OSIM's decision aimed at rectifying the duration of the SPC. Such appeal is not subject

200 Law 64/1991, Article 41, in conjunction with its Implementing Regulations, Article 53.
201 Law 64/1991, Article 35 in conjunction with Article 40(3).
202 MPI's Questionnaire for National Patent Offices of the EU Member States, answer to question No 48 by the OSIM.
203 On the basis of a power of attorney filed with the OSIM.
204 Law 64/1991, Article 37(1) and (2).

to deadlines but the SPC must be still valid at the date on which the appeal is filed and is subject to fee payment.

9.11.2 Post-grant limitation or revocation of the patent

A patent may be limited post-grant as a consequence of an appeal procedure initiated before the OSIM's Board of Appeal against a decision made by the OSIM's Examination Board. The appeal must be filed within three months from the communication of the Examination Board's decision, according to the procedure set down in Article 48 of Law 64/1991 in conjunction with Article 57(4) of its Implementing Regulations.

Any interested person can file a request for revocation of a granted patent before the OSIM, within six months of the publication of the patent's mention. The revocation must be based on the non-patentability of the subject-matter of the patent, insufficiency of disclosure, or the fact that the subject-matter of the patent exceeds the content of the patent application as filed.[205] If the grounds for revocation relate to a part of the patent, the patent will be only partially revoked.[206]

Article 9(1) of Instruction No 146/28.12.2006 states that 'According to Art. 15 (2) and Art.17 of the Regulations, the Patent Law provisions concerning the appeal, revocation and cancellation of patents shall also apply to the certificates'.

9.12 SPECIFIC ISSUES CONCERNING EXTENSION PURSUANT TO ART. 36 OF REG. 1901/2006/EC

In Romania, it is possible to apply for an extension of the SPC term, pursuant to Article 8(2)(d) of Regulation 469/2009/EC in conjunction with Article 36(1) and (3) of Regulation 1901/2006/EC.

The OSIM has enacted guidelines both for the applicants and for the examination of applications for the extension of the SPC term, under the Order of the Director General No 23 of 19 June 2012.

The statement indicating compliance with an agreed completed paediatric investigation plan required by the aforementioned provisions can be filed after the filing of the request for extension within the time limit provided the OSIM. This time limit can be extended if all the diligences for obtaining and filing of the documentation have been taken.

9.13 PAYMENT OF FEES

The filing, examining and issuing of the SPC are subject to fee payment. In addition, the SPC holder must pay annual fees, which are due on the first day of the year of SPC protection. The amount of said fees is indicated in Annex 1, paragraphs 24 and 25

[205] Law 64/1991, Article 49(1). See also Law 64/1991's Implementing Regulations, Article 57(5).
[206] Law 64/1991, Article 49(2).

of Government Ordinance 41/1998 concerning fees to be paid in the industrial property protection field, as amended by Law 381/2005.[207]

If the grant of the SPC takes place after the expiry of the basic patent, the annual fee for the first years of protection must be paid on the date of publishing the mention of the decision to grant the SPC.[208]

9.14 ENFORCEMENT OF THE SPC

The publication of the SPC application in the Official Gazette is merely to inform the public. It does not have the effect of provisional protection. Publication serves as a warning and provides transparency for third parties, with the result that third parties can assess the product for which a certificate can be issued and for what duration.

Third parties cannot benefit from an intervening right during the period between the expiry of the basic patent and the grant of the certificate.

According to Article 56 of Law 64/1991, patent infringement is punished with imprisonment from three months to two years or with a fine. In addition, the patent holder or the licensee is entitled to claim the damages foreseen by civil law and can request to the competent court order the infringing products to be confiscated or destroyed.

Pursuant to Article 62(2) of Law 64/1991 'Customs competence concerning the enforcement of patent/SPC rights at the borders belongs to the National Agency for Fiscal Administration, according to Law 344/2005 Concerning Certain Measures for Ensuring the Enforcement of Intellectual Property Rights within Customs Operations'.

[207] Official Gazette No 6 of 4 January 2006. See Instruction No 146/28.12.2006, Article 6(1)-(4).
[208] Instruction No 146/28.12.2006, Article 6(5).

10 SPAIN

Gabriel González Limas[*] *María Victoria Rivas Llanos*[**]

10.1 INTRODUCTION: THE SOURCES OF LAW

Spain is a Contracting State of the EPC, as well as a Member of the PCT, the PLT and the TRIPS Agreement. Although it is not a Member of the Strasbourg Convention, the domestic provisions are consistent with the substantive provisions of the latter Convention, since they have been harmonised with the EPC. Spain has not signed the UPCA and does not take part in the enhanced cooperation in the area of the creation of unitary patent protection.[209]

Patents are regulated under Law 24/2015 of Patents of 24 July 2015[210] and under Royal Decree 316/2017 of 31 March 2017[211] approving Law 24/2015's Implementing Regulations. Both Law 24/2015 and Royal Decree 316/2017 entered into force on 1 April 2017.

The scope of protection of national patents[212] and the rights conferred by such patents[213] are regulated by provisions with similar wording to that of Article 69 EPC and Article 28 TRIPS Agreement respectively.

The requirements for patentability are the same as those of the EPC.[214] The same is true regarding the requirement of sufficiency of disclosure[215] and the possibility of amending the patent application.[216]

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209 See Regulation (EU) 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 L361/1.

210 Boletín Oficial del Estado (BOE) Núm 177, Sec I, p 62765.

211 BOE Núm 78, Sec I, p 25281.

212 Law 24/2015, Article 68(1): 'El alcance de la protección conferida por la patente o por la solicitud de patente se determina por las reivindicaciones. La descripción y los dibujos servirán para interpretar las reivindicaciones'.

213 Law 24/2015, Article 59(1):
La patente confiere a su titular el derecho a impedir a cualquier tercero que no cuente con su consentimiento:
a) La fabricación, el ofrecimiento para la venta, la introducción en el comercio o la utilización de un producto objeto de la patente o la importación o posesión del mismo para alguno de los fines mencionados.
b) La utilización de un procedimiento objeto de la patente o el ofrecimiento de dicha utilización, cuando el tercero sabe, o las circunstancias hacen evidente que la utilización del procedimiento está prohibida sin el consentimiento del titular de la patente.
c) El ofrecimiento para la venta, la introducción en el comercio o la utilización del producto directamente obtenido por el procedimiento objeto de la patente o la importación o posesión de dicho producto para alguno de los fines mencionados.

214 See Law 24/2015, Articles 4 to 9.

215 Law 24/2015, Article 27(1): 'La invención debe ser descrita en la solicitud de patente de manera suficientemente clara y completa para que un experto sobre la materia pueda ejecutarla'.

216 Law 24/2015, Article 48(5): 'La solicitud de la patente o la patente no podrán modificarse de manera que su objeto exceda del contenido de la solicitud tal como se haya presentado inicialmente'.

As SPCs are concerned, some procedural matters especially applicable to them are regulated under Articles 45 to 47 of Law 24/2015 and Articles 54 to 57 of its Implementing Regulations. The SPTO has not enacted specific Guidelines for the examination of SPC applications.[217]

The national procedural provisions applicable to patents apply also to the SPC, even when the basic patent designated for the procedure is a European patent. This is so, because the SPTO understands the referral of Article 19 of Regulation 469/2009/EC and Article 18 of Regulation 1901/2006/EC as a referral to the national procedure even if the basic patent was granted by the EPO on the basis of the EPC's provisions and not by the SPTO on the basis of the national provisions.

Before the entry into force of Law 24/2015, its predecessor -Law 11/1986 of Patents of 20 March 1986[218]- did not include any provision related to SPCs, the legal term of an ordinary patent was –and still is under Law 24/2015- of 20 non-extendable years from the date of filing.[219] The creation of an SPC title through Regulation EEC No 1768/92,[220] directly applicable in Spain, opened the possibility of obtaining SPCs before the Spanish national authorities.

10.2 INSTITUTIONAL ASPECTS

In Spain, the patent applicant has the option to apply:

a) For a national patent before the Spanish Patent and Trademark Office (SPTO) or the competent body of one of the Spanish autonomous regions[221] pursuant to Law 24/2015;
b) For a European patent before the EPO under the EPC rules or before the SPTO/the competent body of one of the Spanish autonomous regions.

Despite the foregoing, in the case of European patent applications related to inventions made in Spain and which do not claim priority of any previous deposit in Spain, the application must be necessarily filed before the SPTO. If the applicant is either domiciled or has his registered office or is habitually resident in Spain, this will be *prima facie* evidence of the fact that the invention was carried out in Spain.[222]

The SPTO can also act as receiving, designated or elected office[223] as well as international searching authority and international preliminary examining authority[224] for international applications filed under the PCT procedure.

The SPTO is governed by Law 17/1975, of 2 May 1975, on the creation of the autonomous agency Register of the Industrial Property[225] (today SPTO); Law 21/1992,

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217 MPI's Questionnaire for National Patent Offices of the EU Member States, answer to question No 2 by the SPTO.
218 BOE Núm 73, of 26 March 1986, p 11188-11208.
219 Article 58 of Law 24/2015 regulated the duration of the patent with identical wording to Article 49 of Law 11/1986.
220 Oficial Journal of the European Comunities No L 182/2.
221 See Law 24/2015, Articles 22 and 32.
222 Law 24/2015, Article 152(2).
223 Law 24/2015, Article 162 et seq.
224 Law 24/2015, Article 174.
225 BOE Núm 107, of 5 May 1975, p 9421-9423.

of 16 July 1992, of Industry;[226] General Tax Law 58/2003, of 18 December 2003;[227] and by any other legal provision applicable to the autonomous agencies of the Central State's Administration.[228]

The SPTO is an autonomous agency within the Spanish Ministry of Industry of Energy, Tourism and Digital Agenda[229] It has legal personality, as well as economic and administrative autonomy for the attainment of its objectives and the management of its assets and the funds assigned to it.[230]

Law 24/2015 introduced for the first time in Spain substantive examination as the only available system for the concession of patents.[231] The substantive examination, also called preliminary examination of novelty and inventive step, is undertaken by the SPTO's patent examiners, who have a technical background and also a legal training on industrial property.

The SPTO is also the authority competent pursuant to Article 9 of the SPC Regulations to grant SPCs. A substantive examination is provided also for SPC applications. The examiners concerned are graduated in chemistry or biology and have also a legal training on industrial property.[232]

10.3 FILING OF THE APPLICATION

In Spain, an SPC application must be filed before the SPTO by the owner of the basic patent.[233] If the patent is owned by more entities, the SPC application must be filed by an elected common representative, usually an industrial property agent officially accredited by the SPTO.

The application must be accompanied by an application form designed according to the formal requirements stipulated under Article 8 of the SPC Regulations,[234] including the following information:

i. The name and address of the applicant and his representative -when representation is required-;
ii. The number of the basic patent and title of the invention;
iii. The number, date and Member State of the first authorisation to place the product on the market in the EEA -when the marketing authorisation for the territory of Spain was not the first one in the EEA-; and the number and date of the first marketing authorisation to place the product on the market in Spain, accompanied by a copy either of both authorisations or a copy of the Spanish authorisation together with a copy and a translation of the publication of the EEA authorisation in the corresponding official gazette.

