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Supplementary Protection Certificates for Medicinal Products Based on Markush Formulas in the Basic Patent

Can a medicinal product be 'protected' by the basic patent within the meaning of Art. 3(a) Reg. 469/2009 if the claims in the basic patent define the product using a Markush formula?

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Table of contents

1 Introduction

1.1 Thesis topic

A supplementary protection certificate ("SPC") is an intellectual property right which extends the period of protection for patented medicinal products and plant protection products.[1]

A central criterion for granting an SPC is that the product is 'protected' by a basic patent in force.[2] The topic for this thesis concerns SPCs for products based on a Markush formula[3] in the claims of the basic patent. A Markush formula can be described as a related set of chemical compounds, which allows the patented subject matter to cover a large range of related compounds.

The question of when a product can be considered 'protected' by the basic patent within the meaning of Art. 3(a) Reg. 469/2009 has been subject of numerous referrals to the Court of Justice of the European Union ("CJEU"). Nonetheless, the CJEU has yet to deliver a clarification on the application of Art. 3(a) for basic patents using Markush formulas in the claims. The question was referred to the CJEU in case C-114/18 Sandoz v. Searle. The Attorney General issued his opinion on the matter on 11 September 2019,[4] but the case was withdrawn before the CJEU reached its decision.

1.2 Research question

Given the lack of clarity on the subject, the aim for this thesis is to assess the following research question:

Can a medicinal product be 'protected' by the basic patent within the meaning of Reg. 469/2009 Art. 3(a) if the claims in the basic patent define the product using a Markush formula?

This research question raises three closely associated subproblems, which are addressed in this thesis.

1. What is the correct application of Art. 3(a) when assessing whether products based on Markush formulas are 'protected' by the basic patent?

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[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, hereinafter "Reg. 469/2009".

[2] Art. 3(a) Reg. 469/2009.

[3] Section 2.3.

[4] Opinion of Advocate General Hogan in joined cases C-650/17 and C-114/18.

2. Does the number of chemical compounds in a Markush formula affect the assessment of whether the product is 'protected' by a basic patent?
3. Can an SPC validly be issued for a product which was selected from a Markush formula after the priority date of the basic patent, without being specifically mentioned in the basic patent?

1.3 Sources of law

The primary legal basis for granting SPCs for medicinal products is Reg. 469/2009. In accordance with the Treaty on the Functioning of the European Union, regulations *"shall have general application. It shall be binding in its entirety and directly applicable in all Member States"*.[5] For non-EU members under the European Economic Area Agreement (the "EEA Agreement") regulations must be incorporated to the internal legal order to have binding effect.[6]

Under Norwegian law, the Regulation is incorporated in the Patents Act, meaning that the Regulation applies as formal law with any modifications following the EEA Agreement Annex XVII, protocol 1 to the agreement and the EEA Agreement in general.[7] Because the Regulation is an obligation under the EEA Agreement, the Regulation will precede in the event of conflict between the Regulation and other Norwegian legislation.[8]

The CJEU has authority to give rulings on the interpretation of EU law,[9] and consequently, decisions from the CJEU are a significant legal source when interpreting EU regulations.[10] When interpreting secondary acts of EU law (such as regulations), the CJEU is assumed to place much emphasis on a *"teleological and systematic approach"*.[11] The CJEU has previously held that regulations *"must not be interpreted solely on the basis of its wording, but also in the light of the overall scheme and objectives of the system of which it is a part"*.[12]

Furthermore, the Proposal for the Council Regulation (EEC) No 1768/92 of 18 June 1992 (the 'predecessor' to Reg. 469/2009) contains an *explanatory memorandum*,[13] which may provide some legal value on the interpretation of the Regulation. Considering that the wording of Art.

[5] Art. 288 (2) TFEU.
[6] Art. 7 (a) EEA Agreement.
[7] Patents Act § 62 a.
[8] EEA Act § 2.
[9] Art. 267 TFEU.
[10] Sejersted et al. (2011) p. 234, Stemsrud (2015) p. 75.
[11] Max Planck Institute for Innovation and Competition (2018) p. 43.
[12] Case C-292/00 Davidoff & Cie SA and Zino Davidoff SA v Gofkid Ltd para 24.
[13] COM(1990) 101.

3(a) Reg. 469/2009 is materially the same as its predecessor, this memorandum may still provide some guidance on the interpretation of Art. 3(a). However, such preparatory documents are considered to hold limited legal value when interpreting a regulation's provisions.[14]

The *preface* of Reg. 469/2009 may also provide some guidance on the interpretation of the Regulation, as prefaces in regulations are generally presumed to hold some significance when interpreting its provisions.[15]

Despite its legal foundation in EU law, the actual SPCs can be classified as *national rights*. Whereas the Regulation provides the legal basis for SPCs, it is the task for the National Patent Offices of each Member State to grant and issue the actual certificates, based on the conditions set out in the Regulation. SPCs will consequently only have legal effect in the country whose National Patent Office issued it.[16]

Because SPCs are dependent of a basic patent protecting the product, and the certificate being an extension of the protection period initially provided by the patent, the SPC system can be characterized as a 'hybrid' between patent law (which is considered as national law), and EU/EEA law.[17]

The hybrid nature of SPC legislation causes certain challenges when interpreting its provisions. In principle, Reg. 469/2009 and corresponding CJEU case law is EU legislation that shall be interpreted autonomously from national patent law. However, because the SPC legislation contains multiple direct and indirect references to patent law, an important issue that arises is to determine how such provisions shall be interpreted. This is especially relevant for Art. 3(a); the extent of protection provided by the basic patent relies on assessments based on patent law, which in turn is important when determining whether products are 'protected' by the basic patent.

Furthermore, the CJEU makes frequent references to patent law in its case law, without necessarily explaining if or to what extent these references shall be interpreted within their meaning from patent law. An example of this is the CJEU's use of the wording *"directly and unambiguously"* in relation to the two-part test under Art. 3(a), which may be interpreted as a refer-

[14] Sejersted et al. (2011) p. 57.

[15] Ibid.

[16] There are ongoing discussions in the EU concerning the creation of a "unitary SPC" issued by a centralized granting authority in the EU/EEA, and with legal effect in all Member States, but as of writing this thesis, no such legislation has been implemented.

[17] Skurdal Andresen (2019).

ence to the European Patent Office's ("EPO") 'gold standard' for assessing whether patents comply with Art. 123 EPC.[18]

Consequently, an important question that arises is whether Art. 3(a) and apparent references to patent law rely solely on SPC legislation, or if the law governing the basic patent supplements these assessments, and if so, to what extent.

1.4 Scope of the thesis

The main subject of this thesis concerns whether medicinal products may qualify for SPC protection where the product is encompassed in a Markush formula of the basic patent.

SPCs for medicinal products are dependent of being protected by a *valid* basic patent in force, as mentioned below. The use of Markush formulas in patents will frequently challenge the validity of such patents. Patent invalidity, and in particular where such patents make use of Markush formulas, is a comprehensive subject on its own and is not elaborated in this thesis. Accordingly, an important assumption for the discussions below is that any basic patents making use of Markush formulas are *valid*.

Furthermore, the use of Markush formulas in the claims of the basic patent may involve other impediments to the eligibility of an SPC, for example in relation to the concept of 'product'.[19] However, this thesis is focused on the use of Markush formulas in relation to the requirement set out in Art. 3(a).

Finally, SPCs can be issued for both medicinal products and plant protection products. For the following assessment, this thesis is centered on SPCs for medicinal products.

1.5 Remarks on the further assessment

Because my research question concerns SPCs specifically for products based on Markush formulas, in section 2 I elaborate generally on SPCs, their legislative considerations and the substantive requirements set out in Art. 3(a). Considering that the CJEU has a decisive role in interpreting and evolving the conditions laid out in Reg. 469/2009, a substantial part of this assessment is devoted to analyzing CJEU case law concerning the interpretation of Art. 3(a). I also elaborate on the concept of 'product' in section 2.4.1.[20]

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[18] See section 2.6 for further discussion on this subject.

[19] Art. 1(b) Reg. 469/2009.

[20] The elaboration on the concept of 'product' is done briefly, as this is a comprehensive subject. A basic account of this concept is nonetheless necessary as it concerns the protected subject-matter of an SPC.

In section 2.3 I explain Markush formulas in more detail, how such formulas may be used to cover medicinal products in patent claims, and briefly elaborate on how such formulas may present with problems for the eligibility of SPCs pursuant to Art. 3(a).

In section 3, I discuss SPCs for products based on Markush formulas. First, in section 3.1, I discuss issues concerning the use of Markush formulas in patent claims under Norwegian patent law and under the European Patent Convention.[21] Thereafter, I compare these issues with potential challenges that may arise from Art. 3(a) for SPCs based on Markush formulas.

In section 3.2, I discuss the first subproblem referred to in section 1.2, namely, how Art. 3(a) shall be interpreted and applied for products based on Markush formulas. This particularly involves an interpretation of CJEU case law. I also discuss the Opinion of General Hogan in Case C-650.[22]

In section 3.3, 3.4 and 3.5, I discuss the research question and the two remaining subproblems, respectively. These discussions are based upon my findings in section 3.2 as well as relevant case law, before concluding in section 4 with closing remarks.

2 Supplementary Protection Certificates (SPC)

2.1 About SPCs for medicinal products

As mentioned above, an SPC is an intellectual property right which extends the protection term for a patented medicinal product. An SPC is however not an extension of the basic patent in its entirety. The protection conferred by a certificate applies only to the 'product'[23] which is covered by the first marketing authorization[24] to place the product on the market as a medicinal product.[25] In relation to this product the certificate does however confer the same rights as the basic patent.[26]

A patented medicinal product will not automatically be the subject of an SPC once the basic patent expires. SPC protection is an optional supplementary protection requiring that the sub-

[21] European Patent Convention 2000 as adopted by decision of the Administrative Council of 28 June 2001, hereinafter "EPC".

[22] Opinion of Advocate General Hogan in joined cases C-650/17 and C-114/18.

[23] See section 2.4.1.

[24] "Marketing authorization", meaning an administrative authorization procedure in accordance with Directive 2001/83/EC or Directive 2001/82/EC.

[25] Art. 3(b) and 3(d) Reg. 469/2009.

