The Requirements of Art. 3(a) and (c) SPC Regulation and Post-grant Amended Patents

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ABSTRACT

SPCs are linked to a basic patent and presuppose the existence of such a patent. The requirements for the grant of an SPC in Art. 3(a) and (c) SPC Regulation depend on the basic patent and its content. However, patents can be amended, even after they have been granted. It is conceivable that a patent amendment could influence the assessment of these requirements and thus the granting or validity of an SPC. This issue is the subject of this contribution. It is approached by first analysing the requirements for the grant of an SPC in Art. 3(a) and (c) SPC Regulation, in particular their interpretation by the CJEU, as well as the procedural and substantive requirements for a patent amendment. Based on this, the interaction between these two areas of law is examined, recognising that there are similarities. Different potential scenarios are discussed with the result that the requirements for the grant of an SPC in Art. 3(a) and (c) SPC Regulation, in their current interpretation by the CJEU, are suitable to withstand a patent amendment and cannot be circumvented by such an amendment.

1. INTRODUCTION

The existence of a basic patent is a requirement for the grant of a supplementary protection certificate (SPC). The assessment of the requirements in Art. 3(a) and (c) of the Regulation (EC) No 469/2009[1] depends on the basic patent and its content. On the other hand, patent holders are allowed to amend their patents, also after they have been granted. Such a post-grant amendment can influence the assessment of Art. 3 SPC Regulation. It may be possible to circumvent the requirements for the grant of an SPC by a patent amendment. This could be a basis for evergreening strategies. This contribution addresses the question of whether such a risk exists and what an appropriate approach to amended European patents in the context of SPCs for medicinal products is.

The issue has not yet been addressed in the legislation or by case law.[2] The question was referred to the CJEU in *Actavis II*, but was not answered. In the underlying case, the company Boehringer applied for an SPC and received a suggestion from the UK IPO to amend its basic patent in order to qualify for an SPC. The patent was amended as suggested and an SPC was subsequently granted.[3]

In the following, the case law of the CJEU and its interpretation of the requirement in Art. 3(a) SPC Regulation [II] and the requirement in Art. 3(c) SPC Regulation [III] will be analysed. The interpretation by the CJEU is of special importance because the substantive provisions of the legislation correspond almost completely to the initial SPC Regulation, Regulation (EEC) No 1768/92[4], and are therefore over thirty years old. In addition to general criticism of the terms and text of the regulation[5], the phar-

1 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 (Codified version), [2009] OJ L 152/1, as last amended by Regulation (EU) 2019/933 of 20 May 2019, [2019] OJ L 153/1 (hereinafter: SPC Regulation).

2 Cf. Frantzeska Papadopoulou, *Evergreening Patent Exclusivity in Pharmaceutical Products: Supplementary Protection Certificates, Orphan Drugs, Paediatric Extensions and ATMPs* (Hart Publishing 2021) 95–96; Frantzeska Papadopoulou, "Twenty Years of SPC Case Law: A Long Way to Go in the Quest for Clarity" in Hayleigh Bosher and Eleonora Rosati (eds), *Developments and Directions in Intellectual Property Law* (Oxford University Press 2023) 584. See also Christopher Hayes, "An Innovative Decision on Supplementary Protection Certificates for Combination Products?: Actavis Group PTC EHF & Actavis UK Ltd v Boehringer Ingelheim Pharma GmbH & Co KG, Case C-577/13, Court of Justice of the European Union, ECLI:EU:C:2015:165, 15 March 2015" (2015) 10 JIPLP 502, 504.

3 Judgement of 12 March 2015, *Actavis Group PTC and Actavis UK*, C-577/13, EU:C:2015:165 (hereinafter: *Actavis II*), paragraphs 9–24; 41.

4 Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products, 1992 OJ L182/1 (hereinafter: initial SPC Regulation).

5 Frantzeska Papadopoulou, "Supplementary Protection Certificates: Still a Grey Area?" (2016) 11 JIPLP 372, 380; Frantzeska Papadopoulou 2021 (n 2) 133; Frantzeska Papadopoulou 2023 (n 2) 590; Gareth Morgan, Natalie Coan and Tom Errington, "Intellectual Property Rights and Medicines" in Peter Feldschreiber (ed), *The Law and Regulation of Medicines and Medical Devices* (Oxford University Press 2021) para 13.80; Verna Vesanen, "Has the Court of Justice of the EU Clarified for Once

maceutical sector has changed significantly during this period. Not only has technology evolved, but attitudes towards generic companies have also changed.[6] However, the judgements are not always stringent and are sometimes open to different interpretations and were criticised for this.[7] It can be said that the case law is still developing.[8]

The procedural and substantive requirements for post-grant patent amendments are displayed [IV] and the interaction between the requirements for the grant of an SPC and the requirements for patent amendments are considered. Potential circumvention scenarios are presented and discussed [V]. Conclusions and an outlook with regard to the proposal of a new regulation by the European Commission are the subject matter of section VI.

2. PROTECTED BY A BASIC PATENT IN FORCE, ART. 3(A) SPC REGULATION

2.1 Nature of SPCs and Purposes of the SPC Regulation

SPCs for medicinal products are based on Regulation (EC) No 469/2009. They are independent *sui generis* intellectual property rights. Independent in this sense means that the term of patent protection is not extended, but that they are formally separate rights. Nevertheless, the SPC is an ancillary right, requiring the existence of a patent for a medicinal product and a corresponding marketing authorisation in order to be granted. Even so the legislative background is a regulation, unlike other intellectual property rights, SPCs are currently not granted by a centralised European Union office. The right is applied for at and granted by a national authority. The territory of protection is therefore limited to the respective Member State. Also, revocation and enforcement actions take place on a national level.[9]

Art. 3 SPC Regulation presents four cumulative requirements for obtaining an SPC.[10] The product must be covered by a basic patent (a) and a marketing authorisation (b). It must not have been the subject of an SPC before (c) and the marketing authorisation must be the first for the product (d). The purposes behind the SPC Regulation can be discerned from its recitals and from the Explanatory Memorandum attached to the proposal of the initial SPC Regulation. The main objectives pursued with the regulation are the functioning of the internal market, the encouragement of research and development in the health sector and the improvement of the international competitiveness of the European Union.[11]

2.2 General Remarks on Art. 3(a) SPC Regulation

Art. 3(a) SPC Regulation requires the product to be protected by a basic patent in force. The paragraph therefore focuses on the patent. The term "basic patent" is further clarified in the SPC Regulation in Article 1(c). It is defined as a patent which protects a product as such, a process to obtain a product or an application of a product and which is designated by the patent holder for the purpose of the procedure for the grant of an SPC. The product must be protected by a basic patent and the basic patent must be in force. Only the first sub-requirement is related to the wording of the patent and is therefore relevant with regard to patent amendments and thus in the context of this contribution. The application of Art. 3(a) SPC Regulation has proven to be problematic, particularly because of the uncertain meaning of the term "protected". It is or was unclear whether the term is a reference to patent law or a concept of the SPC legislation and how it is to be understood.[12]

2.3 Rules Governing the Basic Patent

In the case *Farmitalia*, the CJEU was asked for the criteria relevant for determining whether or not a product is protected by a basic patent. The CJEU ruled that in this context "reference must be made to the rules which govern that patent".[13] The court argued that patent law is not harmonised in the European Union.[14] Therefore, the determination of the extent of protection of a patent has to rely on non-EU rules which govern the patent.[15]

The CJEU developed this finding further in the judgement *Eli Lilly*. The court added that the Unified Patent Package does not change that there is no EU-harmonisation regarding patent law.[16] It also clarified which these "rules governing patents" are. Relevant are the rules on the

and for All the Law on Supplementary Protection Certificates?" (2017) 39 EIPR 42, 48.

6 Frantzeska Papadopoulou 2016 (n 5) 381; Frantzeska Papadopoulou 2021 (n 2) 135; Frantzeska Papadopoulou 2023 (n 2) 589–590.

7 Verna Vesanen (n 5) 48.

8 Frantzeska Papadopoulou 2021 (n 2) 131–132; Frantzeska Papadopoulou 2023 (n 2) 589. There are currently two new cases pending before the CJEU, mainly concerning the interpretation of Art. 3(a) and (c) SPC Regulation. One is a referral from the Finish Markkinaoikeus (*Teva and Teva Finland*, C-119/22) and the other a referral from the Irish Supreme Court (*Merck Sharp & Dohme, C-149/22*).

9 Max Planck Institute for Innovation and Competition, "Study on the Legal Aspects of Supplementary Protection Certificates in the EU: Final Report" (Directed by Reto Hilty, Publication Office of the European Union 2018) 12–13.