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226 BOE Núm 176, of 23 July 1992, p 25498-2550.
227 BOE Núm 302, of 18 December 2003, p 44987-45065.
228 Royal Decree 903/2017, Article 2(1).
229 Royal Decree 903/2017, Article 2(1).
230 Law 17/1975, Articles 1(2) and 8.
231 Under its predecessor, Law 11/1986 of Patents, substantive examination was an optional system rarely used by the national applicants; transferring the burden of invaliding the patent to the competitor. See Explanatory Memorandum to Law 24/2015, Section I, paragraph 9, and Section IV, paragraph 5 and 6.
232 MPI's Questionnaire for National Patent Offices of the EU Member States, answer to question No 54 by the SPTO.
233 MPI's Questionnaire for National Patent Offices of the EU Member States, answer to questions No 3 and 4 by the SPTO.
234 Law 24/2015, Article 45(1) in conjunction with Royal Decree 316/2017, Article 54(1).

Moreover, the application must contain the title of the product[235] for which the SPC is requested and information[236] proving that the product is protected by the basic patent indicated by its proprietor for the purposes of obtaining the SPC.

Finally, the application must include proof of payment of the application fee. If the application includes a request for paediatric extension, it must be accompanied, in addition to the documentation required pursuant to Article 8(1)(d) of Regulation 469/2009/EC, by a statement on the content of such documentation indicating the EEA Member States to which it corresponds.[237]

The application must be filed within the timeframe indicated in Article 7 of the SPC Regulations. The deadline is calculated according to national law.

10.4 FORMAL EXAMINATION

Upon reception of the application, the SPTO verifies that the application fee has been paid and that the application contains the necessary information for its publication according to Article 9(2) of the SPC Regulations (namely the name and address of the applicant; the number of the basic patent, the title of the invention; the number and date of the first marketing authorisation to place the product on the market in Spain; and where relevant, the number and date of the first authorisation to place the product on the market in the EEA).

If within the information provided to the SPTO there is any missing data required for the SPC application to be published pursuant to Article 9 of the SPC Regulations, the applicant will be notified on this issue and informed that the application will be rejected if the missing data are not provided within 10 days from the publication date of such a notification in the Official Industrial Property Gazette.[238] Once the formal examination has been successfully passed and within three months from such date, the SPTO will publish the application in the Spanish Official Industrial Property Gazette.[239]

10.5 SUBSTANTIVE EXAMINATION

Once the SPC application is published, the SPTO will examine whether the application for an SPC (as well as its extension, if a paediatric extension was requested together with the SPC application) and the product covered by the marketing authorisation meet all the substantive requirements prescribed in the SPC Regulations. The examination is generally performed by a single examiner. However, if the examiner in charge of the SPC application finds any particularly difficult issue or has any doubt

235 Directed at the name of the active substance or combination of active substances included in the marketing authorisation in any of the forms enjoying the protection of the basic patent.

236 Typically, this information is provided in a document furnished as an annex explaining which claims in the basic patent refer to the product for which the SPC is sought. The SPTO does not have any special requirement about how comprehensive the information provided should be. This requirement is based on Article 54.1.a).ii) for medicinal products or Article 54.1.b).ii) for plant protection products, Royal Decree 316/2017, published 31 March 2017.

237 Royal Decree 316/2017, Article 54(1)(c).

238 Law 24/2015, Article 46(2) in conjunction with Royal Decree 316/2017, Article 55(1).

239 Law 24/2015, Article 46(2) in conjunction with Royal Decree 316/2017, Article 55(2).

regarding the application, a group of three examiners will meet to decide on how to proceed.

The SPTO will examine the requirements under Article 3(a), (b) and (c) of Regulation 469/2009/EC or Article 3(1)(a), (b) and (c) of Regulation 1610/96/EC. However, it will not verify *ex officio* whether the requirement of Article 3(d) of Regulation 469/2009/EC or Article 3(1)(d) of Regulation 1610/96/EC has been met[240] and thus, can grant the SPC in absence of such requirement.

Regarding the requirement of Article 3(a) of Regulation 469/2009/EC and Article 3(1)(a) of Regulation 1610/96/EC, the SPTO requires that the product is specified in the claims of the patent, however, it has not adopted guidelines or developed a particular criteria in this regard. Every SPC application is considered on a case-by-case basis, taking into account the rulings of the CJEU, in particular "Medeva" (C-322/10), "University of Queensland" (C-630/10) and "Eli Lilly" (C-493/12).

As the requirement of Article 3(b) of Regulation 469/2009/EC and Article 3(1)(b) of Regulation 1610/96/EC is concerned, the SPTO requires that the marketing authorisation has been granted and is still in force ("vigente") at the date on which the SPC application has been filed.[241] Further, the marketing authorisation must be still in force at the date on which the decision to grant or reject the SPC is taken by the Office. However, whether or not the marketing authorisation is still valid at the SPC's date of grant is not checked by the SPTO.

If the Office finds any irregularity in the submitted documentation (for instance, if the copy of the marketing authorisation is missing[242]) or if the application or its object do not meet the requirements of the SPC Regulations,[243] the existence of such irregularity will be published in the Spanish Official Industrial Property Gazette and the applicant will be notified and informed that the application will be rejected if the irregularity is not rectified within two months (with the possibility of requesting two additional months) from the date of said publication of the existence of an irregularity.[244] Should the deficiency be remedied within the time limit, the date of reception of the rectified application will not be considered as the date of filing. That is to say, the application date does not change when the SPTO receives the rectified application.

The decision of the SPTO[245] on the grant or rejection of the SPC -and, as the case may be, also the paediatric extension- is published in the Spanish Official Industrial

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240 Law 24/2015, Article 46(1) in conjunction with its Implementing Regulations, Article 56(1); and MPI's Questionnaire for National Patent Offices of the EU Member States, answer to question No 53 by the SPTO. See also heading 15.2.8.6 below with regard to third party observations.

241 MPI's Questionnaire for National Patent Offices of the EU Member States, answer to question No 26 by the SPTO.

242 If the applicant can prove that he is not able to provide the SPTO with a copy of the marketing authorisation because the marketing authorisation is hold by a different subject, who is not willing to provide the patent holder with a copy, the SPTO will not reject the SPC application on this ground alone (in this regard, the SPTO follows the CJEU's ruling in Case C-181/95, "Biogen").

243 At this stage of the granting procedure the irregularities might be related to the conditions for obtaining a certificate according to Articles 3, 6, 7 and 8 of the SPC Regulations or Articles 54 and 56 of the Spanish Patent Law 24/2015 (e.g. the SPC application does not include a copy of the marketing authorisation, the product is not protected by the basic patent in force, the applicant is not the holder of the basic patent, or applicant has not provided information proving that the product is protected by the basic patent).

244 Law 24/2015, Article 46(2) in conjunction with Royal Decree 316/2017, Article 56(2).

245 Before the decision on the grant or rejection of the SPC is taken, the applicant can request an informal hearing in order to discuss on the SPC application.

Property Gazette, according to Article 11 of the SPC Regulations.[246] In addition, information on the application for an SPC -and, as the case may be, the paediatric extension- and its grant is entered in the SPTO's Patents Register.[247]

10.6 THIRD PARTY OBSERVATIONS

The new Spanish Law 24/2015, in conjunction with its Implementing Regulations, provides for a complete regulation of the SPC granting procedure. In the wording of these two legal provisions it is not explicitly foreseen the possibility for any third party to file observations before the SPTO during the SPC granting procedure, after publication of the application in the Official Industrial Property Gazette.[248]

However, it is a customary practice to file third party observations before the SPTO during the SPC granting procedure and to carefully assess such observations from interested third parties.

These observations can help the SPTO to find out deficiencies in the application that it would not be capable of identifying on its own motion (e.g., that the marketing authorisation indicated in the SPC application was not the first authorisation granted in the EEA according to Article 3(d) of the SPC Regulations).[249] Nevertheless, it is worth noting that, since the third party is not considered a party in the proceeding, the SPTO does not have any legal obligation to take such observations into consideration or to provide the granting decision with reasons why the third party observations were not taken into account or why they were not convincing enough.

10.7 EFFECT ON THE SPC GRANTING PROCEDURE OF PENDING REVOCATION OR OPPOSITION PROCEDURES AGAINST THE PATENT

According to Article 3(a) of Regulation 469/2009/EC and Article 3(1)(a) of Regulation 1610/96/EC, an SPC shall be granted if the product is protected by a basic patent in force. For this reason, as long as there is no final decision on a revocation or opposition procedure, the SPTO consider that the basic patent is still in force. Therefore, a pending revocation or opposition procedure against the basic patent does not have any effect on the SPC granting procedure before the SPTO.

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246 Law 24/2015, Article 46(2) in conjunction with Royal Decree 316/2017, Articles 56(3) and 57.

247 Royal Decree 316/2017, Article 72(4).

248 Article 36 under its predecessor, Law 11/1986. MPI's Questionnaire for National Patent Offices of the EU Member States, answer to question No 57 by the SPTO. As pointed out by SPTO: "[l]egal grounds for filing third party observations is a much-debated issue in the SPTO. It is true that third party observations were filed based on Article 36 grounds when the prior Spanish Law 11/1986 was in force. This article provided that any person could submit duly reasoned and documented observations to the report on the state of the art. This provision is similar to those of Articles 38 of the Law 24/2015 and Article 32 of its Implementing Regulations. In addition, Article 38 also makes it explicit that these third parties will not be considered part to the patent grant proceedings. However, we [SPTO] indeed expect[s] third party observations to be filed based on Article 38 of the Law 24/2015 and Article 32 of its Implementing Regulations."

249 José Macías Martín, 'Certificados Complementarios de Protección' in Alberto Bercovitz Rodríguez-Cano and Raúl Bercovitz Álvarez (eds), *La Nueva Ley de Patentes: Ley 24/2015, de 24 de julio* (Thomson Reuters 2015).

10.8 GRANTING OR REJECTION OF THE SPC. APPEAL PROCEDURE

Against the decisions of the SPTO is possible to file an appeal ("recurso de alzada") before the director of the SPTO within one month from the publication of the Office's decision.[250]

Any interested party can file this kind of appeal. The concept of interested party is understood in an ample way, including anyone who has a legitimate interest that can be affected by the SPTO's decision.[251] Nevertheless, it is worth noting that this kind of appeal shall only be allowed on grounds of what the SPTO examines *ex officio* (Law 24/2015, Article 46).

The decision of the director of the SPTO regarding the aforementioned appeal can be challenged at a second instance by filing an appeal ("recurso contentencioso-administrativo") before the national administrative courts ("tribunales de lo contencioso-administrativo").[252]

10.9 CALCULATION OF THE PATENT AND SPC DURATION. CALCULATION OF TERMS. RELIEF BEFORE THE SPTO

10.9.1 Calculation of the patent and SPC duration

Pursuant to Article 58 of Law 24/2015, the patent duration is of 20 years, counted from the date of filing of the application.[253]

According to the practice of the SPTO, the date of the first marketing authorisation in the EEA as referred to in Article 13 of the SPC Regulations for the calculation of the SPC term is the date of issue of the marketing authorisation.[254]

10.9.2 Calculation of terms

For the general calculation of time limits indicated in Law 24/2015 or its Implementing Regulations, Law 39/2015 on the Common Administrative Procedure of the Public

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250 Law 24/2015, Article 46(2) and First Additional Provision, in conjunction with Law 39/2015, Articles 121 and 122.

251 Oficina Española de Patentes y Marcas, *Guía de Recursos Administrativos* (11.11.2014). Available at: <https://www.oepm.es/es/invenciones/modelo_utilidad/Informacion_adicional/GuiaRecursosAdministrativos.html>

252 Law 24/2015, Article 54; and MPI's Questionnaire for National Patent Offices of the EU Member States, answer to question No 62 by the SPTO.

