SECTION E – SUPPLEMENTARY PROTECTION CERTIFICATE

The supplementary protection certificate (hereinafter "SPC") extends the duration of the protection of a product (active ingredient) found in the composition of a medicinal or plant protection product covered by a patent that protects a product, a process to obtain a product or an application of a product.

Certificates for **medicinal products** are governed by Regulation (EC) No. 469/2009 of the European Parliament and of the Council of 6 May 2009 (Official Journal of the European Union ["OJ"] L 152/1 of 16 June 2009), codifying Council Regulation (EEC) No 1768/92 of 18 June 1992, which entered into force on 2 January 1993 and was amended in particular by Regulation (EC) No. 1901/2006 of the European Parliament and of the Council of 12 December 2006, which entered entry into force on 26 January 2007.

The conditions governing the grant and validity of certificates for **plant protection products** are laid out in Regulation (EC) 1610/96 of the European Parliament and of the Council of 23 July 1996 (OJ L 198/31 of 8 August 1996). These provisions entered into force on 8 February 1997.

Last paragraph of art. L.611-2 of the French Intellectual Property Code (hereinafter "IPC")
Art. R.617-2 of the IPC
Art.19-1 of Reg. 469/2009

These two regulations contain identical provisions with regard to the conditions governing the grant of a certificate. Where aspects of the application procedure are not dealt with, the provisions applicable under national law with regard to patent applications shall apply.

1. OBTAINING AN SPC: SUBSTANTIVE CONDITIONS

Art. 3 of Reg. 469/2009
Reg. 1610/96

"A certificate shall be granted if, in the Member State [France] 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 (b) is the first authorisation to place the product on the market as a medicinal product."

Art. 7 of Reg. 469/2009
Reg. 1610/96

The application for a certificate shall be lodged within a set time limit (see paragraph e below).

a) Definition of "product"

Art. 1 (a and b) of Reg. 469/2009

- In the context of a "medicinal product", "product" shall mean the "active ingredient or combination of active ingredients of a medicinal product".

A "medicinal product" shall mean "any substance or combination of substances presented for treating or preventing disease in human beings or animals and any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in humans or in animals";

- In the context of "plant protection products", "product" shall mean the "active substance" or the "combination of active substances of a plant protection product".

Art.1 of Reg. 1610/96

Active substances are defined as "substances or micro-organisms including viruses, having general or specific action:
(a) against harmful organisms;
or
(b) on plants, parts of plants or plant products".

"Plant protection products" shall mean "active substances and preparations containing one or more active substances, put up in the form in which they are supplied to the user, intended to:
(a) protect plants or plant products against all harmful organisms or prevent the action of such organisms, in so far as such substances or preparations are not otherwise defined below;
(b) influence the life processes of plants, other than as a nutrient (e.g. plant growth regulators);
(c) preserve plant products, in so far as such substances or products are not subject to special Council or Commission provisions on preservatives;
(d) destroy undesirable plants;
or
(e) destroy parts of plants, check or prevent undesirable growth of plants;

b) The basic patent

1. Origin of the basic patent

Art. 3 (a) of Reg. 469/2009
Art. 3 (1. a) of Reg. 1610/96

A basic patent shall mean a patent that is in force on the filing date of the application for an SPC having effect in France. It can therefore be a French or European patent having effect in France.

2. Suject-matter of the basic patent

- With respect to medicinal products:

Art. 1 (c) of Reg. 469/2009

- The basic patent is a patent that protects the product as such, a process to obtain the product or an application of the product.

ECJ Yissum Research C-202-05

- The application of the product may concern a second medical use if the first application has not already given rise to the grant of an SPC.

Art. 1 (9) of Reg. 1610/96

- With respect to plant protection products:

The basic patent is a patent that protects the product as such, a preparation containing the product, a process to obtain the product or an application of the product.

- Common terms and conditions:

ECJ Medeva C-322/10
Georgetown C-422/10
24/11/2011

Whether it concerns medicinal products or plant protection products, the product must be specified in the wording of the claims of the basic patent. Indeed, given that the scope of protection of the patent is defined by these claims, it is not sufficient for the product that is subject to the SPC application to be described in a working example of the invention.

ECJ Yeda C-518/10
25/11/2011

If a patent claims that a product is composed of two active ingredients but does not make any claim in relation to one of those active ingredients individually, an SPC cannot be granted on the basis of such a patent for the one active ingredient considered in isolation.

