



*Directorate General of the
Library, Research and
Documentation*

RESEARCH NOTE

Supplementary protection certificate for medicinal products

[...]

Subject: Analysis of national case-law on the interpretation of Article 3(a) of Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products.

[...]

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[...]

SUMMARY

I. INTRODUCTION

1. The aim of this research note is to provide a general view of the case-law of certain Member States, as well ¹ as that of Switzerland, on the application of Article 3(a) of Regulation (EC) No 469/2009, concerning the supplementary protection certificate for medicinal products.
2. By virtue of that provision, one of the conditions for the grant of a supplementary protection certificate (SPC) is that the product in respect of which it is sought is protected by a basic patent in force.
3. Often, it is only at the stage of pre-marketing trials that a pharmaceutical undertaking discovers that a particular active ingredient is more effective when combined with other active ingredients. In such a case, the application for an SPC will relate to a combination of active ingredients which have not been expressly referred to in the claims for the basic patent. The courts must then deal with the issue of how to interpret Article 3(a) of the regulation, in view of the divergence between the basic patent and the SPC. ²
4. In general terms, the case-law of the Member States has followed developments in the Court's case-law in this field. From the use, in some cases, of the infringement test, ³ under which a basic patent protects an active ingredient if that ingredient would infringe the basic patent, it has moved towards a claims test deriving, in particular, from the judgment in *Medeva*, of 24 November 2011, C-322/10 ('the

¹ Contributions have been produced for the following Member States: Germany, Belgium, Bulgaria, Spain, France, Greece, Hungary, Ireland, Italy, the Netherlands, Poland, the Czech Republic, the United Kingdom, Sweden. Romanian case-law has been analysed for the purposes of the summary.

² Brückner, C., *Patent- und zulassungsrechtliche Voraussetzungen der Erteilung ergänzender Schutzzertifikate für Arzneimittel*, GRUR International, 2012, pp. 300 and 301.

³ According to some jurists, such use of the infringement test was based on the judgment in *Farmitalia*, C-392/97. See Brückner, C., *Patent- und zulassungsrechtliche Voraussetzungen der Erteilung ergänzender Schutzzertifikate für Arzneimittel*, GRUR International, 2012, p. 300, paragraph 4.

judgment in *Medeva*').⁴ In that judgment it was held that the issue of whether the basic patent protects an active ingredient is to be determined on the basis of a strict interpretation of the claims of the basic patent. It may be recalled however that in its recent case-law, particularly the judgment of 12 December 2013, *Eli Lilly*, C-493/12, the Court has introduced criteria allowing for greater flexibility in the interpretation of the claims of the basic patent. Under that judgment, the basic patent is considered to protect the product specified in the SCP if it was disclosed in the claims (the disclosure test – see Part IV below). The interpretation of Article 3(a) of Regulation (EC) No 469/2009 in national case-law has also been influenced, to some extent, by the judgment of 12 December 2013, *Actavis*, C-443/12,⁵ which refers to the inventive advance embodied in the basic patent, albeit without holding that Article 3(a) of the regulation is to be interpreted on the basis of that criterion.

5. This summary will set out the various tests which are applied in the national legal systems and which, to a great extent, reflect developments in the Court's case-law, these being the infringement test (section II below), the claims test (section III), the disclosure test (section IV) and the inventive advance test (V).

II. THE INFRINGEMENT TEST

6. On a broad interpretation of Article 3(a) of Regulation (EC) No 469/2009, the protection of the basic patent referred to in that provision is available only if the

⁴ See the judgment in *Medeva*, paragraph 25: 'Article 3(a) of Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products must be interpreted as precluding the competent industrial property office of a Member State from granting a supplementary protection certificate relating to active ingredients which are not specified in the wording of the claims of the basic patent relied on in support of the application for such a certificate'.

⁵ See the development of the inventive activity test in one strand of the **United Kingdom** case-law, described in section V.

basic patent would have been infringed by the product in respect of which the SCP is sought (infringement test).