10 Cf. ibid 173.

11 European Commission, Explanatory Memorandum to the Proposal for a Council Regulation (EEC), of 11 April 1990, concerning the creation of a supplementary protection certificate for medicinal products (COM(90) 101 final – SYN255) para 8. The Explanatory Memorandum can still be used, as the conditions for granting an SPC and the relevant recitals of the original proposal have not been changed. Max Planck Institute (n 9) 11.

12 Max Planck Institute (n 9) 180–181.

13 Judgement of 16 September 1999, *Farmitalia*, C-392/97, EU:C:1999:416, paragraph 29 and operative part.

14 At that time European Community. Judgement of 16 September 1999, *Farmitalia*, C-392/97, EU:C:1999:416, paragraph 26.

15 Ibid, paragraph 27.

16 Judgement of 12 December 2013, *Eli Lilly*, C-493/12, EU:C:2013:835, paragraphs 30–31.

extent of protection, which are Art. 69 EPC[17] and the Protocol on the Interpretation of Art. 69 EPC[18] for European patents and corresponding provisions of national patent law for national patents.[19] It follows from these rules, that the claims play a key role but that they need to be interpreted in the light of the description and the drawings.[20] The product must fall under the scope of protection of the basic patent.[21] Not relevant are the rules on the rights conferred by the patent.[22] It is not decisive whether the product would infringe the patent.[23] The CJEU also recognised to have no jurisdiction over the rules of the EPC since the European Union has not acceded to the Convention. It states that it therefore cannot give national courts further guidance on the determination of the extent of patent claims.[24]

2.4 Criterion "Specified in the Wording of the Claims"

In *Medeva*, the CJEU was asked whether Art. 3(a) SPC Regulation precludes SPCs for active ingredients not expressly mentioned in the wording of the claims. The court ruled that the active ingredient(s) of the product need to be "specified in the wording of the claims of the basic patent".[25] Also, on the basis of a claim related to an active ingredient in isolation only an SPC for a product containing a single active ingredient and on the basis of a claim related to a combination of active ingredients only an SPC for the combination can be granted.[26]

It follows indirectly from this that it is not sufficient that the product would infringe the patent, as this would also apply to the combination product if only the individual active ingredient is claimed.[27] Two opinions on the determination of the protection of a product by the basic patent within the meaning of Art. 3(a) SPC Regulation are stated at the beginning of the judgement. According to the first opinion, the wording of the claims is relevant and according to the second opinion it is important whether the product infringes the patent.[28] Although the court does not expressly endorse an opinion, the above and the fact that the formula "specified in the wording of the claims" is based on the wording favour the first view.

The criterion "specified in the claims" was confirmed in subsequent judgements of the CJEU.[29]

2.5 Functional Definitions and the Criterion the Claims Relate to the Product "Implicitly but Necessarily and Specifically"

In the judgement *Eli Lilly*, the CJEU provided more details on the meaning of the formula "specified in the wording of the claims".[30] The court ruled that an active ingredient does not need to be identified in the claims by a structural formula to fulfil the requirement laid down in Art. 3(a) SPC Regulation. An identification by a functional formula is sufficient, if the claims relate "implicitly but necessarily and specifically" to the active ingredient.[31] The court argues with the idea of compensation behind the SPC system and the purpose to incentivise research in the pharmaceutical field. This objective would be undermined without the condition that the product needs to be "specified" in the claims. The lack of such a specified identification would show that the patent holder has not carried out in-depth research and has not made related investments which could be compensated by the SPC protection.[32]

Reference is also made to the question of whether the criteria are different for single active ingredients and combination products.[33] This question was not returned to. However, as no differentiation is made in the further course, it can be assumed that the criteria should not dif-

17 The Convention on the Grant of European Patents (the European Patent Convention) of 5 October 1973 as revised by the Act revising the EPC of 29 November 2000, [2001] OJ EPO Special edition No 4 p 55 (hereinafter: EPC or Convention).

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

19 Judgement of 12 December 2013, *Eli Lilly*, C-493/12, EU:C:2013:835, paragraphs 32–33. It should be noted that these national rules are uniform in Europe, following the wording of Art. 8(3) of the Strasbourg Convention and Art. 69 EPC.

20 Ibid, paragraph 39.

21 Cf. Max Plack Institute (n 9) 196.

22 Judgement of 12 December 2013, *Eli Lilly*, C-493/12, EU:C:2013:835, paragraph 33.

23 Ibid, paragraph 37. Indirectly already from Judgement of 24 November 2011, *Medeva*, C-322/10, EU:C:2011:773, paragraph 27, cf. II.4. See also Franz-Josef Zimmer, Benjamin Quest and Markus Grammel, "Recent Decisions of the European Court of Justice of the European Union on Supplementary Protection Certificates: A Few Answers-Many Questions" (2014) 33 Biotechnology L Rep 171, 173.

24 Judgement of 12 December 2013, *Eli Lilly*, C-493/12, EU:C:2013:835, paragraph 40.

25 Judgement of 24 November 2011, *Medeva*, C-322/10, EU:C:2011:773, paragraph 18 and operative part.

26 Ibid, paragraph 26.

27 Cf. Frantzeska Papadopoulou 2016 (n 5) 377; Paul England, *A Practitioner's Guide to European Patent Law: For National Practice and the Unified Patent Court* (2nd edn, Hart Publishing 2022) 416.

28 Judgement of 24 November 2011, *Medeva*, C-322/10, EU:C:2011:773, paragraph 20.

29 Order of 25 November 2011, *Yeda*, C-518/10, EU:C:2011:779; Order of 25 November 2011, *University of Queensland*, C-630/10, EU:C:2011:780; Order of 25 November 2011, *Daiichi Sankyo*, C-6/11, EU:C:2011:781. See also Max Planck Institute (n 9) 187–189.

30 Cf. Max Planck Institute (n 9) 189.

31 Judgement of 12 December 2013, *Eli Lilly*, C-493/12, EU:C:2013:835, paragraph 39.

32 Ibid, paragraphs 41–43.

33 Judgement of 12 December 2013, *Eli Lilly*, C-493/12, EU:C:2013:835, paragraph 25.

fer.[34] The formula applies to products containing a single active ingredient and to products consisting of a combination of active ingredients.

2.6 The Two-step Test

In the judgement *Teva*, the Grand Chamber of the CJEU developed a two-step test for the application of the formula for functional definitions that the claims must relate to the product "implicitly but necessarily and specifically". First, the product must "necessarily fall under the invention" and second, the product must be "specifically identifiable".[35] The relevant perspective is that of a person skilled in the art.[36] The basis for assessment consists of the information disclosed by the basic patent, the prior art at the filing or priority date of the patent and the skilled person's common general knowledge.[37] This also applies for combination products. The combination must necessarily fall under the invention and each of the active ingredients must be specifically identifiable.[38]

The first condition of the two-step test is further clarified. The product must be "a specification required for the solution of the technical problem disclosed by the patent".[39]

The judgement *Royalty Pharma* is mainly a confirmation of the judgement *Teva*.[40] The CJEU provided more details on the second condition of the two-step test and the related level of disclosure. It must be possible to "infer directly and unambiguously" from the patent specification that the product falls within the scope of protection of the basic patent. The court also clarified that a product does not fulfil this condition if it is developed after the filing date of the patent application, following an independent inventive step.[41] This would extend the protection conferred by the basic patent and contradict the idea of compensation.[42]

2.7 Requirement for the Product to "Constitute the Subject Matter of the Invention"

In the judgements *Actavis I* and *Actavis II*, the CJEU developed the requirement that the product must be protected "as such" or "constitute the subject matter" of the basic patent. More details on the requirement can be found in part III on Art. 3(c) SPC Regulation, as it was initially developed in this context. In *Actavis II*, the CJEU refered to Art. 3(c) and Art. 3(a) SPC Regulation, which made the location of the requirement less clear.[43] After the *Actavis* judgements, it was discussed in the scholarly literature whether the CJEU adopted the concept of "core inventive advance", proposed by the referring court.[44]

In *Royalty Pharma* the CJEU clarified that the concept of "core inventive advance" is not relevant and is not applied in the context of Art. 3(a) SPC Regulation. Relevant are instead the claims and the technical specifications of the invention.[45] This condition, afterwards, is only relevant, if at all, in the context of Art. 3(c) SPC Regulation.

It is unclear whether the concept of "core inventive advance" is the same as the concept "subject matter of the invention". Nevertheless, the CJEU already in *Teva* did not base its statement that the combination product in the main proceedings does not seem to fulfil Art. 3(a) SPC Regulation on the ground that one active ingredient does not "constitute the subject matter of the invention", but on the ground that the new two-step test does not seem fulfilled. After the *Actavis II* decision, it was in any case not clear whether the condition applies in the context of Art. 3(a) SPC Regulation and seems now denied.

