



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

Annex VI: Questionnaire for the National Patent
Offices of the EU Member States

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Annex VI: Questionnaire for the National Patent
Offices of the EU Member States

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ABBREVIATIONS

Art.	Article
Civ	Civil Division (UK)
CJEU	Court of Justice of the European Union
Dir. 91/414/EEC	Council Directive of 15 July 1991 concerning the placing of plant protection products on the market
Dir. 2001/82/EC	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
Dir. 2001/83/EC	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
EC	European Community
EMA	European Medicines Agency
EPC	European Patent Convention
EPO	European Patent Office
EUIPO	European Union Intellectual Property Office
EWHC	England and Wales High Court
MA	Marketing Authorisation
PLT	Patent Law Treaty
PCT	Patent Cooperation Treaty
para./paras.	paragraph(s)
Reg. 469/2009/EC	Regulation 469/2009/EC of 6 May 2009 concerning the supplementary protection certificate for medicinal products
Reg. 1610/96/EC	Regulation 1610/96/EC of 23 July 1996 concerning the creation of a supplementary protection certificate for plant protection products
Reg. 1234/2008/EC	Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products
SPC	Supplementary Protection Certificate
UPC	Unitary Patent Court

QUESTIONNAIRE FOR THE NATIONAL PATENT OFFICES OF THE EU MEMBER STATES¹

1 NATIONAL PROVISIONS IMPLEMENTING THE SPC REGULATIONS AND NATIONAL AUTHORITIES

1. Has your Member State enacted specific provisions implementing Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products (hereinafter Reg. 469/2009) and Regulation (EC) No 1610/96 of the European Parliament and of the Council of 23 July 1996 concerning the creation of a supplementary protection certificate for plant protection products (hereinafter Reg. 1610/96)? Has your country made use of the option provided for under Art. 19 Reg. 469/2009 and Art. 19 Reg. 1610/96 and provided special procedural provisions for SPCs? Could you share with us any English translations you may have of the relevant provisions?
2. Has your Office enacted guidelines for the examination of SPC applications? Could you share with us an English translation of the guidelines or a version in the original language?

¹ Questions No 18, 19, 20, 21, 22, 34, 35, 36 and 37 have been suggested by the UK Intellectual Property Office.

2 SPC APPLICANT, PATENT OWNER AND MA HOLDER

3. In your jurisdiction, is the licensee of the basic patent entitled to file an application for an SPC if authorised by the patentee?
4. If the national or European patent has been transferred, but the transfer has not been registered in the national or European register, who is entitled to file the SPC application in your jurisdiction?
5. In your jurisdiction, must the SPC applicant be also the holder of the MA to which the application refers pursuant to Art. 8(1)(a)(iv) and Art. 3(b) Reg. 469/2009 and Reg. 1610/96? If the answer is no, may the applicant refer to a third party authorisation even if no contractual relationship with this third party exists and no evidence for the consent of the said third party to the grant of the SPC is submitted? If the patentee can not provide your Office with a copy of the third party MA pursuant to Art. 8(1)(b) Reg. 469/2009 on which the application refers to, how does your Office proceed?
6. In your view, does the case law of the CJEU implicitly provide an answer to the question whether, and under which conditions, the applicant may refer to a third party authorisation? See for instance CJEU *Eli Lilly*, para. 43² and CJEU *Biogen*³.
7. *De lege ferenda*, the legislature could regulate this aspect. Different options are possible:
 - a) The applicant may refer to a third party MA whether the holder of the MA agrees or not.
 - b) The applicant may refer to the third party MA only when the third party concerned agrees and evidence for that party's consent is included in the application.
 - c) The applicant may refer to the third party MA only when he himself has obtained a (more recent) MA for the product concerned.
In your opinion, which of the above-mentioned solutions is more consistent with the purposes of both Regulations?

