Supplementary Protection Certificates (SPC)

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When the basic patent claims a class of products defined through a functional definition, the French IP Office usually considers that, if the active ingredient for which SPC protection is sought can easily be identified by one skilled in the art as being implicitly but necessarily and specifically protected by the basic patent, the SPC can be granted. **14**

This can be the case when the functional definition covers a limited number of known products. However, if the functional definition covers an active ingredient which was not known at the filing date of the SPC application, the French IP Office considers that the condition set by the *Eli Lilly* and *Medeva* decisions are not met.[6] **15**

The expected decisions of the Court of Justice in case C-650/17 (*Royalty Pharma Collection Trust*) should provide further guidance on this matter. **16**

Regarding SPCs for a combination of products, the French Supreme Court[7] considered that an SPC for the association between the antihypertensive telmisartan and the diuretic HCTZ, cannot be the subject of an SPC since there was no claim relating to such an association, but only claims for the product telmisartan alone. The fact that the patent referred to diuretics in general, in its description, but not explicitly to HCTZ, was considered as being insufficient for the SPC to be granted. **17**

When a granted patent only includes claims referring to a single active ingredient, without making reference to the association thereof with another active ingredient, an association then cannot, in principle, give rise to the granting of a valid SPC. Nevertheless, if the association is referred to in the patent description, it may be envisioned to limit the claims so that said association is identified therein. **18**

The French IP Office and Courts long refused to allow amendment of a claim relating to an active ingredient, to add to that active ingredient another active ingredient referred to solely in the patent description, considering that amendment not to be a limitation of the patent. **19**

The Supreme Court of Appeals however found that such an amendment did indeed constitute a limitation, such that in future, it should be possible to make such amendments for the purpose of obtaining an SPC for an association of active ingredients, which was not initially claimed in the granted patent.[8] **20**

But the limitation must be made when the SPC application is still pending before the French IP Office. Indeed, the Court of Appeal of Paris, which handles appeals against the decisions rendered by the French IP Office, can only decide on the facts which were presented before the French IP Office. This means that, if the limitation is made after the SPC has been rejected, the Court of Appeal cannot take the limitation into consideration.[9] **21**

An SPC sought for an association between the active ingredients ritonavir and lopinavir was rejected by the French IP Office on the grounds that the claims of the basic patent protected ritonavir alone. The Court of Appeals of Paris[10] approved the French IP Office's decision by finding that an SPC can only be granted on condition that the composition of active ingredients is protected by the basic patent "*which means that it must be claimed as such*". **22**

[6] French IP Office decisions regarding SPC applications filed by Royalty Pharma Collection Trust, 13 December 2016.

[7] Supreme Court of Appeal (Cour de Cassation), *Boehringer Ingelheim v. Directeur de l'INPI*, 26 November 2013.

[8] Supreme Court of Appeal (Cour de Cassation), *Syngenta v. Directeur de l'INPI*, 19 March 2013 [Annex A4.II.], and in the same case, Court of Appeal of Paris, 25 October 2013.

[9] Court of Appeal of Paris, *Syngenta v. French IP Office*, 30 May 2014.

[10] Court of Appeal of Paris, *Abbott Laboratories v. Directeur de l'INPI*, 19 January 2005.

23 The Court of Appeals of Paris however considered that an SPC sought for an association of active ingredients was acceptable when the claims of the basic patent protected one of the active ingredients of the association as such, in combination with a carrier, when the patent description specifies that a carrier can be any other active ingredient.[11]

24 In the *Bayer* case,[12] the claims of the basic patent protected the product flufenacet alone. The Marketing Authorization invoked in support of the SPC application had been allowed for an association between flufenacet and another active ingredient, metosulam. The SPC had been filed for the flufenacet product alone. Curiously, the French IP Office considered that the product to which the SPC was directed should not be flufenacet alone, but in fact the flufenacet + metosulam association concerned by the Marketing Authorization. The French IP Office then granted the SPC for that association, without the agreement of the applicant. The Court of Appeal of Paris found that the SPC should not have been granted with a product definition not approved by the applicant and that flufenacet alone should be protected. The decision for grant by the French IP Office was thus overturned, and the SPC re-granted for flufenacet alone.

2. Article 3(b) of the Regulation

25 According to Article 3(b) of the Regulation, in order for an SPC to be granted, it is necessary for the product to have obtained a Marketing Authorization as a medicinal product, in accordance with Directive 2001/83/EC, or Directive 2001/82/EC.