253 The period is computed from date to date being the first one the date of filing of the patent application and the second one the same day of the month as that of the filing date 20 years later. For instance, for a patent filed on 15 October 2015:

i)	expiry date of the basic patent;	15 October 2035
ii)	start date of the SPC;	16 October 2035
iii)	maximum expiry date of the SPC without paediatric extension, (maximum five year term);	15 October 2040
iv)	maximum expiry date of the SPC with paediatric extension (the extended five year term);	15 April 2041

254 MPI's Questionnaire for National Patent Offices of the EU Member States, answer to question No 15 by the SPTO. As pointed out by Spanish NPO: "[it] refers only to Spanish MA. However, when it comes to the first national MA in the EEA, after the CJEU´s ruling in case C-471/14 (*Seattle Genetics* Case) if the applicant can give reliable evidence of the date of the MA notification, the SPTO would consider that notification date as relevant. So far this has only happened once."

Administration[255] applies.[256] Article 30(3)-(5) of Law 39/2015 regulates the calculation of time limits in similar terms to Rule 131(2) and (3) of the EPC. When a period is expressed in days, computation will start on the day following the day on which the notification or the publication of the relevant administrative act took place. When fixed in months or years, the term starts on the day following the date of notification or publication of the corresponding act and ends on the same day in the month or year of expiration. If in the month of expiration there was no day equivalent to the one in which the computation begins, it will be understood that the term expires on the last day of the month. When the last day of the term is a non-working day, it will be extended to the next working day.

10.9.3 Relief before the SPTO for missed deadlines

Article 53 of Law 24/2015 in conjunction with Articles 70 and 71 of its Implementing Regulations foresees the possibility that the patent applicant (or any other party in a proceeding regulated under Law 24/2015) requests re-establishment of rights when, in spite of all due care required by the circumstances having been taken, he was unable to observe a time limit vis-à-vis the SPTO and the non-observance of this time limit had the direct consequence of causing the refusal of the patent application or of a request, or the deeming of the application to have been withdrawn, or the revocation of the patent, or the loss of any other right or means of redress.

The above-mentioned provision is a common provision for all proceeding regulated under Law 24/2015, including that of the SPC applications (in particular, with regard to the deadline to file an SPC application pursuant to Article 7 of the SPC Regulations and the deadline to pay the SPC maintenance fee pursuant to Article 184(5) of Law 24/2015).

The request for re-establishment of rights must be filed in writing within two months of the removal of the cause of non-compliance or within twelve months of the date of expiry of the missed time limit, whichever is earlier. The omitted act must also be completed within this time. If the request for re-establishment is due to the lack of payment of the maintenance fee, the deadline for filing the request is twelve months from the date of expiry of the deadline of six months with surcharge established in Article 185(2) of Law 24/2015.[257]

The request for re-establishment of rights will not be deemed to have been filed until the prescribed fee[258] has been paid.

The decision of the SPTO regarding the grant or rejection of the request will be published in the Spanish Official Industrial Property Gazette and is open to appeal, which must be filed before the director of the SPTO within one month from its publication.

255 BOE Núm 236, Sec I, p 89343.
256 Royal Decree 316/2017, Article 68(1).
257 Law 24/2015, Articles 53(2)(ii).
258 Law 24/2015, Annex 1.1.

10.10 REPRESENTATION BEFORE THE SPTO

Pursuant to Article 175 of Law 24/2015, the representation of the applicant before the SPTO is only mandatory if he is not resident in an EU Member State. If the applicant has his residence outside the EU, he must be represented by an industrial property agent officially accredited by the SPTO pursuant to Article 179 of Law 24/2015 and according to the requirements of Articles 176 and 177 of the same Law.

10.11 POST-GRANT AMENDMENT OF THE SPC DURATION. POST-GRANT LIMITATION OR REVOCATION OF THE PATENT

10.11.1 Post-grant amendment of the SPC duration

According to the reply of the SPTO to question No 65 of MPI's Questionnaire for National Patent Offices of the EU Member States, the post-grant amendment of the SPC duration is not contemplated under the Spanish Patent Law or its Implementing Regulation and thus, this possibility currently does not exist in Spain.

10.11.2 Post-grant limitation or revocation of the patent

According to Article 105 of Law 24/2015, the patent owner can file a request before the SPTO to post-grant limit the patent -through the amendment of the patent claims- or to revoke it, at any point during the life time of the patent and also during the SPC term.[259]

The SPTO will grant the request for limitation of the patent as long as the modified patent claims are clear and concise and the limitation does not extend the protection conferred by the patent.[260]

The SPTO will reject the request for limitation or revocation of the patent if there are existing rights in rem, call options, seizure rights or licences inscribed in the Patents Register and the owners of those rights have not given their consent to such limitation or revocation. The SPTO will also reject the post-grant limitation or revocation of the patent if there is a judicial action claiming the ownership of the patent or other property rights over the patent are inscribed in the Patents Register and the claimant has not given his consent.

If there is a pending judicial proceeding regarding the validity of the patent, the request to limit the patent must be authorised by the court seized of the case.

Pursuant to Article 107 in conjunction with Article 104 of Law 24/2015, both the limitation and the revocation of the basic patent have retroactive effect. The amended claims will determine the protection conferred by the patent, which will determine the protection conferred by the SPC to the extent that the limitation of the basic patent

[259] This was not possible before the entry into force of Law 24/2015, since its predecessor Law 11/1986 did not allow it.

[260] Law 24/2015, Article 106(1) in conjunction with Articles 28 and 48(6). See also Articles 84 and 123(3) EPC.

affects the product protected by the SPC.[261] The retroactive effect of the limitation/revocation of the basic patent will not affect final decisions regarding patent infringement or contracts concluded before such limitation/revocation. Notwithstanding the foregoing, it is possible to request compensation for damages and reimbursement of the amounts paid under the above-mentioned contract.[262]

10.12 SPECIFIC ISSUES CONCERNING EXTENSION PURSUANT TO ART. 36 OF REG. 1901/2006/EC

The SPC applicant has the possibility to apply for a six-month extension of the SPC term when the product covered by the marketing authorisation is a medicinal product directed at the paediatric population according Article 1(2) of Regulation 1901/2006/EC.

The applicant can file the application for an extension of the SPC term together with the SPC application or separately, no later than two years before the expiry of the SPC.[263]

For the SPTO to grant such extension, the application must meet the requirements of Article 8(1)(d) of Regulation 469/2009/EC in conjunction with Article 36 of Regulation 1901/2006/EC. If the SPTO finds any error or deficiency in the documentation submitted by the applicant according to Article 8(1)(d) of Regulation 469/2009/EC, the Office will give the applicant two months from the notification of such irregularity - with the possibility of requesting two additional months- to rectify it. If the irregularity is not corrected within the given time limit, the extension of the SPC term will be rejected.[264]

The extension of the SPC term is subject to revocation under the circumstance foreseen in Article 16(1) of Regulation 469/2009/EC (i.e. when it was granted contrary to the provisions of Article 36 of Regulation 1901/2006/EC). The SPTO is however not allowed to revoke a granted extension of the SPC term on its own motion.[265]

10.13 PAYMENT OF FEES

According to Article 8(4) of Regulation 469/2009/EC and Article 8(2) of Regulation 1610/96/EC, the Member States may provide that a fee is to be payable upon application for an SPC and the extension of its duration. In line with these provisions, Law 24/2015 requires the payment of such fees, the amount of which is specified in Annex 1.1.

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261 See Regulation 469/2009/EC and Regulation 1610/96/EC, Article 15(1)(c).
262 Law 24/2015, Article 104(3).
263 Regulation 469/2009/EC, Article 7(3) and (4).
264 MdPI's Questionnaire for National Patent Offices of the EU Member States, answer to question No 69 by the SPTO.
265 MPI's Questionnaire for National Patent Offices of the EU Member States, answer to question No 70 by the SPTO.

In addition, as foreseen by Article 12 of the SPC Regulations, the maintenance of the SPC is subject to fee payment. Before the SPTO, this fee must be paid in one instalment and its amount is determined according to the duration of the SPC.[266]

The time frame for the payment of the maintenance fee for the SPC or its extension starts on the date of its entry into force. If such a date is earlier than the date of publication of the grant of the SPC or of its extension in the Spanish Official Industrial Property Gazette, the payment must be made within three months from such a publication date. If the date of entry into force is the same or later than the publication date of the grant, the payment must be completed within three months from the date of entry into force.[267]

If the deadline for payment of the maintenance fee has expired without its amount having been made effective, it can still be paid with a 25 percent surcharge within the first three months of delay and with a 50 percent surcharge within the following three months, until a maximum of six months of delay.[268]

10.14 ENFORCEMENT OF THE SPC

According to Article 5 of the SPC Regulations, a granted SPC confers the same rights as conferred by the basic patent but limited to the product covered by the marketing authorisation. Under Law 24/2015, this includes the rights to stop others from making or selling the product[269], right to compensation for damages, seizure of the infringing product, etc.[270]

In addition, pursuant to Article 67.1 of Law 24/2015:

> From the date of its publication, the patent application confers on its holder the right to a provisional protection, consisting on the right to request a compensation, reasonable and adequate to the circumstances, from any third party that, between the date of publication of the patent application and the date of publication of the patent grant, has made use the invention in a way that would be forbidden after such period by virtue of the patent.

Accordingly, a published SPC application creates an expectation of a future right in the same way as a published patent application provides a provisional protection.

The national Civil and Criminal Courts according to the scope of their respective competences- will hear all disputes rose as a consequence of the enforcement of actions derived from the provisions contained in Law 24/2015.[271]

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266 Law 24/2015, Article 47 and Annex 2.1.1.
267 Law 24/2015, Article 184(5).
268 Law 24/2015, Article 185(2).
269 Law 24/2015, Article 59(1). Please note that the so-called experimental use exception and the Bolar exemption are foreseen under Law 24/2015, Article 61(b) and (c).
270 Law 24/2015, Articles 70-78.
271 Law 24/2015, Article 116.

11 SWEDEN

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11.1 INTRODUCTION: SOURCES OF LAW

Sweden has signed and ratified all relevant agreements in the field of patents, both European and international. This includes TRIPS, the EPC, the PCT, the PLT and the Strasbourg Convention. Sweden is also a Contracting Member State of the UPCA and is a party to the enhanced cooperation for the creation of a unitary patent protection.

You may obtain a patent in Sweden by filing a national patent application either directly to the Swedish Patent and Registration Office (PRV) or as a national phase entry of a PCT application. You may also obtain a patent by filing a European patent application at the EPO directly or as a regional phase entry of a PCT application. The provisions governing both the national and European (Swedish) patents and applications are set out in the Swedish Patents Act.[272]

Since the national patent law is aligned with the provisions of the EPC, the provisions and conditions for national and European patents are to a large degree uniform. The scope of protection of national patents and the rights conferred by such patents are regulated by provisions with wording similar to that of Article 69 EPC and Article 28 TRIPS agreement respectively[273].

The scope of protection of European patents is governed in national proceedings by Article 39 of the Swedish Patents Act which is equivalent to Article 69 EPC. The rights conferred by the European patents are subject to the same provisions that apply to national patents.

The Swedish provisions governing the patentability of an invention are similar to those in Articles 52 to 57 EPC (see Articles 1 and 2 of the Swedish Patents Act). The same goes for the revocation grounds in Article 138 EPC that are aligned with Swedish provision in Article 52 of the Swedish Patents Act.

