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Validity of supplementary protection certificates (SPCs): French and European clarifications

A ruling by the interim judge of the Paris Court of First Instance of 5 April 2018, against the background of the opinion of the Advocate General of the EUCJ of 25 April 2018, on the same subject, have provided some clarification on the validity of SPCs.

Supplementary protection certificates (SPC) are governed by the Regulation (EC) no. 469/2009 of 6 May 2009, of the European Parliament and Council concerning the supplementary protection certificate for medicinal products (hereafter the "EC Regulation no. 469/2009").

The system implemented by the EC Regulation no. 469/2009, in particular its article 3 concerning the conditions for obtaining a SPC[1], has caused difficulties in interpretation since its creation.

One of the main sources of divergence among judges resides in article 3(a) of the EC Regulation no. 469/2009, according to which a SPC is only granted if it covers a product[2] "*protected*" by the basic patent. The difficulty in determining the notion of "*protection*" by the basic patent is explained by the "*tension*"[3] that exists the rules relating to the extent of the patented invention and, on the other hand, those related to patent infringement[4].

In light of the abundant litigation in the matter and a varied application of the Regulation by the domestic courts, the intervention of the Court of Justice to set the extent of the protection of the basic patent became indispensable. Step by step, EU case law has delivered the keys to interpreting article 3 of the EC Regulation no. 469/2009. It has done so however by using generic terms that grant a margin of appreciation to the domestic courts.

It is in this context that the French judge recently had the opportunity provide further clarification on medicaments and SPCs, in an interim ruling of 5 April 2018[5] of the Paris Court of First Instance.

Paris TGI, 5 April 2018 *Merck vs MSD*: context

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[1] *The certificate is 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;
b) a valid authorisation to place the product on the market as a medicinal product has been granted in accordance with Directive 2001/83/EC or Directive 2001/82/ EC, as appropriate;
c) the product has not already been the subject of a certificate;
d) the authorisation referred to in point (b) is the first authorisation to place the product on the market as a medicinal product.

[2] *The "product" is defined in article 1(b) of the EC Regulation no. 469/2009 as being "the active ingredient or combination of active ingredients of a medicinal product".*

[3] *EUCJ, Opinion of the Advocate General Mr Melchior Wathelet, 25 April 2018, case C-121/17, Teva UK Ltd, Accord Healthcare Ltd, Lupin Ltd, Lutin (Europe) Ltd, Generics (UK) trading as 'Mylan' v/ Gilead Sciences Inc., §63*

[4] *A simple and explicit illustration given in the Truvada case by the Advocate General of the Court of Justice, Mr Melchior Wathelet, provides a better understanding of this distinction:*
"A medicinal product composed of active ingredients A+B would infringe a patent and give rise to infringement proceedings even if the claims of the patent related only to active ingredient A. On the other hand, it is clear that active ingredient B, which is not specified anywhere in the claims, does not fall within the extent of the invention and is not 'protected' by the patent in question" (EUCJ, Opinion of the Advocate General Mr Melchior Wathelet, 25 April 2018, cited above, §59 and 60).

[5] *Paris TGI, interim measures order, 5 April 2018, GR no. 18/52397*

The ruling relates to a dispute between Merck Sharp & Dohme Corp. and MSD France (hereafter together "MSD") and Biogaran on the validity of the SPC obtained by MSD for the medicinal product INEGY.

On 14 September 1994, MSD filed an application for the delivery of EP 0 720 599. This patent, entitled "*hydroxy-substituted azetidinone compounds useful as hypocholesterolemic agents* ", was granted on 19 May 1999. It claims in particular ezetimibe (alone and in combination with statins), an active ingredient used in the treatment of atherosclerosis and cholesterol reduction.

On the basis of this patent and a marketing authorization (MA) granted on 11 June 2003 in France for the medicament ZETROL containing ezetimibe as the sole active ingredient, MSD obtained a first SPC for this active ingredient, called the "ezetimibe SPC". The SPC was delivered on 4 February 2005 and expired on 17 April 2018[6].

On 28 July 2005, MSD obtained a MA in France for a combination of ezetimibe with simvastatin for the medicament INEGY, on the basis of which MSD obtained a second SPC for this combination, called the "combination SPC". The latter was granted on 21 December 2006, with an expiry date of 2 April 2019.