[26] Art. 5 Reg. 469/2009.

stantive requirements set out in the Regulation are satisfied. Furthermore, SPC must be applied for with a National Patent Office in the jurisdiction one seeks SPC protection in. Such application must be filed within six months from the marketing authorization was granted, or, where the marketing authorization is granted before the basic patent is granted, from the time the basic patent was granted.[27]

Considering that SPCs provide a different and, practically almost always, lesser form of protection than patents, and the fact that multiple SPCs may be granted based on a single basic patent,[28] SPCs are often referred to as a *sui generis* intellectual property right,[29] in the sense that they are a unique right 'of their own' with respect to patents.

Regardless of this characterization, however, it is essential to emphasize that SPC are entirely dependent on a basic patent in force, which may consist of a national patent or European patent.[30] SPC protection is only eligible for medicinal products that are 'protected' by such a basic patent, which is the central subject for this thesis.

An SPC extends the exclusive protection time for the medicinal product for a maximum period of five years, yet the maximum period of exclusivity for the holder of both a patent and an SPC shall not exceed 15 years from the time the product obtains its first marketing authorization.[31]

2.2 Legislative considerations

Any person who has made an invention that is *new*, involves an *inventive step*[32] and is susceptible of *industrial application*, may upon application be granted a patent for that invention.[33] An *invention* may be described as a practical solution of a problem where the solution has technical character, technical effect and is reproducible.[34] Medicinal products for human use are therefore eligible for patent protection, provided the conditions of patentability are met.

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[27] Art. 7 Reg. 469/2009.

[28] Case C-484/12 Georgetown University v. Octroicentrum Nederland.

[29] Stief/Bühler (2016) p. 11.

[30] Art. 2 EPC.

[31] Recital 9, 10 and Art. 13 Reg. 469/2009.

[32] See section 2.4.2.

[33] Patents Act §§ 1 and 2, Art. 52 EPC. See Stenvik (2020) for further reading on patents and conditions of patentability.

[34] Stenvik (2020) p. 119.

A patent gives the proprietor exclusive rights to the invention for a period of 20 years from the filing date of the patent application.[35] The rights conferred by a patent can be described as a 'right to prohibit'; a negative right that entitles the proprietor to prohibit others from exploiting the invention during the protection period.[36] However, for patents concerning medicinal products for human use, the *effective* protection period will often be significantly reduced.

Before a pharmaceutical company is allowed to place a medicinal product for human use on the market, the product needs to be the subject of a *marketing authorization*,[37] which requires extensive and time-consuming clinical trials. This regulatory delay shortens the effective protection period for such products, which is often as short as 10-12 years, and in some cases as short as 7-8 years,[38] after which the proprietor loses market exclusivity for the product.

Hypothetically, pharmaceutical companies could undergo the clinical trials and attain a marketing authorization *before* filing for patent, which could leave the proprietor with the possibility of avoiding the regulatory delay these procedures causes on the patent protection period. However, several circumstances normally prevent this. In order to avoid the invention losing *novelty* (meaning that the invention is *new*, which is a requirement for patentability) by becoming known to the public, and to avoid competitors attaining patent protection for the same invention before them, it is normally necessary and preferable to file for patent at an early stage of inventing the product. Thus, this hypothetical strategy of escaping the regulatory delay is rarely feasible.

Moreover, a very small percentage of tested substances are approved as drugs, and the cost of developing a new drug is estimated to be in the range of $800 million.[39] Consequently, it may require many years of market exclusivity before such development of new drugs are profitable. Conversely, without any remedy of the regulatory delay, the development of new drugs may not be profitable.

The preface of Reg. 469/2009 emphasizes the importance of the development of new drugs. Moreover, it holds that pharmaceutical research *"plays a decisive role in the continuing improvement in public health"*,[40] and that without any favorable rules to compensate for the re-

[35] Patents Act §§ 3 and 40, Art. 63 EPC para 1.

[36] Stenvik (2020) p. 288.

[37] An administrative authorization procedure in accordance with Directive 2001/83/EC or Directive 2001/82/EC.

[38] Stenvik (2020) p. 344.

[39] Stief/Bühler (2016) p. 3.

[40] Preface (2) Reg. 469/2009.

duced effective protection period, such medicinal products may not continue to be developed in Europe or the Community.[41]

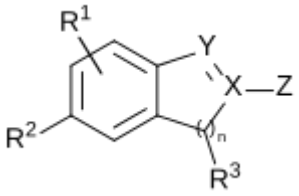
Consequently, the EU created the Supplementary Protection Certificate, first in 1992 with the implementation of Reg. 1768/92.[42] According to the regulation's proposal, the aim of the regulation was to *"[i]mprove the protection of innovation in the pharmaceutical sector"*[43] by remedying the reduced effective protection time for medicinal products. Specifically, the aim was to *"ensure that research-based industry has a market exclusivity of sufficient length to permit recovery of their investments"*.[44]

The SPC is however not meant to compensate for the entirety of the regulatory delay, as the maximum extended protection period provided by a certificate is five years, whereas it may often take substantially longer than this to achieve a marketing authorization. It follows from the preface that *"[a]ll the interests at stake, including those of public health, in a sector as complex and sensitive as the pharmaceutical sector should nevertheless be taken into account. For this purpose, the certificate cannot be granted for a period exceeding five years."*[45]

Any extension of the protection period for medicinal products will correspondingly result in a longer period where generic versions of the same drugs are kept off the market.[46] Accordingly, the Regulation seems to be the result of a carefully weighted balancing of the relevant interests; on the one hand, to encourage pharmaceutical innovation by remedying the regulatory delay, while on the other, to restrict this additional period of protection in the interest of public health by ensuring access to generic versions of drugs.

2.3 Markush formulas

A Markush formula[47] can be described as *"[a] generalized formula or description for a related set of chemical compounds, used in patent applications"*.[48] In the picture to the right,[49] a theoretical example of a Markush formula is presented, where Y, X etc. consist of pre-defined substances, whereas R^1, R^2 etc. may consist of a



[41] Preface (3) Reg. 469/2009.
[42] Council Regulation (EEC) No 1768/92 of 18 June 1992.
[43] COM(1990) 101. p. 3.
[44] COM(1990) 101. p. 14.
[45] Preface (10) Reg. 469/2009.
[46] Stief/Bühler (2016) p. 3.
[47] Often referred to as Markush "groupings", "structures", "formulas", "formulae" etc., hereinafter "formulas".
[48] Oxford Reference (2021).
[49] Wikipedia (2021).

wide range of potential substituents to be selected from certain groups or classes.

In the "Sandoz v. Searle" case, Justice Arnold described Markush formulas as following:

> *"(...) the practice of (...) representing the class of compounds by means of a structural formula which consists of a specified backbone with substituents typically denoted by R1, R2, etc. and by means of statements in the specification and/or the claims defining the kinds of substituent which R1, R2, etc. may consist of. This enables large classes of compounds to be very compendiously defined by such formulae, rather than laboriously writing out long lists of compounds or groups of compounds. Such formulae are referred to as "Markush formulae" and claims containing such formulae are referred to as "Markush claims".*[50]

Using such formulas in patent claims may be a practical method of claiming a class of chemical compounds, since it allows the claimed subject-matter to cover a large number of individual chemical compounds without having to write out each one specifically. The practice of using Markush formulas in patents is accepted under Norwegian patent law as well as with the European Patent Office.[51]

Accordingly, an applicant for a patent may claim a large class of various compounds by using a Markush formula in one or more of the patent claims. Such formula may claim each individual compound possible to construe when replacing each substituent in the formula (R^1, R^2 etc.) with substances from the designated groups.

The number of individual compounds claimed in a Markush formula may be extremely large. In the "Sandoz v. Searle" case, which Advocate General Hogan opined on, the referring court held that *"the estimated number of compounds covered by claim 1 of the patent in question in Case C-114/18 was somewhere between 7 x 10^{135} and 1 x 10^{377}"*.[52]

Because of the high number of potential compounds claimed in a Markush formula, the use of such formulas in the basic patent may entail several obstacles in relation to the validity and scope of the basic patent, as well as the requirements for granting SPC. As mentioned in section 1.4, only the latter will be discussed in this thesis.[53]

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[50] England and Wales High Court (Patents Court), "Sandoz v. Searle", [2017] EWHC 987 (Pat) para 42.

[51] EPO Guidelines Part F section 3.2.5, NIPO (Norwegian Intellectual Property Office) Patent Guidelines Part C Chapter III section 6.3.2.

[52] Opinion of Advocate General Hogan in joined cases C-650/17 and C-114/18 para 24.

[53] See section 3 et seq.

2.4 Art. 3(a) Reg. 469/2009

Art. 3(a) of the Regulation reads as follows:

> *"A certificate shall be granted if, in the Member State in which the application referred to in Article 7 is submitted and at the date of that application:*
> *(a) the product is protected by a basic patent in force;"*

2.4.1 The concept of 'product'

The protected subject-matter of an SPC extends only to the 'product' which is covered by the marketing authorization and the basic patent.[54] It follows from Art. 3(d) and 3(b) of the Regulation that only one SPC may be granted per 'product'.

Within the meaning of the Regulation, a 'product' means the *"active ingredient or combination of active ingredients of a medicinal product"*.[55] A 'medicinal product' is defined as any substance or combination of substances which may be used to prevent, treat or diagnose human or animal diseases and physiological functions.[56]

In consequence, an SPC does not protect the patented medicinal product as a whole (considering that the patent protection may cover several embodiments of the product). The protection of an SPC extends only to the active ingredients of the product which is covered in the marketing authorization.

Whereas 'active ingredient' is not defined in the Regulation, the CJEU has expounded on the interpretation of the term. In Case C-631/13, the CJEU held that active ingredients *"concerns substances producing a pharmacological, immunological or metabolic action of their own"*.[57] Therefore, 'active ingredients' does not cover substances forming part of a medicinal product which do not have an effect on the human or animal body 'of their own'.[58]

Accordingly, *excipients* (which can be described as substances in a medicinal product *"that are included in a pharmaceutical dosage form not for their direct therapeutic action, but to aid the manufacturing process, to protect, support or enhance stability, or for bioavailability*

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[54] Art. 4 and 3(a) Reg. 469/2009.

[55] Art. 1(b) Reg. 469/2009.

[56] Art. 1(a) Reg. 469/2009.

[57] Case C-631/13 Arne Forsgren v Österreichisches Patentamt para 25.