26 The Court of Appeal of Paris considered that an SPC could not be granted for an active ingredient to which the Marketing Authorization did not explicitly relate. Thus, when the Marketing Authorization concerns a salt of an active ingredient and the SPC application had been made in relation to another salt of that active ingredient, the French IP office took the position that an SPC application cannot be granted as being not in conformity with Article 3(b). It has been held that the fact that the salt concerned in the Marketing Authorization was transformed in the medicinal product into another salt, namely, the one protected by the basic patent is not sufficient. The Court of Appeal confirmed the position of the French IP Office and found that the SPC could only be granted for the salt explicitly concerned by the Marketing Authorization.[13]

3. Article 3(c) of the Regulation

27 According to Article 3(c) of the Regulation, an SPC may be granted if the product has not already been the subject of an SPC.

28 The applicant for an SPC may make reference to a Marketing Authorization of which it is the holder, or to that of its licensee. However, the French IP Office does not examine the matter of whether the holder of the Marketing Authorization has given permission to the patent proprietor to file an SPC making reference thereto. In practice, this leads to the granting of SPCs based on marketing authorizations belonging to a competitor of the SPC proprietor.

29 The question of the validity of an SPC granted on the basis of a Marketing Authorization belonging to a third party has already been raised before the French courts, but no answer has been provided by the Judge.[14] To date, it would appear that the French IP Office has not changed its practice on this question, despite the Lilly decision by the

[11] Court of Appeal of Paris, *Syngeta Participations AG v. Directeur de l'INPI*, 9 December 2005.
[12] Court of Appeal of Paris, *Bayer AG v. Directeur de l'INPI*, 10 September 2003.
[13] Court of Appeal of Paris, *Alza Corporation v. INPI*, 11 May 2011.
[14] First Instance Court of Paris, *ALK Abello A/S v. SA. Stallergènes*, 7 October 2009.

CJEU, which noted that to obtain an SPC a patent proprietor should not be able to rely on the Marketing Authorization for a medicinal product developed by a third party, otherwise the purpose of the Regulation would be undermined (point 43 of the order).

Nevertheless, in accordance with CJEU case law,[15] the French IP Office accepts to grant SPCs for the same product if they are based on different patents, belonging to distinct proprietors. **30**

The French IP Office considers that when an SPC has been granted to proprietor A or to a co-ownership including proprietor A, a second SPC for the same product cannot be granted to proprietor A, whether as sole applicant or co-applicant. French Courts have approved this position.[16] **31**

When an SPC has been granted on the basis of a patent which, later on, is revoked by the EPO or French Courts, a second SPC for the same active ingredient, in the name of the same patent proprietor, can be granted by the French IP Office. **32**

However, in such a case, the French IP Office requests that French Courts render a decision to declare that the first SPC is invalid under Article 15(1)(c) of the Regulation. French Courts already accepted to revoke a former SPC in such conditions,[17] so that a second SPC was granted to the same proprietor, for the same product. **33**

The question as to whether the active ingredient subject of a first SPC is the same active ingredient as that for the newly filed SPC application has raised specific issues for biological products. **34**

Thus, the French IP Office decided that an SPC for a truncated protein cannot be granted when a former SPC had already been granted for the full-length protein, because they were regarded as being one and the same product. In that case, the two active ingredients had the same International Non-Proprietary Name (INN). French Courts approved the position of the French IP Office.[18] This is a situation which is often met for biological products which, although they are structurally different, are authorized with the same INN. **35**

4. Article 3(d) of the Regulation

Lastly, according to Article 3(d), in order for the SPC to be granted the Marketing Authorization must be the first for the product in France. The French IP Office does examine this point, by carrying out checks with the health authorities, or, for SPCs relative to plant protection products, with the Ministry of Agriculture. **36**

In order to be considered as a first Marketing Authorization in France, the Marketing Authorization upon which the SPC is based must not be distinguished from an earlier Marketing Authorization uniquely on account of the presence of different excipients, even if those different excipients lead to a different effect for the active ingredient. What is required is for the product covered by the Marketing Authorization to consist of an active ingredient or an association of active ingredients, that is to say a product which of itself confers a therapeutic effect of its own in relation to the particular indication.[19] **37**

The French IP Office grants SPCs making reference not only to the first Marketing Authorization for the product as such, but also for later marketing authorizations granted for the same product, but for a different application, this being in accordance **38**

[15] CJEU, *AHP Manufacturing B.V. v. Bureau for Voorde Indurstriële Eigendom*, 3 September 2009, C-482/07 [Annex A1.X.].

[16] Court of Appeal of Paris, *Medeva AB v. Directeur Général de l'INPI*, 19 December 2017.