The SPC system was introduced in Sweden when Regulation (EEC) 1768/92 came into force.

Sweden has six procedural provisions that are explicitly for SPCs. These concern the payment of fees and the time limit to submit a written reply to a notice etc. [274] Furthermore, many of the procedural provisions that are applicable to patent

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[272] An unofficial translation of the Swedish Patents Act can be found at: https://www.prv.se/globalassets/dokument/patent/informationsmaterial/the-patents-act---unofficial-translation.pdf.
[273] For the Swedish provisions please see for example Article 3 or 39 of the Swedish Patents Act.
[274] The procedural provisions explicitly for SPCs can be found in Articles 105 and 106 of the Swedish Patents Act, Articles 67 and 68 of the Swedish Patents Decree and Articles 56 and 59 of the Swedish Patent Regulations.

applications and patents are also applicable on SPCs as specified in Article 19 of the Regulation (EC) 469/2009 and Article 18 of the Regulation (EC) 1610/96.

11.2 INSTITUTIONAL ASPECTS

PRV was created in 1885, financing has changed over time. From January 1, 2017 PRV is a government financed authority under the supervision of the Ministry of Enterprise and Innovation.

PRV employs around 350 persons and has two offices, one in Stockholm and one in Söderhamn.

PRV is the government authority for intellectual property rights in Sweden including the examination and granting of applications for said rights, namely trademarks, designs and patents. Copyright issues also fall within our area of operation. PRV is also the national competent authority to examine and grant SPCs according to Article 9(1) of the SPC regulations.

PRV is a patent search and examination authority that performs all the steps in the patent process. Under the national patent procedure, PRV, after a first administrative/formal examination, directs the application to the relevant technical department, within the authority, for a substantive examination. Our patent examiners all have a technical background with an expertise in the technical field they work.

Since PRV is the authority for examining and granting both patents and SPCs we have the advantage of having highly experienced and technically qualified personnel to examine the SPC applications. Examination of SPCs is entrusted to a small group of examiners (2 lawyers and 4 patent examiners). The lawyers and patent examiners work closely together, the lawyers handling all the legal aspects of the application and the examiners doing the substantive examination. The four examiners are all senior patent examiners with many years of experience (two are specialized in organic chemistry / medicinal chemistry and two are specalized in biotechnology).

11.3 FILING OF THE APPLICATION

It is the owner of the basic patent, or an authorized representative, that is eligible to file a SPC application in Sweden. If there are several proprietors they must all have a common representative in the SPC application. The requirements in Article 8 of the SPC regulations must be fulfilled and the application must also contain information on where, in the basic patent, the product is protected. If the application is submitted by a representative, we also need a duly signed Power of Attorney from the proprietor(s).

The application must be filed within 6 months from the date on which the patent is granted or within 6 months from the date on which the market authorization is granted (Article 7 of the SPC regulations). As mentioned above many of the procedural rules applicable to patents and patent applications are also applicable to SPC applications. Thus for example an applicant may ask for a re-establishment of rights if said time limit has lapsed and no application has been filed. However they, of course, need a legitimate reason.

Finally, a proof of payment of the application fee is to be included in the application.

If the application includes a request for paediatric extension, required documentation pursuant to Article 8(1) (d) of Regulation (EC) 469/2009 must also be included.

The SPC applications are published in "Svensk Patenttidning" within four weeks of their filing. The same goes for an application for an SPC extension. The applications and their status are also available via the Swedish Patent Database and file inspection on the PRV website: www.prv.se.

In the application form, a product definition specifying for which product the SPC is sought should be given. The naming of the product is preferably identical to the naming of the active ingredient(s) in the marketing authorization, however, other ways of naming the active ingredient(s) may also be used as long as the product is clearly defined, e.g. both the INN name and chemical name are accepted. References to nonactive ingredient(s), such as adjuvants and excipients, are not permitted in the product definition.

According to Swedish practice, the expression "in all acceptable salts" is accepted on the basis of Regulation (EC) 1610/96, recital 13 where salts are explicitly mentioned, provided that all acceptable salts are protected by the basic patent. However, we do not accept general expressions such as "in any form protected by the basic patent", "derivatives", "biosimilars" and "therapeutic equivalents" in the product definition. These expressions are not considered to clearly identify/define the product and, consequently, Article 3 cannot be assessed.

We have the same practice regarding the product definition regardless of whether the basic patent is based on a product, process or use, i.e., in principle, the definition of the product shall be the same as the naming of the active ingredient(s) in the marketing authorization. In case of a process patent, if it is not evident that the product is possible to obtain by the claimed process, the applicant is invited to show that this is the case. In this context, it does not matter whether it is possible to obtain the product directly as a result of the claimed process. In case of a second medical use patent, the use shall not (and cannot) be present in the product definition. Only a product (active ingredient(s)) may be the subject of a certificate (Regulation (EC) 469/2009, Article 2).

11.4 FORMAL EXAMINATION

The SPC examination is divided in primarily two steps, the formal examination and the substantive examination. If during the formal examination an irregularity is observed, eg. the marketing authorization is missing, the applicant is notified of the irregularity and is given a three-month time limit (you may ask for a two-month extension) to rectify this irregularity. Once the formal examination is over and all necessary documents and information are in order the application is directed to the patent examiners for the substantive examination.

11.5 SUBSTANTIVE EXAMINATION

The Swedish Patent and Registration Office (PRV) examines *ex officio* the substantive requirements for granting SPCs. The examination is carried out by four patent examiners with qualifications in organic chemistry/medicinal chemistry and biotechnology. Any legal aspects are handled by a lawyer.

The substantive examination includes an assessment of Articles 3(a)-3(d).

As regards the assessment of Article 3(a), the claims shall be interpreted in the light of the description according to Article 39 of the Swedish Patents Act and Article 69 EPC and the Protocol on the interpretation of that provision, respectively. An SPC may only be granted if the claims, when applying the above interpretation, relate implicitly, but necessarily and specifically to the product (active ingredient(s)) in question. This test is also valid when the product is defined in functional terms. The assessment also includes considering whether the product is protected "as such" by the claims, i.e. whether the product falls within the core inventive advance of the basic patent.

As regards the assessment of Article 3(b), the marketing authorization has to be in force at the date of filing of the SPC application.

As regards the assessment of Article 3(d), the CJEU case C-130/11 (Neurim) is interpreted so that the first marketing authorization is the first in which the product has been approved for a therapeutic indication that corresponds to the indication protected by the basic patent. The therapeutic indication is interpreted as being a disease condition. We apply this practice irrespective of whether the earlier marketing authorization was for veterinary or for human use. The marketing authorization according to Article 3(d) does not have to be in force on the filing date of the SPC application. The examination regarding Article 3(d) includes a search for earlier marketing authorizations on the Swedish Medical Products Agency's website and in their register.

As regards the assessment of Article 3(c), we consider it applicable in the case an applicant applies for an SPC for a product for which the same applicant has already been granted an SPC. In this respect it is irrelevant whether the second SPC relies on a later marketing authorization, (i.e. another therapeutic indication) since it has been established by the CJEU that the Neurim case does not influence the definition of the concept "product".

The practice applied by PRV is found in our guidelines which are available in Swedish on the PRV website.

11.6 THIRD PARTY OBSERVATIONS

According to Swedish administrative law any relevant information that is submitted in a matter must be considered before taking a decision. Thus, if a third party submits observations in an SPC application the examiner must consider whether the submitted observations are of relevance to the matter. If it is relevant the examiner must take the observation into consideration when taking the decision. Observations that are considered of less importance may just be disregarded without any requirement to

communicate the reasons (i.e. there is no need for a decision to grant with reasons). If a third party has submitted observations in an SPC application, this party is still not regarded as a party in the matter. Therefore, PRV is not obligated to provide any third party with a reason to the decision.

11.7 DECISION TO GRANT OR TO REFUSE

If the SPC application may be granted PRV notifies the SPC owner of the decision and also notifies the owner of the date and number of "Svensk Patenttidning" in which the decision will be published (Article 11(1) of the SPC regulations). The grant of the SPC is also registered in the Swedish patent register and made available in the Swedish Patent Database.

If the opposite occurs and the SPC application is rejected PRV notifies the applicant of the rejection. However, before a final decision is taken, the applicant is notified regarding the obstacles to the grant of the SPC and is given the opportunity to submit comments and arguments before the final decision is taken. In the same way as for grants, the rejected decision is then published in "Svensk Patenttidning" (Article 11(2) of the SPC regulations) and registered in the Swedish patent register and made available in the Swedish Patent Database.

The applicant has the right to request a hearing before a panel of examiners before any decision is made (Article 10 decree (2007:1111) with instructions to the Patent and Registration office).

11.8 PAYMENT OF FEES

Anyone who applies for an SPC or extension of the period for an SPC shall pay an application fee (Article 105 of the Swedish Patents Act). Also an annual fee shall be paid for the SPC. The fee year is computed from the date when the protection commenced to be valid and thereafter from the corresponding date (Article 105 of the Swedish Patents Act). The annual fee is always due on the last day of the same month as the SPC entered into force. The fees are as follows:

Application fee	5000 SEK
Annual fee	10 000 SEK
Application fee for paediatric extension	3000 SEK

Table 11.1:

11.9 APPEAL AGAINST THE DECISION OF THE OFFICE

According to Article 26 of the Swedish Patents Act the applicant of a patent application has the right to appeal a final decision of PRV. The appeal must be submitted to PRV within two months from the date of the decision. Thus, as specified in Article 18 of Regulation (EC) 469/2009 and Article 17 of Regulation (EC) 1610/96 the applicant for an SPC also has the right to appeal. The appeal shall be addressed to the Patent and Market Court, but sent to PRV. PRV will then forward the appeal to the Patent and

Market Court, provided the appeal has been submitted in time. If ordered to by the Patent and Market Court, PRV will submit observations to the Court during the appeal procedure.

Regarding Article 17(2) of Regulation (EC) 1610/96 it has been tried by the Swedish Patent and Market Court whether said article allows the applicant to appeal a decision at any time (based on the grounds of said article) regardless of the deadline of two months for any other appeal.[275] The court's reasoning was that looking at 17(1) it would not be clear whether an incorrect duration of an SPC could constitute grounds for an appeal. 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 jurisdiction one may only appeal a negative decision). But because of Article 17(2), the court continued, one may appeal a granted SPC solely based on the fact that the 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.

Thus, the Patent and Market Court stated that said article does not provide the applicant with the right to amend at any time the duration of the certificate. There is a pending case at the Swedish Patent and Market Court of Appeal regarding inter alia the application of Article 17(2) and the outcome of this case will be very interesting.

11.10 Calculation of the patent and SPC duration. Calculation of terms. Reinstatement of rights before PRV

According to Article 40 of the Swedish Patents Act a granted patent may be kept in force until twenty years have passed from the date when the patent application was filed. The patent expires on the date of its application, eg. a patent filed 2017-08-08 expires at midnight on 2037-08-08.

According to Article 13 of the SPC regulations, the certificate takes effect at the end of the lawful term of the basic patent for a period equal to the elapsed period between the date on which the application for a basic patent was lodged and the date of the first authorization to place the product on the market in the Community, reduced by a period of five years. The maximum duration of the certificate may not exceed five years.

The date of a Swedish marketing authorization is the date of the decision, but in accordance with the CJEU Seattle Genetics[276] decision, if the first marketing authorization in the EU as referred to in Article 13 of the SPC regulations is a European marketing authorization, its date is considered to be the date of notification. PRV also apply Seattle Genetics on any other national marketing authorization if the applicant can prove that the marketing authorization enters into force on the date of notification, and if the applicant can indicate said date through any official documentation.