[58] Case C-631/13 Arne Forsgren v Österreichisches Patentamt para 23.

or patient acceptability")[59] cannot be the subject of an SPC,[60] considering that these substances do not have an effect of their own.

In Case C-673/18, the CJEU held that the term 'product' is not dependent of the *"manner in which that product is used"*.[61] Consequently, an already existing active ingredient or combination of active ingredients may not constitute a new 'product' on the grounds that the same active ingredients are authorized for new therapeutic applications.[62] The same decision overturned the earlier *Neurim* decision,[63] where the CJEU held that it is possible under certain circumstances to attain new SPCs for new therapeutic applications of products that have already been subject of an earlier SPC.

Several other issues may arise in relation to the concept of 'product', such as where there are discrepancies between how the product appears from the basic patent and the marketing authorization.[64] For the purposes of this thesis, this subject will not be commented further.

2.4.2 The product must be 'protected' by a basic patent in force

A natural interpretation of the wording in the provision implies that the product must be covered in the basic patent. However, the wording is not clear with regard to what 'protected' specifically entails or how this assessment shall be made. It is also unclear from the wording whether 'protected' refers to the law governing the basic patent, or if 'protected' must be interpreted as an autonomous concept within the Regulation.

Because the wording of the provision is unclear in this regard, several procedures for determining whether products are 'protected' by the basic patent could initially seem plausible.

A first option could be an infringement test under patent law. A patent gives an exclusive right to prohibit others from exploiting the invention covered by the patent.[65] The extent of protection conferred by a patent shall be determined by the patent *claims*,[66] which according to the accompanying protocol on its interpretation must be interpreted in a manner that combines a fair protection for the patentee with a reasonable degree of certainty for third parties.[67]

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[59] Haywood, Glass (2011).

[60] Stenvik (2020) note 3.

[61] Case C-673/18 Santen SAS v Directeur général de l'Institut national de la propriété industrielle para 44.

[62] Case C-673/18 Santen SAS v Directeur général de l'Institut national de la propriété industrielle para 47.

[63] Case C-130/11 Neurim Pharmaceuticals (1991) Ltd v Comptroller-General of Patents.

[64] Stief/ Bühler (2016) p. 12.

[65] Patent Act § 2.

[66] Art. 69 EPC, Patent Act § 39.

[67] Protocol on the Interpretation of Art. 69 EPC Art. 1.

Such protection may also extend to equivalent elements of the patent.[68] This procedure could imply that the product is 'protected' by the basic patent where the product would infringe the basic patent pursuant to patent law.

Another option could be a 'standard disclosure test' on the basis of patent law. A granted patent or a pending patent application may not be *amended* in such a way that it contains subject matter which extends beyond the content of the application as filed.[69] This procedure could imply that the product is 'protected' by the basic patent given that the product does not constitute an unlawful amendment of the basic patent, meaning that the product is sufficiently disclosed in the patent claims.

A third option could be a 'core inventive advance'-test, which would suggest that the product is 'protected' by the basic patent if that product embodies the 'inventive advance' of the invention covered by the basic patent. In order for an invention to be patentable, the subject matter must involve *inventive step*, meaning that the invention is not obvious to the person skilled in the art.[70] A 'person skilled in the art' refers to a hypothetical person with common knowledge in the relevant field of science. This test would require an assessment of which parts of an invention constitute its inventive 'step' or 'advance', and consequently, the product would be protected provided it embodies the invention's 'inventive advance'.

One problem with the first two approaches is that they depend on assessments pursuant to national patent law. According to the Study on the Legal Aspects of Supplementary Protection Certificates in the EU, *"(...) the substantive provisions governing national patents, on the one hand, and the substantive provisions governing European patents, on the other hand, have mostly identical wording"*.[71]

Despite the *"mostly identical wording"* of the substantive provisions of the national patent laws and the EPC, however, patent law is not formally harmonized within EU/EEA.[72] Moreover, the EPC and the national patent laws are admittedly not entirely identical, and because of the lacking harmonization, any similar provisions may in any case be interpreted differently by the courts of the Member States. Consequently, if applying one of the first two approaches, the substantive requirements in Art. 3(a) might potentially be enforced differently in each Member State.

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[68] Protocol on the Interpretation of Art. 69 EPC Art. 2.

[69] Art. 123 (2) EPC, Patents Act § 13.

[70] Art. 52 EPC, Stenvik (2020) p. 215.

[71] Max Planck Institute for Innovation and Competition (2018) p. 64.

[72] Justice Birrs et al. (2016) p. 161.

This could potentially lead to a situation where the eligibility of an SPC varies on which Member State one seeks SPC protection in, which would undermine a central objective behind the Regulation, namely, to provide a *"uniform solution at Community level"*, thereby *"preventing the heterogeneous development of national laws leading to further disparities which would be likely to create obstacles to the free movement of medicinal products within the Community and thus directly affect the functioning of the internal market"*.[73]

Because of the CJEU's decisive role in interpreting EU Regulations, the provision must be applied in accordance with the CJEU's decisions. As elaborated further below in section 2.5, the CJEU has considered and commented on each of the three tests elaborated above, before ultimately adopting an 'identification test'[74] for assessing whether products are 'protected' by the basic patent. This test requires the product to be sufficiently identifiable in the claims of the basic patent.

2.4.3 Challenges when interpreting Art. 3(a)

A significant challenge when interpreting Art. 3(a) is to distinguish SPC legislation from patent law. As mentioned above, the provision and corresponding case law contains several references to patent law. Since the Regulation in principle shall be interpreted autonomously, the question that remains is whether patent law shall affect the assessments pursuant to Art. 3(a), and if so, to what extent.

This can be illustrated with a few examples. One type of challenge arises where there is doubt whether patent law has any relevance for the interpretation of the provisions in the Regulation. For instance, where the Regulation requires a product to be 'protected' by a basic patent, this could feasibly be interpreted as a question of whether the product falls within the scope of the basic patent, relying on patent law.

In other situations, the SPC legislation makes direct references to patent law, for example about what protection an SPC confers.[75] Another situation is where the CJEU makes more *indirect* references to patent law, such as stating that an assessment must be made from the point of view of a *"person skilled in the art"*.[76] This is a familiar concept from patent law, where it refers to a hypothetical person with common knowledge in the relevant field of science. The question that arises here is whether this concept must be interpreted solely within

[73] Recital (7) Reg. 469/2009.

[74] Stief/Bühler (2016) p. 14.

[75] Art. 5 Reg. 469/2009.

[76] Case C-121/17 Teva UK Ltd and Others v Gilead Sciences Inc, para 57.

its meaning from patent law, or if their meaning is altered when applied in SPC legislation, and if so, to what degree.

Such ambiguity with regard to how provisions must be interpreted is unfortunate and may have considerable impact on the assessment. For instance, where the CJEU requires a product to be within what the person skilled in the art may infer *"directly and unambiguously"* from the patent,[77] this might be a reference to EPO's 'gold standard' for assessments pursuant to Art. 123 EPC, or it may simply be the wording of choice by the CJEU, without intending any reference to EPO. Whether this criterion must be interpreted in accordance with the EPO's practice, or simply according to a natural interpretation of the wording, may have decisive influence on the assessment, considering that the EPO's understanding must follow their case law and is presumed to be strict, whereas the latter understanding leaves the wording open for interpretation.

Consequently, determining how the provisions and decisions from the CJEU must be interpreted is imperative for a correct assessment of Art. 3(a) as well as remaining SPC legislation.

2.5 Evolution of CJEU's interpretation of Art. 3(a)

According to the Study on the Legal Aspects of Supplementary Protection Certificates in the EU, the previous CJEU case law on the interpretation of Art. 3(a) can be categorized in three phases.[78]

The first phase refers to Case C-392/97 (*Farmitalia*), which was the first decision by the CJEU on the interpretation of Art. 3(a). In the decision, the CJEU held that in order to determine whether a product is 'protected' by the basic patent, *"reference must be made to the rules which govern that patent"*.[79] Apparently, according to the CJEU in this decision, the assessment pursuant to Art. 3(a) relied solely on national patent law, while not specifying which of the national rules governing the basic patent would decide the matter.[80] As patent law is not harmonized in the EU/EEA, this requirement (and its reference to the law governing the basic patent) was subsequently interpreted differently by the courts and patent offices in the Member States.[81]

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[77] This is elaborated further below in para 2.6.

[78] Max Planck Institute of Innovation and Competition (2018) p. 181.

[79] Case C-392/97 Farmitalia Carlo Erba Srl. para 29.

[80] Which in principle could e.g. be an infringement test or a standard disclosure test, as discussed above in section 2.4.2.

[81] Max Planck Institute of Innovation and Competition (2018) p. 182.

The second phase refers to Case C-322/10 (*Medeva*). In its decision, the CJEU introduced a new criterion, stating that Art. 3(a) precludes the granting of an SPC for active ingredients that are not *"specified in the wording of the claims"* of the basic patent.[82] The Court did not explicitly state whether they rejected or confirmed the earlier decision in *Farmitalia,* but the Court addressed the issue concerning the heterogenous development of the interpretation of Art. 3(a) between the Member States.[83] Accordingly, a feasible interpretation is that the "specified in the wordings" requirement was an autonomous criterion separately from the (non-harmonized) law governing the basic patent, intended to ensure a uniform solution.

The third phase refers to Case C-443/12 (*Actavis I*) and Case C-577/13 (*Actavis II*). In these decisions, the CJEU made reference to the "core inventive advance" of the invention when assessing Art. 3(a). However, the CJEU also made this reference for Art. 3(c),[84] where it was seemingly utilized to prevent several SPCs being granted for the same product in slightly adjusted versions, where the "core inventive step" is the same. Thus, it remained unclear whether this criterion referred to Art. 3(a) or Art. 3(c), and therefore its relevance for the assessment pursuant to Art. 3(a).

As elaborated below, the CJEU has since rejected the "core inventive step"-test and assessments relying solely on patent law for the purposes of Art. 3(a), and instead developed an "identification-test" through the *Teva* and *Royalty Pharma* decisions, similar to the principles laid out in the *Medeva* decision.