[17] First Instance Court of Paris, *SAS Novartis Pharma AG v. Directeur de l'INPI*, 5 April 2018.

[18] Supreme Court of Appeal (Cour de Cassation), *The Government of the USA v. Directeur Général de l'INPI*, 16 May 2018.

[19] First Instance Court of Paris, *ALK Abello A/S v. SA. Stallergènes*, 7 October 2009.

with the *Neurim* decision[20] of the Court of Justice. As it happens, this decision of the Court of Justice has been rapidly applied by French courts.[21]

39 Nevertheless, the question as to what a different application is, was later discussed before the Court of Appeal of Paris.[22] The Court referred this question to the Court of Justice of the European Union.[23] This is the first and sole question that French Courts referred to the Court of Justice.

40 The question as to whether or not an active ingredient has already been authorized has been particularly critical in the field of biological products. The French IP Office considers that when an SPC is applied for an active ingredient which is the subject-matter of a previous Marketing Authorization, the conditions of Article 3(d) of the Regulation are not fulfilled, even when it can be shown that, although both active ingredients have the same name, they have a different chemical structure. French Courts have approved the French IP Office's position so far.[24]

III. Grant Procedure for SPCs in France

41 In order to obtain the grant of an SPC by the French IP Office, the applicant must file an application for grant and pay a filing fee.[25]

42 The application must include the following information:
- the identity of the basic patent,
- the date and number of the Marketing Authorization in or for France and, if applicable, the date and number of the Marketing Authorization in the European Economic Area,
- the International Non-proprietary Name (INN) of the product for which the protection is sought,
- the name and the address of the SPC applicant,
- as may be required, the link between that product and the basic patent.

43 It is also important for the SPC applicant to be the true proprietor of the basic patent. The Court of Appeal of Paris indeed found that an SPC could not be asserted if it had been filed by the former proprietor of the basic patent, even if the latter was the proprietor registered on the National Register of Patents.[26]

44 When a patent is assigned, it is also recommended that the assignment be registered on the National Register of Patents in order for the SPC application to be filed in the name of the registered proprietor.

45 The SPC application is published within a short period (generally 3 to 4 weeks) of its filing date.

46 The SPC application is examined by an examiner of the French IP Office for its conformity with the provisions of Article 3 of the Regulation. Formal objections may also be raised by the Examiner. The SPC applicant is given a period of two months from the date of reception of notification by the examiner of those objections to file its

[20] CJEU, *Neurim Pharmaceuticals v. Comptroller General of Patents*, C-130/11 [Annex A1.XX.].
[21] Court of Appeal of Paris, *Merck v. Directeur Général de l'INPI*, 15 February 2013 [Annex A4.IV.].
[22] Court of Appeal of Paris, *SAS Santen v. Directeur Général de l'INPI*, 9 October 2018.
[23] CJEU, Santen SAS, C-673/18.
[24] Court of Appeal of Paris, *SA Laboratoire Français du Fractionnement et des biotechnologies v. Directeur Général de l'INPI*, 20 January 2017 and *Loyola University of Chicago v. Directeur Général de l'INPI*, 19 December 2017.
[25] On 15 February 2020, this fee amounts to 520 Euros.
[26] Court of Appeal of Paris, *Laboratorios Almirall S.A. v. Mylan S.A.S.*, 25 November 2009.

arguments or to make the required amendments to the request for grant. This time limit can be extended by two further months upon request.

The examiner may raise objections as to the definition of the product, in particular in relation to its conformity with the product name in the Marketing Authorization. **47**

The French IP Office attaches importance to the product name as given in the Marketing Authorization, even though a certain degree of latitude is given. Thus, if the product in the Marketing Authorization is a product in its free form, it is generally authorized to define the product of the SPC not only as the free form, but also in the form of one of its derivatives, for example its salts and its esters, provided that those forms are protected by the basic patent. **48**

It is possible to amend the definition of the product in response to an examiner's objection. **49**

If the examiner considers that the response of the applicant to his objections is insufficient, he then issues a draft decision to reject the SPC application. A period of two months, extendable by two further months, is given to the applicant to reply to the objections raised in the draft rejection decision. If, once again, the examiner considers that his objections remain founded despite the applicant's arguments, a rejection decision is issued. **50**

It is possible to appeal to the Court of Appeal of Paris against rejection decisions of the French IP Office within one month, extended by two months for foreign entities. The decision of the Court of Appeal may itself be submitted to the authority of the Supreme Court of Appeal. **51**

Appeals against decisions by the Director of the French IP Office do not have the character of a full rehearing. Thus, the Court of Appeal will rule on the basis of the same documents as those produced during the examination procedure of the SPC, without, in principle, any possibility of adding thereto. **52**