² Case C-493/12 *Eli Lilly and Company Ltd v Human Genome Sciences Inc* [2013]: : "In the light of the objective of Reg. 469/2009/EC, the refusal of an SPC application for an active ingredient which is not specifically referred to by a patent issued by the EPO relied on in support of such an application may be justified – in circumstances such as those in the main proceedings and as observed by Eli Lilly – where the holder of the patent in question has failed to take any steps to carry out more in-depth research and identify his invention specifically, making it possible to ascertain clearly the active ingredient which may be commercially exploited in a medicinal product corresponding to the needs of certain patients. In such a situation, if an SPC were granted to the patent holder, even though – since he was not the holder of the MA granted for the medicinal product developed from the specifications of the source patent – that patent holder had not made any investment in research relating to that aspect of his original invention, that would undermine the objective of Reg. 469/2009/EC, as referred to in recital 4 in the preamble thereto".

³ Case C-181/95 *Biogen Inc v Smithkline Beecham Biologicais SA* [1997].

8. If the legislature opted for the solution indicated in Question 7(a), would such a rule create an incentive for competitors of the holder of a (potential) basic patent to postpone obtaining a MA until the relevant basic patent has expired?

9. Consider the following hypothetical provision (see also Rule 151 EPC):

“Where the basic patent is owned by multiple proprietors, the SPC application must be filed by all the proprietors either jointly or through a common representative”.

Would such a provision reflect the current practice of your Office? If not, why not?

3 REG. 469/2009/EC AND REG. 1610/96/EC IN FORCE: THE DEFINITIONS

10. Reg. 469/2009/EC does not define the concept of “active ingredient”. Would the following definition provide more legal certainty? Please comment on the pros and cons of such a definition.

“(b) An active ingredient of the medicinal product is the product intended to exert a pharmacological, immunological or metabolic effect of its own with a view to restoring, correcting or modifying physiological functions or to make a medical diagnosis that falls within the therapeutic or diagnostic indications covered by the wording of the marketing authorisation granted under Directive 2001/82/EC and Directive 2001/82/EC to which the SPC application refers.”

Related Recital

“(2) The concept of ‘active ingredient’ for the purposes of the Regulation only includes the substance indicated as an active substance pursuant to the MA and having an effect that falls within the therapeutic or diagnostic effect covered by the wording of the marketing authorisation. The concept does not include adjuvants or any other substance or ingredient of the medicinal product that, pursuant to the marketing authorisation to which the SPC application refers pursuant to Art. 8(1)(a)(iv) Reg. 469/2009, do not have a pharmacological, immunological or metabolic effect on the human or animal body of their own covered by the wording of the MA.”

11. Reg. 1610/96/EC has clarified that the issue of a certificate for a product consisting of an active substance does not prejudice the issue of other certificates for “derivatives (salts and esters) of the substance, provided that the derivatives are the subject of patents specifically covering them”, see Recital No 14. Reg. 1610/96/EC has not clarified, however, under which conditions the derivative may be considered a different product within the meaning of Art. 3 Reg. 1610/96/EC or Reg. 469/2009/EC. Consider the following hypothetical provision (inspired by Art. 10 Dir. 2001/83/EC)

“The different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active ingredient shall be considered to be the same active ingredient, unless they differ significantly in their properties with regard to safety and/or efficacy”.

In your view, would this provision provide criteria that are predictable, ensure sufficient protection for pharmaceutical innovation and reduce the potential for life-cycle strategies?

12. Does your Office consider medical devices to be medicinal products within the meaning of Art. 1(a) Reg. 469/2009/EC? What is the practice of your Office with respect to medicinal products that are to be administered as a medicinal product through an implantable medical device?
13. Both Regulations refer several times expressly or implicitly to the date of the MA. However, they do not define what the date of grant of the MA is for the purposes of the Regulations. Does your Office apply a uniform understanding by interpreting Art. 3, Art. 7 and Art. 13 Reg. 469/2009/EC or Art. 3, Art. 7 and Art. 13 Reg. 1610/1996/EC? What is

this understanding? Is there a difference between national and centralised MAs?