[275] See case, PMÄ 10959-16, 10962-16, 10963-16, 10969-16, 10971-16.
[276] Case C-471/14 Seattle Genetics Inc. [2015].

In accordance with CJEU Merck[277] PRV grants SPCs with negative duration to allow a possible paediatric extension.

PRV uses the following method in calculating the duration of the SPC:

- Date of issuance of the marketing authorization (notification or granting according to Seattle Genetics case) + 15 years minus 1 day.
- Thus, if the patent is filed on 2006-05-02 and it lapses on 2026-05-02 and the date of issuance of the marketing authorization is 2015-06-24 the duration of the SPC will be between 2026-05-03 to 2030-06-23.

However of course, as stated above, the duration of an SPC can never be more than a maximum of 5 years.

As mentioned above an applicant may request for a re-establishment of rights if the applicant has not complied with a time limit. Article 72 of the Swedish Patents Act state that:

> If the applicant or the patent holder has, despite having observed all due care required by the circumstances, suffered a loss of rights because he or she has not performed an act at the Patent Authority within the time limit prescribed in this Act or under the authority of this Act and then he or she performs the act within two months from the removal of the cause of the non-compliance, but at the latest within one year from the expiry of the respite, the Patent Authority shall declare the act to have been performed in due time. If the applicant or the patent holder wishes to obtain such a declaration, he or she shall within the time limit prescribed above, file a request to that effect with the Patent Authority and pay a fee.

This provision also applies to SPCs.

11.11 Grant of a request for paediatric extension pursuant to Article 9 of SPC Regulation (EC) 469/2009 and Article 36 of Regulation (EC) 1901/2006

As mentioned in section 3 above, PRV is also the responsible authority for the examining and granting of SPC paediatric extensions. The application usually does not need any substantial examination instead the examination aims to check that the application is filed no later than two years before the expiry of the SPC, and that all required documents have been submitted. The following documents must be attached to the application:

- a copy of the statement indicating compliance of the marketing authorization with an agreed completed paediatric investigation plan as referred to in Article 36(1) of Regulation (EC) 1901/2006
- and the proof of marketing authorization in all the Member States

If there is an irregularity in the application PRV will notify the applicant and the applicant is given 3 months to rectify said irregularity (with a possible 2-month extension) otherwise PRV will reject the application. A granted paediatric extension is published in "Svensk Patenttidning" within one month and the same goes if said

[277] Case C-555/13 Merck Canada Inc. [2014].

application is rejected. The paediatric extension is subject to revocation in accordance with Article 16(1) of Regulation (EC) 469/2009. PRV is not the competent authority to invalidate SPCs with a paediatric extension. Such a request must be referred to the Patent and Market Court.

11.12 POST-GRANT LIMITATION OR REVOCATION OF THE PATENT

The owner of a patent may according to Article 40a of the Swedish Patents Act request to limit or to revoke the patent. The amendment has a retroactive effect on the scope of protection conferred by the patent.

If an SPC has been granted and the basic patent of said SPC is limited or revoked in such a way that the product covered by the SPC is no longer protected by the basic patent, then according to Article 15(c) of the SPC regulations the SPC is invalid. PRV is not the competent authority to invalidate the SPC which mean PRV will not decide to invalidate the SPC, however PRV will publish in "Svensk Patenttidning" that according to Article 15 of the SPC regulations said SPC is no longer valid.

The proprietor of an SPC may also surrender the SPC causing said right to expire (Article 14 b of the SPC regulations), this will also be published in "Svensk Patenttidning".

11.13 EFFECT ON THE SPC GRANTING PROCEDURE OF PENDING REVOCATION OR OPPOSITION PROCEDURES AGAINST THE PATENT

It is quite usual for SPC applicants to request a stay of the SPC proceedings because of pending opposition or revocation proceedings against the basic patent. PRV usually deny said requests since each matter to which a person is a party shall be handled as simply, rapidly and economically as is possible without jeopardising legal security, according to Article 7 of the Administrative Procedure Act. Said article means that a delay of a matter can only be tolerated if it is absolute necessary in order for the decision to be based on a satisfactory basis (JO Decision No. 1792-2007). Also in a decision from 2013 from the Court of Patent Appeals, a pending opposition proceeding did not constitute grounds for a stay in the SPC proceedings.[278]

If the SPC is granted and the basic patent is later revoked or limited so that the product of the SPC is no longer covered by said patent, then according to Article 15 of the SPC regulations said SPC is no longer valid and PRV will proceed as mentioned above.

11.14 ENFORCEMENT OF THE SPC

According to Article 106 of the Swedish Patents Act and in conjunction with Articles 4 and 5 of the SPC regulations, the provisions in Chapter 9 of the Swedish Patents Act

[278] PBR Case No. 09-265.

on liability shall also apply to SPCs. Thus the holder of a SPC or the licensee can enforce his rights, limited to the product covered by the SPC, in the same way as a holder of a patent.

According to Article 3 of the Swedish Patents Act the following acts are exempted from the exclusive right:

> *1.* use which is not commercial,
> *2.* use of a product protected by patent which is put on the market within the European Economic Area by the holder of the patent or with his consent; as regards biological material this applies also to uses in the form of reproduction or multiplication of a product when the reproduction or multiplication is a necessary element of the use for which the biological material has been put on the market, provided that the product obtained is not later used for further reproduction or multiplication.
> *3.* use of the invention for experiments which relate to the invention itself,
> *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 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,
> *5.* preparation in pharmacies of medicines in accordance with a prescription by a physician in an individual case or acts relating to medicines prepared in such cases (Act 2006:254)

12 THE NETHERLANDS

Dr. M.W. Martijn de Lange[*] *Peter R. Slowinski*[**]

12.1 INTRODUCTION: THE SOURCES OF LAW

The Netherlands is one of the contracting states to the European Patent Convention. Furthermore the Netherlands is a member of the European Union and signed on to the Agreement on the Unitary Patent Court Agreement. Although it is possible to apply for an SPC on the basis of a national patent granted under the Dutch Patent Act, this has seldom happened and practically all basic patents have been issued by the European Patent Office.

Articles 92 to 98 of the Dutch Patent Act contain a few provisions on SPCs. In particular they designate the Netherlands Patent Office as the authority to process SPC applications and allow fees to be levied on the filing of an SPC application and maintenance fees after grant of the SPC.

The General Administrative Law Act (Dutch: Algemene Wet Bestuursrecht) is also relevant when it comes to procedural provisions which the SPC regulation does not provide.

12.2 INSTITUTIONAL ASPECTS

The Netherlands Patent Office is part of the Netherlands Enterprise Agency (Dutch: Rijksdienst voor Ondernemend Nederland or RVO), which is part of the Ministry of Economic Affairs.

There are currently 4 technical examiners and 1 legal examiner involved in SPCs. They all devote only a minor part of their time to SPCs. The technical examiners all hold a doctorate in chemistry, biology or biotechnology. Although a Dutch national patent cannot be refused or invalidated by the Dutch Patent Office on substantive grounds, the examiners will write search opinions on patent applications and invalidity opinions on granted patents, and therefore are still experienced in this area. Decisions at first instance are always taken by a technical examiner. The appeals division consists of 3 members one of whom is the legal examiner.

The Netherlands Patent Office has not issued any guidelines on the examination of SPCs.

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12.3 FILING OF THE APPLICATION AND PUBLICATION

The filing of the application is published in the Patent Bulletin (Dutch: Hoofdblad Industriële Eigendom), which appears weekly, and in the online patent register,[279] which is updated daily and also includes inspection of the entire file.

The Netherlands Patent Office provides application forms on their website. They include a box for the name of the product, which the applicant can, and always will, enter.

If the deadline for filing the application under article 7 of the Regulation has been missed a re-establishment of right procedure may be started, just as one could for failure to observe a particular time limit regarding a patent.

12.4 FORMAL EXAMINATION. COPY OF THE MARKETING AUTHORISATION

The Netherlands Patent Office has yet to encounter a situation where in an SPC application procedure the applicant was unable to furnish a copy of the marketing authorisation, which was the subject of the CJEU case C-181/95 from the 1990s.

In the case of SPC extensions based on national marketing authorisations sometimes the applicant is unable to furnish a copy of the updated marketing authorisation, i.e. the marketing authorisation which includes the results of the paediatric investigations. The reason is that some national health authorities do not prioritise the issuance of such updated authorizations, although they are instructed to do so within 30 days in the end-of-procedure notification from the reference member state. The Netherlands Patent Office has decided that this should not unnecessarily obstruct the grant of the SPC extension.

12.5 SUBSTANTIVE EXAMINATION

The Netherlands Patent Office verifies all the requirements under the Regulation and does not solely rely on the information provided by the applicant. The databases of the European Medicines Agency and the Netherlands Medicines Evaluation Board will be consulted to see if earlier marketing authorizations for the same product have been granted. The Netherlands Patent Office does not routinely check the equivalent databases in all the other member states.

Currently (June 2017) some very fundamental issues concerning the interpretation of articles 3(a), 3(c) and 3(d), are pending before the Court of Justice of the European Union and/or the Dutch courts. The examination of SPC applications which are similar to those cases may be put on hold pending the outcome of such court proceedings.

The Netherlands Patent Office is compelled to treat similar cases in a similar fashion. It is however not possible to articulate our view on the conditions of article 3 and the case law here in just a few sentences.

[279] <http://mijnoctrooi.rvo.nl/fo-eregister-view/>.

MPI has posed us the specific question if the marketing authorization must still be in force at the date on which the SPC application is filed or is it sufficient that it was granted before this date.

Our answer is that this is not required under article 3, but we may warn the applicant that the office may, after grant, immediately declare the SPC to have lapsed under article 14(d) of the SPC Regulation.

12.6 THIRD PARTY OBSERVATIONS

Third parties may file observations. In practice the objections will be similar to what the examiner has already put to the applicant.

12.7 EFFECT ON THE SPC GRANTING PROCEDURE OF PENDING REVOCATION OR OPPOSITION PROCEDURES AGAINST THE PATENT

The applicant usually asks for a stay of the SPC proceedings if the patent is under attack, which the Netherlands Patent Office will grant.

12.8 GRANTING OR REJECTION OF THE SPC. APPEAL AND REVOCATION PROCEDURES

Leading up to a decision at first instance there may be a first office action setting out the objections, a written response from the applicant followed by a hearing.

The applicant can file an appeal against the grant or refusal of the application within 6 weeks of the decision, a term set by the General Administrative Law Act. The appeal will be handled by a three member panel of the Office. It usually also includes a hearing.

The decision on appeal has to be appealed to the Administrative Court of the Hague. Finally the decision of the Administrative Court may be appealed to the Administrative division of the Council of State.

The specialised patent chambers of the Court of The Hague and the Appeals Court of the Hague have the exclusive authority in the Netherlands to handle patent and SPC invalidity actions.

12.9 CALCULATION OF THE PATENT AND SPC DURATION. CALCULATION OF DEADLINES. RELIEF BEFORE THE OFFICE

12.9.1 Calculation of the patent and SPC duration

The 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.

The expiry date of the SPC, i.e. the last day of protection, is calculated as 15 years minus 1 day from the relevant date of the marketing authorization or 25 years minus 1 day from the filing date of the patent, whichever is the shortest.

12.9.2 Calculation of terms

This issue is not controversial in the Netherlands.