3. EARLIER SPC, ART. 3(C) SPC REGULATION

It is obvious that the requirement in Art. 3(a) SPC Regulation depends on the basic patent and its content. The requirement in Art. 3(c) SPC Regulation, on the other hand, at first glance seems to depend only on the existence of earlier SPCs. It follows from the case law of the CJEU that the basic patent and its content are also relevant for the interpretation of this provision in certain cases.

Art. 3(c) SPC Regulation requires that the product has not already been the subject of an SPC. In the centre of this provision is therefore the product. The term "product" is defined in Art. 1(c) SPC Regulation and means the active ingredient or combination of active ingredients of a medicinal product. The relevant differentiations for Art. 3(c) SPC Regulation are whether the same or different patent holders are involved and whether the same or different products are at issue. The latter differentiation is used in cases of minor changes to the product, for example the use of a different salt or ester,[46] and for cases concerning combination products.

34 Cf. Roberto Romandini, "Art. 3(a) SPC Legislation: An Analysis of the CJEU's Ruling in Teva (C-121/17) and a Proposal for Its Implementation" [2019] GRUR Int. 9, 10.

35 Judgement of 25 July 2018, *Teva UK and Others*, C-121/17, EU:C:2018:585, paragraph 52.

36 Ibid, paragraph 47.

37 Ibid, paragraphs 48–50.

38 Ibid, paragraphs 53, 55.

39 Ibid, paragraphs 47–48.

40 Cf. Oswin Ridderbusch and Alexa von Uexküll, *European SPCs Unravelled: A Practitioner's Guide to Supplementary Protection Certificates in Europe* (2nd edn, Kluwer Law International BV 2021) s 1.02.B.1.

41 Judgement of 25 July 2018, *Teva UK and Others*, C-121/17, EU:C:2018:585, paragraph 50 and operative part.

42 Ibid, paragraph 46.

43 Judgement of 12 December 2013, *Actavis Group PTC and Actavis UK*, C-443/2012, EU:C:2013:833 (hereinafter *Actavis I*), paragraph 43 and operative part; Judgement of 12 March 2015, *Actavis Group PTC and Actavis UK*, C-577/13, EU:C:2015:165, paragraph 39 and operative part. See also Max Planck Institute (n 9) 195; Roberto Romandini (n 34) 10.

44 Max Planck Institute (n 9) 195; Tony Rollins, Nicola Dagg and Steven Baldwin, "From Takeda to Teva v Merck: Are We Treading the Right Path on Combination Product SPCs? (Part 2)" (2017) 39 EIPR 697, 699; Verena Vesanen (n 5) 47.

45 Judgement of 30 April 2020, *Royalty Pharma Collection Trust*, C-650/17, EU:C:2020:327, paragraphs 31–32.

46 Explanatory Memorandum (n 11) para 36; Jules Fabre and Sarah Taylor, "Supplementary Protection Certificates in Europe: Clarity at Last?"

Criteria for the differentiation whether an active ingredient and a combination containing that active ingredient are the same or different products were developed in the *Actavis* judgements. The CJEU ruled that an SPC for a combination, additional to an already granted SPC for a single active ingredient, can only be granted, under Art. 3(c) SPC Regulation, if the added active ingredient is protected "as such" or "constitutes the subject matter of the invention" of the basic patent.

It follows from *Actavis I* that, although the product is at the centre of Art. 3(c) SPC Regulation, the basic patent must be taken into account when deciding whether the product is the same as of an earlier SPC of the applicant.[47] In the situation that several SPCs or SPC applications are based on the same patent, it is decisive under Art. 3(c) SPC Regulation whether the concerned active ingredient(s) is/are protected "as such" by the basic patent within the meaning of Art. 3(a) SPC Regulation. The combination of active ingredient A with active ingredient B, which is protected as such by the basic patent, is a different product than active ingredient A in the context of Art. 3(c) SPC Regulation. The combination of active ingredient A with active ingredient B, which is not protected as such by the basic patent, is the same product as active ingredient A.

In *Actavis II*, the CJEU interprets the expression "as such" with the conclusion that it means that the product needs to "constitute the subject-matter of the invention".[48] The expression belongs to the requirement for SPC protection in Art. 3(a) and Art. 1(c) SPC Regulation. The product must be protected as such by the basic patent. The expression needs to be interpreted autonomously.[49] A product is protected "as such" by the basic patent within the meaning of Art. 3(a) and Art. 1(c) SPC Regulation if it "constitutes the subject matter if the invention". Then it is a different product in the context of Art. 3(c) SPC Regulation. It is also interesting, with regard to patent amendments, that even so the combination product in the main proceedings was expressly mentioned in the claims of the patent, that was not enough. Something more is required, the product needs to "constitute the subject matter of the invention".[50]

The concept of "core inventive advance" was not mentioned anymore in this decision, which makes the adoption of this concept even more uncertain.[51] In this regard, after the explicit rejection of the applicability of this concept in the context of Art. 3(a) SPC Regulation by the CJEU in *Royalty Pharma*, the question was raised how this influences the interpretation of Art. 3(c) SPC Regulation.[52] This question was also referred to the CJEU for a preliminary ruling by the Finish Markkinaoikeus (Market Court).[53] Here the view is taken that the requirement, that active ingredient B of a combination product must "constitute the subject matter of the invention" and therewith be protected "as such", is still applicable. In *Teva* the CJEU still referred to this requirement[54], while in *Royalty Pharma* it was expressed that a "core inventive advance" test was already not adopted in *Teva*.[55] Besides, the CJEU never expressly adopted a "core inventive advance" test, also not in the context of Art. 3(c) SPC Regulation. The formula "constitute the subject matter of the invention" could implement a different test.

4. POST-GRANT PATENT AMENDMENTS

In the following, it will be dealt with the procedural and substantive conditions for post-grant patent amendments of European patents as a prerequisite for the later analysis. This discussion will address post-grant amendments, that are amendments to the patent, as opposed to pre-grant amendments, that are amendments to the patent application. Corrections also belong to the category of amendments, but will not be discussed further as they relate to linguistic errors, errors of transcription and obvious decisions which cannot influence the granting of an SPC.[56] To be permitted, patent amendments must be admissible and allowable.[57] It is important to consider both, the formal and substantive aspects, in order to fully assess the possibilities and freedoms of the patent holder.

4.1 Admissibility of Amendments

The admissibility of an amendment depends on the type of procedure.[58] European patents can be amended before

(2021) 40 Biotechnology L Rep 325, 330.

47 Cf. Christopher Brückner, "Wie Geht Es Weiter Nach Actavis?" [2015] GRUR Int. 896 para 13; Christopher Brückner and Robert Lelkes, "Abstract Functional Combinations after Actavis: What Future?" (2016) 11 JIPLP 212, 213; Franz-Josef Zimmer, Benjamin Quest and Markus Grammel (n 23) 175; Max Planck Institute (n 9) 194; 250; Peter Meier-Beck, "Kein Schutzzertifikat Für Äquivalente?: Oder: What Is Meant by „the Product Is Protected by a Basic Patent in Force"?" [2018] GRUR 657, 661.

48 Judgement of 12 March 2015, *Actavis Group PTC and Actavis UK*, C-577/13, EU:C:2015:165, paragraph 38.

49 Ibid, paragraph 32.

50 Charleen O'Keeffe and John Sugrue, "The Supplementary Protection Certificate for Medicinal Products: Recent Developments and Outlook" [2022] EHPL 127, 129; Christopher Hayes (n 2) 503–504; Frantzeska Papadopoulou 2016 (n 5) 374; Frantzeska Papadopoulou 2021 (n 2) 95; Frantzeska Papadopoulou 2023 (n 2) 583; Oswin Ridderbusch and Alexa von Uexküll (n 40) s 1.02.B.3.

51 Frantzeska Papadopoulou 2016 (n 5) 374–375; Frantzeska Papadopoulou 2021 (n 2) 95; Frantzeska Papadopoulou 2023 (n 2) 583.

52 AstraZeneca v Swedish Patent and Registration Office, Supreme Court (Högsta domstolen) Ö 5978-21 73 (2024) GRUR Int. 231, 233; Jules Fabre and Sarah Taylor (n 46) 330.

53 Referral *Teva and Teva Finland*, C-119/22.

54 Judgement of 25 July 2018, *Teva UK and Others*, C-121/17, EU:C:2018:585, paragraph 42.

55 Judgement of 30 April 2020, *Royalty Pharma Collection Trust*, C-650/17, EU:C:2020:327, paragraph 31.

56 Rule 139, 140 of the Implementing Regulations to the Convention on the Grant of European Patents (November 2023) (hereinafter: Implementing Regulations).