14. *De lege ferenda*, the legislature could define the date on which the MA is deemed to be granted for the purposes of the Regulation. As far as the latter aspect is concerned, the following options are possible:
 - i. The date of the notification of the decision.
 - ii. The date of the decision.
 - iii. The date of the publication.

Which solution do you prefer and for what reason?

15. On what date does the national authorisation granted by the competent national agency of your country take effect? Can indicate the relevant domestic provisions for your answer?

4 THE REGIME IN FORCE: ART. 3(A) REGS. 469/2009/EC AND 1610/96/EC

16. According to the CJEU, a product is protected by the basic patent within the meaning of Art. 3(a) Reg. 469/2009/EC when it is specified in the wording of the claims of the basic patents (see for instance decision C-6/11⁴). Does this case law provide a clear test in your view?
17. If the answer to the previous question is no, do you agree with the following statement:

According to the case law of the CJEU (see decision C-493/12⁵), the fact that the product falls within the scope of protection of one patent claim of the basic patent within the meaning of Art. 69 EPC (or any domestic provision corresponding to Art. 69 EPC) is a necessary but not sufficient requirement to consider a product as being protected by the basic patent within the meaning of Art. 3(a) Reg.469/2009/EC.

18. In your practice or case law, does a medicinal product need to be specified or identified in the claims of the basic patent to meet the requirements of Art. 3(a) Reg. 469/2009/EC?
19. If the answer to Question 18 is yes, are there any rules as to how specific the product must be described in the claims?
20. If the product is generally covered by the claims, but individually identified only in the description, e.g. by name or structural formula, is that sufficient to meet the requirements of Art. 3(a) of both Regulations? If not, would you accept an amendment of the claims to include a product that is identified in the description?
21. In the practice of your Office or in the national case law is it a necessary or sufficient requirement that the medicinal product is protected by the basic patent in the sense of Art. 69 EPC / Protocol on Art. 69 EPC or the corresponding national provision?
22. Is the claim category (i.e. product, method, use) relevant for the answer to Question 21 (see Art. 64(2) EPC and CJEU C-630/10 *Queensland*, headnote 3⁶)?
23. *De lege ferenda*, the legislature could amend Art. 3(a) Reg. 469/2009/EC in order to ensure greater legal certainty. Different options are possible:

a) The introduction of the following paragraph:

“The product is protected by a basic patent in force and is, be it explicitly or implicitly, directly and unambiguously disclosed to the skilled person in said basic patent and in the patent application as filed.”

⁴ Case C-6/11 *Daiichi Sankyo v Comptroller* [2011].

⁵ Case C-493/12 *Eli Lilly and Company Ltd v Human Genome Sciences Inc* [2013].

⁶ Case C-630/10 *University of Queensland v Comptroller* [2011].

According to this standard, the SPC may only be granted for subject matter to which the patent may be lawfully limited without violating Art. 123(2) EPC. Would such a provision provide a clearer test for resolving future disputes? What are the shortcomings of such a redrafting in your view?

b) The adoption of an infringement test with the following wording:

"The product is protected when it falls, literally or under the equivalence doctrine, within the scope of protection of the basic patent pursuant to Art. 69 EPC and corresponding national provisions."

Would such a provision provide a clearer test for resolving future disputes? What are the advantages and the shortcomings of such a redrafting?

c) The adoption of the "core inventive advance" test (as formulated in English case law⁷), pursuant to which

the subject matter of the SPC is protected by the basic patent when two requirements are cumulatively met:

- i. it falls within the scope of protection of the patent, and
- ii. it represents the core inventive advance of the invention.

Would such a legislative amendment provide a clearer test for the interpretation of Art. 3(a) SPC Regulations? Please comment on the pros and cons.