2.6 Current interpretation of Art. 3(a) after *Teva* and *Royalty Pharma*

In *Royalty Pharma,*[85] the CJEU largely followed and confirmed the test laid out in *Teva.*[86]

The CJEU held in *Teva that "(…) the rules for determining what is 'protected by a basic patent in force' within the meaning of Article 3(a) of Regulation No 469/2009 are those relating to the extent of the invention covered by such a patent, just as is provided, in the case before the Court, in Article 69 of the EPC and the Protocol on the interpretation of that provision(…)".*[87] The same principle was repeated in *Royalty Pharma* paragraphs 34 through 36.

[82] Case C-322/10 Medeva BV v Comptroller General of Patents, Designs and Trade Marks para 28.

[83] Case C-322/10 Medeva BV v Comptroller General of Patents, Designs and Trade Marks paras 23-24.

[84] Art. 3(c) requires that the product has not already been the subject of an SPC.

[85] Case C-650/17 Royalty Pharma Collection Trust v. Deutsches Patent- und Markenamt.

[86] Case C-121/17 Teva UK Ltd and Others v Gilead Sciences Inc.

[87] Case C-121/17 Teva UK Ltd and Others v Gilead Sciences Inc, para 32.

This indicates that in order for a product to be 'protected' by a basic patent, the product must be encompassed by the basic patent in accordance with the rules relating to the extent of the invention pursuant to national patent law as well as Article 69 EPC and the accompanying protocol on its interpretation.

However, the assessment pursuant to Art. 3(a) is *not* an infringement assessment.[88] Instead, the test outlined by the CJEU requires the product to be *identifiable* in the patent with some degree of specificity. For the assessment, the CJEU separates between two different scenarios.

The first scenario is where the product is "expressly mentioned" in the patent claims.[89] In this scenario, the product is accordingly 'protected' by the basic patent and consequently the requirement in Art. 3(a) is satisfied.

The second scenario is where the product is *not* "expressly mentioned" in the patent claims. Such products may still satisfy the requirement in Art. 3(a), provided that the product is sufficiently 'identifiable' from the patent claims. This requires that the claims in the basic patent must *"relate implicitly but necessarily and specifically"* to the product.[90]

In *Royalty Pharma*, this test was formulated as meaning that a product, where that product is not expressly mentioned in the patent claims, must be *"necessarily and specifically covered"* by one of those claims in order to be 'protected' by the basic patent. This test requires that two cumulative conditions are met, as outlined by the CJEU:

> *"First, the product must, from the point of view of a person skilled in the art and in the light of the description and drawings of the basic patent, necessarily come under the invention covered by that patent. Second, the person skilled in the art must be able to identify that product specifically in the light of all the information disclosed by that patent, on the basis of the prior art at the filing date or priority date of the patent concerned."*[91]

As mentioned above, a "person skilled in the art" is a familiar concept from patent law, where it refers to a theoretical person with general knowledge in the relevant field of profession.[92] This hypothetical person is used as a standard when determining whether a patent has in-

[88] Case C-121/17 Teva UK Ltd and Others v Gilead Sciences Inc para 33.

[89] Case C-650/17 Royalty Pharma Collection Trust v. Deutsches Patent- und Markenamt para 37.

[90] Case C-121/17 Teva UK Ltd and Others v Gilead Sciences Inc, para 37.

[91] Case C-650/17 Royalty Pharma Collection Trust v. Deutsches Patent- und Markenamt para 37.

[92] Stenvik (2020) p. 199.

ventive step and novelty. An important question that arises is whether this concept must be interpreted exclusively within its meaning from patent law. When the CJEU makes such an explicit reference to a concept from patent law, without elaborating on its interpretation, presumably this suggests that the concept must be interpreted in accordance with patent law.

For the concrete assessment, it is firstly necessary to distinguish between products that are "expressly mentioned" in the basic patent from products that are not. If the product is expressly mentioned in the basic patent, the product will consequently be 'protected' by the basic patent. The CJEU does not elaborate on what this specifically requires, but presumably it indicates that the product must somehow appear explicitly from the basic patent.

Where the product is not "expressly mentioned" in the basic patent, the product may nevertheless be 'protected' by the basic patent, provided a test consisting of two cumulative conditions outlined by the CJEU is satisfied.

The first condition pursuant to this test requires that the product must *"come under the invention covered by that patent"*. In *Royalty Pharma*, the Court held that sitagliptin, a DP IV inhibitor, met the functional definition used by one of the claims in the basic patent, and thus *"necessarily comes within the scope of the invention covered by the basic patent"*.[93] Accordingly, being encompassed in a functional definition was deemed sufficient. For the purposes of this thesis, provided that a product is validly encompassed by a Markush formula in the claims of the basic patent, the first condition will presumably be satisfied.

The second condition entails that the person skilled in the art must be able to *"identify that product specifically in the light of all the information disclosed by that patent, on the basis of the prior art at the filing date or priority date of the patent concerned"*.

An important question under this assessment is to determine the level of disclosure required, meaning *how specifically* the product must be identifiable. The CJEU addressed this question in *Royalty Pharma*, stating that:

> *"In order to determine whether the second condition referred to in paragraph 37 of the present judgment is satisfied, it is, more specifically, for the referring court to ascertain whether the subject matter of the SPC concerned 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 from the specification of that patent*

[93] Case C-650/17 Royalty Pharma Collection Trust v. Deutsches Patent- und Markenamt para 38.

as filed, based on that person's general knowledge in the relevant field at the filing date or priority date, and in the light of the prior art at the filing date or priority date."[94]

The decisive question under the second condition of the two-part test is whether the product is within the limits of what the person skilled in the art is able to infer *directly and unequivocally* from the specification of the basic patent as filed. The wording implies that the product must lie within what the person skilled in the art is able to deduce from the basic patent with a high degree of specificity.

Furthermore, the wording of "directly and unequivocally" and "directly and unambiguously"[95] are formulations known from the European Patent Office Board of Appeal as the 'Gold standard' for assessing whether amendments to the patent is compliant with Article 123 (2) EPC.[96] It is not clear from the wording whether these terms must be interpreted in accordance with case law from the EPO Boards of Appeal. Considering that this would have a prominent impact on the application of Art. 3(a), it seems reasonable to deduce that these terms must be interpreted autonomously (without influence of EPO case law), given that the CJEU did not mention the EPO in its decision.

The assessment of whether the product is within the limits of what the person skilled in the art could infer must be made on the basis of the 'prior art' as well as the skilled person's 'general knowledge in the relevant field' at the filing date (or an earlier priority date, if relevant) of the patent concerned. 'Prior art' is a familiar concept from patent law, where it refers to information that is publicly known and may be of relevance for the assessments of novelty and inventive step. Whereas 'common general knowledge' is also a familiar concept from patent law, *"general knowledge in the relevant field"* (as formulated by the CJEU) has a slightly different wording. The CJEU did not elaborate on what this concept entails, or whether the two terms have conflicting meanings. Considering that 'common general knowledge' refers inter alia to *"everything that is required of the skilled person"*,[97] who in turn possesses general knowledge about the relevant field in question, one interpretation might suggest that these terms must be interpreted correspondingly.

An important element of the assessment refers to the fact that the skilled reader must identify the product viewed from the *filing date* or *priority date*. The same principle applies under

[94] Case C-650/17 Royalty Pharma Collection Trust v. Deutsches Patent- und Markenamt. para 40.

[95] Ibid. para 42.

[96] European Patent Office Enlarged Board of Appeals G 0002/10 (Disclaimer/SCRIPPS) of 30.8.2011.

[97] Justice Birrs et al. (2016) p. 214.

patent law when determining the scope of a patent application or issued patent and is meant to ensure that the proprietor does not unduly extend the rights conferred by the patent beyond what was originally featured in the claimed invention. A patent shall not reward subsequent innovation performed after the priority date. Furthermore, the assessments of novelty and inventive step shall not be affected negatively by an innovation made after the priority date (increasing the person skilled in the art's knowledge, thereby increasing the threshold for the assessment of inventive step). Accordingly, the filing or priority date effectively functions as a 'cut-off point' regarding its scope.

Additionally, the CJEU holds that this assessment must be done on the basis of *"all the information disclosed by that patent"*.[98] A central starting point for making this assessment must be the patent claims, but the wording used by the CJEU (*"all the information"* disclosed by the patent) implies that guidance for this assessment may also be found elsewhere, such as the patent description and drawings, which is permissible under patent law.[99] This seems to be in accordance with the general starting point outlined by the CJEU, namely, that the assessment pursuant to Art. 3(a) must in principle be based upon the rules relating to the extent of the protection for the basic patent. This may however give rise to certain issues, for instance to *what extent* guidance may be sought in the description and drawings, and, perhaps even the applicant's correspondence with the patent office, which under some jurisdictions may be relevant for determining the scope of the patent.[100]

To summarize, a product may be 'protected' by the basic patent despite not being expressly mentioned in the claims, provided it is necessarily and specifically covered by one of those claims. This assessment requires the product to 'come under the invention' covered by that patent, and that the person skilled in the art is able to identify that product specifically in the light of all the information disclosed by the patent.

3 SPCs for products based on Markush formulas

3.1 Issues concerning the use of Markush formulas in patent claims under Norwegian patent law and the European Patent Convention (EPC)

Before discussing the research question and subproblems in section 3.2 et seq., this thesis features a brief elaboration on some issues regarding the interpretation of patent claims making

[98] Case C-650/17 Royalty Pharma Collection Trust v. Deutsches Patent- und Markenamt, para 37.

[99] In accordance with Patents Act § 39, Art. 69 EPC.

[100] Stenvik (2020) p. 366.

use of Markush formulas under *patent law*, before performing a comparative analysis of problems concerning the interpretation of such claims under patent law and for SPCs under the Regulation.

3.1.1 Determining the scope of the claims

The extent of protection conferred by a patent is determined by the claims in the patent.[101] The patent's description may serve as guide to understanding the claims in the patent. With regard to the claims, these must be interpreted in accordance with the Protocol on the Interpretation of Art. 69 EPC Art. 1 and 2, which states the following:

> *"Article 69 should not be interpreted as meaning that the extent of the protection conferred by a European patent is to be understood as that defined by the strict, literal meaning of the wording used in the claims, the description and drawings being employed only for the purpose of resolving an ambiguity found in the claims. Neither should it be interpreted in the sense that the claims serve only as a guideline and that the actual protection conferred may extend to what, from a consideration of the description and drawings by a person skilled in the art, the patentee has contemplated. On the contrary, it is to be interpreted as defining a position between these extremes which combines a fair protection for the patentee with a reasonable degree of certainty for third parties.*
>
> *For the purpose of determining the extent of protection conferred by a European patent, due account shall be taken of any element which is equivalent to an element specified in the claims."*

The protection conferred by a patent must consequently depend on an interpretation of the claims, in addition to any descriptions and drawings. This protection is not limited to the literal meaning of the wording used in the claims, and the protection does extend to certain equivalent elements from the claims.

