

13. SUPPLEMENTARY PROTECTION CERTIFICATE (DRUG PATENT) (“SPC”)

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The relevant **Romanian patent law and regulation**, and European Council regulations are:

- ✓ Law no. 64 of 1991 regarding Patents
- ✓ The Instruction no. 146 of December 28, 2006 issued by the State Office for Inventions and Trademarks (“**OSIM**”) Concerning the Supplementary Protection Certificate for Drugs and the Supplementary Protection Certificate for Plant Protection Products (“**Instruction 146**”), as amended
- ✓ Council Regulation (EEC) no. 469/2009 of May 6, 2009 Concerning the Creation of a Supplementary Protection Certificate for Medicinal Products (“**Regulation 469/2009**”), repealing Council Regulation (EEC) 1768/92
- ✓ Regulation (EC) no. 1610/96 of the European Parliament and of the Council of July 23, 1996 Concerning the Creation of a Supplementary Protection Certificate for Plant Protection Products
- ✓ Order no. 23 of 2012 on the Approval of the Instructions Regarding the Extension of the Duration of the SPC

Requirements for the granting of an SPC in Romania

Requirements under the Regulation no. 469/2009

According to the provisions of the consolidated version of the Regulation 469/2009, an SPC may be granted in case of a patented drug in Romania, if two cumulative conditions are met:

- (i) the respective drug is protected by a valid patent;
- (ii) the first marketing authorization for the respective drug was granted after January 1, 2000.

The Regulation no. 469/2009 further provides that the possibility for applying for a certificate shall be open for a period of six months starting no later than the date of accession of Romania to European Union in case that the six-month term for filing the SPC application, calculated from the date when the authorization to put the product on market was granted, expired.

According to the provisions of Regulation no. 469/2009, apart from the specific requirements mentioned above, the SPC will be granted if, at the date of filing the application:

- a. a valid authorization to place the drug on the market as a medicinal product granted in accordance with the Directive 2001/83/CE or the Directive 2001/82/CE is in effect;
- b. an SPC was not previously issued for the respective drug;

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- c. the marketing authorization referred to at item (a) above is the first authorization to place the drug on the market as a medicinal product.

Requirements under the Instruction 146

According to the Instruction 146, the SPC application has to fulfill the following requirements:

- (i) the application was submitted within the time limits stipulated in Regulation no. 469/2009;
- (ii) the Romanian Patent Office, i.e. OSIM must determine if the application was submitted within the 6-month period from Romania's accession to the EU, for drugs and plant protection products, respectively, with regard to which the first authorization to place the product on the market as a drug or a plant protection product in Romania was obtained after January 1, 2000;
- (iii) the application is accompanied by a copy of the valid authorization to place the drug on the market in Romania;
- (iv) the application contains, where necessary, information relating to the first authorization to place the drug on the market, in EEA, and a copy of the authorization published in an appropriate official publication;
- (v) the basic drug patent is in force on the date of filing the application;
- (vi) the applicant for the issuance of an SPC is the same entity as the initial patent holder – in case of a change of patent holder the relevant transfer documentation must be submitted as well.

The Instruction 146 issued by OSIM provides that an SPC application must be filed, *inter alia*, together with a copy of the Marketing Authorization for the respective drug in effect at the date of filing the application.

According to the above-mentioned Instruction, the Marketing Authorization for Romania is:

- a. an authorization valid in Romania for drugs for human use issued by the National Drug Agency, according to Law no. 95 of 2006 regarding the Health Reform;
- b. an authorization valid in Romania for drugs for veterinary use issued by the Sanitary-Veterinary and Food Safety National Authority;
- c. an authorization for a drug for human or veterinary use, valid in Romania, issued by the European Medicines Agency (“**EMA**”);
- d. a homologation certificate of the plants protection products issued by the Inter-Ministry Commission for the Homologation of the Plants Protection Products.

Effects of the granting of an SPC

According to the provisions of Regulation no. 469/2009, the SPC has the same effects as the base patent, subject to the provisions of the said Regulation, i.e. only for the drug covered by the Marketing Authorization filed for the granting of the SPC. The SPC, if granted, produces its effects from the date of the expiry of the base patent up to the date of expiry of the SPC.

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According to the Patent Law no. 64 of 1991 as amended (“Patent Law”), the patent confers to its owner an exclusive right of exploitation throughout its entire duration. Also, the manufacturing, using, offering for sale, or selling of a product protected by a patent without the consent of the patent owner is prohibited.

According to the Patent Law, the infringement of the patent rights is considered counterfeiting, which is a criminal offence, punishable with imprisonment for a period ranging from 3 months up to 2 years, or by a fine ranging from Lei 10,000 up to Lei 30,000, i.e. around EUR 2,800 up to EUR 8,220.

Exceptions

By way of exception, the actions mentioned above, which were carried out before the publication of the patent application, or before receiving a cease and desist notice from the applicant for a patent with a certified copy of the drug patent application appended, or an SPC with a certified copy of the SPC application appended, are not considered to be infringements.