24. In the case of combination products⁸ we understand the "core inventive advance test" in the following terms: if the basic patent discloses and claims the compound Y, and this patent includes claims directed to a combination of Y with another compound X, the combination involving Y and X should be regarded as eligible for SPC protection only when the claim directed to such a combination is "independently valid" over the claim to the single active ingredient Y.⁹ Do you agree with this understanding?
25. Consider the case of a hypothetical invention consisting in preparing a new class of compounds that may be used as therapeutic products. The patent includes a Markush claim or generic product claim directed to the chemical formula of this class of compounds. If the SPC is requested for one compound covered by this product claim, do the core inventive test and a (direct) infringement test lead to identical outcomes? If not, what are the differences?

⁷ *Actavis Group PTC EHF & Anor v Sanofi Pharma Bristol-Myers Squibb SNC* [2012] EWHC 2545 (Pat).

⁸ Under the expression "combination product" we understand a combination of two active ingredients.

⁹ Under the expression "independently valid" we understand that the combination of the active ingredient Y with another active ingredient is novel and inventive against a prior art (fictionally) including the single active ingredient Y. As a consequence, the claim directed to the combination is valid even if the claim directed to the single active ingredient Y is not.

26. If the applicant files the SPC application before the MA has been granted, but while the “basic patent” is still in force, and submits the MA as soon as the latter becomes available, may a valid SPC be granted in your jurisdiction? Does it make a difference if the basic patent to which the SPC application refers expires before the MA has become available and/or has been submitted to your Office? See Referral C-567/16¹⁰.
27. In the United States, it is possible to obtain an extension even if the patent expires before the MA has been granted. The patentee can indeed file an application for an interim extension before the expiration date of the patent. Do you see a practical need for amending the EU Regulations in this regard?
28. If the answer to Question 27 is yes, should the legislature provide the patent owner with the right to file a provisional SPC application as under US law, or should it provide the patentee with the possibility to file a request for re-establishment of rights? If the latter is the case, would it be appropriate to provide third parties in good faith with intervening rights (see, for instance, Art. 122(5) EPC)?
29. What happens if the patent is granted more than 20 years after the filing date? Is the grant of an SPC still possible? Do you have data concerning the question how often under your jurisdiction a patent is granted after the expiration date?
30. In your jurisdiction, is it possible to amend the national patent or the national fraction of a European patent after grant? Is it possible to amend the patent claims even if the patent has expired?
31. Does your national law provide requirements for amending the national patent that are identical to or consistent with Art. 123(2) and (3) EPC?
32. If the amendment of the patent is consistent with Art. 123 EPC or corresponding provisions of national law and, because of this amendment of the basic patent, the SPC application satisfies Art. 3(a) Reg. 469/2009/EC as interpreted by the CJEU or by your Office, would your Office grant an SPC?

¹⁰ *Merck Sharp v Comptroller* [2016] EWHC 1896 (Pat).

5 ART. 3(B) AND (D) REG. 469/2009/EC

33. Consider the following amended wording of Art. 3(b) Reg. 469/2009/EC:

“(b) a valid authorisation to place the product **or a combination of active ingredients including the product** on the market as a medicinal product has been granted **in the Member State in which the application referred to** in Article 7 is submitted in accordance with Directive 2001/83/EC or Directive 2001/82/EC, as appropriate”.

Would such wording reflect the practice of your patent office? Would it be consistent in your view with the case law of the CJEU? If not, why not?

34. Reg. 1234/2008/EC describes revised variation details for an MA for medicinal products. In your view, should the variation of an MA be considered a new MA for the purposes of Art. 3(b) and (d) Reg. 469/2009/EC? Or does the amount of investment necessary for the related clinical research not justify such a qualification?

35. Certain changes to an MA, however, are so relevant that it is not possible to follow the variation procedure. These changes, listed in Annex I to Reg. 1234/2008/EC, must be introduced through an extension of the MA application. In your view should such an extension be a new MA for the purposes of Art. 3(b) Reg. 469/2009/EC? If your answer is no, when do you think that it would be justified to consider it a new MA for the purposes of Art. 3(b) and (d) Reg. 469/2009/EC?