7. The effect of the infringement test is that protection extends to any product containing a number of active ingredients capable of infringing the patent, even if it also contains an active ingredient which was not expressly mentioned in the wording of the claims of the basic patent.⁶ The scope of protection of the patent may go beyond the claims and include imitations as well as reproductions.⁷
8. The approach taken in the **Swiss** case-law is still expressly based on the infringement test, as has been recently confirmed. The Federal Patent Court has rejected an approach based on the claims or the disclosure test (both of which are described below). It considered the Court's case-law and concluded, with particular reference to the judgment in *Medeva*, that it should not be applied in Switzerland.⁸
9. Turning to the courts of Member States of the Union, until the judgment in *Medeva* they had applied the infringement test in certain cases. In **Belgium** for example, the Anvers Commercial Court had held, on the basis of the judgment in *Farmitalia*, C-392/97, that a medicinal product was protected by the basic patent if the combination referred to in the SPC was capable of amounting to infringement of the patent.⁹ The Belgian court considered that the infringement test offered greater legal certainty than there would be under a more restrictive application of Article 3(a) of the regulation, which might lead to 'artificial patent

⁶ Brückner, C., Patent- und zulassungsrechtliche Voraussetzungen der Erteilung ergänzender Schutzzertifikate für Arzneimittel, GRUR International, 2012, pp. 300 and 301.

⁷ See the judgment of the Swiss Federal Administrative Court of 18 August 2011, B-3245/2010; paragraph 5.2 (Panitumumab).

⁸ Swiss Federal Patent Court, judgment of 3 October 2017, O2017_001, paragraph 35.

⁹ Antwerp Commercial Court, judgment of 13 May 2011, IRDI 2012, p. 42, note by Weynants, L., and Weyne, L.

drafting’, with patent applicants referring to a series of combined treatments in order to avoid issues of interpretation.

10. In the **United Kingdom**, until delivery of the judgment in *Medeva*, two approaches to the interpretation of Article 3(a) of Regulation (EC) No 469/2009 had been established, one based on the infringement test and one on the claims test (as to which, see below).
11. In **France**, the infringement test had been rejected in the case-law before the judgment in *Medeva*.¹⁰
12. In **Germany**, the Federal Patent Court has observed that the direction of national case-law in this field has been altered by the judgment in *Medeva* and the Order of 25 November 2011, *University of Queensland* (C-630/10), and that the assessment can no longer be made by reference to the scope of protection of the basic patent.¹¹

III. THE CLAIMS TEST

13. On a narrower approach, the requirement that ‘the product is protected by a basic patent in force’ is interpreted as meaning that all the active ingredients in the medicinal product must have been expressly mentioned in the claims for the patent in question (the claims test).

¹⁰ Paris Court of Appeal, judgment of 19 January 2005, No 04/14435, *Abbott Laboratories v Director of INPI*, available at: <https://www.darts-ip.com/>: ‘the consequences in terms of infringement which have been relied on by the applicant being inoperative as regards the grant of SPCs’.

Paris Court of Appeal, judgment of 6 November 2009, No 09/06530, *Daiichi Sankyo Company v Director of INPI*: JurisData No 2009-017789: ‘it does not assist [the applicant] to argue that the combination in question has the same characteristics as claim 5; the question is whether that combination is protected by the patent and not whether it infringes it’.

¹¹ Federal Patent Court, judgment of 2 May 2012, 3 Ni 28/11 (*Ranibizumab*). In that case, however, the Federal Patent Court observed that the SPC would not have been granted even if the infringement test had been applied, given that under the national case-law, the active ingredient in question did not fall within the scope of protection of the basic patent.