According to the Patent Law, *inter alia*, the following are not considered an infringement of the rights conferred by the patent mentioned:

- (i) if the activities prohibited by the Patent Law are carried out in private and not for a commercial purpose; the production or, as the case may be, the use of the invention are carried out exclusively for private use and not for commercial purpose.
- (ii) the use for experimental/testing purposes, exclusively with non commercial purpose, of the object of the patent.

Also, the Regulation for the Application of the Patent Law provides that conducting tests and required studies for the purpose of obtaining the authorization to put on the market a drug, as well as the practical requirements which results from such test and studies are not considered being an infringement of the rights provided for by the Patent Law.

Test batches

The Romanian legislation regarding drugs does not provide any regulations regarding pilot batches. However, according to the representatives of the National Drug Agency, the Guidelines issued by EMEA also apply in Romania starting with January 1, 2007, i.e. the date of accession of Romania to EU.

Test batches may be regarded as being part of the practical requirements for the obtaining the marketing authorization. Therefore, the production of the validation/test/pilot batches may not be considered as an infringement of the rights conferred by the patent/SPC.

Thus, according to the Note for Guidance on Process Validation issued by the EMEA, the size of the pilot batch should be of to at least 10% of the production scale batch, i.e. provided that the multiplication factor for the higher sized of the pilot batch does not exceed 10.

Also, for oral solid dosage forms this size should generally be of 10% of the production scale, or 100,000 units, whichever is higher.

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Publication of the Decisions regarding the SPC

The SPC application, together with a brief mention on the decision of OSIM with regard to the granting or dismissal of the SPC application is published in the Romanian Official Bulletin of Intellectual Property (“**BOPI**”) – SPC Section.

Also, OSIM makes available at its offices the copy of the Marketing Authorization on which the SPC is based, for consultation by the public.

Protection of the rights conferred by an SPC

The owner of an SPC may take the following actions in order to enforce the intellectual property rights conferred by the SPC.

Criminal investigation

According to the Patent Law, the infringement of the patent rights is considered counterfeiting, which is a criminal offence, punishable with imprisonment for a period ranging from 3 months up to 2 years.

The criminal investigation may be initiated *ex officio* by the authorities, or following the complaint of the owner of an SPC.

For the damages caused by the counterfeiting, the owner of the patent, or in this case of the SPC, is entitled to compensation, and may request to the competent court the seizure, and, as the case may be, the destruction of the counterfeited products, substances, and of the equipment which directly served for the production of the counterfeited products.

Legal action for damages

The Patent Law provides that the infringer of patent rights is liable for damages to the patent owner. The value of the damages may be calculated depending on the basis of the market value of the infringing products, or of the products protected by the SPC.

The claim for compensation for damages filed in a criminal case is exempted from the payment of the stamp fee. In the case of filing a legal action in a civil court, the plaintiff must pay a stamp fee calculated on the basis of the value of the claim. The resolution of a criminal case usually takes more time than that of a civil case.

Filing of motions for obtaining injunction orders

The owner of the SPC may apply for an injunction to stop the activities which are allegedly infringing on the rights conferred by the SPC. The issuance of an injunction can take from 1 - 2 weeks until 1 - 2 months from the date of filing the application. The injunction order may be subject to appeal.

Opposing the issuance of an SPC

The opposition against an SPC application may challenge (i) the validity of the base patent, and/or of (ii) the Marketing Authorization of the product for which the SPC is requested.

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Revocation

The procedure for opposing the granting of an SPC requires the filing of an application for the revocation of the SPC, according to the provisions of the Instruction 146. The application for revocation can be filed by any person during a 6-month term following the publication of the decision of granting the SPC.

Such application for the revocation of an SPC will be heard by the Appeals Commission of OSIM. The Appeals Commission will serve a copy of the application for the revocation of the SPC on the applicant, who can file a reply within 3 months as of the date of receipt.

The appeals pending before the Appeals Commission of OSIM are included in a list of pending cases, which is published periodically on the website of OSIM.

The decisions issued by the Appeals Commission of OSIM with regard to appeals and application for the revocation must be issued within 3 months from their respective date of filing with OSIM.

However, in practice, there may be several hearings before the said Appeals Commission, and it may take up to 6 months until the issuance of the decision of the Appeals Commission of OSIM. Thereafter, such decision must be drafted and notified to the parties within 15 days, but in practice, it may take longer, i.e. up to 1-2 months.

This means that the procedure regarding the examination of the application for the revocation of the SPC may take up to eight (8) months until the decision of the Appeals Commission is drafted and notified to the parties.

The decision of the Appeals Commission of OSIM may be further appealed with the competent court, i.e. with the Bucharest Tribunal, within 30 days from the date of notification to the parties.

The decision of the Bucharest Tribunal may be further appealed before the Bucharest Court of Appeals within 15 days as of the date when it was notified to the parties.

Legal action for cancellation

According to the Patent Law, a legal action for cancellation of the SPC can be filed with the Bucharest Tribunal. There is no deadline for filing such legal action for cancellation of an SPC.

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