36. Reg. 1234/2008/EC refers to three types of variation which have different implications depending “on the impact of the change on the quality, safety or efficacy of the medicinal product”. This includes type II variations, that is major variations that do not constitute “*an extension and which may have a significant impact upon the quality, safety or efficacy of the medicinal product concerned*” (Art. 1(3) Reg. 1234/2008/EC). Does any application for a type II variation constitute a new MA for the purposes of Art. 3(b) and (d) Reg. 469/2009?

37. Is a type II MA variation sufficient to meet the requirements for a “different application of the same product” as set out in the answer to Questions 1 and 3 in the decision by the CJEU in *Neurim*¹¹ (see especially paras. 25–27)?

¹¹ Case C-130/11 *Neurim Pharmaceuticals (1991) Ltd v Comptroller* [2012].

6 ART. 3(c) REG. 469/2009/EC

38. In decision C-443/12¹², the CJEU maintained that Art. 3(c) Reg. 469/2009/EC precludes the patent holder from obtaining a second SPC for a combination including compound Y and compound X when the patent holder has already obtained an SPC for the single compound Y. This limitation does not apply when the combination represents “*a totally separate innovation*”. As we understand it, with this judgment the Court has *de facto* adopted a similar approach to the core inventive test discussed in Questions 24-25, but it has based it on Art. 3(c) Reg. 469/2009/EC. Do you agree with this understanding?
39. Take the following fictional case. A basic patent is granted for a compound Y. Dependent claims are directed to combinations including such a compound and a diuretic agent. A first MA is granted for the compound Y. A second MA is granted for a combination including Y and the specific diuretic agent X. Let us assume that such a combination is sufficiently disclosed pursuant to Art. 83 EPC, but that it is not possible to limit the patent to the specific combination including X without violating Art. 123(2) EPC, because the compound X is not mentioned at all in patent application as filed. Further, according to the information available to your Office, no dependent claim directed to a combination Y–X would be independently valid. The patentee files a second SPC application for the combination Y–X based on the MA granted for Y–X. Under the practice of your patent office can a valid SPC be granted in this case?
40. In the fictional case discussed above, does the result differ in the practice of your Office if the applicant has filed a divisional application where claims directed to a combination comprising Y and another product are included and then the said applicant indicates as the basic patent in the SPC application the patent granted on the basis of that divisional application?
41. Under your jurisdiction is it possible to circumvent the requirement based on Art. 3(c) Reg. 469/2009/EC by filing several patent applications on the same date or within the 18 months before the publication of the first application, or by filing several divisional applications and then transferring some of them before or after grant to a third company?
42. Take the following case: Applicant A files a first SPC application directed to substance X based on Patent No. 1 owned by Applicant A. Applicants A and B file a second SPC application directed to the same substance X based on Patent No. 2 owned by Applicant A and B. How does your Office proceed in this case?

¹² Case C-443/12 *Actavis Group PTC EHF & Anor v Sanofi Pharma Bristol-Myers Squibb SNC* [2013].

7 CALCULATION OF TERM AND DEADLINES

43. In calculating the term of a European patent pursuant to Art. 63 EPC do you apply Rule 131(3) EPC?
44. Which rule do you apply in calculating the term of a national patent?
45. Which rule do you apply in calculating deadlines for the procedure before your Office?
46. The Regulations do not adopt any rule for calculating the term of the SPC or for calculating the term of the basic patent for the purposes of the Regulations themselves. They do not stipulate any rule to calculate the deadlines for filing an SPC or for the procedure before the national office. Would you welcome a uniform and generally applicable rule? Would the wording of Rule 131 EPC¹³ be an appropriate normative model?
47. Art. 11(1)(ii) and (2) PLT and Art. 121 EPC provide for the right of a patent applicant or owner to request further processing with respect to the application or patent in cases where the applicant or the patent owner has failed to comply with a time limit fixed by the Office. Does your patent act contain similar provisions? Do these provisions apply to SPC applications? Would you expect harmonisation to have a positive impact in this regard?
48. Art. 12 PLT and Art. 122 EPC provide for the right of the owner or applicant to obtain a re-establishment of rights when a failure to comply with a time limit has occurred in spite of due care and the failure has the direct consequence of causing a loss of rights. Does your patent act contain similar provisions? Do these provisions apply to SPC applications? Do you expect a positive impact from a unification of the law in this regard?