ECJ Eli Lilly C-493/12
12/12/2013

An active ingredient which is given a functional definition in the claims of a patent can be 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, that the claims relate, implicitly but necessarily and specifically, to the active ingredient in question.

In the specific case where the claims of a patent concern a product defined by means of a Markush formula, it is sufficient for the product to fall within the scope of this formula without having to be specifically identified.

ECJ M.I.T. C-431/04
04/05/06

However, if the medicinal product is composed of an active substance and a substance that has no therapeutic effect of its own but is used to obtain a pharmaceutical form of the medicinal product necessary for the therapeutic efficacy of the first substance, only the first substance shall be deemed to be the product. The second substance shall be deemed to be an excipient.

ECJ GSK C-210/13
14/11/2013

Likewise, a combination of two substances–where one is an active ingredient with therapeutic effects of its own and the other is an adjuvant–shall not be considered a "combination of active ingredients" even though the adjuvant makes it possible to increase these therapeutic effects.

ECJ Bayer CropScience AG C-11/13
19/06/14

In the more specific case of safeners, it is necessary to verify whether the substance in question has a "toxic, phytotoxic or plant protection action of its own".

ECJ Forsgren C-631/13
15/01/2015

An SPC cannot be granted for substances having a therapeutic effect of their own where such effect is not set out in the related marketing authorisation (hereinafter "MA"). It must therefore be verified that the "active ingredient" produces a pharmacological, immunological or metabolic action of its own, which is covered by the therapeutic indications set out in the MA.

c) The first MA

The MA must be the first authorisation granted in France to place the product on the market as a medicinal or plant protection product.

Therefore, it cannot be a renewal or a confirmation of an MA granted previously.

1. Origin of the MA

With respect to medicinal products, the MA is granted by the French Agency for Veterinary Medicinal Products (*Agence nationale du médicament à usage vétérinaire* – ANMV), the French Agency for Medicinal and Health Product Safety (*Agence nationale de sécurité du médicament et des produits de santé* – ANSM) or the European Medicines Agency (EMA).

With respect to plant protection products, the MA is granted by the French Ministry of Agriculture.

2. Date of the MA

Art. 3 (b) of Reg. 469/2009
Art. 3 (1. b) of Reg. 1610/96

The French Industrial Property Office (*Institut national de la propriété industrielle* – hereinafter "INPI"), together with the various medicinal product bodies and the French Ministry of Agriculture, verifies that the MA indicated on the request for the grant of a certificate is the first MA granted for the product in France

The "date" of a French MA is the date on which the authorisation was granted: in accordance with French administrative law, a decision favourable to the addressee–in particular a decision granting the addressee certain rights–is enforceable upon signature without requiring notification.

ECJ Seattle Genetics C-471/14 06/10/2015

Regarding MAs granted by the European Union, the "date" of an MA is defined by EU law. It can be defined as the date on which the applicant was given notification of the decision granting the MA.

3. Subject-matter of the MA

ECJ Medeva C-322/10
Georgetown C-422/10 24/11/2011

An MA must be granted for placing a product on the market as a medicinal or plant protection product. The fact that the MA also covers other active ingredients than those for which the SPC is requested shall not prevent the latter from being granted.

Should several MAs be granted on the same day, it is up to the applicant to choose which authorisation shall feature on their request: only one MA may be indicated on the request for the grant of a certificate.

ECJ Neurim Pharmaceutic als C-130/11 19/07/2012

A new medical use of an active ingredient may be granted an SPC based on the corresponding MA, even if the product has already been granted an MA for the first medical use. The SPC will be granted provided the basic patent is a patent covering the second medical use of an active ingredient or of a combination of active ingredients for which the MA was granted. The SPC will therefore only cover the new use of the active ingredient subject to the basic patent.
The notion of "new medical use of an active ingredient or of a combination of active ingredients" must be strictly interpreted.

d) Exclusion of dual protection

Art. 3 (c) of Reg. 469/2009
Art.3 (1. c) of Reg. 1610/96

The product must not already have been the subject of an SPC in the name of the same holder.

The review of an SPC request therefore includes a background check.

ECJ AHP Manufacturing C-482/07 03/09/2009

The check takes into account all SPCs previously granted in France, irrespective of the date. Consequently, for medicinal products, the check takes into account certificates delivered under French Law no. 90-510 of 25 January 1990 and SPCs granted under Regulation (EEC) no. 1768/92 or Regulation (EC) 496/2009.

The check shall be carried out on the product subject to the request, as defined above.