12.9.3 Relief before the office for missed deadlines

As mentioned under 15.2.8.3 a re-establishment of right procedure may be started if the application is not filed on time.

Deadlines set by the office in their communications have always been observed by applicants.

12.10 REPRESENTATION BEFORE THE OFFICE

Representatives must be registered as Dutch patent attorneys or lawyers.

12.11 POST-GRANT AMENDMENT OF THE SPC DURATION.

Requests for rectification of the SPC duration under Article 17(2) of Regulation 1610/96/EC may be filed at any time.

12.12 SPECIFIC ISSUES CONCERNING EXTENSION PURSUANT TO ART. 36 OF REG. 1901/2006/EC

In principle updated (with paediatric information) marketing authorisations in all member states are necessary. Only when the national health authorities fail to issue these authorisations on time the applicant may rely on an older authorisation.

Withdrawal of the orphan designation (art. 36(3)) is not a condition listed in the SPC Regulation and therefore not part of the examination. It can however be ground for invalidity.

12.13 PAYMENT OF FEES

There are fees for filing an SPC application or SPC extension application (544 Euro each) and maintenance fees for granted SPCs ranging from 1,600 Euro in year 1 to 2,400 Euro in year 5 and 1,300 Euro for a paediatric extension in year 6.

12.14 ENFORCEMENT OF THE SPC

The SPC may be enforced on the basis of the same provisions that exist for patents.

There is no specific provision in the Dutch Patent Act that confers a right on a published SPC application.

13 UNITED KINGDOM

Fiona Warner Michael Warren** Jason Bellia*** Philip Mountjoy**** Lawrence Cullen******

13.1 INTRODUCTION: THE SOURCES OF LAW

The UK has signed and ratified all relevant European and international agreements in the field of patents, including TRIPS, the EPC, the PCT, the PLT and the Strasbourg Convention. The UK is also a Signatory State of the UPCA and is party to the enhanced cooperation for the creation of unitary patent protection.

Patent protection in the UK is obtainable by filing a European patent application (at the EPO, either directly or as a regional phase entry of a PCT application), or by filing a national patent application (at the Intellectual Property Office, either directly or as a national phase entry of a PCT application). The provisions governing both national and European (UK) patents and patent applications are set out in the Patents Act 1977 (as amended)[280].

Harmonisation of UK law with various provisions of the EPC (as well as the CPC and PCT) is ensured by Section 130(7) of the Patents Act, which declares that certain provisions are "*so framed as to have, as nearly as practicable, the same effects in the United Kingdom as the corresponding provisions of the European Patent Convention, the Community Patent Convention and the Patent Co-operation Treaty have in the territories to which those Conventions apply*". Provisions covered by this section include those governing patentability, the meaning of infringement, extent of invention and grounds for revocation.

Thus, for example, the extent of protection afforded by national patents[281] is interpreted in accordance with Article 69 EPC and its associated Protocol. Also, infringement rights conferred by national patents[282] are, where relevant, interpreted in accordance with Articles 29 to 31 CPC. Further, Sections 77 and 78 of the Patents Act ensure that the same interpretations apply to EP(UK) patents and patent applications.

Similarly, patentability requirements[283] and the grounds for revocation[284] are entirely consistent with corresponding provisions of the EPC (namely, Articles 52 to 57 EPC for patentability and Articles 138 and 139 EPC for revocation).

The UK is one of several EPC Contracting States that interprets the term specified in Article 63(1) EPC ("20 years from the date of filing of the application") as meaning

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280 An unofficial consolidation of the Patents Act as currently amended (produced by Patents Legal Section) can be viewed at: http://bit.ly/2tqiD3r.
281 Section 125 of the Patents Act.
282 Section 60 of the Patents Act.
283 Sections 1(1) to 1(4) and 2 to 6 of the Patents Act.
284 Section 72(1) and (2) of the Patents Act.

that the last day that a patent can be in force is *the day before* the 20th anniversary of its filing. Other EPC Contracting States take the view that the last day that a patent can be in force is the 20th anniversary of its filing. As discussed in section 9a below, the UK's approach to calculating patent term reads onto the calculation of SPC term.

In addition to directly applicable provisions of Regulations nos. 469/2009 and 1610/96, UK law on SPCs is governed by Section 128B and Schedule 4A of the Patents Act, as well as various relevant provisions of the Patents Rules 2007 (as amended), most notably Rule 116.

Numerous provisions of the Patents Act are applied to SPCs by way of paragraph 1(2) of Schedule 4A. Amongst other things, these cover aspects of pre- and post-grant procedure, including: making of application[285]; general power to amend application before grant[286]; reinstatement of applications[287]; observations by third party on patentability[288]; general power to amend specification after grant[289]; surrender of patents[290]; opinions by the Patent Office[291]; administrative provisions[292]; and rules[293].

13.2 INSTITUTIONAL ASPECTS: THE GRANTING AUTHORITY

For the UK, the granting authority specified in Article 9(1) of Regulation 469/2009 is the Intellectual Property Office (IPO). This is reflected in paragraph 1(2) of Schedule 4A, which, by specifying Section 14(1) of the Patents Act as one of the provisions applying to SPCs, requires every SPC application to be made in the prescribed form at the Patent Office (of which IPO is the operating name).

The IPO is an official UK government body. More specifically, the IPO is an executive agency of the Department for Business, Energy & Industrial Strategy[294].

In addition to handling the examination and grant of SPCs, the IPO is responsible for: the examination and grant of UK patent applications; and the provision (upon request) of non-binding opinions on the infringement or validity of a patent or an SPC. Examination of SPCs is entrusted to a small number of examiners (currently 2) who specialise in SPCs, but who also retain responsibilities for examining patent applications in the relevant technology.

For those SPC applications where the applicant requests a hearing at the IPO, decisions upon grant or rejection are taken by a designated (senior) officer at the IPO (a so-called "Hearing Officer"). At present, the IPO assigns hearings on SPCs to a Hearing Officer having detailed knowledge of the law relating to SPCs and the technology involved.

285 Section 14(1), (9) and (10).
286 Section 19(1).
287 Sections 20A and 20B.
288 Section 21.
289 Section 27.
290 Section 29.
291 Sections 74A and 74B.
292 Sections 117 to 118.
293 Section 123.
294 https://www.gov.uk/government/organisations/intellectual-property-office.

All SPC examiners and Hearing Officers at the IPO are entrusted with reaching decisions upon SPC validity in connection with all aspects of Article 3 (and Article 2) of the SPC Regulations; however, only Hearing Officers have the authority to reach a decision to refuse an SPC application in situations where the applicant disputes such a decision being made (as discussed further in section 8 below).[295]

13.3 FILING OF THE APPLICATION.

The deadlines for filing SPC applications in the UK are governed by Article 7 of Regulations nos. 469/2009 and 1610/96. The IPO calculates time periods expressed in Article 7 of the two Regulations in accordance with the Euratom Regulation (No. 1182/71)[296].

In accordance with Article 19 of Regulation 469/2009 (and Article 18 of Regulation 1610/96), the IPO applies to SPCs many of the same procedural provisions that are applicable to UK patents and patent applications. These provisions include Rule 108(1) of the Patents Rules 2007 (as amended), which provides the IPO with discretion to extend certain time limits.

Amongst the time limits that may be extended under Rule 108(1) are the filing deadlines specified in Article 7 of the SPC Regulations[297]. The IPO has exercised its discretion (and excused the late filing of an SPC application) in circumstances where an application was late-filed due to "unforeseen circumstances", and where the applicant "acted promptly to rectify the situation"[298].

Under current practice, the view of the IPO is that Article 3(b) only requires a valid Marketing Authorisation (MA) to have been granted, but that there is no requirement for the MA to still be in force on the date that the SPC application is filed. Thus, it appears that an SPC application may still be filed even if the MA has been withdrawn (or has lapsed) prior to date of filing of the application[299].

With regard to an SPC application, the view of the IPO is that all substantive requirements, as specified in Article 3, must be satisfied at the time of filing of the application[300]. In this respect, if no MA has been granted in the UK by the date of filing of the application, the absence of that MA is not viewed by the IPO as an "irregularity" that can be corrected after filing[301].

By way of contrast, the IPO views the absence of documents required to perfect an SPC extension application (those specified in Article 8(d) of Regulation 469/2009) as representing an "irregularity" that can be corrected after filing[302]. However, under

295 Manual of Patent Practice (MoPP) (https://www.gov.uk/guidance/manual-of-patent-practice-mopp), 130.05, Schedule.
296 MoPP, SPM 7.03.
297 MoPP, SPM 7.01.
298 Abbott Laboratories' SPC application, BL O/302/02.
299 MoPP, SPM 3.03.
300 MoPP, SPM 3.01.
301 Merck Sharp & Dohme's SPC application, BL O/117/16.
302 E I Du Pont Nemours & Co. v UK Intellectual Property Office [2009] EWCA Civ 966.

current practice, such an "irregularity" must be corrected before the expiry date of the (unextended) SPC[303].

According to Rule 116, Patents Form SP1 must be used for the filing of an SPC application, and Patents Form SP4 for the filing of an SPC extension application. Each such form must contain a request for grant and be accompanied by the prescribed fee, as set out in Schedule 1 of the Patents (Fees) Rules 2007 (as amended).

For filing an SPC application, Patents Form SP1 demands the provision of the following.

a) The information and documentation stipulated in Article 8(1)(a) to (c) of the SPC Regulations.
b) Additional information comprising:
    i. the EC Regulation (469/2009 or 1610/96) under which the application is made;
    ii. the expiry date of the basic patent;
    iii. the date of grant of the basic patent (if later than the date of the first UK authorisation for the product); and
    iv. a definition of the product in respect of which an SPC is sought.

Also, except in situations where it is self-evident, the IPO expects applicants to provide whatever information is necessary to confirm that the product in question is protected by the basic patent (e.g. by specifying a claim of the basic patent that "reads on" to the product, or by explaining how the product falls within the scope of a general formula in the claim)[304].

In the UK, definition of the "product" by reference to the proprietary name for the medicinal product is objectionable because it includes substances other than the active ingredient(s). IPO practice requires that the "product" be defined by reference to the relevant International Non-proprietary Name(s) (INN) – if available - or a formal (e.g. IUPAC) chemical name(s) (where no INN has been assigned). For biological active ingredients, the IPO also accepts the use of common names. Finally, in relation to the decision in *Farmitalia* (C-392/97) which states that an SPC is "capable of covering the product in any of the forms enjoying the protection of the basic patent", 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 salts and esters", this would form part of the product definition. This practice extends to both chemical and biological active ingredients.

The IPO has no standard accepted form of words to admit biosimilars to the product definition, and would consider what forms are protected by the basic patent when making this assessment.

As regards the product definition for process claims, UK practice is not to consider the process as part of the product definition, in line with the judgment in *Queensland* (C-630/10). Similarly, as regards medical use claims, in order to abide by both *Yissum* and *Neurim*, the UK does not accept incorporation of the therapeutic indication into the product definition.

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303 Otsuka Pharmaceuticals' SPC application, BL O/098/15.
304 MoPP, SPM 8.06.

For filing an SPC extension application, Patents Form SP4 demands the provision of the following.

a) The documentation stipulated in Article 8(1)(d) of Regulation 469/2009.
b) Additional information / documents comprising:
   i. the name and address of the applicant and his agent (if any);
   ii. the number, title and expiry date of the basic patent;
   iii. the number and date of the MA containing the statement of compliance;
   iv. an indication of whether the product has been authorised in all Member States by way of a "centralised" MA or by way of national MAs;
   v. a definition of the product in respect of which an SPC extension is sought;
   vi. the number of the SPC or SPC application that is to be extended (if that number exists at the time of filing); and
   vii. where the SPC to be extended has been granted, a copy of the granted certificate.