Particular proceedings have been implemented for all SPCs filed as from 12 November 2014. Thus, the French IP Office must take a position on such an SPC application within one year from its filing date. If no decision is taken during this period of time, the SPC application is deemed refused (Articles R.617-2–1 and R.617-2–2). **53**

However, the one-year period of time is interrupted if the French IP Office raises an objection. In such a case, the one-year period resumes in full as from the date when a reply has been made to the objection raised by the Examiner. **54**

This new rule has implications for the examination procedure. Thus, French SPC applications are rapidly examined. In addition, it is currently not possible to obtain a suspension of the procedure for an SPC application until events which could affect the outcome of the SPC are expected, such as ongoing opposition proceedings on the basic patent or a decision expected from the Court of Justice. **55**

There are no provisions in the IP Code for third party observations against an SPC application. The French IP Office therefore considers that such third-party observations are not admissible. Nevertheless, such observations are filed, and the French IP Office forwards them to the SPC applicant, purely by way of information. The observations do not form part of the publicly accessible file. **56**

The French IP Office generally manages to grant or reject SPC applications before expiry of the basic patent. However, it is possible for the French IP Office's decision to be reached after expiry of the patent. **57**

IV. Scope of Protection

58 According to Article 4 of Regulation 469/2009, the protection conferred by the basic patent extends to the product, covered by the authorization to place the medicinal product on the market and for any use of the product as a medicinal product that has been authorized before the SPC expiry date.

59 According to Article 5, regarding the effect of the certificate, and subject to the provisions of Article 4, the certificate shall confer the same rights as conferred by the basic patent and shall be subject to the same limitations and the same obligations.

60 The rights conferred by a patent in France are provided by Article L.613-3 and L.613-4 CPI. According to Article L.613-3 CPI, save the content of the patent proprietor, the following acts are forbidden: manufacture, offer, putting on the market, use, importation, exportation, transshipment, or the holding for seas purposes the product subject of the patent.[27]

Article L.613-4 CPI relates to contributory infringement.

61 As Article 5 of the regulation provides that the certificate confers the same rights as the basic patent, one should have thought that the above-mentioned act of infringement provided by French law also applies to SPCs. However, French Courts, in several decisions, have considered that the rights afforded by SPCs should be limited to offering and putting on the market the product, but not the other acts of infringement, which are forbidden with respect to patents.[28] This narrow construction of the regulations provisions was not followed in another case.[29] The Court of Appeal of Paris indeed considered that the infringer was forbidden to manufacture, offer, put on the market, use, import and hold generic medicaments protected by an SPC. These latter decisions seem to be more consistent with the wording of Article 5 of Regulation 469/2009.

62 Furthermore, it is now clear that in France, the scope of protection of an SPC granted for a product A extends to any medicament containing product A and any other active substance. This was clarified by the French Supreme Court[30] in perfect consistency with the CJUE caselaw.[31]

V. Duration of SPCs

63 The French IP Office determines the term of SPCs in two different manners. When the SPC has a term of less than five years, the French IP Office considers that its date of expiry falls on the anniversary of the Marketing Authorization. When the term of the SPC is five years, the French IP Office considers that its expiry falls on the day before the anniversary of the filing date of the patent. This difference in calculation has not given rise to any decision by a French court.

64 The decision to grant an SPC may be the subject of an appeal by third parties, if the date of the first Marketing Authorization in the EEA, indicated in the granted SPC,

[27] Article L.613-3 CPI was amended on 11 March 2014 to add, among the act of infringement, exportation and transshipment.

[28] First instance Court of Paris, *E.I. Du Pont De Nemours and Company, v. S.A.S. Mylan*, 12 February 2010; Court of Appeal of Paris *E.I. Du Pont De Nemours and Company, v. S.A.S. Mylan*, 15 March 2011; First Instance Court of Paris, *Novartis v. Actavis*, 28 January 2011; Court of Appeal of Paris *Novartis v. Actavis*, 16 September 2011.

[29] Court of Appeal of Paris, *Novartis v. Mylan*, 21 March 2012.

[30] Supreme Court, *Novartis v. Actavis*, 15 January 2013.

[31] CJEU *Novartis A. G. v. Actavis UK Ltd*, 9 February 2012, case C–442/11 [Annex A1.XIX.].

proves to be incorrect, as provided by the Article 17(2) of Regulation (EC) No 1610/96 for plant protection products (which also applies to SPCs for medicinal products, according to Article 17 of Regulation (EC) No 1610/96[32]). As of 1 November 2009, such appeals have to be made to the Court of Appeal of Paris alone.