57 Guidelines for Examination in the European Patent Office (EPO 2023) s H.I.

58 Ibid s H.II.1.

the EPO and before national authorities and courts. Something all post-grant amendments have in common is that they take retroactive effect.[59]

Patent amendments in front of the EPO take effect in all Contracting States. The first option is the limitation procedure, regulated in Art. 105a–105c EPC. It can be initiated by the patent holder (Art. 105a EPC). The limitation is an amendment of the claims. The description and drawings may be changed if necessary due to changes in the claims.[60] The patent holder is limited in such a way that the limitation is a "reduction in the extent of protection conferred by the claims".[61] The second option is the opposition procedure, regulated in Art. 99–105 EPC. The subject matter of the amendment is not limited, possible are amendments of the claims, the description and the drawings. The patent holder is limited in such a way that the opposition procedure cannot be initiated by the patent holder[62] and that the amendments must be occasioned by the grounds for opposition in Art. 100 EPC.[63] The amendment must therefore be related to the patentability requirements in Art. 52–57 EPC (Art. 100a EPC), to the sufficiency of disclosure (Art. 100b EPC) or to subject matter not disclosed in the original application in accordance with Art. 123(2) or Art. 76(1) EPC (Art. 100c EPC).

Patent amendments in national instances are possible in all procedures relating to the validity of the patent. Even so a national procedure, the revocation procedure is partially regulated in the Convention in Article 138. The amendments concerned are amendments of the claims. They are national amendments and therefore only take an effect on the respective territory.[64] It follows from Art. 138(2) and (3) EPC that a patent amendment is only possible in form of a limitation. It follows from the above that the patent holder already from the procedural perspective is somehow limited.

There is another relevant perspective on these procedures. Failure to comply with Art. 123(2) EPC is a ground for opposition (Art. 100(c) EPC) and for revocation (Art. 138(1)(c) EPC) and failure to comply with Art. 123(3) EPC is a ground for revocation (Art. 138(1)(d) EPC). They can be raised by third parties to take action against unlawfully amended patents.

4.2 Allowability of Amendments

Patent amendments are allowable if they comply with Art. 123(2), Art. 123(3) and Art. 84 EPC. This means they do not contain subject matter which extends beyond the content of the application as filed (Art. 123(2) EPC), extend the protection conferred by a patent (Art. 123(3) EPC) or introduce deficiencies with regard to Art. 84 EPC.[65] Also, the amended patent must fulfil requirements that have to be met by all patents.[66]

The limitations in Art. 123(2) and (3) EPC must be assessed separately.[67] They are mutually independent.[68] The applicable burden of proof is the strict standard of "beyond reasonable doubt".[69]

4.2.1 Added Subject Matter, Art. 123(2) EPC

According to Art 123(2) EPC, a European patent application or a European patent may not be amended in such a way that it contains subject matter which extends beyond the content of the application. Since this contribution deals with post-grant amendments, only these will be discussed and referred to in the following. The purpose of the provision is to ensure a fair balance between the interests of the patent holder and the interest in legal security of third parties. The patentee is not allowed to gain an unwarranted advantage by adding subject matter to the patent not disclosed in the original application.[70]

An important step for developing a standard for the assessment of Art. 123(2) EPC was made by the Enlarged Board of Appeal in opinion G 3/89 and decision G 11/91.[71] The court held that the term "content of the application" in Art. 123(2) EPC means the parts of the patent relating to the disclosure, more concrete the description, the claims and the drawings.[72] In its order, it stated that a correction of these parts can only be made "within the limits of what a skilled person would derive directly and unambiguously, using common general knowledge, and seen objectively and relative to the date of filing, from the whole of these documents as filed".[73] In other words, the

59 Guidelines for Examination in the European Patent Office (EPO 2023) s H.IV.3.1.

60 Rule 95 of the Implementing Regulations.

61 Guidelines for Examination in the European Patent Office (EPO 2023) s D.X.4.3.

62 L Bently and others, *Intellectual Property Law* (6th edn, Oxford University Press 2022) 461.

63 Rule 80 of the Implementing Regulations.

64 Cf. Kiefer, "EPÜ Art. 138" in Uwe Fitzner, Sebastian Kubis and Theo Bodewig (eds), *BeckOK Patentrecht* (30th edn, CH Beck 2023) para 1.

65 Guidelines for Examination in the European Patent Office (EPO 2023) s H.I.

66 Ibid s H.IV.2.1; L Bently and others (n 62) 461.

67 Guidelines for Examination in the European Patent Office (EPO 2023) s H.IV.3.4.

68 Decision of the Enlarged Board of Appeal of 2 February 1994, *Limiting feature/ADVANCED SEMICONDUCTOR PRODUCTS*, G 1/93, EP:BA:1994:G000193.19940202, paragraph 13; Case Law of the Boards of Appeal of the European Patent Office (10th edn, EPO 2022) s II.E.2.

69 Decision of the Technical Board of Appeal 3.3.3 of 27 February 2007, T 307/05, EP:BA:2007:T030705.20070227, paragraph 3.3.1; Case Law of the Boards of Appeal of the European Patent Office (10th edn, EPO 2022) s II.E.5.

70 Decision of the Enlarged Board of Appeal of 2 February 1994, *Limiting feature/ADVANCED SEMICONDUCTOR PRODUCTS*, G 1/93, EP:BA:1994:G000193.19940202, paragraph 9; Case Law of the Boards of Appeal of the European Patent Office (10th edn, EPO 2022) s II.E.1.1; Guidelines for Examination in the European Patent Office (EPO 2023) s H.IV.2.1.

71 Cf. Case Law of the Boards of Appeal of the European Patent Office (10th edn, EPO 2022) s II.E.1.1.

72 Opinion of the Enlarged Board of Appeal of 19 November 1992, G 3/89, EP:BA:1992:G000389.19921119 and Decision of the Enlarged Board of Appeal of 19 November 1992, *Glu-Gin/CELTRIX*, G 11/91, EP:BA:1992:G001191.19921119, paragraph 1.4 and headnote I. The Technical Board of Appeal considered the questions of the pending referral in G 3/89 to be decisive and referred the same questions. Therefore, the answers and reasonings in both decisions are the same.

73 Ibid, paragraph 3 and headnote I.

relevant perspective is that of a skilled person. She or he must, on the basis of the description, the claims and the drawings and her or his common general knowledge, be able to derive the changes to be made objectively, directly and unambiguously. The relevant point in time is the date of filing. In decision G 2/10 it is referred to the formula developed in G 3/89 and G 11/91 as the disclosure test or "gold standard" for the assessment of the compliance of an amendment with Art. 123(2) EPC.[74] At the latest since this decision, it is clear that the formula applies not only to corrections, but to all types of amendments.

4.2.2 Extension of Protection, Art. 123(3) EPC

According to Art. 123(3) EPC, a European patent may not be amended in such a way as to extend the protection it confers. This provision applies only to granted patents and not to patent applications. Rules for determining the extent of protection conferred by a European patent, as referred to in Art. 123(3) EPC, can be found in Art. 69 EPC and its Protocol. According to Art. 69(1) EPC, the protection conferred is determined by the claims of the patent. The claims are interpreted in the light of the description and the drawings.[75] Therefore, Art. 123(3) EPC does not only apply to amendments to the claims, but also to amendments to the description and the drawings.[76] In the EPC 2000, this now results directly from the wording.[77] The purpose of Art. 123(3) EPC is the protection of third-party interests. Third parties should be able to rely and base their actions on the scope of protection of the patent as granted, knowing that protection can only be limited, not extended, and that an act which does not infringe the patent as granted does not infringe an amended version.[78] The patent holder is, within these boundaries, free to change the wording and terminology of her or his patent.[79]

The protection conferred must be differentiated from the rights conferred. The rights conferred are, in accordance with Art. 64(1) EPC, regulated by the national law of the Contracting States. The protection conferred is determined by the claims, in accordance with Art. 69 EPC and its Protocol. The rights conferred depend on the extent of protection but also on the national provisions relating to infringement, which, for example, regulate which acts of third parties are infringing and what remedies the patent holder is entitled to. The determination of the protection conferred can be described as a determination of "what" is protected, while the rights conferred are related to the "how" of protection. In the context of Art. 123(3) EPC only the protection conferred is relevant.[80]

The assessment of Art. 123(3) EPC requires a comparison of the extent of protection of the patent before and after the amendment. The comparison does not relate to the single amended claims, but to the claims in totality or the claims as a whole. The totality of claims before the amendment is compared to the totality of claims after the amendment.[81]

If the protection is extended depends on whether the subject matter of the claims is "more or less narrowly defined" after the amendment.[82] The subject matter of a claimed invention consists of two aspects, first, the category or type of the claim and second, the technical features.[83]

5. INTERACTION AND POTENTIAL CIRCUMVENTION SCENARIOS

Comparing the findings in section II and III with the substantive limitations for patent amendments in Art. 123(2) and (3) EPC, there appear to be some similarities. For the assessment of Art. 3(a) SPC Regulation, it is essential to determine the scope of the basic patent. The scope of protection is also central to the limitation in Art. 123(3) EPC. It must not be extended. In the context of both provisions, the extent of patent protection is determined in accordance with Art. 69 EPC and its Protocol. The provisions on limitation and revocation procedures also relate to the scope of patent protection. In these procedures the scope can only be narrowed.