14. The effect of the claims test is that a combination of active ingredients in respect of which an SPC is sought cannot be regarded as being protected by the basic patent if the claims for that patent do not specify that combination of active ingredients.
15. The **Greek** courts take this approach to the interpretation of Article 3(a) of Regulation (EC) No 469/2009.¹² An SPC is only granted to a product where the active ingredient or ingredients are specified in the wording of the claims of the basic patent. The claims test is also used in **Romanian** case-law of 2012 and 2013.¹³
16. In the **Czech Republic**, the decision-making practice of the Intellectual Property Office also seems to be based on a restrictive interpretation of Article 3(a) of Regulation (EC) No 469/2009. Once again, the main criterion is whether the product in question is referred to in the claims of the basic patent. The application of Article 3(a) of the regulation has not yet been considered by the Czech courts, however.
17. The French courts apply the claims test.¹⁴ The Paris Court of Appeal has, notably,

¹² ΣτΕ 1905/2012 (Council of State) NOMOS, ΣτΕ 737/2014 (Council of State), NOMOS.

¹³ See the judgments of the Bucharest Court of Appeal of 4 December 2012, No 2608, and of 23 April 2013, No 982.

¹⁴ Paris Court of Appeal (CA), judgment of 19 January 2005, No 04/14435, *Abbott Laboratories v Director of INPI*, available at: <https://www.darts-ip.com/>, Paris CA, 9 April 2008, No 07/15741, *Health Research v Director of INPI*: JurisData No 2008-362305 and Paris CA, 6 November 2009, No 09/06530, *Daiichi Sankyo Company v Director of INPI*: JurisData No 2009-017789. The latter judgment led to a judgment of the Court of Cassation staying the proceedings pending the outcome of references for preliminary rulings in *Medeva* (C-322/10) and *Daiichi Sankyo* (C-6/11): Cass. com., 10 May 2011, No 10-13.882, *Daiichi Sankyo v Director-General of INPI*: JurisData No 2011-008683. On 10 July 2012, after the Court of Justice had given judgment in those matters, the appellant discontinued the proceedings.

rejected an interpretation of the judgment in *Medeva* based on the perspective of a person skilled in the art.¹⁵

IV. THE DISCLOSURE TEST

18. Under the disclosure test, the product is required to have been disclosed in the basic patent in order to be regarded as being protected¹⁶ A product can be regarded as having been disclosed if it can be identified in the claims of the basic patent. The disclosure test differs from the claims test in that it is not tied to a strictly literal interpretation of the wording of the claims.
19. The courts of the Member States apply the disclosure test following the judgment in *Eli Lilly*. For the sake of completeness, it may be recalled that in that judgment the Court, which was dealing with a patent issued by the European Patent Office, held that it is sufficient for the active ingredient in question to be ‘covered by a functional formula in the patent claims ... 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 [European Patent

¹⁵ Paris CA Paris, Div. 1, Ch. 2, 23 May 2013, Nos 12/16012 and 12/16016: ‘whereas the interpretation of the *Medeva* case-law advocated by the Sanofi companies is not pertinent having regard, in particular, to the wording of the decisions given and the objective of harmonisation pursued by the European legislature.’

In its judgment of 15 August 2010 4a O 109/12 (*Irbesartan*), which concerned the same basic patent, the Düsseldorf Regional Court held that an SCP could be granted. The claims at issue used the general term ‘Diuretikum’ rather than the name of the active ingredient, ‘HTC’. Nevertheless, on the facts of that case the Regional Court held that a person skilled in the art would understand that the general term referred to the active ingredient in question.

¹⁶ This is now the prevailing test in most of the Member States: Germany, Bulgaria, Hungary, Spain, Italy, the Netherlands, Poland, the United Kingdom and Sweden.

Convention] and the Protocol on the interpretation of that provision,¹⁷ that the claims relate, implicitly but necessarily and specifically, to the active ingredient in question, which is a matter to be determined by the referring court’.¹⁸

20. The Protocol on the Interpretation of Article 69 of the European Patent Convention (EPC) introduces the perspective of a person skilled in the art as a tool for the interpretation of the claims of the basic patent, without making it a test in the full sense.
21. The effect of the disclosure test is that a combination of active ingredients in respect of which an SPC is sought cannot be regarded as being protected by the basic patent if that combination cannot be identified in the claims for that patent.
22. In **Germany**, the Federal Patent Court interprets the judgment in *Eli Lilly* as meaning that the active ingredient in question must be described in sufficiently concrete terms in the claims, if it is to be regarded as falling within the ‘subject matter of the patent’.¹⁹ In that context, the Federal Patent Court emphasises the difference between the subject matter of the patent (*Schutzgegenstand*) and its