¹³ See Rule 131 (Calculation of periods)

(1) Periods shall be laid down in terms of full years, months, weeks or days.

(2) Computation shall start on the day following the day on which the relevant event occurred, the event being either a procedural step or the expiry of another period. Where the procedural step is a notification, the relevant event shall be the receipt of the document notified, unless otherwise provided.

(3) When a period is expressed as one year or a certain number of years, it shall expire in the relevant subsequent year in the month having the same name and on the day having the same number as the month and the day on which the said event occurred; if the relevant subsequent month has no day with the same number, the period shall expire on the last day of that month.

(4) When a period is expressed as one month or a certain number of months, it shall expire in the relevant subsequent month on the day which has the same number as the day on which the said event occurred; if the relevant subsequent month has no day with the same number, the period shall expire on the last day of that month.

(5) When a period is expressed as one week or a certain number of weeks, it shall expire in the relevant subsequent week on the day having the same name as the day on which the said event occurred.

8 CONTENT OF THE SPC APPLICATION. PROCEDURAL ISSUES

49. According to our understanding, neither of the SPC Regulations requires the application to include one or more “patent claims” indicating the subject matter for which protection is sought. Does your Office agree with this understanding?
50. Are patent claims, though not required, nevertheless admitted in the SPC Application by your Office?
51. Would you find it appropriate to include a provision in the Regulation requiring the applicant to file patent claims in the SPC application? In providing your answer, take into consideration that according to our understanding the SPC could be requested for forms of the product different from the form that is the subject of the MA.
52. Does your Office provide for a full examination of national patents?
53. Does your Office provide for an examination of all requirements provided under Art. 3 Reg. 469/2009/EC? Does your office follow a principle of *ex officio* examination ?
54. What is the background of the examiners involved? Do they have legal or technical training, or both?
55. If the examiner has objections to the grant of the SPC, does your national law provide the applicant with the right to request a hearing before a panel of examiners? If so, what is the legal basis of the corresponding right?
56. What information is published by the national authority relating to the application for an SPC and/or its status? Which documents are open to public inspection?
57. Is it possible for third parties to file observations during the SPC granting procedure? If the answer is yes, is it possible to file observations anonymously or through a front man (for instance, a law firm)? What is the legal basis for such a right?
58. Is the patentee obliged under your national law to inform the Office of the existence of revocation or opposition proceedings against the basic patent?
59. If revocation proceedings against the patent are pending, does this circumstance, if alleged by a third party or communicated by the applicant, have any impact on the procedure?
60. In your jurisdiction, is it possible to file an opposition against national patents?

61. If the Regulations were to be amended in order to allow opposition against SPCs, would you expect a positive impact from such a reform on the quality of the granted rights and the transparency of the system?
62. Are appeals against grant or rejection decisions within the meaning of Art. 18 Reg. 469/2009/EC and Art. 17 Reg. 1610/96/EC provided for by the national law applicable in your jurisdiction? What authority is competent to hear them?
63. The Regulation does not provide an obligation to submit complete and true information requested under Art. 8 Reg. 469/2009/EC (obligation to state the truth; *Wahrheitspflicht*). Does such an obligation exist under the national law of your jurisdiction? If this obligation exists, what are the sanctions for violating it?
64. Do you see any practical need for providing the applicant with the right to limit the product definition included in the SPC application after grant before the granting authority in *ex-parte* proceedings (in analogy to Art. 105a EPC) or before the court in *inter partes* revocation proceedings (in analogy to Art. 138(3) EPC) ?
65. Has Art. 17(2) Reg. 1610/96/EC been implemented in your legislation? Is the appeal aimed at rectifying the duration of the certificate provided for under Art. 17(2) Reg. 1610/96/EC subject to deadlines? Do you see a practical need for providing the applicant with the right to amend at any time the duration of the certificate or for the Office to amend *ex officio* such duration?
66. Do you see any practical need for introducing the right to file SPC divisional applications in analogy to Art. 76 EPC?
67. In your experience as an SPC examiner, are there aspects of the national granting procedure in one or more countries that constitute a burden on the applicant or on the national office, and/or where harmonisation would be sensible?