The INPI shall verify whether the product is already subject to a certificate and/or that such product is not included in the extended claims in the case of certificates governed by French law no. 90-510 of 25 January 1990.

ECJ Actavis I C-433/12 07/03/2013

An SPC for A, granted on the basis of a patent for which it is the innovative active ingredient, precludes the grant of an SPC for A+B based on the same patent if B is not "protected by the patent as such", even if it is referred to under generic terms such as "beta-blocking compound", "calcium antagonist", "diuretic", "non-steroidal anti-inflammatory" or "tranquilliser", etc. The two SPCs would in fact be considered to be "connected, wholly or in part, with the same product".

ECJ Actavis I C-577/13 12/12/2013

An SPC for A, granted on the basis of a patent for which it is the innovative active ingredient, also precludes the grant of an SPC for A+B based on the same patent, even if A+B is covered by a subsequent claim, for example following a limitation, since B is not the "subject-matter of the invention".

ECJ Georgetown University C-484/12 12/12/2013

However, if product A has already been subject to an SPC on the basis of a patent for which it is the innovative active ingredient, this SPC shall not preclude the grant of an SPC for A+B, provided A+B constitutes a totally separate innovation protected by a separate patent.

Similarly, an SPC granted for A+B shall not preclude the grant of an SPC for B based on the same patent provided that A+B, as well as B taken individually, are protected "as such" by that patent.

e) Time limit for submitting the application for a certificate

Art. 7 (1) of Reg. 469/2009
Reg. 1610/96

The application for an SPC must be lodged within six months of the date on which the first MA for the product was granted in France or on French territory.

The date of this MA is determined as outlined in section 1 c) 2. above.

Art.7 (2) of Reg. 469/2009 Reg. 1610/96

In the event that the MA was granted before the basic patent was granted, the SPC application must be lodged within six months of the date on which the patent was granted.

If the basic patent is a European patent designating France, the six-month period will run from the date of grant of the patent by the European Patents Office (EPO).

2. OBTAINING AN SPC: FORMAL REQUIREMENTS

Art. 8 of Reg. 469/2009 Reg. 1610/96

The application for a certificate shall contain:

- a request for the grant of a certificate,
- a copy of the first MA granted in France,
- where applicable, a copy of the publication in the Official Journal of the MA number obtained outside of France, within the European Union.

a) The request for the grant of a certificate

- the request shall contain: the first name and surname or the company name of the applicant(s), as well as their address(es), and where applicable, the name and address of the representative to whom all letters must be sent;

- the references of the basic patent, i.e. its origin, the national or European application number, the publication number, the date of filing, the date of grant, and, where applicable, the date of filing of the translation, as well as the title of the invention;

ECJ Seattle Genetics C-471/14 06/10/2015

- the references of the first MA granted in France, i.e. the dossier number, the date on which it was granted or the date of notification (see section 1 c) 2. above) and the date of the last renewal, the name of the product–i.e. the international non-proprietary name (INN)–or the usual common name or chemical name of the active ingredients of the medicinal product;

- where applicable, if the MA referred to in France is not the first MA for the product to be placed on the market as a medicinal or plant protection product in the European Union, the references of the first decision, as well as the country in which it was granted; the name of the product (see above) and the legal provision under which the authorisation procedure was carried out.

Where applicable, the application shall state that it includes a request for a paediatric extension of the SPC (see point 5 below).

b) A copy of the first MA granted in France, including in particular the number and date of the authorisation, the name of the product, and the summary of its main characteristics.

c) Where applicable, a copy of the publication in the Official Journal of the first administrative decision granting MA in the European Economic Area for the product, as well as the extracts making it possible to define the qualitative composition of the active ingredient(s), as well as a translation of such extracts in French.

Protocol 1 to the Porto Agreement of 2 May 1992 (L. no. 93-1274 of 2/12/1993, OJ 3/12/1993; D. no. 94-193 of 1/02/1994 in which the Agreement was published, OJ 10/02/1994)

Since the entry into force on 1 January 1994 of the Porto Agreement on the European Economic Area (hereinafter the "EEA"), the territory taken into consideration includes the 28 Member States of the European Union, Iceland, Norway and, since 1 May 1995, Liechtenstein.

Not all of the Member States have a publication procedure for MAs. In this instance, it is enough to state the therapeutic indications and the date on which the MA was granted, or, where applicable, the date of notification of the MA.