An SPC can be granted even if its duration is less than the basic patent to which it refers. There is an interest for the patent proprietor to obtain the grant of such SPCs with negative duration, when paediatric extensions based on the SPC can be granted. **65**

However, as paediatric extensions provide effects for a period of 6 months after the SPC has expired, only SPCs expiring six months before the basic patent are granted by the French IP Office. The Court of Appeal of Paris has considered than an SPC negative for 7.5 months cannot confer an actual positive protection.[33] Therefore, the French IP Office can refuse such SPCs. **66**

Renewal fees must be paid to maintain the SPC, when the SPC enters into force. These fees should, at the latest, be paid on the anniversary of the filing date of the basic patent. The French IP Office also accepts that a one-off payment of all of the SPC renewal fees be made in the year preceding the entry into force of the SPC (Article R.617-1 CPI). This possibility is however very rarely chosen by SPC proprietors. **67**

VI. Waiver of SPCs

The SPC proprietor may willingly relinquish its SPC rights. The question however arises as to the effective date of this waiver. **68**

In this connection, Article L.613-24 CPI states, first paragraph, that the patent proprietor may, at any time, relinquish its patent. The fourth paragraph of Article L.613-24 states that "*the effective date of the waiver is retroactive to the filing date of the patent*". In accordance with Article 19 of the Regulation, the provisions of Article L.613-24 should apply to SPCs. Consequently, relinquishing an SPC must, as is the case when relinquishing a patent, take effect as from the SPC filing date[34] (*ex nunc*) **69**

But if the provisions of Article L.613-24 CPI were applied, would they not contradict Article 14 of the Regulation? This article states that an SPC will lapse if the SPC holder surrenders it. **70**

It seems that this provision should be interpreted as meaning that the waiver of the SPC takes effect as from the date of the waiver (*ex nunc*). At least, this is a position taken by the Dutch Octrooicentrum Nederland, as expressed in the CJUE decision in case C-484/12.[35] **71**

Thus, it appears that the date at which the surrender of an SPC takes effect still needs to be decided by the French Court or, possibly also, the CJUE. **72**

VII. Paediatric Extensions

For a paediatric extension to be granted by the French IP Office, the applicant should submit the following documents and information: **73**

[32] Court of Appeal of Nancy, *Allerbio v. Directeur de l'INPI and Stallergènes*, 14 June 2010 [Annex A4.III.].
[33] Court of Appeal of Paris, *F. Hoffman-La Roche AG v. INPI*, 5 July 2013 [Annex A4.V.].
[34] This provision was amended by the Act of 4 August 2008. Indeed, prior to this amendment, the waiver of a title took effect from the publication date of the waiver, not the filing date of the title.
[35] CJEU, *Georgetown University v. Octrooicentrum Nederland*, C-484/12 (12 December 2013) [Annex A1.XXVI.], see point 24.

- a copy of the granted SPC,
- a copy of the statement indicating compliance with an agreed completed Paediatric Investigation Plan (the "compliance statement"),
- when applicable, a copy of the national Marketing Authorizations in all the Member States, in accordance with Article 8(d)(i) and (ii) of the Regulation,
- the name of the applicant.

A filing fee must also be paid.[36]

74 The French IP Office request form comprises two boxes that should be checked by the applicant to declare that the medicinal product is not an orphan drug, and it does not benefit from a one-year extension of the period of protection of the Marketing Authorization.

75 The French IP Office examiner may raise objections against the paediatric extension if one of the above-mentioned conditions has not been fulfilled. The applicant has a two-month deadline to overcome this objection.

76 Lastly, a fee must be paid when filing the paediatric application.[37]

77 If one of the documents or information is missing at the filing date, the French examiner issues a communication for irregularities, with a two-month time-limit to reply. This time-limit may be extended once by two months. Afterwards, if the applicant has not satisfactorily replied to the Examiner's request, a draft decision to refuse the paediatric extension is issued. A further two months are given to reply. The draft decision to refuse becomes definitive if the applicant still has not complied with the examiner's request.[38]

78 As for SPCs, the French IP Office must decide on a paediatric extension within a period of one year from its filing date. Otherwise, it is deemed rejected. If an objection is raised by the examiner, the one-year period is interrupted and resumes in full as from the date the applicant files a reply to the examiner's objection.

[36] On 15 February 2020, this fee amounts to 470 Euros.
[37] On 15 February 2015, this fee amounts to 470 Euros.
[38] Court of Appeal of Paris, *Otzuka Pharmaceuticals Ltd.*, 23 September 2014.