There are also strong similarities between the formula used in *Royalty Pharma* to define the criterion that the product must be "specifically identifiable", the second condition of the two-step test for functional definitions, and the disclosure test or "gold standard" for the assessment of Art. 123(2) EPC. The product is "specifically identifiable" if it falls within the limits of what a person skilled in the art is objectively able, at the filing date or priority date of the basic patent, to infer directly and unambiguously from the specification of that patent as filed, based on that person's general knowledge in the relevant field at the filing or priority date, and in the light of the prior art at the filing date or priority date.[84]

74 Decision of the Enlarged Board of Appeal of 30 August 2011, *Disclaimer/SCRIPPS*, G 2/10, EP:BA:2011:G000210.20110830, paragraph 4.3.

75 Cf. Guidelines for Examination in the European Patent Office (EPO 2023) s H.IV.3.2.

76 Decision of the Enlarged Board of Appeal of 2 February 1994, *Limiting feature/ADVANCED SEMICONDUCTOR PRODUCTS*, G 1/93, EP:BA:1994:G000193.19940202, paragraph 11; Guidelines for Examination in the European Patent Office (EPO 2023) s H.IV.3.2.

77 Case Law of the Boards of Appeal of the European Patent Office (10th edn, EPO 2022) s II.E.2.

78 Decision of the Enlarged Board of Appeal of 2 February 1994, *Limiting feature/ADVANCED SEMICONDUCTOR PRODUCTS*, G 1/93, EP:BA:1994:G000193.19940202, paragraph 9; Case Law of the Boards of Appeal of the European Patent Office (10th edn, EPO 2022) s II.E.2.1; Guidelines for Examination in the European Patent Office (EPO 2023) s H.IV.3.1.

79 Case Law of the Boards of Appeal of the European Patent Office (10th edn, EPO 2022) s II.E.2.2.

80 Decision of the Enlarged Board of Appeal of 11 December 1989, G 2/88, EP:BA:1989:G000288.19891211, paragraph 3.3.

81 Ibid, paragraph 3.2.

82 Ibid, paragraph 4.1.

83 Ibid, paragraph 2.6.

84 Judgement of 30 April 2020, *Royalty Pharma*, C-650/17, EU:C:2020:327, paragraph 40.

In the following, the individual criteria identified by the CJEU are analysed in detail and possible circumvention scenarios are presented. These scenarios are then compared with the possibilities offered by patent law.

5.1 Patent Amendment in *Actavis II* and the Criterion "Constitute the Subject Matter of the Invention"

The patent amendment in *Actavis II*, mentioned in the introduction, will be discussed first. The claim previous to the amendment related to a combination of active ingredient A and another active ingredient, described by a functional definition. After the amendment a specific combination of active ingredient A and active ingredient B was claimed. The CJEU held that an SPC for the combination cannot be granted because, even so expressly mentioned, the active ingredient B does not "constitute the subject matter of the invention" and is therefore not protected "as such" by the basic patent. The patent amendment therefore did not enable the granting of an SPC.

In the context of Art. 3(c) SPC Regulation it is decisive whether an active ingredient "constitutes the subject matter of the invention" and is protected "as such" by the basic patent. A changed outcome therefore only seems possible by an amendment related to the "subject matter of the invention" of the patent. The meaning of this phrase has not yet been fully clarified. In the scholarly literature, it was partially followed from *Actavis I* that the combination of active ingredients must be a separate invention from the single active ingredient A.[85] This could be examined by an inventive step analysis, as known from patent law, on the basis of a fictional prior art, including the active ingredient A.[86] It was also assumed that the combination could be a separate invention if it had a new therapeutic effect, which was not the case in *Actavis I*.[87] Therefore, it could be helpful to clearly state a new therapeutic effect in the patent description and therewith present the combination as a separate invention.[88] This would have to be compatible with the requirements for patent amendments. The clarification of an effect by an amendment of the description is not contrary to Art. 123(2) EPC if the technical feature was clearly disclosed in the application as filed and the effect, not or not fully mentioned before, can be deduced without difficulty by a person skilled in the art from the original application.[89] Regarding a new effect, compliance with Art. 123(2) EPC must be carefully assessed.[90] The combination of active ingredients must therefore be clearly disclosed in the original application. The new effect must be directly and unambiguously derivable from the claimed combination and the rest of the application for a skilled person to satisfy the disclosure test. This seems difficult because the new effect, since it is new, is not part of the common general knowledge and was not deduced from the patent specification in the examination. Such a patent amendment will usually not be possible.

Significance was also attached to the granting of a new patent.[91] On the other hand, the existence of a separate patent does not mean that the combination product is a separate invention. It is, for example, possible to file a divisional application (Art. 76 EPC) or a subsequent application (Art. 87 EPC).[92] Also, it follows from Art. 3(2) s. 1 of Regulation (EC) No 1610/96[93] that only one SPC can be granted to the same patent holder for the same product, even so she or he owns more than one basic patent for that product. This indicates the legislator's intention that whether products are the same does not depend on protection in one or more basic patents.[94] Consequently, the *Actavis* case law should also be applicable in this situation.[95] The existence of a separate patent therefore does not make a difference.[96]

It should be kept in mind that the conditions, except the condition "subject matter of the invention" are not clarified or approved by the CJEU. It seems difficult to make a change to the subject matter of the invention of a patent by an amendment because it goes to the very substance of the patent.[97]

85 Christopher Brückner (n 47) para 13; Christopher Brückner and Robert Lelkes (n 47) 213; Christopher Hayes (n 2) 504; Franz-Josef Zimmer, Benjamin Quest and Markus Grammel (n 23) 175; Max Planck Institute (n 9) 194; 250; Oswin Ridderbusch and Alexa von Uexküll (n 40) s 1.02.B.3; 1.02.D.4.b; Paul England (n 27) 426; Tony Rollins, Nicola Dagg and Steven Baldwin (n 44) 703.

86 Max Planck Institute (n 9) 207.

87 Judgement of 12 December 2013, *Actavis Group PTC and Actavis UK*, C-443/2012, EU:C:2013:833, paragraph 15; Christopher Brückner (n 47) para 14; Christopher Brückner and Robert Lelkes (n 47) 213; Markus Ackermann, "Aus Eins Mach Zwei: Mit Teilanmeldung & Co. Zum Zweiten Schutzzertifikat?" [2019] PharmR 429, 439; Markus Ackermann, "Lies Don't Travel Far: Article 3(c) of the SPC Regulation from a German Perspective: Germany, Higher Regional Court of Düsseldorf, I-2 U 63/18, 15 March 2019" (2019) 14 JIPLP 918, 920: 921. See also Darren Smyth and Timothy Belcher, "Another SPC Referral from the UK: High Court Asks CJEU for 'More' Guidance...: Teva UK Ltd & Ors v Gilead Sciences Inc [2017] EWHC 13 (Pat)" (2017) 12 JIPLP 535, 536.

88 Franz-Josef Zimmer, Benjamin Quest and Markus Grammel (n 23) 179 also suggests providing as much information as possible about possible combination products.

89 Decision of the Technical Board of Appeal 3.5.1 of 29 July 1983, *Low-tension switch/ SIEMENS*, T 37/82, EP:BA:1983:T003782.19830729, headnote I; Case Law of the Boards of Appeal of the European Patent Office (10th edn, EPO 2022) s II.E.1.11.6; Guidelines for Examination in the European Patent Office (EPO 2023) s H.V.2.1.

90 Guidelines for Examination in the European Patent Office (EPO 2023) s H.V.2.2.

91 Frantzeska Papadopoulou 2021 (n 2) 96; Frantzeska Papadopoulou 2023 (n 2) 584; Franz-Josef Zimmer, Benjamin Quest and Markus Grammel (n 23) 177; 178; Max Planck Institute (n 9) 207; Oswin Ridderbusch and Alexa von Uexküll (n 40) s 1.02.B.3; D.5.

92 Markus Ackermann PharmR (n 87) 434; Max Planck Institute (n 9) 207.

93 Regulation (EC) No 1610/96 of the European Parliament and of the Council of 23 July 1996 concerning the creation of a supplementary protection certificate for plant protection products, [1996] OJ L 198/30, as last amended by the Treaty of Accession of Croatia of 24 February 2012, [2012] OJ L 112/10.