9 SPECIFIC ISSUES CONCERNING THE PLANT PRODUCT REGULATION

68. The CJEU decided in Case C-229/09¹⁴ that provisional MAs granted pursuant to Art. 8(1) of Dir. 91/414/EEC are MAs in the sense of Art. 3(1)(b) of Reg. 1610/96/EC. Art. 13(3) of Reg. 1610/96/EC states that “*For the purposes of calculating the duration of the certificate, account shall be taken of a provisional first marketing authorization only if it is directly followed by a definitive authorization concerning the same product*”. What is the current practice of your Office for calculating the duration of an SPC if there is no definitive authorisation available at the time of grant? Does this provision lead to problems in practice? If yes, how could these be avoided?

¹⁴ Case C-229/09 *Hogan Lovells International LLP v Bayer CropScience AG* [2010].

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

69. According to Art. 8(1)(d) of Reg. 469/2009/EC, requests for an extension of the duration shall contain "(i) a copy of the statement indicating compliance with an agreed completed paediatric investigation plan" and "(ii) where necessary, [...] proof of possession of authorisations to place the product on the market of all other Member States". What is the current practice of your Office, if documents (i) and/or (ii) are (partially) not filed with the request? Can these be filed later and until what (ultimate) deadline? Are there circumstances in which a request for an extension can be granted with documents missing?
70. If an extension of the duration is granted pursuant to Art. 36 Reg. 1901/2006/EC and the patent is revoked, does your Office of its own motion revoke the extension? If the answer is no, would you welcome a provision that amended Art. 16(2) Reg. 469/2009/EC and allowed the granting authority referred to in Art. 9(1) Reg. 469/2009/EC to revoke of its own motion the extension of the duration? See Art. 14 Reg. 469/2009/EC.

11 FEES

71. Could you provide us with a table showing the fees for SPCs, if any, that must be paid to your Office?

12 UNITARY PATENT AND SPC

72. According to our understanding, a European patent with unitary effect is a patent within the meaning of Art. 3(a) Reg. 469/2009/EC. Therefore, it can be the basis for granting an SPC. Do you agree with this understanding?
73. There is a difference between the current SPC and patent regimes. In the case of patents, it is possible to obtain a bundle of patents valid in several countries through a single application before the EPO. This option does not exist for SPCs. Several national applications are necessary. Therefore, it is being considered to create an SPC with unitary effect based on an MA with pan-European effect. Do you consider that there is a need for the creation of an "SPC with unitary effect"?
74. If yes, what authority should grant it?
- a) National patent offices on the basis of a mutual recognition system;
 - b) An EU authority such as the EUIPO;
 - c) An EU authority such as the EMA;
 - d) The EPO;
 - e) A virtual patent office created on the basis of new EU rules and composed of examiners from selected national patent offices.

Please comment on the advantages and shortcomings of the different models.

75. If you opted for a mutual recognition system, in which language should an SPC be filed and prosecuted?
- a) In the language of the selected Office;
 - b) In English.
76. In which language should the title of protection be granted, and possibly translated?
- a) If national offices are the granting authority, in the language of the granting office plus English;
 - b) All languages of the countries for which the SPC is sought;
 - c) Two-language solution as in the EUIPO.
77. Should the decisions of the SPC granting body be subject to appeal before the UPC or before an EU Court as in the case of EU trade marks or designs?

78. Should the SPC only be granted when the product is covered by a European MA?

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79. Do you have further comments or questions which, from your experience and point of view, have not been addressed in this questionnaire and which are important to the SPC system?

Munich, 27. February 2017

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Annex VI: Questionnaire for the National Patent Offices
of the EU Member States