Specific case of MAs in Liechtenstein: as no MAs are granted in this country, which approves Swiss MAs, the INPI checks the list of Swiss MAs awaiting approval in Liechtenstein. Only when the MA has been approved can it be considered the first MA within the EEA.

d) Appended items

The application for a certificate must be accompanied by:

- the representative's delegation of power, where applicable (unless he/she is an industrial property attorney or a lawyer);
- proof of payment of the required filing fee.

NB: This fee must not be confused with the renewal fee paid for the maintenance in force of the basic patent or the SPC itself.

e) Publication of the application for a certificate

Art. 9-2 of Reg. 469/2009 Reg. 1610/96

SPC applications which meet the requirements laid down in the applicable texts are made public in the form of:

- A notification in the French Industrial Property Journal for Patents (BOPI Brevets);
- an entry in the French Patent Register;
- the availability of the application to the public (see point 7 below).

The INPI can send, at the request of any person and in return for a fee, a statement showing the annual fees paid for an SPC and the date of the last payment.

3. GRANT OF THE CERTIFICATE

Art. 10 of Reg. 469/2009

After the application has been recognised as being in compliance with the provisions of the regulation, the SPC is granted, unless the applicant withdraws their request.
It the application is not compliant, the applicant can rectify irregularities (e.g. the name of the product, MA references) at the request of the examiner who will give them a deadline for their response.

Art. 11-1 of Reg. 469/2009 Reg. 1610/96

The grant of an SPC is entered in the French Patent Register and is notified in the BOPI.

This notification states the duration of the protection (expiry date).

a) Legal duration of the certificate

Art. 13 of Reg. 469/2009

Art.8-1d of Reg. 469/2009

The SPC shall take effect "at the end of the lawful term of the basic patent for a period equal to the period which elapsed between the date on which the application for a basic patent was lodged and the date of the first authorisation to place the product on the market in the Community, reduced by a period of five years."

"The duration of the certificate may not exceed five years."

ECJ C-471/14 Seattle Genetics 06/10/2015

"For the purposes of calculating the duration of the certificate, account shall be taken of a provisional first marketing authorization only if it is directly followed by a definitive authorization concerning the same product."

Art. 13-3 of Reg. 1610/96 (17) Whereas

The method used to calculate the date of the first MA in the European Union is indicated in section 1 c) 2. above.

If the first MA in the EU is a national MA granted by a Member State other than France, the applicant is responsible for providing proof of the date of effect of this MA under the national law of this State.

In the case of studies with a view to paediatric use, the duration of protection may be subject to a one-off extension of six months provided the necessary conditions are fulfilled (see point 5 below – Extension of SPCs).

b) Maintenance in force

Art. 12 of Reg. 469/2009

The maintenance in force of the certificate is subject to the payment of annual fees, which are due, at the latest, on the last day of the anniversary month of the filing of the basic **patent**.

The total payment of all annual fees is possible in the year prior to the entry into effect of the certificate.

Art. L.612-19, Art. R. 411-17 of the IPC

Unlike for patents, the amount does not gradually increase.
The required annual fee may be paid within an additional period of six months, subject to payment of an additional late payment fee.

In the event of payment default, the rights attached to the certificate shall be revoked by decision of the Director General of the INPI.

Art. L.613-22 of the IPC

Art. L.612-16 of the IPC

If the holders are able to provide a legitimate reason, they may submit an appeal in order to have their rights reinstated within two months of the removal of the cause of non-compliance and within one year maximum after the expiry of the grace period. This same period shall apply to the payment of the annual fees.

4. REJECTION OF THE APPLICATION FOR A CERTIFICATE

Art. 10 -2 and 10-4 of Reg. 469/2009

The SPC application shall be rejected if it is not made within the required time frame and in compliance with the formal requirements, after the applicant has submitted their observations and, where applicable, altered their request (see point 6 below).

Art. L.411-4 of the IPC
Art. D.411-19-1 of the IPC

The rejection of an SPC application may be subject to an appeal before the Paris Court of Appeal (see section E, 3.2. of the INPI publication *La délivrance des brevets et des certificats d'utilité* [Grant of patents and utility certificates] – available in French only).

5. EXTENSION OF SPCS

Art. 36 of Reg. 1901/2006

Art. 13-3 of Reg. 469/2009

Art. 8 of Reg. 469/2009

Regulation 1901/2006 of 12 December 2006 on medicinal products for paediatric use provides for the possibility of obtaining a six-month extension of SPCs for medicinal products that have been subject to research with a view to their use in the paediatric population.