94 Markus Ackermann PharmR (n 87) 439.

95 Ibid.

96 Ibid; Mike Snodin, "Three CJEU Decisions That Answer Some Questions but Pose Many More" (2014) 9 JIPLP 599, 604.

97 This is also what Justice Arnold said about the "core inventive advance" test. A criterion that focuses on the substance and not on the wording of the patent cannot be circumvented by drafting (or an amendment). *Teva UK Ltd & Ors v Gilead Sciences Inc* [2017] EWHC 13 (Pat), para 97.

5.2 Criterion Product "Falls under the Scope of Protection of the Basic Patent"

For the purposes of Art. 3(a) SPC Regulation, the product must fall under the scope of protection of the basic patent as determined by claim interpretation in accordance with Art. 69 EPC and its Protocol. If the product does not fall under this scope, it would be conceivable to extend the scope in a way that the product falls within it. This would be contrary to Art. 123(3) EPC. The provision prohibits the extension of the patent scope by an amendment. The amended version of the patent can therefore only have the same or a narrower scope compared to the original patent. The scope of protection is determined on the basis of the same rules (Art. 69 EPC and its Protocol). Therefore, if the product does not fall under the scope of the original patent, this cannot be changed by an amendment. It should also be noted that in the procedures initiable by the patent holder, the limitation and the revocation procedure, only a limitation, which means a narrowing of the patent scope, is allowed.

5.3 Criterion Product is "Specified in the Wording of the Claims"

5.3.1 Claims to Single Active Ingredients and to Combinations

The product for compliance with Art. 3(a) SPC Regulation must also be "specified in the wording of the claims". It follows from this that if the patent claims a single active ingredient, only an SPC for a single active ingredient can be granted and not for a combination product. The grant of an SPC for a combination product would no longer fail on this ground if the patent was amended in a way that the claim refers to a combination of active ingredients. Regarding Art. 123(3) EPC, a claim to a combination of active ingredients is narrower than a claim to a single active ingredient, because the active ingredient is no longer protected in absolute terms, but only in the combination. The amendment would therefore be in accordance with Art. 123(3) EPC[98] and could also be initiated by the patent holder because it is a limitation. The amendment must also comply with Art. 123(2) EPC. The resulting combination must fulfil the disclosure test or "gold standard". It is not necessary that the information is contained in the claims. It is enough if it follows from the description or the drawings.[99] Such a patent amendment therefore seems possible in certain individual cases in which the combination can be directly and unambiguously derived from the description or drawings.

In the opposite situation, the patent claims a combination of active ingredients, amending the patent in a way that it claims a single active ingredient, is not possible because of Art. 123(3) EPC. The scope of a claim for a single active ingredient is broader than of a claim related to a combination.[100] Such an amendment can, depending on the individual case, also be contrary to Art. 123(2) EPC. The removal of features from a claim, if there is no "clear and unambiguous basis for a claim lacking these features in the application as originally filed" adds subject matter within the meaning of this provision.[101]

5.3.2 Structural and Functional Definitions

The product can be "specified in the claims" by a structural or a functional definition. Since there is an additional condition for functional definitions, it could simplify the procedure for the grant of an SPC if a functional definition is amended into a structural definition.[102] A structural definition is typically narrower than a functional definition. The change of a functional definition into a structural definition can at least not broaden the scope of the patent and is therefore in line with Art. 123(3) EPC. Such an amendment is also allowed by Art. 123(2) EPC if the active ingredient(s) defined by the structural definition are disclosed in the original patent, whereby an implicit disclosure is sufficient. A functional definition does not disclose a specific active ingredient, but it might be deducible from the rest of the patent specification.[103]

Since functional definitions are also sufficient in the context of Art. 3(a) SPC Regulation, one can only speak of an actual circumvention if the conditions differ. To be precise, a circumvention is only possible if the disclosure standard in the context of patent amendments is broader than the conditions for functional definitions in the context of the SPC Regulation, because then a product can be added to the claims which would not have been accepted on the basis of the functional definition before.

5.4 Criterion Claims Relate to the Product "Implicitly but Necessarily and Specifically"

The product can be "specified in the claims" by a functional definition if the claims relate to the product "necessarily and specifically". This needs to be assessed by a claim interpretation in accordance with Art. 69 EPC and its Protocol. The formula contains two cumulative conditions. Both conditions need to be assessed from the perspective of the person skilled in the art on the basis of the

98 Cf. Decision of the Enlarged Board of Appeal of 11 December 1989, G 2/88, EP:BA:1989:G000288.19891211, paragraph 4.1; Case Law of the Boards of Appeal of the European Patent Office (10th edn, EPO 2022) s II.E.2.5.1.

99 Cf. Guidelines for Examination in the European Patent Office (EPO 2023) s H.V.3.2.

100 Cf. Ibid s H.V.3.1; Case Law of the Boards of Appeal of the European Patent Office (10th edn, EPO 2022) s II.E.2.4.1.

101 Decision of the Board of Appeal of 20 February 2009, *Delivery of audio recordings/KOCHIAN*, T 1726/06, EP:BA:2009:T172606.20090220, paragraph 1.3.1; Case Law of the Boards of Appeal of the European Patent Office (10th edn, EPO 2022) s II.E.1.4.2. See also Guidelines for Examination in the European Patent Office (EPO 2023) s H.V.3.1.

102 Cf. Franz-Josef Zimmer, Benjamin Quest and Markus Grammel (n 23) 178.

103 Cf. Decision of the Technical Board of Appeal 3.2.6 of 11 August 2016, T 88/12, EP:BA:2016:T008812.20160811, paragraph 4; Case Law of the Boards of Appeal of the European Patent Office (10th edn, EPO 2022) s II.E.1.10.1. See also Guidelines for Examination in the European Patent Office (EPO 2023) s H.IV.2.4 example three.

patent specification, that person's general knowledge and the prior art at the filing or priority date of the patent.

5.4.1 Sub-criterion Product Must "Necessarily Fall under the Invention Covered by the Patent"

First, the product must necessarily fall under or come within the invention covered by the patent. This sub-condition was interpreted to require the product to fall under the scope of protection of the basic patent with a qualification. From the use of the term "necessarily" and also the formula "a specification required for the solution of the technical problem disclosed by the patent" and the emphasis on the use of the term "optionally" in the basic patent in *Teva*, it was followed that it is not sufficient if the product is only covered by the claims by an optional element.[104] It should be repeated at this point that in the case of a combination product the sub-condition must be fulfilled with regard to the combination as a whole.

The qualification makes the criterion narrower than the substantive limitations for patent amendments, more concrete Art. 123(3) EPC, for which only the extent of patent protection is relevant, without a qualification. It seems like the criterion could be fulfilled by amending an optional element into a necessary one, for example cancelling the term "optionally" in a patent. This would be consistent with Art. 123(3) EPC because a claim related to a necessary and an optional element is broader than a claim related to two necessary elements. The former contains two alternatives, protection for the necessary element alone and protection for the necessary element combined with the optional element. The claim related to two necessary elements does not protect one of these elements alone. Since the amendment is a limitation, a procedure for a patent amendment can be initiated by the patent holder. Such an amendment may also be in accordance with Art. 123(2) EPC, if it has a basis in the original application and the resulting combination of features is "in line with the teaching of the application as originally filed".[105] This will have to be assessed on a case-by-case basis.

5.4.2 Sub-criterion Product Must Be "Specifically Identifiable"

The second sub-condition of the formula that the claims must relate to the product "necessarily and specifically" is that the product must be "specifically identifiable". It should be repeated in this context that with regard to combination products, each of the active ingredients of the combination must be "specifically identifiable". This condition could be a disclosure standard.[106] This is supported by the fact that the CJEU in *Royalty Pharma* uses the expression "level of disclosure" in this context.[107] If the condition is a disclosure standard, this could be an own standard of the SPC system or a disclosure standard from patent law. There are two different disclosure standards in European patent law. First, there is the disclosure standard for sufficiency of disclosure, regulated in Art. 83 EPC. According to the provision, the European patent application shall disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. This standard is satisfied if a skilled person can reproduce the invention on the basis of the original application documents and common general knowledge without any inventive effort and undue burden.[108] This standard applied to the SPC system would be nothing more than a direct infringement test. Any product that falls under a valid patent claim, interpreted in accordance with Art. 69 EPC, would satisfy Art. 3(a) SPC Regulation.[109] The second disclosure standard is the one already introduced above, applicable in the context of Art. 54, Art. 87 and Art. 123(2) EPC. Disclosed is what "a skilled person would derive directly and unambiguously, using common general knowledge, and seen objectively and relative to the date of filing, from the whole of the