For its part, Biogaran, which produces generic medicinal products, fulfilled all the steps for the marketing of the speciality EZETIMIBE/SIMVASTATIN, intended for launch before the expiry of the "combination SPC".

In this context, MSD summoned Biogaran to an interim hearing on 15 February 2018, to seek a ruling of imminent infringement of the "combination SPC" and to order interim measures. For its part, Biogaran challenged the validity of this SPC on the ground that it does not meet the delivery conditions of a second SPC from a same basic patent.

Clarification of the criteria set out by CJEU case law

In a remarkably didactic wording, the French ruling provided some welcome clarification

The court provides a thorough synopsis of the critera relied upon by the Court of Justice interpreting EC Regulation no. 469/2009. More specifically the court recalls that in order to obtain a second SPC on the basis of the same basic patent [7], two conditions must be met cumulatively:

- the product must be specified as such in the claims of the basic patent, and
- the product must be the core of the invention[8].

A product specified in the basic patent: the key role of the claims

The precursor judgment - as the commented ruling highlights - that points out the importance of the claims in the determination of what is "protected" by the basic patent in the meaning of article 3 of the EC Regulation no. 469/2009 is the *Medeva*[9] ruling, shortly followed by *Daiichi*[10], *Yeda*[11] and *Queensland*[12]. All of these judgments confirmed the necessity of an explicit specification of the active ingredients in the claims of the basic patent. In other words, an active ingredient is only "protected" by the basic patent in the meaning of article 3(a) of the EC Regulation no. 469/2009 if it is *"specified in the wording"* of its claims.

The court continues, in its case law history, with the judgment *Eli Lilly*[13]. In the latter, the Court of Justice specified what it meant by *"specified in the wording of the claims"*. According to it, it is not necessary that the product is specified by means of a structural formula. The active ingredient may be described by claims in a purely functional manner, on the condition that it is defined (i) implicitly, (ii) but necessarily and (iii) specifically. The Court however remains vague as to where to place the cursor to consider that an active ingredient is described in a sufficiently "specific" manner so as to fall under the scope of article 3(a) of the EC Regulation no. 469/2009.

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[6] *By having obtained an extension of six months on the basis of article 36, I of the EC Regulation no. 1901/2006 of the European Parliament and Council of 12 December 2006 on medicinal products for paediatric use.*

[7] *On this point, one recalls that in the judgment Georgetown of the Court of Justice (EUCJ, 12 December 2013, case C-484/12, Georgetown University v/ Octrooicentrum Nederland), the latter held that several SPC could be obtained on the basis of one and the same basic patent, when the latter protects each product subject matter of each SPC.*

[8] *"However, to obtain a second SPC from the same basic patent, the combination must not only be specified as such in a claim, it must also be in itself the core of the invention" (Paris District Court, interim ruling, 5 April 2018, cited above, p. 12).*

[9] *EUCJ, 24 November 2011, case C-322/10, Medeva BV v/ Comptroller General of Patents*

[10] *EUCJ, 25 November 2011, case C-6/11, Daiichi Sankyo*

[11] *EUCJ, 25 November 2011, case C-518/10, Yeda Research and Development Company and Aventis Holdings*

[12] *EUCJ, 25 November 2011, case C-630/10, University of Queensland and CSL*

[13] *EUCJ, 12 December 2013, case C-493/12, Eli Lilly and Company Ltd v/ Human Genome Sciences Inc.*

In the French ruling, this first condition does not create any difficulty to the extent that the active ingredients subject matter of the SPC in question are specified explicitly in the basic patent[14]. The court therefore does not provide any detail on the degree of specificity to be used in case of an implicit specification of the active ingredient in the claims.