For SPC extension applications, the IPO may require the provision of further information if it is not immediately apparent that the product in question has completed the agreed Paediatric Investigation Plan and been authorised in all Member States (e.g. where the "decentralised" procedure has been used). Such further information may include, for example, a list of relevant national MAs for the medicinal product in all Member States[305].

Especially for medicinal products authorised by the European Medicines Agency, it is possible that all of the documents required to support an SPC extension application may be publicly available. Thus, in theory, there is nothing (other than practical difficulties in obtaining certain documentation, e.g. for products authorised through the "decentralised" route) to prevent extensions being awarded in respect of SPCs held by parties other than the sponsor of the clinical trials in the paediatric population. However, the IPO's Manual of Patent Practice does not comment on this issue.

13.4 FORMAL EXAMINATION

Formal examination by the IPO[306] determines whether an SPC application:

- is in the required form;
- is accompanied by the prescribed fee;
- was lodged within the period prescribed by Article 7;
- contains the information prescribed by Article 8(1)(a);
- is accompanied by a copy of the (or each) first MA as specified in Article 8(1)(b); and
- contains, where appropriate, the information and notice specified in Article 8(1)(c) regarding the first MA in the Community.

The IPO also determines whether the basic patent was in force on the date of filing of the SPC application.

Similar checks are carried out for SPC extension applications, as is a determination of whether the application:

[305] MoPP, SPM 8.12.
[306] MoPP, SPM 10.01.

- contains the information and documents specified in Article 8(1)(d); and
- with regard to the SPC to be extended, specifies a pending application (as required by Article 8(2)) or provides a copy of a granted certificate (as required by Article 8(3))[307].

The procedure of the IPO in circumstances where the MA supporting the application is missing is described in section 5 below.

13.5 SUBSTANTIVE EXAMINATION

The IPO usually conducts substantive examination at the same time as formalities examination[308]. For an SPC application, substantive examination invariably includes an assessment of compliance with the requirements of Articles 3(a), 3(b) and 3(c). The IPO also considers compliance with Article 3(d) as required, as discussed further below.

Under its current practice, the IPO will accept that an SPC application complies with Article 3(a) if the product for the application is specified/identified in the wording of the claims of the basic patent and, "having regard to the normal canons of claim interpretation" it is:

i. indicated in a claim;
ii. encompassed by a Markush formula;
iii. shown to result from the process protected by the basic patent; or
iv. encompassed by a functional definition[309].

The IPO may ask the applicant to provide evidence in respect of point (iii) or point (iv) above, for example evidence in the form of a witness statement[310].

For assessing compliance with Article 3(a) (and/or Article 3(c)) for a product defined as a combination of active ingredients, the current practice of the IPO is to consider whether the combination is "protected as such" by the claims of the basic patent. In doing this, the IPO may assess whether the combination forms "part of the subject matter or innovation of the patent", and whether it falls within "the core inventive advance" of the patent[311].

For claims in process format, the IPO assesses compliance with Article 3(a) by determining whether "the product identified in the patent claims is the product deriving from the process protected by that patent". For the purposes of that determination, the view of the IPO is that it does not matter whether it is possible to obtain the product directly as a result of the claimed process. Thus, the IPO will not require the applicant to provide evidence of whether a product that is suitably "identified" in a process claim has been (or could be) produced by the process steps recited that claim[312].

307 MoPP, SPM 10.08.
308 MoPP, SPM 10.04.
309 MoPP, SPM 3.02.5.
310 MoPP, SPM 3.02.5.
311 MoPP, SPM 3.02.6.
312 MoPP, SPM 3.02.4.

This approach stems from the decision of the CJEU in *Queensland* (C-630/10), which made this point specifically in its ruling[313]. It reflects the consistent distinction that is made in CJEU case law between the requirements necessary to grant an SPC in terms of what the basic patent specifies or identifies and, once granted, what protection is offered by the SPC derived from that basic patent. This distinction is discussed in *Icahn School of Medicine at Mount Sinai* BL O/552/14, in which the Hearing Officer applied *Queensland* in granting an SPC for a biological product where the authorised product did not have to be prepared by the process disclosed in the basic patent – it was considered necessary simply to determine if they both related to the same product for the purposes of granting an SPC.

However, for the purposes of determining the protection offered by such a granted SPC for infringement purposes, it is not yet known what scope will be afforded to an SPC granted on the basis of a claim to a process that is not used in the production of the authorised medicinal product. This is because the scope afforded to any SPC granted on the basis of a process claim has not yet been tested in the UK courts. The SPC may provide the necessary protection in so far as it relates to the active ingredient in the authorised product when it is made by the process of the claim. On the other hand, it is possible that it may be considered that (a) it does not provide any effective scope of protection (e.g. where the process cannot be used to produce the authorised product), or (b) will provide a scope of protection that does not encompass the authorised product (e.g. where the process can be used, but is in fact not used, to produce that product).

If, in connection with a particular product, the claims of a basic patent do not comply with Article 3(a), the IPO will permit the applicant to make post-grant amendments with a view to rectifying this deficiency. The current practice of the IPO is to permit such amendments even after the SPC application has been filed[314].

In connection with SPC applications for which the authorised product is a medical device, the practice of the IPO is to view EC design examination certificates relating to such devices as not meeting the requirements of Article 3(b)[315].

The IPO interprets the requirements of Article 3(c) in the light of Article 3(2) of Regulation 1610/96. Thus, with respect to a single product, the IPO will grant a certificate to each different holder of a basic patent that protects the product (but will not grant more than one certificate to a single applicant holding multiple patents protecting that product)[316].

Currently, the IPO does not establish compliance of SPC applications with the provisions of Article 3(d) by conducting a formal search. Instead, if there is reason to do so, the IPO will consider in detail whether the requirements of Article 3(d) are satisfied by way of an "informal" (basic internet) search. The IPO might do this upon the basis of information provided to it: by the applicant; in third party observations; or in another SPC application for the same product[317]. If the examiner at the IPO does

313 C-630/10, paragraphs 40-41.
314 MoPP, SPM 3.02.1.
315 MoPP, SPM 3.02.3.
316 MoPP, SPM 3.04.2.
317 MoPP, SPM 10.05.

require further information in order to make a determination in relation to Article 3(d), the applicant is asked to furnish this within a prescribed period.

Under its current practice, the IPO grants SPCs in respect of applications having similar underlying fact patterns to the *Neurim* case (i.e. where there is a "new" patent for a medical indication of a product for which a certificate has already been granted). However, in such cases, the IPO may ask the applicant to show that the indication in the MA is within the scope of protection of the basic patent, in accordance with paragraph 26 of the CJEU's judgment in *Neurim*[318]. Whilst the IPO's Manual of Patent Practice does not comment on the matter, it is not expected that the authorisation used to support a "*Neurim*-style" SPC will need to be a separate authorisation falling outside of the concept of "global marketing authorisation" (for the purposes of Directive 2001/83). In this respect, the IPO has granted "*Neurim*-style" SPCs upon the basis of a variation of an existing MA wherein the date of authorisation is the date of the variation to incorporate the indication in the MA as protected by the basic patent.

In accordance with paragraph 25 of the CJEU's judgment, the IPO considers that the scope of a "*Neurim*-style" SPC extends only to the authorised use. Although the UK courts have approved of this interpretation, they have nonetheless submitted questions to the CJEU to determine if a Neurim-style SPC may also extend to new formulations (*Abraxis Bioscience LLC v The Comptroller General of Patents* [2017] EWHC 14 (Pat)). Furthermore, the IPO will not seek to include the authorised medical use in the definition of the product[319].

For SPC extension applications, the IPO conducts substantive examination on the requirements of Article 8(1)(d) of Regulation 469/2009 and Article 36 of Regulation 1901/2006. In particular, the IPO examines whether:

- the MA identified includes the required compliance statement (as specified in Article 36(2) of Regulation 1901/2006 and Article 8(1)(d)(i) of Regulation 469/2009);
- the product is authorized in all Member States (as required by Article 36(3) of Regulation 1901/2006); and
- as required by Article 36(3) and (4) of Regulation 1901/2006, the product has not already been the subject of an alternative reward of extended Orphan Market Exclusivity or extended Regulatory Data Protection[320].

In cases where the IPO requires further information in order to make a determination, the applicant is set a deadline for furnishing that information. Under the provisions of Rule 108(1) of the Patents Rules 2007 (as amended), the IPO has the discretion to extend any such deadline.

The IPO will not reject an SPC application solely on the ground that a copy of the MA mentioned in Article 8(1)(b) is not provided together with the application. Whilst the IPO can take action of its own accord to make good the absence of the copy of the MA,

318 MoPP, SPM 3.05.2.
319 MoPP, SPM 3.05.2.
320 MoPP, SPM 10.09.

it will not do so unless and until the applicant has established that he is unable to provide the missing copy[321].

Thus, where an applicant is unable to obtain a copy of the MA from the person holding it, the IPO will first require evidence of this. It will then require the provision of information from the MA issuing authority (such as a gazette notice, a letter or an extract from a database) that is sufficient to enable the IPO to verify both the date of the MA and the identity of the authorised product. The IPO will then seek from the issuing authority a copy of the Summary of Product Characteristics (SmPC) for the authorised product. This is usually conducted on a confidential basis, such that the copy of the SmPC is made available neither to the applicant nor to the public[322].

If the notice specified in Article 8(1)(c) does not exist, the requirements of Article 8(1)(c) may instead be met by provision of a copy of the MA itself, or any other document proving that the MA has been issued. Documents in a language other than English language should be accompanied by a translation (which need not be verified, unless there is reason to doubt the accuracy of the translation)[323].

As mentioned in section 3 above, if an SPC extension application is filed without one or more of the documents specified in Article 8(1)(d), the missing documents can be supplied after filing (as the correction of an "irregularity"), but only before expiry of the unextended SPC.

The IPO will consider requests for accelerated examination that are supported by a reasoned statement for the request. However, the allowance of a request for accelerated examination cannot lead to grant of a certificate until at least three months have elapsed from the date that the notice of filing of the application was published in the Patents Journal. This is to allow for the filing of third-party observations (discussed in section 7 below)[324].

In a dedicated section of its Manual of Patent Practice, the IPO publishes (regularly updated) information on its practices regarding the examination of SPC applications.

13.6 PUBLICATION OF THE APPLICATION

The practice of the IPO is to publish SPC applications, as well as SPC extension applications, promptly after their filing. Details of SPC applications are published in the Patents Journal. However, details of such applications are often available at an earlier date *via* the IPO's online registers. Where an SPC has been filed in respect of a basic patent, a link to an entry on the IPO's register of SPCs is added to the entry for the basic patent on Ipsum (IPO's Online Patent Information and Document Inspection Service), and *vice versa*.

For an SPC application, the publication in the Patents Journal includes the date of filing of the application and the details prescribed by Article 9(2), based upon the information provided by the applicant (on Form SP1). The published information

321 MoPP, SPM 8.04.1.
322 MoPP, SPM 8.04.1.
323 MoPP, SPM 8.05.1.
324 MoPP, SPM 10.04.1.

includes the generic name of the product, which the IPO determines by reference to the MA document if it is not provided by the applicant on Form SP1[325]. The same information is published in the Patents Journal for SPC extension applications, with any additional information necessary being taken from Form SP4[326].