104 Oswin Ridderbusch and Alexa von Uexküll (n 40) s 1.02.B.1; Roberto Romandini (n 34) 16.

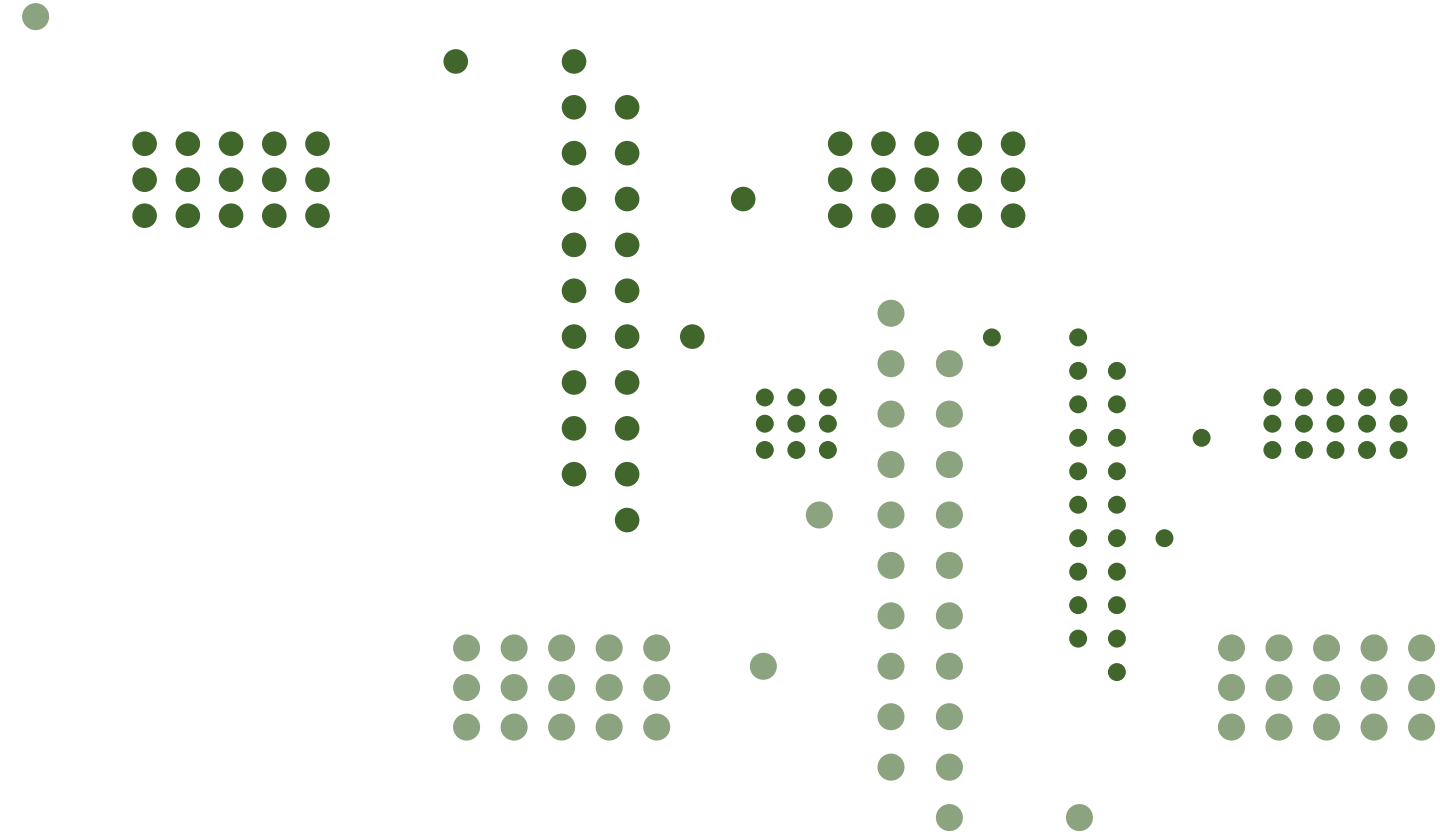
105 Decision of the Technical Board of Appeal 3.3.3 of 4 January 1996, *Water-soluble polymer dispersion/HYMO CORPORATION*, T 583/93, EP:BA:1996:T058393.19960104, paragraph 4.5; Case Law of the Boards of Appeal of the European Patent Office (10th edn, EPO 2022) s II.E.1.11.4.

106 Roberto Romandini (n 34) 17.

107 Judgement of 30 April 2020, *Royalty Pharma*, C-650/17, EU:C:2020:327, paragraph 39.

108 Decision of the Board of Appeal 3.5.1 of 6 July 2007, *RAID apparatus/FUJITSU*, T 629/05, EP:BA:2007:T062905.20070706, paragraph 4.; Case Law of the Boards of Appeal of the European Patent Office (10th edn, EPO 2022) s II.C.4.1; Roberto Romandini (n 34) 17.

109 Roberto Romandini (n 34) 17.



patent specification as filed".[110] It is also referred to as "individualised disclosure".[111]

There are several pro- and con-arguments regarding the adoption of one of these standards. The fact that the CJEU does not explicitly refer to either of these disclosure standards from patent law is an argument against them.[112] On the other hand, the CJEU consistently refers to the law governing the basic patent for the determination of the condition "protected by the basic patent" within the meaning of Art. 3(a) SPC Regulation, which implies that the relevant distinction is a distinction from patent law.[113] One particular argument against the adoption of the first described disclosure standard is that it would introduce an infringement test and the CJEU did not consider a patent infringement by the product to be sufficient or relevant in the context of Art. 3(a) SPC Regulation, for example in the judgements *Medeva* and *Eli Lilly*.

Regarding the second disclosure standard, there are some parallels. The CJEU in *Royalty Pharma* stated that the condition is not fulfilled for a product developed after the filing date, following an independent inventive step. Such a product would also not be individually disclosed since the assessment is made from the perspective of a skilled person on the filing date. At this point in time, the product had not yet been developed and the skilled person is not inventive.[114] Therefore, she or he cannot derive the active ingredient directly and unambiguously from the patent specification at that time. Also, the formula the claims relate to the product "necessarily and specifically" resembles formulations used in the context of the disclosure standard in relation to implicit disclosure.[115]

Furthermore, it is noticeable that the formula defining the disclosure test for Art. 123(2) EPC and the formula used by the CJEU to concretise the expression "specifically identifiable" are similar. "Specifically identifiable", according to the CJEU, means that the product is "within the limits of what a person skilled in the art is objectively able, at the filing date or priority date of the basic patent, to infer directly and unequivocally or unambiguously[116] from the specification of that patent as filed, based on that person's general knowledge in the relevant field at the filing or priority date, and in the light of the prior art at the filing date or priority date."[117] In both formulas, the perspective is that of a skilled person. She or he must objectively be able to infer the product or subject matter directly and unambiguously from the patent specification as filed.

Two aspects seem different. First, while the relevant point in time in the CJEU judgements is the filing date or priority date of the basic patent, the Enlarged Board of Appeal regarding the second disclosure standard from patent law only refers to the filing date. This allows two

110 Opinion of the Enlarged Board of Appeal of 19 November 1992, G 3/89, EP:BA:1992:G000389.19921119 and Decision of the Enlarged Board of Appeal of 19 November 1992, *Glu-Gin/CELTRIX*, G 11/91, EP:BA:1992:G001191.19921119, paragraph 3 and headnote I.

111 Roberto Romandini (n 34) 17.

112 Cf. Ibid 18.

113 Cf. Max Planck Institute (n 9) 206; Roberto Romandini (n 34) 10.

114 Cf. Paul England (n 27) 7.

115 Max Planck Institute (n 9) 192. According to Decision of the Technical Board of Appeal 3.3.6 of 28 September 2004, *Particulate detergent composition/UNILEVER*, T 860/00, EP:BA:2004:T086000.20040928, paragraph 1.1 implicitly disclosed is "what any person skilled in the art would consider was necessarily implied by the patent application as a whole". See also Case Law of the Boards of Appeal of the European Patent Office (10th edn, EPO 2022) s II.E.1.3.3.