Under Norwegian patent law, the scope of the patent is limited to what may be deduced from the claims according to an *objective understanding* of the claims *by the person skilled in the art*, assessed from the patent filing or priority date.[102] Additionally, the skilled reader may seek guidance in the description and drawings of the patent.[103]

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[101] Patents Act § 39, Art. 69 EPC.

[102] Rt. 1997 p. 1749 on page 1756.

[103] Ibid.

Consequently, for patents making use of Markush formulas, the exact scope of the claims (interpreted in the context of *patent law*) depends at least partially on the person skilled in the art's understanding of the formula at the filing or priority date interpreted in accordance with Art. 69 EPC and the accompanying protocol on its interpretation. Where such formulas contain a very large number of different compounds, determining the exact scope of the claims may be complicated due to its breadth.

3.1.2 Enablement and clarity

Art. 83 and 84 EPC states that the 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"*, and that *"[t]he claims shall define the matter for which protection is sought. They shall be clear and concise and be supported by the description"*. The same principles are repeated in the Norwegian Patents Act § 8.

Accordingly, the application must be clear and enable the person skilled in the art to reproduce the invention in its entirety. According to case law from EPO, this requires inter alia that the person skilled in the art is able to carry out the invention based on the teaching of the patent without *"undue burden"* or without needing *"inventive skill"*.[104] Furthermore, a prerequisite for carrying out an invention is that the patent enables the reader to *identify* the relevant subject-matter from inspecting the patent,[105] which in itself is a similar type of assessment to the two part test pursuant to Art. 3(a).

One potential problem may therefore occur where the formula encompasses compounds that the person skilled in the art is not able to carry out, for example because that compound is not identifiable, practically viable, or caused by a lack of required instructions. Another potential problem for patents claiming different chemical compounds through the use of Markush formulas is that they may *"cover compounds which do not show the claimed activity"*,[106] as formulated by Advocate General Hogan, which might result in *insufficiency*, meaning the requirement set out in Art. 83 EPC is not satisfied.

3.1.3 Comparative analysis of problems associated with the use of Markush formulas in patents and SPCs

As elaborated above, the main requirement pursuant to Art. 3(a) as interpreted according to the latest case law is that the product must be sufficiently identifiable for the person skilled in the art, assessed in the light of the information provided by the basic patent.

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[104] T 0727/95 (Cellulose/WEYERSHAEUSER) of 21.5.1999.

[105] T 0412/93 (Erythropoietin/KIRIN-AMGEN) of 21.11.1994.

[106] Opinion of Advocate General Hogan in joined cases C-650/17 and C-114/18 para 23.

The main problem for the eligibility of SPC for products based on Markush formulas pursuant to Art. 3(a), is that encompassing a product in such extensive formulas may impede the possibility of sufficiently identifying the product. Where a product is encompassed among potentially millions or billions of other individual compounds, it may require thorough research by the reader in order to identify the specific product. Thus, it might be unclear whether such products may satisfy the requirement laid out in Art. 3(a).

This situation is similar to some of the issues that may appear with regard to patents making use of Markush formulas. For instance, under patent law, determining the exact scope of a Markush claim relies on the person skilled in the art's understanding of the claims. Furthermore, some of the assessments under patent law rely on what the skilled reader was able to confer from the patent without 'undue burden' or 'inventive skill', which implies that the invention must be somewhat easily accessible to the skilled reader from inspecting the patent claims and specification.

This is somewhat similar to the 'identification-assessment' under Art. 3(a) adopted by the CJEU, insofar the decisive issue is what the person skilled in the art was able to identify from assessing the basic patent and its claims. However, the two assessments are ultimately different and feature different thresholds, as a mere valid Markush claim is not sufficient for SPC protection pursuant to Art. 3(a), as mentioned above.

3.2 What is the correct application of Art. 3(a) when assessing whether a product based on a Markush formula is 'protected' by the basic patent?

Despite several decisions by the CJEU concerning the interpretation of Art. 3(a), the CJEU has not yet explicitly decided how Art. 3(a) must be applied for products based on Markush formulas. In principle, several applications of Art. 3(a) may initially seem plausible.

One possible application, as outlined in a 2017 decision of the England and Wales High Court by Justice Arnold, entails that a product is protected by the basic patent when it is encompassed by a Markush formula in the claims, provided that the product embodies the invention's 'core inventive advance'.[107] Considering that the CJEU has since rejected the "core inventive advance" test for the purposes of Art. 3(a),[108], this approach seems less relevant.

[107] England and Wales High Court (Patents Court), "Sandoz v. Searle", [2017] EWHC 987 (Pat).

[108] Case C-650/17 Royalty Pharma Collection Trust v. Deutsches Patent- und Markenamt, para 32.

Another potential application of Art. 3(a) for Markush claims relies on an infringement assessment. This approach does not seem relevant either, given that the CJEU has consistently held in later decisions that a mere infringement of the basic patent is not sufficient for a product to be protected by said patent. Additionally, provided the basic patent validly includes a Markush formula, an infringement test would potentially mean that every single compound in said formula is eligible for SPC protection under Art. 3(a),[109] which would probably be considered inconsistent with remaining CJEU case law.

3.2.1 Opinion of General Hogan in Case C-650/17

The perhaps closest legal source commenting explicitly on the eligibility of an SPC for products based on Markush formulas pursuant to Art. 3(a) is the Opinion of Advocate General Hogan in joined cases C-650/17 and C-114/18. The Advocate General's opinions are not binding for the CJEU and does not have authoritative legal value. However, the CJEU does often follow the Advocate General's opinions, which may give these opinions some limited legal value.

The opinion concerns the "Sandoz v. Searle" case from England and Wales High Court,[110] as was briefly mentioned above in section 1.1. The case was referred to the CJEU in a request for a preliminary ruling pursuant to Art. 267 TFEU. After the Advocate General had issued his opinion, but before the CJEU could decide on the matter, the case was withdrawn.

The case concerned a product described in the SPC as Darunavir, which was marketed under the trademark *"Prezista"*, a *"protease inhibitor used in an anti-retroviral medication for the treatment of the HIV virus and AIDS"*. The case concerned the validity of the SPC; more specifically, the question was whether the product was "protected" by the basic patent pursuant to Art. 3(a).

Darunavir was not featured in the approximately 100 compounds specifically disclosed in the specification of the basic patent. However, Darunavir was encompassed by a Markush formula in the basic patent, consisting of a very large number of compounds. According to the referring court, *"the estimated number of compounds covered by claim 1 of the patent in question in Case C-114/18 was somewhere between 7 x 10^{135} and 1 x 10^{377}"*. For the referring court it was unclear if this would satisfy the condition laid out in Art. 3(a), and therefore referred the following question to the CJEU:

[109] Max Planck Institute of Innovation and Competition (2018) p. 209.

[110] England and Wales High Court (Patents Court), "Sandoz v. Searle", [2017] EWHC 987 (Pat).

"Where the sole active ingredient the [sic] subject of a [SPC issued under Regulation No 469/2009] is a member of a class of compounds which fall within a Markush definition in a claim of the patent, all of which class members embody the core inventive technical advance of the patent, is it sufficient for the purposes of Article 3(a) of [Regulation No 469/2009] that the compound would, upon examination of its structure, immediately be recognised as one which falls within the class (and therefore would be protected by the patent as a matter of national patent law) or must the specific substituents necessary to form the active ingredient be amongst those which the skilled person could derive, based on their common general knowledge, from a reading of the patent claims?"[111]

The Advocate General argues in his opinion that the 'core inventive advance', which the referring court presumes is relevant for the assessment, is of no relevance for Art. 3(a).[112] Furthermore, the Advocate General considers the two-part test from *Teva* to be technologically neutral in nature, and that *"the form of a claim — as opposed to its substance or content — is not, in any sense, decisive, provided it satisfies the test in question"*.[113]

In conclusion, the Advocate General considers that SPCs may in principle be 'protected' by the basic patent, even where a product is covered by a Markush formula, provided the two-part test from *Teva* is satisfied.

3.2.2 Does the 'two-part test' apply for products based on Markush formulas?

The Advocate General considers the two-step test to be the relevant application of Art. 3(a) for products based on Markush formulas. Although the *Teva* decision and its corresponding two-part test was created in the context of combination drugs, the test was confirmed in *Royalty Pharma* in the context of products based on functional claims in the basic patent.

Functional definitions in patent claims typically describe a technical result, without necessarily defining the process required to achieve said result. This context is similar to patent claims making use of a Markush formula, insofar the scope of both types of claims may involve a large number of potential compounds and active ingredients. Accordingly, the fact that the CJEU has confirmed the two-part test for products based on functional claims may imply that the test shall also be applied to products based on Markush formulas.

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[111] Opinion of Advocate General Hogan in joined cases C-650/17 and C-114/18 para 30.

[112] A view joined by the CJEU in the decision in *Royalty Pharma*.

[113] Opinion of Advocate General Hogan in joined cases C-650/17 and C-114/18 para 62.

One could however argue that the two-part test is not particularly well-suited for products based on Markush formulas. As mentioned, this particular test originated from the decision in *Teva*. The problem in question was whether a medicinal product under the name *"Truvada"*, containing two active ingredients, namely, TD and emtricitabine, was 'protected' by the basic patent. The basic patent only expressly mentions TD and contains no explicit reference to emtricitabine. The question was if emtricitabine was sufficiently identifiable through the phrase *"other therapeutic ingredients"* in the claims, which was necessary for this combination (constituting Truvada) to be considered 'protected' by the basic patent.

In this context, the requirement of whether the product is 'identifiable' may seem appropriate. The test seemingly asks if the information provided by the basic patent leads the person skilled in the art to the relevant subject matter, despite not being explicitly mentioned in the patent. More specifically for *Teva*, the decisive question was if the phrase *"other therapeutic ingredients"* interpreted in the light of all the information provided by the basic patent, made emtricitabine identifiable for the person skilled in the art.