¹⁷ See the Protocol on the Interpretation of Article 69 of the European Patent Convention (EPC) of 5 October 1973, as revised by the Act revising the EPC of 29 November 2000: ‘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. Nor should it be taken to mean 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 patent proprietor has contemplated. On the contrary, it is to be interpreted as defining a position between these extremes which combines a fair protection for the patent proprietor with a reasonable degree of legal certainty for third parties.’

¹⁸ See the judgment in *Eli Lilly*, C-493/12, paragraph 39 and operative part.

¹⁹ See the order of the Federal Patent Court of 17 October 2017, 14 W (pat) 12/17, paragraphs 5 and 8, available at: <http://juris.bundespatentgericht.de/cgi-bin/rechtsprechung/document.py?Gericht=bpatg&Art=en&sid=a7224e8875e7ebb07d6175c3aaf1974d&nr=29346&pos=0&anz=1&Blank=1.pdf>.

scope of protection (*Schutzbereich*). According to that court, Article 69 EPC serves to determine not only the scope of protection of the patent, but also its subject matter.²⁰ It is worth noting that the Federal Patent Court rejected the argument, advanced by the applicant in the main proceedings, that under the judgment in *Eli Lilly*, the outcome depended on the inventive advance test (as to which see below), on the basis that in its view, it was the subject matter of the patent, and not the scope of protection, that played the decisive role.²¹

23. One strand of the **United Kingdom** case-law interprets the criteria established in the judgment in *Eli Lilly* as meaning that a product is to be regarded as protected, for the purposes of Article 3(a) of Regulation (EC) No 469/2009, if it is within the scope of the claims. The product will be protected if, following an examination of the wording of the claims, which must take in any general terms enlarging their scope, such as ‘comprising’, it falls within the scope of the claims.²² As to the level of detail required, the High Court doubted that a functional definition could be sufficient, expressing its preference for a structural definition. It was hard, for example, to imagine how a particular antibody could be identified in the claims as

²⁰ See paragraph 7 of the order of the Federal Patent Court referred to in footnote 20 above.

²¹ To that extent, the Federal Patent Court takes a contrary position to the High Court of England and Wales.

²² *Eli Lilly & Co Ltd v Human Genome Sciences Inc* [2014] EWHC 2404 (Pat), paragraph 66: ‘The proviso relates to products which are combinations of active ingredients and is necessary to reflect the Medeva approach where the claims contain some general word or words extending their extent beyond the principal scope of the claims, typically by the use of a word such as “comprises”. In the absence of such an extending word, the claims have a focused scope and the question is simply whether the product falls within the scope of the claims. In the language of Medeva, the question is whether the product (i.e. the combination of active ingredients) is “specified” in the claims, a question which is answered by a close examination of the claims. If general words are included, the position is different. The product does not fall within the focus of the claims and is not within its scope apart from the general words. In such a case, the product is not “specified” any more than it is “specified” where the general words are absent.’

falling within a class of antibodies by a purely functional definition, without reference to a structural description.²³

24. In **Bulgaria**²⁴ and **Hungary**²⁵, the courts have had occasion to consider whether a combination of three active ingredients, covered by the SCP application, was protected by the basic patent, in circumstances where only two of those active ingredients were mentioned in the claims. They considered whether the claims of the basic patent implicitly extended to the active ingredients referred to in the SCP application and, on that basis, held that the condition in Article 3(a) of Regulation (EC) No 469/2009 was not fulfilled. In **Bulgaria**, in a more recent judgment, the Supreme Administrative Court has affirmed the central importance of the claims in determining whether a product is protected by a basic patent.²⁶ In the case in question, the claims described the function and therapeutic effect of the active ingredients to which the SCP application related. The Supreme Administrative Court concluded that the active ingredients were covered by the functional formulation in the claims and held that the condition in Article 3(a) of Regulation (EC) No 469/2009 was fulfilled.