116 Judgement of 30 April 2020, *Royalty Pharma*, C-650/17, EU:C:2020:327, paragraph 42.

117 Ibid, paragraph 40.

interpretations. The reference to the filing date could mean the effective date of the patent, which is usually the filing date, but could also be the priority date. On the other hand, according to a literal interpretation of the formula, what is meant is the filing date, irrespective of the effective date of the patent. This second interpretation would have the consequence that the common general knowledge for the respective assessments could differ. There can be up to twelve months between the priority date and the filing date (cf. Art. 87(1)(b) EPC). Second, in both cases the skilled person's common general knowledge is relevant but the CJEU also refers to the prior art.[118] The prior art as such is not relevant for the disclosure test,[119] but a piece of prior art can be part of the common general knowledge.[120] It could be concluded that prior art in the CJEU formula means common general knowledge.[121] On the other hand, it does not seem likely that this was intended since both, the prior art and the common general knowledge are mentioned in the judgements *Teva* and *Royalty Pharma*. It seems more likely that both of these sources of information should be taken into account.[122] This interpretation leads to a further difference in comparison with the disclosure test. Even so there is an overlap between the common general knowledge and the prior art,[123] the consideration of the prior art can lead to a different outcome.[124]

In the patent at hand in *Royalty Pharma*, the active ingredient "sitagliptin" was not disclosed in individualised form.[125] The CJEU was asked by the German Bundespatentgericht (Federal Patent Court) whether the product must be "provided as a specific embodiment".[126] This expression from German law is equal to the individualised disclosure.[127] The CJEU held that this is not necessary, but that the product must be "specifically identifiable, in the light of all the information disclosed by that patent, by a person skilled in the art, based on that person's general knowledge in the relevant field at the filing date or priority date of the basic patent and on the prior art at that date."[128] This is another argument against the standard for patent amendments and the standard in the context of Art. 3(a) SPC Regulation are the same.

Taking into account these arguments, it seems like "specifically identifiable" does not implement a disclosure standard from patent law but is an SPC-own standard. Comparing the disclosure test for the assessment of Art. 123(2) EPC and the criterion "specifically identifiable", the relevant point in time for the latter is the effective date of the patent, while for the former it may always be the filing date. The relevant point in time differs for subsequent applications for which the effective date is the priority date. There can be a period of up to twelve months between the two dates. During this time, the skilled person's common general knowledge may have changed. In particular, new information may have been added. This may have an influence on what the skilled person can derive from the patent specification. The criterion from the SPC Regulation appears to be narrower in this regard. The other difference is the inclusion of prior art in the context of Art. 3(a) SPC Regulation. This creates a greater diversity of sources of information. In addition, the prior art is more up-to-date and more open to new ideas and developments. In this respect, the criterion of the SPC Regulation appears to be broader. If one takes both differences together, the basis of the common general knowledge on the filing date and the basis of the prior art on the priority date, the differences no longer seem so great because it takes some time for a piece of prior art to become common general knowledge. The result may be different in individual cases, but in general the criterion of the SPC Regulation seems broader than the disclosure test for Art. 123(2) EPC. In addition, the first difference is not certain. It therefore does not seem possible to circumvent this criterion by amending the patent.

6. CONCLUSIONS AND OUTLOOK

Summarising the above, for most of the criteria it is not possible to achieve a different result by amending the patent. The requirement in Art. 3(a) SPC Regulation and the requirements for a patent amendment are even partially similar. To achieve a different result is only possible in individual cases. It is possible under certain circumstances to amend a claim related to a single active ingredient to a claim related to a combination of active ingredients V.3.1. The other scenario that has been identified is that an optional feature is amended to an essential feature V.4.1. Both cases do not seem very attractive for patent holders, as they limit the scope of patent protection and thus also the scope of a potential SPC. Both cases also result in a combination of active ingredients to which Art. 3(c) SPC Regulation applies, if the patent holder has already obtained an SPC for one of the active ingredients.

It can therefore be concluded that there is no risk that the conditions for granting an SPC in Art. 3 SPC Regulation, in their current version and interpretation, can be circumvented by patent amendments. Consequently,

118 Cf. Jules Fabre and Sarah Taylor (n 46) 332.

119 Paul England (n 27) 421; Roberto Romandini (n 34) 18.

120 Paul England (n 27) 13.

121 *Teva UK Limited and Others v. Gilead Sciences Inc* [2018] EWHC 2416 (Pat), para 17.

122 Roberto Romandini (n 34) 18 with reference to Darren Smyth, "Teva v Gilead – C-121/17 Provides Some Clarity on Combination Product" (*The IP Alchemist*, July 26, 2018) <http://www.ipalchemist.com/blog/teva-v-gilead-c-12117-provides-some-clarity-on-combination-products/> accessed March 7, 2024. See also Oswin Ridderbusch and Alexa von Uexküll (n 40) s 1.02.B.1; Paul England (n 27) 421.

123 Opinion of AG Hogan of 11 September 2019, *Royalty Pharma*, C-650/17, EU:C:2019:704, paragraph 70.

124 Cf. Roberto Romandini (n 34) 18.

125 Roberto Romandini (n 34) 18.

126 Judgement of 30 April 2020, *Royalty Pharma*, C-650/17, EU:C:2020:327, paragraph 21.

127 Federal Patent Court, 14 W (pat) 12/17 2017, para 10; *Sandoz Limited and Hexal AG v GD Searle LLC and Janssen Sciences Ireland UC* [2018] EWCA Civ 49, para 74; Roberto Romandini (n 34) 19.

128 Judgement of 30 April 2020, *Royalty Pharma*, C-650/17, EU:C:2020:327, paragraph 43.

there is no reason not to base the examination on the patent in its currently valid version. From the author's point of view, this is a positive outcome. The SPC Regulation and the conditions for the grant of an SPC result from certain purposes. The principal aim of the SPC legislation is to provide a financial incentive to the patent holder, but this aim is not without limits. At the same time, the purpose is to achieve a balance with other interests, in particular public health. Art. 3(c) SPC Regulation in particular is based on this purpose. The provisions of the SPC Regulation create a balance of interests. This should be respected, regardless of whether one personally considers the balance of interests to be successful or in keeping with the times. The patent holder should not be able to gain an unjustified advantage by amending the patent. This is also the general background to the substantive legal limitations on patent amendments.

On 27th April 2023, the European Commission has issued proposals for new SPC regulations as part of the Intellectual Property Action Plan.[129] Regarding the substantive aspects, the Explanatory Memoranda to the proposals expressly state that these features and their current interpretation by the CJEU are not to be modified or further clarified.[130] These regulations also make no explicit statements on patent amendments. Despite this, new recitals have been added, which are intended to implement CJEU case law. The Explanatory Memoranda refer to *Teva*, among others, as settled case law.[131] Recital 8 of the proposal for national SPCs and homonymous recital 16 of the proposal for unitary SPCs implement CJEU case law on Art. 3(a) SPC Regulation, in particular *Teva* and *Royalty Pharma*. The "product should fall within the scope of one or more claims of that patent, as interpreted by the person skilled in the art by the description of the patent on its filing date". Functional definitions are sufficient if the active ingredient(s) is or are "specifically identifiable in the light of all the information disclosed by that patent". In the Explanatory Memoranda it is also stated that a product corresponding to a functional definition must "necessarily [come] within the scope of the invention covered by that patent, even if it is not indicated in individualised form as a specific embodiment in the patent, provided that it is specifically identifiable from the patent".[132] This phrase from *Royalty Pharma* was seen as an argument against the adoption of the disclosure test for Art. 123(2) EPC. The proposals also seem to accept that a single active ingredient and a combination of active ingredients can be the same product,[133] which can be followed from the *Actavis* judgements. It is noticeable that only fragments of the case law of the CJEU are adopted. For example, the criterion "specified in the claims" is not addressed. Furthermore, the wording chosen differs in part from the judgements of the CJEU. The term "filing date" is used, although according to case law, the effective date is decisive. In addition, the controversial question of the relevance of the concepts of "core inventive advance" and "constitute the subject matter of the invention" in the context of Art. 3(a) and (c) SPC Regulation, which is also the subject of the new referrals to the CJEU, is not addressed.

The proposals do not contain any changes to the aspects identified as relevant with regard to patent amendments, but rather confirm the case law. If the proposed regulations are adopted as they stand, this will not lead to a change in the statements made on the relationship to patent amendments.

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Anna is a recent graduate from the LLM programme in European Intellectual Property Law and delivered her master thesis on the topic of this article.

129 Proposal for a Regulation of the European Parliament and of the Council on the unitary supplementary certificate for medicinal products, and amending Regulation (EU) 2017/1001, Regulation (EC) No 1901/2006 as well as Regulation (EU) No 608/2013, COM(2023) 222 final 1; Proposal for a Regulation of the European Parliament and of the Council on the supplementary protection certificate for medicinal products (recast), COM(2023) 231 final 1–2.

130 Proposal for a Regulation on the unitary supplementary certificate for medicinal products (n 129) 11; Proposal for a Regulation on the supplementary protection certificate for medicinal (n 129) 11.

131 Proposal for a Regulation on the unitary supplementary certificate for medicinal products (n 129) 11; Proposal for a Regulation on the supplementary protection certificate for medicinal products (n 129) 12.

132 Proposal for a Regulation on the unitary supplementary certificate for medicinal products (n 129) 11; Proposal for a Regulation on the supplementary protection certificate for medicinal products (n 129) 12.

133 Cf. Proposal for a Regulation on the unitary supplementary certificate for medicinal products (n 129) recital 17; Proposal for a Regulation on the supplementary protection certificate for medicinal products (n 129) recital 9.