The same requirement may initially not seem equally appropriate for products specified by means of a Markush formula. A Markush formula is, as elaborated above, designed to encompass a large number of compounds. Moreover, the various compounds are encompassed in a way that allows the reader to construe each compound, if given enough time (i.e. construing the relevant formula and replacing the variables with the stated substances that are to be chosen from the different groups).

If this assessment of what the person skilled in the art was able to identify were to be done retrospectively, or 'looking back' from time of filing the SPC to see if the product is covered in the Markush formula, the product might easily be 'protected' by the basic patent. Such interpretation might ask whether the person skilled in the art is able to determine that the product is mentioned somewhere in the Markush formula. Given that the product is mentioned somewhere in the formula, the skilled reader would, according to this interpretation, 'know what to look for' and consequently easily determine that the product is encompassed in the relevant formula.

This interpretation is likely contrary to CJEU's case law, considering that the CJEU has held that the product must be identifiable on the basis of the prior art at the filing date, or if applicable, an earlier priority date,[114] as mentioned in section 2.6.

[114] Case C-650/17 Royalty Pharma Collection Trust v. Deutsches Patent- und Markenamt, para 37.

Accordingly, this implies that the test must rather be made 'looking forward', meaning that the product must have been identifiable for the person skilled in the art at the filing date or priority date of the basic patent. Considering that a Markush formula may potentially cover a very large number of different compounds, this test must require that the information contained in the basic patent 'leads' the reader to the specific product, assessed from the basic patent's filing or priority date.

Considering the above, as well as the Advocate General's opinion that the two-part test is the central test for all products pursuant to Art. 3(a), and the CJEU's latest case law which focuses solely on the identification test, the two-part test laid out in *Teva* and *Royalty Pharma* appears to be the correct application of Art. 3(a) for products based on Markush formulas.

3.3 Can a product be 'protected' by the basic patent if the claims in the basic patent define the product using a Markush formula?

As mentioned above, Advocate General Hogan is of the opinion that Art. 3(a) *"does not preclude the grant of an SPC for an active ingredient covered by (...) a Markush formula provided, however, that the two-part test set out in (...) Teva (...) is satisfied".*

Whereas the opinion of the Advocate General does not have substantial legal value on its own, this view seems to be consistent with the latest decisions from the CJEU. In both *Teva* and *Royalty Pharma,* the Court has held that an *express mention* of the product is not necessary in order to satisfy the requirement set out in Art. 3(a), provided the product is specifically identifiable. Given that encompassing a product in a Markush formula will presumably not constitute an *express mention,* these statements may suggest that SPC protection is possible for such products, provided the two-part test is satisfied.

Furthermore, in *Eli Lilly*,[115] the CJEU held that Art. 3(a) *"does not, in principle, preclude an active ingredient which is given a functional definition in the claims (...) being regarded as protected by the patent, on condition that it is possible to reach the conclusion on the basis of those claims, interpreted inter alia in the light of the description of the invention, as required by Article 69 of the EPC and Protocol on the interpretation of that provision, that the claims relate, implicitly but necessarily and specifically, to the active ingredient in question".*[116] This was repeated in *Royalty Pharma* .[117]

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

[116] Case C-493/12 Eli Lilly and Company Ltd v Human Genome Sciences Inc para 39.

[117] Case C-650/17 Royalty Pharma Collection Trust v. Deutsches Patent- und Markenamt, para 36.

The requirement that the claims must *"relate, implicitly but necessarily and specifically"* to the active ingredient is, as elaborated under section 2.5, the 'predecessor' to the current two-part test.

Considering the similarities between functional definitions and Markush formulas, this statement may indicate - in an authoritative source, as opposed to the Advocate General's opinion - that products based on Markush formulas are not as such precluded from SPC eligibility pursuant to Art. 3(a). The authors of "Intellectual Property Law" is of the same opinion; that when the *Eli Lilly* decision states that identification of a product through a structural or functional formula is permissible for satisfying Art. 3(a), the same principle must apply for Markush formulas.[118]

Furthermore, there does not seem to be any valid reason as to why products based on Markush formulas shall automatically be excluded from SPC protection pursuant to Art. 3(a), even where such products do satisfy the two-part test.

Consequently, the decisive issue for the eligibility of SPC pursuant to Art. 3(a) for products based on Markush formulas appears to depend on whether such products may satisfy the two-part test.

3.3.1 May products based on Markush formulas satisfy the two-part test?

As mentioned above, encompassing a product in a Markush formula will in itself not constitute an 'express mention' of the product. Accordingly, the decisive criterion for SPC eligibility pursuant to Art. 3(a) is whether such products may satisfy the two-part test. Furthermore, the premise is that by being encompassed in such a formula, the product necessarily 'comes under the invention' covered by the basic patent.

Ultimately, under these assumptions, the question that remains is whether the person skilled in the art is able to 'identify that product' specifically, in accordance with the second step of the two-part test.

The CJEU has held that this criterion requires the product to be within what the person skilled in the art is able to infer *"directly and unequivocally"* from the patent. Besides indicating that a high degree of specificity is required, the exact level of disclosure required is not clear. Another question is what specifically the person skilled in the art must be able to identify from the Markush formula.

[118] Bently et al. (2018) p. 713.

Considering that the main issue is about determining the exact degree of specificity required, and how this test materializes for products based on Markush formulas, it may be helpful to illustrate the problem through the use of a spectrum.

In one end of the spectrum, the most extreme interpretation suggests that *every* compound encompassed in a Markush formula is specifically identifiable. One might defend this interpretation by arguing that the person skilled in the art would, if given enough time, be able to identify each single compound encompassed by the formula. This interpretation was Searle and JSI's principal argument in case C-114/18.[119] The idea of allowing every single compound claimed in a Markush formula to be eligible for an SPC under Art. 3(a) was considered *"relatively generous towards the patent holder"* in the Study on the Legal Aspects of Supplementary Protection Certificates in the EU.[120]

This interpretation does not seem consistent with CJEU case law. The CJEU have held that it is not sufficient that the person skilled in the art is able to identify the product *per se*. It is required that the person skilled in the art is able to identify the product *specifically*; the product must be within what the person skilled in the art is able to infer *"directly and unequivocally"* from the specification of the patent as filed.[121]

Additionally, this assessment cannot be made 'in hindsight'. As mentioned in section 2.6, the theoretical assessment of what the skilled reader was able to identify must be made from the perspective of the filing or priority date.

This implies that a mere possibility of identifying the product among potentially millions of other compounds, with no other information pointing at the particular product, is not sufficient; the information provided by the basic patent, in addition to the reader's general knowledge, assessed from the priority date, must somehow 'lead' the person skilled in the art to the specific product to an appreciable extent. This is also in accordance with the opinion of Advocate General Hogan, who was of the view that a Markush formula does not in itself constitute an express mention of a product.[122]

In the other end of the spectrum concerning the interpretation of Art. 3(a) for products based on Markush formulas, a second interpretation might suggest that products encompassed by a

[119] Opinion of Advocate General Hogan in joined cases C-650/17 and C-114/18 para 58.

[120] Max Planck Institute for Innovation and Competition (2018) p. 209.

[121] Case C-650/17 Royalty Pharma Collection Trust v. Deutsches Patent- und Markenamt, para 40.

[122] Opinion of Advocate General Hogan in joined cases C-650/17 and C-114/18 para 60.

Markush formula in the claims of the basic patent may *never* be sufficient to satisfy the requirement in Art. 3(a). This interpretation does not seem feasible either. Considering the CJEU has consistently held that the decisive criterion is whether the product is specifically identifiable, a product encompassed by a Markush formula may in principle be 'protected' by the basic patent provided some information in the basic patent makes this product specifically identifiable. This latter point of view also harmonizes with Advocate General Hogan's opinion.

Consequently, this suggests that encompassing a product in a Markush formula will not in itself satisfy the requirement in Art. 3(a), nor is it an automatic disqualification for the eligibility of SPC under Art. 3(a). The question that remains is examining when such products may satisfy Art. 3(a) and how the identification-assessment shall be performed.

In *Royalty Pharma*, the CJEU formulated the requirement (although for products covered by functional formulas) as such:

> *"In so far as, where the product is not explicitly disclosed by the claims of the basic patent, but is covered by a general functional definition, such as that used by the basic patent at issue in the main proceedings, a person skilled in the art must be able to infer directly and unambiguously from the specification of the patent as filed that the product which is the subject of the SPC comes within the scope of the protection afforded by that patent."*[123]

Accordingly, the person skilled in the art must be able to infer that the product *"comes within the scope of the protection afforded by that patent"*. This might suggest that is it not necessary to do a hypothetical assessment of whether the person skilled in the art was able to easily derive the specific product from an assessment of the Markush formula and the specification of the patent. It rather suggests that the person skilled in the art must be able to establish directly and unambiguously that the product comes within the protection of the Markush formula, and thus the protection provided by the patent, assessed from the filing or priority date of the basic patent.

A natural interpretation of the phrase *"directly and unequivocally"*, and *"directly and unambiguously"*, implies that the person skilled in the art must be able to establish very clearly that the product comes within the protection afforded by the basic patent. As mentioned above,

[123] Case C-650/17 Royalty Pharma Collection Trust v. Deutsches Patent- und Markenamt para 42.

this assessment must be made in the light of *"all the information"* provided by the patent, but the patent claims will naturally be central for this assessment.

In conclusion, my findings and interpretations on the relevant legal sources indicate that medicinal products may be 'protected' by basic patents that define the product through a Markush formula. However, the mere fact that a product is encompassed in such a formula is not in itself sufficient to satisfy Art. 3(a). Something more is required; the product must be sufficiently identifiable to the person skilled in the art, on the basis of the information provided by the patent as well as the prior art. On this basis, the person skilled in the art must be able to infer directly and unequivocally that the product *comes within the scope of the protection* afforded by the Markush formula and the basic patent.

3.3.2 Assessment of selected scenarios involving Markush formulas

On the basis of the requirements pursuant to Art. 3(a) as elaborated above, I discuss in the following what may typically be required in order for products claimed through Markush formulas to satisfy Art. 3(a) in a few selected scenarios. This involves a discussion about *what other information* in the basic patent, in addition to the Markush formula, may lead the skilled reader to the specific product, and to *what degree* the information must identify the product.