An SPC may only be extended once.

a) Content of the application for an extension of the duration

The application for an extension of the duration of the SPC must include the following:

- the application form for an extension of the duration, which must indicate:
  - the first name and surname or the company name of the applicant(s), as well as their address(es), and where applicable, the name and address of the representative to whom all letters must be sent;
  - the number of the SPC or of the related SPC application, the publication number of the basic patent;
  - that the medicinal product subject to the MA is not an orphan medicinal product and does not benefit from the one-year extension of the marketing protection period;
- the copy of the EMA or ANSM statement showing that the MA application complies with a completed paediatric investigation plan (PIP).
  This statement must also indicate that the summary of the product characteristics reflects the results of studies conducted in compliance with said PIP in each country of the European Union.

Art. 8-4 of Reg. 469/2009

- proof of payment of the fee payable upon application for the extension of the duration of a certificate.

Where applicable, the following items must also be provided:

- the copy of the SPC if it has been granted;
- if the MA application forming the basis of the request was made at a national level, the copy of the corresponding MAs in all of the other Member States (27) making it possible to identify the product subject to the SPC. Where applicable, a translation in French of the information required to examine the application may be requested by the INPI.

The MAs must cover the same active ingredient but not necessarily the same medicinal product. They do not necessarily have to cover a medicinal product for paediatric use.

b) Time limit for the application for an extension of the duration

Art. 7-4 and 7-5 of Reg. 469/2009

The application for an extension of the duration of a certificate already granted shall be lodged not later than two years before the expiry of the certificate.

Art. 10 -3 and 10-6 of Reg. 469/2009

However, any irregularities in the application may be rectified within the time limit granted by the examiner.

c) Acceptance of the application for an extension of the duration

Art. 10-1 of Reg. 469/2009

If the application for the extension of the duration is completed within the given time line, the application shall be accepted.

Art. 13-3 of Reg. 469/2009

The duration of the SPC will therefore be extended by an additional six months.

d) Rejection of an application for the extension of the duration

Art. 10-2 and 4-6 of Reg. 469/2009

If an application for the extension of the duration does not satisfy the substantive, formal and deadline conditions, and if it has not been possible to rectify the irregularities contained therein, it shall be rejected by decision of the Director of the INPI.

Art. L.411-4 of the IPC
Art. D.411-19-1 of the IPC

This decision may be subject to an appeal before the Paris Court of Appeal (see Part I, section E, 3.2. of the INPI publication *La délivrance des brevets et des certificats d'utilité* [Grant of patents and utility certificates] – available in French only).

e) Publication

Art. 11-3 of Reg. 469/2009

The application for the extension of the duration of the SPC is notified in the BOPI and entered in the French Patent Register, as is the rejection or acceptance of such application.

The publication of the acceptance of the application shall state the new expiry date of the SPC.

6. IMPLIED REJECTION OF AN APPLICATION FOR A CERTIFICATE OR FOR THE EXTENSION OF THE DURATION OF THE SPC PURSUANT TO FRENCH DECREE NO. 2015-1436 OF 6 NOVEMBER 2015

Decree No. 2015-1436 of 6 Nov. 2015

Under French decree no. 2015-1436 of 6 November 2015, the SPC grant procedure is subject to the "silence is deemed refusal" principle after a period of one year from the filing date of the application. This period shall be interrupted in the event that the INPI provides notification of an irregularity.

The provisions of this decree shall be applicable to all SPC applications filed after 12 November 2014.

Consequently, all irregularities relating to the application shall be notified within a period of one year from the filing date of said application.

If the observations presented do not allow for the objection to be lifted or if the irregularities are not rectified within the stated time frame, the SPC application shall be subject to a draft refusal or a letter informing the applicant that their response has not allowed the objection to be lifted. This draft refusal shall be issued within a period of one year from the date of the applicant's response to the notification of irregularity.

Should the applicant fail to rectify the situation following a draft refusal, or if the observations made do not allow for the objection to be lifted, a refusal or a letter shall be addressed to the applicant indicating that their response was not sufficient to lift the objection. This refusal or letter shall be issued within one year of the date of the applicant's response to the draft refusal.

Within the context of the examination, the applicant who has been set a time limit to submit their observations or to rectify their request, may obtain an extension of this response time on written request. This extension may not exceed a maximum of four months.

7. ACCESS TO THE ELEMENTS CONSTITUTING THE SPC APPLICATION