²³ *Eli Lilly & Co Ltd v Human Genome Sciences Inc* [2014] EWHC 2404 (Pat), paragraph 72: ‘The Court states that, in principle, a functional definition can be sufficient. It is not likely that the Court, in saying that, intended the test to be so high that it would be impossible or virtually impossible in practice for an active ingredient ever to be sufficiently indicated by a functional definition alone. If it is necessary to go beyond the claims (interpreted in the light of the description as required by Article 69) and to find in the description something which identifies the active ingredient in some detailed way, I find it hard to imagine what that “something” could be other than a structural description and hard to imagine how a particular antibody within a class of antibodies which are claimed by the claims could be identified individually by a purely functional definition. The Court surely cannot have been saying that functional definitions in the claims are good enough in principle but only if the description contains some sort of structural definition.’

²⁴ See the judgment of the Supreme Administrative Court of 6 August 2014, No 10607.

²⁵ See the judgment of the Supreme Administrative Court of 22 March 2017, 3. Pfv.IV.21.502/2016/3.

²⁶ See the judgment of 23 June 2016, No 7647.

25. The **Spanish** courts also apply the criteria established by the Court in the judgment in *Eli Lilly*.²⁷ In relation for example to a combination of active ingredients which was covered by the SCP application, but had not been expressly mentioned in the claims, the High Court of Justice of Madrid held that such a literal interpretation of the claims was not the only possible approach to their interpretation. If, on analysis of the function of the active ingredient specified in the SCP, it could be seen to have the same manner of action as the active ingredient expressly specified in the claims, it could be regarded as being protected by the basic patent.²⁸
26. In **Ireland**, the High Court set out the approach to be taken in its judgment in *Novartis v. The Controller of Patents, Designs and Trademarks*.²⁹ Like the Supreme Court,³⁰ the High Court held that the interpretation of a patent is a question of law and took a purposive approach to the interpretation of the claims. In that regard, it held that the interpretation of the claims could not rest entirely on the words used, but had to take account of the way in which those words would be understood by the audience to whom the claims were addressed, made up of persons experienced in the field. The emphasis was thus on the understanding of persons skilled in the art, who were experienced in the field, rather than the intention of the person who had drafted the claims.

²⁷ Judgments of the Supreme Court of 29 May 2015, No 2402/2015; of the Madrid High Court of Justice of 9 September 2016, No 639/2016; of the Supreme Court of 15 December 2014, No 5145/2014, and of the Valencia High Court of Justice of 29 October 2016.

²⁸ Judgment of the High Court of Justice of Madrid of 9 September 2016, No 639/2016.

²⁹ [2007] IEHC 442, not published.

³⁰ *Ranbaxy Laboratories Limited v Warner Lambert Co.* [2006] 1 IR 193: 'A patent specification should be given a purposive construction rather than a purely literal one derived from applying to it the kind of meticulous verbal analysis in which lawyers are too often tempted by their training to indulge. The question in each case is: whether persons with practical knowledge and experience of the kind of work in which the invention was intended to be used, would understand that strict compliance with a particular descriptive word or phrase appearing in a claim was intended by the patentee to be an essential requirement of the invention so that any variant would fall outside the monopoly claimed, even though it could have no material effect upon the way the invention worked.'