For the following discussion, it is important to reiterate that the assessment of whether the product is 'specifically identifiable' must be performed from the hypothetical perspective of the person skilled in the art. Consequently, pieces of information (alone or in combination) that might not provide any guidance for the unskilled reader, might conversely implicate, identify, describe or otherwise lead the *skilled* reader to the specific product, based on this person's knowledge in the relevant chemical field and of the prior art.

3.3.2.1 Structure of the patent claims

A first scenario may relate to how the *composition* or *structure* of the different claims in the patent might make the product specifically identifiable to the skilled reader.

Patents may consist of one or several patent claims. These claims can be *dependent* or *independent*. *Dependent claims* are typically claims that feature all traits from the claims which they are dependent of (i.e. the independent claims).[124] *Independent claims*, on the other hand,

[124] Stenvik (2020) p. 73.

are claims that do not refer to other claims in the patent.[125] Accordingly, dependent claims in a patent may *concretize* or otherwise *specify* the subject-matter of an independent claim.[126]

In this scenario, claim 1 may relate to a very broad class of compounds through the use of a Markush formula, from wherein the relevant product may be derived. Considering that a mere mentioning of a product in such a formula is not sufficient for satisfying Art. 3(a), the question for this scenario is what other information conferred by the *composition* of the remaining claims may lead the skilled reader to the specific product, thereby satisfying Art. 3(a).

One example under this scenario may be where another dependent claim in the patent *precisely defines* the product, for instance by claiming a product within the formula 'characterized by' its precise composition. Depending on how explicit such reference appears to the skilled reader, this information may possibly be characterized as an 'express mention', thereby satisfying Art. 3(a) without further assessment of the two-part test. Where such information is relatively explicit (yet not explicit enough to not constitute an express mention), the two-part test may presumably easily be satisfied provided some other information also points to the product.

Another example might be where other claims in the patent *narrows* the class in claim 1, thus 'leading' the skilled reader closer to the relevant product. If for instance there are four other claims (dependent of claim 1) in the same patent that refers to the same formula, but provides a narrower and more specified list of potential substituents for the formula, the combination of this information would point out certain preferable compounds, leading the skilled reader closer to identifying the relevant product.

Another example might be where the dependent claims refer to similar compounds, or compounds with preferred properties or functions. Given the circumstances, an inspection of the similar compounds might 'point' the reader to the relevant product, for instance because the specific product appears as a preferred and related solution to the same technical problem represented by the recited, similar compounds. Where the skilled reader must seek guidance in such 'indirect' information, the threshold for satisfying Art. 3(a) may presumably require information which to a large extent leads the reader to the product.

The decisive issue for assessing whether situations under this scenario satisfy Art. 3(a) will presumably depend on the information conferred by the formula viewed in the light of the other claims together with the common general knowledge in the field, and how specifically

[125] Stenvik (2020) p. 73.

[126] Stenvik (2020) p. 73.

the information leads the skilled reader to the product. As mentioned, compliance with Art. 3(a) requires that the product is identifiable from the patent with a high degree of specificity.

3.3.2.2 Guidance from the specification of the patent

While the extent of protection of a patent shall be determined by the patent claims, the *description* and *drawings* (sometimes collectively referred to as the 'specification' of the patent) shall nevertheless also be used to interpret the claims.[127] The CJEU has repeatedly held that the description, drawings as well as *"all the information"* disclosed by a patent is relevant for the assessment of what the skilled person is able to identify from the patent in accordance with Art. 3(a).[128]

This scenario refers to situations where the patent claims do not *in itself* identify the product to a sufficient degree, but where the description and drawings *in combination* with the claims provide guidance such that the skilled reader may identify the product. One question under this scenario is how much guidance the specification must provide.

This depends partially on how much guidance the *claims* provide. Where the claims disclose the product to a high extent (yet not enough to satisfy Art. 3(a) as such), a product may still be protected by the basic patent where the specification adds modest further guidance, because the combined disclosure under these circumstances may be sufficient to satisfy Art. 3(a). And conversely, where the claims disclose the product to a low degree, more is required from the specification in order to comply with Art. 3(a). The decisive issue for the assessment pursuant to Art. 3(a) is the *combined* degree of disclosure, based on "all the information" conferred by the patent; a lesser degree of disclosure in the claims may be remedied by a larger degree of disclosure in the specification, and *vice versa*.

Nonetheless, it is important to emphasize that the primary source of determining the scope of the patent lies with the patent claims. Furthermore, under Norwegian patent law it is believed that the *description* of the invention is the foremost source of guidance from the specification, whereas any drawings in the specification will generally be of less value for interpreting the claims, as these typically merely exemplifies ways in which the invention *may* be carried out.[129] It is unclear whether these principles must be applied when interpreting a patent in accordance with the two part test for compliance with Art. 3(a).

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[127] Art. 69 EPC, Patents Act § 39.

[128] Case C-650/17 Royalty Pharma Collection Trust v. Deutsches Patent- und Markenamt, para 37.

[129] Stenvik (2020) p. 366 et seq.

There are many ways the *description* may offer guidance to the skilled reader. One example may be where the claims point to certain compounds, but without specifically identifying the product as such, and where the description holds compounds as "having utility as HIV protease inhibitors" as preferable compounds. Such information might, in combination with the claims and the reader's general common knowledge about which compounds might exhibit such properties, lead the reader to the specific compound.

Any *drawings* in the patent might include examples or various embodiments of the invention. These may also, in combination with the claims, lead the reader to the specific product. Where the specific product is *exemplified* through a literal representation, Art. 3(a) must presumably be satisfied as such. Where similar compounds or compounds with similar properties are exemplified, this might weigh in favor of the product being identifiable provided this information somehow implicates the product to the skilled reader.

Embodiments featured in the drawings might refer to 'preferred compounds' or groups of these. Where the specific product is featured as a preferred compound, this might imply that the product is specifically identifiable. However, where the specification contains a very large number of preferred compounds, or large categories of 'preferred compounds', 'especially preferred compounds' and so forth, the level of guidance conferred by this information might be diluted.

3.3.2.3 Data from preclinical research

As mentioned in section 2.2, a medicinal product intended for human use must be the subject of a marketing authorization before the proprietor may place the product on the market. A marketing authorization requires inter alia extensive clinical testing on humans to test the product's desired function and to uncover any harmful adversary effects.

Many proprietors will however seek patent protection at an early stage of development, before any clinical trials have been conducted. In these cases, the research documenting any medicinal effect in the invention will often be the result of *preclinical research* (research conducted before any human experiments), which may be *in vitro*-studies (experimenting in test tubes in a laboratory) or *in vivo*-studies (in living organisms, normally animals at this stage).[130]

This scenario may therefore refer to situations where the claims and specification do not in itself provide sufficient guidance to satisfy Art. 3(a), but where the examples feature data

[130] The Norwegian Medicines Agency (2021).

from preclinical research. The question under this scenario may therefore be when such data may contribute with additional guidance for the skilled reader.

The data from such preclinical research may be featured in the examples and may consist of results from experiments on specific embodiments or groups of embodiments. Such data might offer important information on the qualities of the various embodiments, such as the product's *effectiveness* (i.e. if and possibly to what extent it achieves the desired effect) and whether the product entails any harmful side-effects.[131]

Such information might provide substantial guidance to the skilled reader, e.g. regarding which compounds appear preferable, as the skilled reader would likely pursue products belonging to a class of compounds with favorable qualities. Moreover, data from preclinical research may also provide guidance to the reader concerning *why* certain groups of compounds show the desired effect as opposed to others, which might lead the reader closer to the specific product.

However, the amount of data from preclinical studies is normally modest compared to the amount of data acquired by the remaining research necessary to obtain a marketing authorization. Consequently, where the specific product is mostly a result of the *clinical* research (as opposed to the preclinical research), guidance from the preclinical research will not necessarily lead the reader to the product. Because the filing or priority date of the basic patent functions as a 'cut off'-point with regard to the assessment of what the skilled reader was able to identify, only the information that was available from the perspective at this date may be taken into account when determining what the skilled reader was able to identify.

Furthermore, where the finalized product is contrary to what the preclinical research included in the patent might suggest, such information will likely weigh *against* the specific product being identifiable.

The decisive question for whether such research may assist the reader in specifically identifying a product will therefore depend on whether this information provides any actual guidance to the specific product. Whether a product is specifically identifiable in such circumstances depends, as mentioned above, partly on how much guidance the claims and other information conferred by the patent provides, as it is the combined level of guidance that decides whether a product is specifically identifiable.

[131] The Norwegian Medicines Agency (2021).

3.4 Does the number of chemical compounds in a Markush formula affect the assessment of whether the product is 'protected' by a basic patent?

Based on my findings above, the decisive question for whether products based on Markush formulas may be considered 'protected' by the basic patent, relies on whether that product is specifically identifiable for the skilled reader, on the basis of the information conferred by that patent. Such information might e.g. be conveyed by the patent claims, the specification of the patent or data from preclinical research, as discussed above.

This would perhaps suggest that the *breadth* of the Markush formula – meaning how many individual compounds are covered by the formula – is irrelevant, because the important assessment relies on whether enough information provided by the patent leads the skilled reader to determine that the product comes under the protection afforded by the basic patent. This may in principle be assessed regardless of the breadth of the Markush formula.

However, it is possible that the identification-assessment will be affected by the breadth of the Markush formula. As mentioned above, a Markush formula may theoretically cover as many as 1×10^{377} individual compounds. On the other hand, a Markush formula may also in principle be used to cover only a limited number of different compounds.[132] Accordingly, there may exist large differences with respect to the breadth of Markush claims.

Where a product is encompassed in a Markush formula of extensive breadth, the reader will be faced with a larger range of options and alternative possible compounds. This might in turn require a higher degree of disclosure from the patent before the reader is able to identify the product. Conversely, where the reader is faced with a formula consisting of fewer compounds, the reader will be faced with less options, making the specific product more readily available upon inspecting the patent. This might make the 'identification process' easier, thus requiring a lesser degree of information directing the skilled reader to the relevant product.

Accordingly, this suggests that the number of compounds in a Markush formula may impact the assessment pursuant to Art. 3(a) Reg. 469/2009, by implicitly increasing the threshold with regard to the identification requirement for products based on Markush formulas that contain a vast number of different compounds.

[132] Although this is probably less likely, considering that such formulas are typically used in order to claim extensive classes of compounds.