But what happens when the product is described *implicitly* in the claims? It would seem that the key for interpretation resides in *"the wording or the interpretation of the wording of the claims of the granted patent"*[15]. The Advocate General of the Court of Justice, Mr Melchior Wathelet, argues that *"a product is protected by a patent within the meaning of Article 3(a) of Regulation No 468/2006 if, on the priority date of the patent, it would have been obvious to a person skilled in the art that the active ingredient in question was specifically and precisely identifiable in the wording of the patent claims. In the case of a combination of active ingredients, each active ingredient must be specifically, precisely and individually identifiable in the wording of the patent claims.[16]"* According to him, *"the name of the active ingredient or its chemical composition does not need to be referred to expressly in the claims. [17]"*

A product at the core of the invention

By referring in particular to two judgments of the EUCJ, the French judge recalls that a product falls under the scope of protection of the basic patent is a necessary but not sufficient condition. To constitute a product protected by a patent in the meaning of article 3(a) of the EC Regulation no. 469/2009, it must also constitute "the subject matter of the invention".

In fact, *Sanofi*[18] set out the principle that the product "protected" by the basic patent is that which constitutes *"the core inventive advance"*, *"the heart of the inventive activity subject matter of the patent"*. In the same sense, *Boehringer*[19] added that the active ingredient that may be subject to an SPC must constitute "*the subject matter of the invention"*.

In the commented case, the court rules that the combination SPC does not fulfil the second condition, that it does not meet the *"additional criteria defined by the EUCJ that requires that the claim related to the combination reveals the core of the invention"*[20]. In this case, it would have been required that the combination ezetimibe/simvastatin constitutes in itself a separate invention at the core of the basic patent.

To achieve this result, the court operates two distinctions in its reasoning:
- a first distinction between the "combination" of active ingredients and their simple "juxtaposition". In this case, each active ingredient is independent and does not require the *"implementation of the other to operate"*;
- a second distinction between a "new" combination and a combination "subject matter of the invention". In fact, a combination may fulfil the criteria of novelty concerning its patentability, without however constituting the core of the invention in the meaning of EU case law.

In this case, the basic patent does not propose any test for the combination of ezetimibe and simvastatin, and *"does not reveal any advantage in taking ezetimibe and simvastatin in the same pill compared to taking a medication containing only ezetimibe and another medication containing only simvastatin."*[21]

This ruling gives a concrete illustration at a national level, of the second criteria set out by the Court of Justice that requires that the product mentioned in the claims of the basic patent also constitute the core of the invention of the latter.

As has been stated, the EC Regulation no. 469/2009 has been subject to a large number of non-harmonised judgments.

At the initiative of the Commission, it is planned to introduce in the next few months an exemption on manufacturing activities (a manufacturing waiver) in relation to article 5 of the Regulation. The Commission has also planned, within a year, to propose a more in-depth review of the Regulation, in order, in particular, to ensure greater legal security. Clarifications would be welcome for all stakeholders in the sector.

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[14] *"Thus the claim 17 meets the condition set out by the EUCJ since it specifically describes simvastatin in combination with ezetimibe" (Paris TGI, interim ruling, 5 April 2018, cited above, p. 12).*
[15] *EUCJ, Opinion of the Advocate General Mr Melchior Wathelet, 25 April 2018, cited above, §72*
[16] *EUCJ, Opinion of the Advocate General Mr Melchior Wathelet, 25 April 2018, cited above, §81*
[17] *EUCJ, Opinion of the Advocate General Mr Melchior Wathelet, 25 April 2018, cited above, §82*
[18] *EUCJ, 12 December 2013, case C-443/12, Actavis v/ Sanofi*
[19] *EUCJ, 12 March 2015, case C-577/13, Actavis v/ Boehringer*
[20] *Paris District Court, interim ruling, 5 April 2018, cited above, p. 12.*
[21] *Paris District Court, interim ruling, 5 April 2018, cited above, p. 13*

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[15] *EUCJ, Opinion of the Advocate General Mr Melchior Wathelet, 25 April 2018, cited above, §72*

[16] *EUCJ, Opinion of the Advocate General Mr Melchior Wathelet, 25 April 2018, cited above, §81*

[17] *EUCJ, Opinion of the Advocate General Mr Melchior Wathelet, 25 April 2018, cited above, §82*

[18] *EUCJ, 12 December 2013, case C-443/12, Actavis v/ Sanofi*

[19] *EUCJ, 12 March 2015, case C-577/13, Actavis v/ Boehringer*

[20] *Paris District Court, interim ruling, 5 April 2018, cited above, p.* 12.

[21] *Paris District Court, interim ruling, 5 April 2018, cited above, p. 13*