27. The same applies in **Sweden**,³¹ the **Netherlands**,³² and **Italy**,³³ where the Courts attach particular weight to the perspective of a person skilled in the art. The decisive factor in determining whether the product was disclosed in the claims is whether the claims are liable to be understood in that way by a person skilled in the art, or whether it would be obvious to a person skilled in the art that the claims designate the product in question. In the Swedish and Dutch cases, the judges refer expressly to the judgment in *Eli Lilly*.
28. In **Poland**, the courts interpret the claims strictly, but try nonetheless to go beyond the literal interpretation. In relation to an application for an SCP including the active ingredient solifenacin, which had not been mentioned in the claims of the basic patent, the Warsaw Regional Administrative Court held that the active ingredient was covered by the basic patent, given that the claims referred to chemical structures corresponding to that of solifenacin.³⁴ In another judgment, the same court referred to the inventive advance as a criterion to be used in making the assessment.³⁵ The basic patent in question related only to products obtained directly through the use of the invented method, which were benzimidazoles and their salts, including telmisartan and its salts. The court observed that the administration of the product consisting of a combination of telmisartan and hydrochlorothiazide led to a greater reduction in blood pressure than could be achieved by either of the active ingredients administered separately. The combination was therefore a technical solution to a different problem from that identified in the patent for benzimidazoles. Accordingly, the court held that

³¹ For example, the judgment of the Patentbesvärärätten of 30 November 2015, No 13-57.

³² Rechtbank Den Haag, judgment of 19 July 2017, available at: [ECLI:NL:RBDHA:2017:8031](https://eclis.nl/ECLI:NL:RBDHA:2017:8031).

³³ Milan District Court, judgments of 22 and 29 December 2012; 6 March 2013; 20 April 2013; *Revue de droit industriel* 2013, II, p. 169.

³⁴ See judgment of the Warsaw Regional Administrative Court of 15 November 2016, VI SA/Wa 1087/16.

³⁵ See judgment of the Warsaw Regional Administrative Court of 15 September 2014, VI SA/Wa 1900/13.

an SCP could not be granted. It appears however that the courts apply the criteria referred to above on a case-by-case basis, and have not identified any general principles or further criteria.

V. THE INVENTIVE ADVANCE TEST

29. Under the inventive advance test, the condition in Article 3(a) of Regulation (EC) No 469/2009 is fulfilled where the product to which the SCP relates infringes the basic patent because it contains an active ingredient, or a combination of active ingredients, embodying the inventive advance (or technical contribution) of the basic patent. Where the product is a combination of active ingredients, the combination must embody the inventive advance of the basic patent.
30. This test is derived from the *Actavis* case referred to above, notwithstanding that the Court did not rule, in that matter, on the question concerning Article 3(a) of Regulation (EC) No 469/2009, but only on the question concerning Article 3(c) of that regulation.³⁶
31. One strand of the **United Kingdom** case-law applies the test of whether the product in respect of which the SCP is sought embodies the inventive advance of the basic patent.³⁷ The inventive advance test is not intended to refine the interpretation of the claims but to identify the substance of the patent.
32. The inventive advance test differs from the infringement test in that it involves identifying, as a first step, the core inventive advance of the basic patent, and then determining whether it is embodied by the active ingredient or combination of

³⁶ In paragraph 41 of its judgment in *Actavis*, C-443/12, the Court stated that ‘it should be recalled that the basic objective of Regulation No 469/2009 is to compensate for the delay to the marketing of what constitutes the core inventive advance that is the subject of the basic patent’.

³⁷ *Teva UK Ltd and Others v Gilead Sciences Inc.* [2017] EWHC 13 (Pat), paragraph 83.

active ingredients in question. The infringement test is broader in that it is satisfied if the active ingredient or combination of active ingredients in question relate to an essential element of the invention which is intended to implement that invention. Nevertheless, it is conceivable that these two approaches may lead to the same outcome.

VI. CONCLUSION

33. While, until the judgment in *Medeva*, the courts of certain legal systems sometimes applied the infringement test, the current position, following that judgment and the judgment in *Eli Lilly*, is that the disclosure test is applied by the courts of most of the Member States considered. The claims test is applied in **France** and **Greece**, and also, to judge from the available decisions, in the **Czech Republic** and **Romania**.
34. It is to be noted however that a further criterion has emerged in one strand of the **United Kingdom** case-law, and that this is not based on the interpretation of the claims, but on a comparison between the claims and the inventive advance described in the SCP application.
35. The **Swiss** courts have expressly rejected the claims test and the disclosure test, and continue to apply the infringement test.

[...]