3.5 Can an SPC validly be issued for a product which was selected from a Markush formula after the priority date of the basic patent, without being specifically mentioned in the basic patent?

As mentioned in section 2.6, an important principle in patent law and when assessing Art. 3(a) is that the extent of protection must be assessed from the patent's filing or priority date. Neither a patent nor a patent application may be amended in such a way that it contains subject matter which extends beyond the protection the patent confers, or the content of the application as filed.[133]

Consequently, the filing or priority date of the patent is the 'cut-off point' for assessing the extent of protection conferred by the patent. If one were to deviate from this principle, the proprietors of patents would be able to extend their right of exclusivity beyond the patented subject matter.

For medicinal products, this principle is sometimes challenged. As elaborated in section 2.2, inventors of medicinal products will often file for patent at an early stage of developing products. Consequently, the proprietors may realize after the filing date, following additional research, that the medicinal product achieves the desired effect ideally if produced in a slightly adjusted version, in combination with other substances or in an otherwise altered form with respect to how the product was originally intended.

Where a basic patent encompasses a wide range of products through a Markush formula, the proprietor may therefore in theory 'choose' any product from within this formula, after the filing date, when applying for SPC for a medicinal product. This would allow the proprietor to choose the ideal product from within the formula after the filing date, provided that the product is indeed 'protected' by the basic patent in accordance with Art. 3(a), as elaborated above.

However, where the proprietor develops or selects the final product after the patent filing date, another question concerning the eligibility of SPC pursuant to Art. 3(a) arises, which stems from the CJEU's decision in *Royalty Pharma.*

3.5.1 Relevance of the third question in *Royalty Pharma* for this assessment

In the decision, the CJEU answered a question by the referring court regarding products developed after the filing date of the basic patent application. The question was formulated by the CJEU as such:

[133] Art. 123 EPC, Patents Act §§ 13, 19 (2).

> *"By its third question, the referring court asks whether Article 3(a) of Regulation No 469/2009 must be interpreted as meaning that a product is not protected by the basic patent in force, within the meaning of that provision, if, although it is covered by the functional definition in the claims of that patent, it was developed after the filing date of the application for the basic patent, following an independent inventive step."*[134]

The question regards the situation where a product is covered in a functional definition in the basic patent, but despite being covered, the product is not developed until after the filing date of the basic patent. This is possible because functional definitions may claim compounds that are not explicitly described – as mentioned above, functional definitions typically claim compounds by describing its functions, rather than describing its properties. Thus, a functional definition may cover compounds that are not yet known at the filing date.

Although the question (and as elaborated below, the CJEU's conclusion) only specifically concerns products based on functional definitions, the same question appears to be very relevant for products based on Markush formulas.

As mentioned, Markush formulas may encompass extremely many different compounds, many of which may be unknown at the filing date. This may hypothetically allow the proprietor to claim a large class of different compounds at the filing or priority date, and to select the ideal compound from within this formula following subsequent research conducted after filing the basic patent application, but before filing for SPC protection.

Following the decision in *Royalty Pharma*, the possibility of performing such subsequent selections was clarified.

Generally, Art. 3(a) requires a product to be specifically identifiable to the skilled reader assessed from the filing or priority date of the basic patent, which itself restricts which products are eligible for SPCs. Additionally, for situations like the one mentioned above, the CJEU has developed a new requirement pursuant to Art. 3(a) through answer to the third question in the decision, which reads as following:

> *"It follows that a product which is the subject of an SPC or an SPC application, and which was developed after the filing date or priority date of the basic patent, following*

[134] Case C-650/17 Royalty Pharma Collection Trust v. Deutsches Patent- und Markenamt, para 44.

an independent inventive step, cannot be regarded as coming within the scope of the subject matter of the protection conferred by that patent."[135]

In the ensuing paragraph of the decision, the CJEU stated that *"[t]he fact that such a product comes under the functional definition given in the claims of the basic patent cannot invalidate that interpretation"*.[136] The wording suggests that the principle shall have general application for assessments pursuant to Art. 3(a), also where the product falls within the scope of the basic patent, as it shall apply unhindered of the fact that the product comes under the functional definition in the claims of the basic patent.

The CJEU concludes by answering the third question such that *"a product is not protected by a basic patent in force, within the meaning of that provision, if, although it is covered by the functional definition given in the claims of that patent, it was developed after the filing date of the application for the basic patent, following an independent inventive step"*.[137] This suggests that where a product may otherwise be 'protected' by the basic patent, such products are precluded from satisfying Art. 3(a) where the product was developed after the filing date of the basic patent following an independent inventive step.

Accordingly, the decisive question that remains is to determine how *"independent inventive step"* must be interpreted.

3.5.2 When will a subsequent selection of a product from a Markush formula constitute an independent inventive step within the meaning of *Royalty Pharma*?

As mentioned in section 2.4.3, a challenge that sometimes appear when interpreting CJEU decisions concerning Art. 3(a) is its direct and indirect references to patent law. *Inventive step* is a familiar term from patent law, where it refers to one of the fundamental requirements for patentability; an invention has inventive step where it is not obvious to the person skilled in the art.[138]

The CJEU did not clarify how *"independent inventive step"* shall be interpreted, and whether its interpretation is affected by its meaning from patent law. Moreover, it is unclear how the addition of *"independent"* affects the assessment.

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[135] Case C-650/17 Royalty Pharma Collection Trust v. Deutsches Patent- und Markenamt, para 47.

[136] Case C-650/17 Royalty Pharma Collection Trust v. Deutsches Patent- und Markenamt, para 48.

[137] Case C-650/17 Royalty Pharma Collection Trust v. Deutsches Patent- und Markenamt, para 50.

[138] Stenvik (2020) p. 168 et seq.

One interpretation, taking into account its meaning from patent law, may suggest that the subsequent development must amount to an inventive step in order to preclude the product from SPC eligibility. This might suggest that the subsequent selection must not have been 'obvious to the person skilled in the art', which would allow *some* subsequent research, considering that this threshold is somewhat significant.

In its reasoning, the CJEU held that *"[w]ere the results from research which took place after the filing date or priority date of that patent to be taken into account, an SPC could enable its holder unduly to enjoy protection for those results, even though they were not known on one or other of those dates"*.[139] Furthermore, the CJEU argued that it would be contrary to the objectives behind the Regulation *"to grant an SPC for a product which is not covered by the invention which is the subject of the basic patent, inasmuch as such an SPC would not relate to the results of the research claimed under that patent"*.[140]

The CJEU's reasoning may suggest that *any* research conducted after the filing or priority date is precluded when assessing the product's eligibility for an SPC pursuant to Art. 3(a).

The objectives of the Regulation imply that where the innovation was performed after the filing or priority date, there may not be a legitimate legislative reason to grant the protection afforded by an SPC.

On the other hand, as mentioned above in section 2.2, inventors of medicinal products will often be 'forced' to apply for patent at an early stage in order to avoid losing novelty and losing the invention to competitors. Considering that pharmaceutical research is one of the fundamental objectives behind the Regulation,[141] one might argue that allowing some subsequent research will promote early-stage research, and thus help achieve said objective. However, this argument must presumably be of very limited value, considering it is directly contrary to the CJEU's reasoning in *Royalty Pharma* paragraphs 45 through 46.

One possible interpretation of the 'independent'-criterion may simply be to reiterate that the research must be performed after the filing or priority date, i.e. independently of the research leading up to the original basic patent.

Ultimately, it is not clear from the decision how this criterion must be interpreted.

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[139] Case C-650/17 Royalty Pharma Collection Trust v. Deutsches Patent- und Markenamt, para 45.

[140] Case C-650/17 Royalty Pharma Collection Trust v. Deutsches Patent- und Markenamt, para 46.

[141] Preface (2) et seq. Reg. 469/2009.

A feasible interpretation might suggest that where the proprietor selects the subject-matter from a Markush formula following research performed after the filing or priority date, that product is precluded from satisfying Art. 3(a), unless that specific selection was considered *obvious* to the person skilled in the art at the filing or priority date. This interpretation relies on the understanding of 'inventive step' from patent law, which might seem reasonable considering the CJEU's wording. Moreover, this might suggest that the existence of a later patent protecting the same product is a factor weighing against the product being protected by the original basic patent,[142] as a later patent necessarily must involve inventive step to be validly granted.

This interpretation implies that some subsequent selection from within the formula is allowed, provided the subsequent selection is *obvious* to the skilled reader from reading the basic patent.

4 Conclusion and closing remarks

My findings indicate that products based on Markush formulas may qualify for SPCs pursuant to Art. 3(a), provided the product either is expressly mentioned or satisfies the two-part test as laid out by the CJEU in its recent decisions.

In my opinion, it is possible to express some criticism regarding the current interpretation of Art. 3(a). The CJEU's numerous references to terms from patent law result in confusion regarding how the requirements must be understood and how the assessments must be made. Whenever the CJEU refers to terms such as *"independent inventive step"* or *"directly and unambiguous"*, without elaborating on what these terms mean, those who apply the law is faced with the option of interpreting these terms within their meaning of patent law, or according to their literal interpretation (or a combination). As of writing this thesis, it is unclear how many of the requirements the CJEU has laid out shall be interpreted, which is unfortunate.

The Regulation was meant to provide for a *"simple, transparent system which can easily be applied by the parties concerned"*.[143] It is discussable whether this aim is satisfied today. One solution could be for the CJEU to properly address how the recently introduced terms shall be interpreted (especially where these have distinct meanings from patent law).

Moreover, the two-part test (in its current form) is criticized by some for not allowing proprietors and others to predict with a reasonable degree of certainty whether products are 'protect-

[142] Stenvik (2020) note 8.

[143] COM(1990) 101. p. 10.

ed' by the basic patent. It is noteworthy that the Study on the Legal Aspects of Supplementary Protection Certificates in the EU (delivered before the *Teva* decision) identified three possible criteria for assessing compliance with Art. 3(a), namely, a standard disclosure test (pursuant to Art. 123 (2) EPC), an infringement test and a 'core inventive advance'-test, and found that the latter provided some advantages over the others.[144] The CJEU rejected all three in favor of the two-part test. As the two-part test by now seems cemented by the CJEU, it might be preferable if the CJEU chose to clarify the various requirements (as mentioned above in this section), and thereby possibly ensuring a simpler, more transparent system.

[144] Max Planck Institute of Innovation (2018) p. 220.

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