The IPO also publishes details of any corrections that it considers to be allowable and that affect details of the SPC application that have already been published[327].

Copies of documents filed in connection with SPC applications cannot (yet) be viewed *via* any of the IPO's online databases. However, in accordance with Rules 48 and 54, copies of such documents can be obtained by submitting a written request to the IPO (in the prescribed form, accompanied by the prescribed fee). This does not apply to documents covered by Rule 51 or Rule 53, including "internal" documents prepared by the IPO and documents in respect of which a request for confidentiality has been granted.

13.7 THIRD PARTY OBSERVATIONS

The IPO will consider any third party observations that:

a) address the question whether a published SPC application is valid application having regard to Article 3, 8(1)(d) as applied to SPCs and extensions respectively;
b) are in writing; and
c) are made before the SPC in question in granted[328].

In this respect, the IPO follows the same practice for SPCs as it does for patents under Section 21 of the Patents Act. Under this practice, and in accordance with Rule 29 of the Patents Rules, the IPO will raise objections based upon third party observations if:

- in the light of those observations, the examiner is persuaded that the SPC application does not comply with the specified requirements of the relevant Regulation; and
- the IPO has not raised the relevant objections in a previous examination report.

Under Rule 33, the applicant is sent a copy of any observations that are filed by a third party before grant of the SPC.

By filing observations, the third party does not become a party to the proceedings. Thus, even if such observations are filed, proceedings for the examination of SPC applications remain *ex parte*. In this respect, if the IPO decides to grant the application, they are under no formal obligation to explain either why objections raised by the third party were unpersuasive, or how those objections were overcome by the applicant's arguments. Nevertheless, the IPO's reasoning on such points may emerge from the written record if, at any point, the examiner raises any objections based upon (or in accordance with) the third party observations.

325 MoPP, SPM 9.02.
326 MoPP, SPM 9.02.1.
327 MoPP, SPM 10.14.
328 MoPP, SPM 10.06 and SPM 10.10.

As discussed in section 8 below, the applicant for an SPC is able to request a hearing before the IPO reaches a final decision to either grant or reject the application. In accordance with Rule 84, any such hearings that take place are normally open to the public (unless the application has not been published, or where the IPO agree that there are good reasons to grant a request from the applicant for the hearing to be held in private). Also, under Rule 75, the IPO publishes advance notice of hearings. Thus, in theory, and provided that the IPO is informed in advance, third parties are able to attend hearings relating to SPC applications. However, as mere observers, third parties are not permitted to make submissions (oral or otherwise) at the hearing.

After grant of an SPC, third parties may apply to the IPO for a declaration of lapse (Article 14(d))[329] or invalidity (Article 15 or, for SPC extensions, Article 16)[330]. Applications for such declarations must be submitted using Form SP3. Alternatively, third parties may ask the IPO (under the provisions of Section 74A of the UK Patents Act) to provide a non-binding opinion on validity of the SPC [331].

13.8 GRANT / REFUSAL PROCEDURE

A certificate (and/or extension thereof) is granted if: (a) the applicant overcomes (by way of amendments, corrections and/or submissions) all objections raised on formal and/or substantive grounds; and (b) at least three months have elapsed from the date that the notice of filing of the SPC application was published in the Patents Journal (see section 5 above).

However, if the applicant's written submissions do not persuade the IPO that the conditions for grant of the SPC are met, the IPO will either pursue the outstanding objection(s) or initiate the rejection procedure. Further objections, if pursued, are typically outlined in written correspondence. Nevertheless, telephone or in-person interviews are also possible[332].

If inclined to reject the SPC application, the IPO informs the applicant in writing of the examiner's opinion and the reasons therefor. Unless the applicant requests a hearing, or a decision based on the correspondence on file, the application is then rejected[333].

If the applicant requests a hearing, the IPO agrees a date for the hearing with the applicant. After the date for the hearing has been fixed, the substantive examiner at the IPO will (if necessary) write to the applicant to set out the issues to be decided and to provide advance notice of any precedents that the IPO intends to rely upon. Hearings are usually conducted at the IPO's premises (in Newport or sometimes in London), though they may be conducted by telephone or video conference, provided that those attending are content to do so.

Whilst the substantive examiner may be present at the hearing, it is a designated (senior) officer at the IPO (a so-called "Hearing Officer") who has responsibility for deciding upon grant or rejection of the application at the hearing.

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329 MoPP, SPM 14.03.
330 MoPP, SPM 15.02 and SPM 15.05.
331 MoPP, SPM 15.05.
332 MoPP, SPM 10.16.
333 MoPP, SPM 10.17.

If the applicant requests that the decision be made on the basis of the correspondence on file, the Hearing Officer will issue a written decision without a hearing taking place.

13.9 CALCULATION OF THE PATENT AND SPC DURATION

As discussion in section 1 above, the last day that a patent can be in force in the UK is the day before the 20th anniversary of its filing.

With regard to the calculation of SPC duration, the IPO's Manual of Patent Practice expresses the view that the maximum period defined by Article 13 of the SPC Regulations is either:

a) a period of 15 years from the date of the first MA to place the product on the market in the Community; or
b) a period of 5 years from the date on which the SPC takes effect,

whichever is the lesser[334].

In practice, this means that the expiry date of SPCs in the UK is the earlier of:

(a1) the day before the 15th anniversary the date of the first MA to place the product on the market in the Community; and

(b1) the day before the 25th anniversary of the filing date of the basic patent.

The terms specified in (a1) and (b1) above arise from the UK interpretation of the term afforded to patents in the UK (i.e. determination of SPC duration according to the formula specified in Article 13, as opposed to by direct application of the 15 year period specified in Recital (9) of Regulation 469/2009).

In support of this, the decision of the Hearing Officer in Genzyme Corporation (BL O/418/13) states that "the 15 years of exclusivity referred to in recital (9) is made up of (a) the remaining protection provided by the patent once the marketing authorisation has taken effect and (b) up to a total of an additional five years further protection provided by the SPC which takes effect once the patent protection has expired". It further notes that the formula is a calculation of an interval between two dates, which calculated duration is applied to the end of the patent term.

The expiry date of an SPC for which an extension has been granted is 6 months later than the earlier of dates (a1) and (b1) above[335].

It is possible for an SPC to expire earlier than either of the dates mentioned in (a1) and (b1) above, but only if the applicant elects to pay some (but not all of) the annual fees for the SPC before it comes into effect[336]. It may also expire early as a result of the certificate holder surrendering the SPC.[337]

334 MoPP, SPM 13.04.
335 MoPP, SPM 13.07.
336 MoPP, SPM 12.02 and SPM 12.03.
337 MoPP, SPM 14.09-14.12.

With regard to the annual fees, the IPO provides the certificate holder with at least two months' notice of the date on which the fees are payable[338].

13.10 CALCULATION OF TERMS. RELIEF BEFORE THE IPO FOR MISSED DEADLINES

The IPO calculates the time periods expressed in Article 7 in accordance with Regulation (EEC, Euratom) No 1182/71[339]. However, those periods may, in theory, be subject to a discretionary extension of time (under Rule 108(1), see section 3 above).

As discussed in section 3 above, extensions of time do not apply to the substantive requirements for an SPC application as specified in Article 3 of the Regulations. Thus, those requirements must be satisfied at the time of filing of the application. On the other hand, if documents as specified in Article 8(d) of Regulation 469/2009 are absent at the time of filing an SPC extension application, their absence can be corrected as an "irregularity" between filing of the extension application and expiry of the unextended SPC.

As discussed in section 5 above, Rule 108(1) also provides the IPO with the ability to extend (at its discretion) any period of time that it sets for responding to objections or correcting deficiencies in connection with SPC applications.

Further, because Schedule 4A makes Sections 20A and 20B of the Patents Act applicable to SPC applications, it is at least theoretically possible to reinstate such applications that have been refused or deemed withdrawn due to failure of the applicant to meet certain requirements by a deadline set by the IPO. Amongst other things, the request for reinstatement must satisfy the IPO that the failure of the applicant to meet certain requirements by the original deadline was "unintentional".

The IPO does not grant extensions of time in respect of the period specified for paying the (annual) fees necessary to bring the SPC into effect – there is a period of six months after the period when the fees should be paid where they can be paid with a penalty for late payment. This is not an extension of time as such, but a statutory additional period provided by paragraph 5(b) of Schedule 4A. The decision in *Tulane Education Fund v Comptroller General of Patents* [2012] EWHC 932 (Pat) concluded that, once this additional period has expired, there is no opportunity for the owner to restore the SPC, as section 28 of the Patents Act (which allows this for patents on the "unintentional" test) is not made applicable to SPCs in Schedule 4A.[340].

There is no set deadline by which examination of an SPC application must be concluded. Thus, for example, it is possible, but not common, for examination of an SPC application to be concluded sometime after expiry of the basic patent. Nevertheless, the practice of the IPO is to prioritise the examination of SPC applications for which the basic patent has expired, or is about to expire[341].

338 MoPP, SPM 12.08.
339 MoPP, SPM 7.03.
340 MoPP, SPM 12.14.1.
341 MoPP, SPM 10.04.

For a certificate that has lapsed under Article 14(d) (i.e. due to withdrawal of the MA(s) upon which the certificate is based), the view of the IPO is that such a certificate automatically takes effect again from the date of a new MA that places the product on the market. The exception to this general practice is where, prior to the date of the new MA, the certificate has also been declared invalid or lapsed on another ground[342].

13.11 APPEAL PROCEDURE

As discussed in section 8 above, the applicant has the option to request a hearing before the IPO reaches an adverse decision in connection with a SPC application. Whether or not the applicant requests such a hearing, they have the right to file an appeal against any adverse decision taken by the IPO[343]. All such appeals must be filed at the Patents Court (which is part of the High Court of England and Wales), within a fixed period (usually 28 days) from the IPO's decision.

13.12 ARTICLE 17(2)

The IPO has not established a bespoke procedure for appeals under Article 17(2) of Regulation 1610/96 that are aimed at rectifying the duration of the certificate (where the date of the first MA in the Community is incorrect). Nevertheless, in practice, the IPO:

- does not impose any time limit with regard to the filing of such appeals;
- accepts 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 maximum expiry date.

13.13 ENFORCEMENT OF THE SPC

The protection provided by an SPC may be enforced by action for infringement as if the SPC were a patent. This has the consequence that, in England and Whales, Rule 63 of the Civil Procedure Rules dictates that claims for infringement of SPCs must be started in either the Patents Court or the Intellectual Property Enterprise Court (IPEC). That rule does not apply to proceedings in Scotland or Northern Ireland, where different (local) courts have jurisdiction to hear actions for infringement. If both parties agree, it is also possible for an infringement action to be started before the Comptroller (see Section 61(3) of the Patents Act), although this has not been used to date.

Paragraph 4(2) of Schedule 4A of the Patents Act applies to SPCs the provision (Section 69(2) of the Patents Act) that forms the basis of "provisional protection" for unpublished applications. Thus, once a certificate has granted, the proprietor is entitled to bring proceedings for infringement in respect of acts that "*would, if the certificate had been granted on the date of the publication of the application, have*

[342] MoPP, SPM 14.06.
[343] MoPP, SPM 10.17.

infringed not only the certificate as granted but also the certificate for which the application was made". By virtue of Paragraph 1(1)(b)(ii) of Schedule 4A, similar rights apply to applications for SPC extensions.

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

Annex I: National Reports EU

Publications Office

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