Romania

SPCs for medicinal and plant protection products: new considerations

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When Romania joined the European Union on January 1 2007, new regulations regarding industrial property protection came into force. Article 19a of Romania's accession treaty states that "any medicinal product protected by a valid patent and whose first authorization for the placing on market was obtained after January 1 2000, could be granted a certificate in Romania. For the situations in which the period provided by Art. 7(1) has expired, the solicitation for a certificate is possible within a term of six months, staring at latest, at the date of accession". The period referred to in Article 7(1) is six months commencing from the date when the medicament product obtained market authorisation.

In addition, from June 2009 the new title of protection for the paediatric extension of supplementary protection certificates (SPCs), as provided in Regulation 469/2009, also became available in Romania.

Legal basis

The legal basis for SPCs in Romania is laid down in the following EU regulations:

- EC Regulation 1768/92 concerning the creation of an SPC for medicinal products;
- EC Regulation 469/2009 concerning SPCs for medicinal products (codified version); and
- EC Regulation 1610/96 concerning the creation of an SPC for plant protection products.

The Romanian Patent and Trademark Office (RPTO) issued specific instructions regarding application of the regulations in Romania on December 28 2006.

The market authorisation regime for medicinal products is set out in:

- Title XVII of Law 95/2006; and
- Order 1199 of October 2 2006 issued by the Ministry of the Public Health for approval of the withdrawal/suspension of certain market authorisations by the National Medicament Agency, before Romania's accession to the European Union.

European regulations are directly applicable in all EU member states; however, an SPC is requested and granted at the national level.

Overview of SPCs filed between 2007 and 2011

The evolution of SPC protection in Romania follows the same characteristics as most countries joining the new system of IP protection: the maximum number of SPC applications were registered in the first year of the protection system being in place, and the the number of SPC applications filed in following years then settled.

Only four paediatric SPC extensions have been filed in Romania since 2009 – relatively few.

Of the SPC applications filed in 2007 (101), almost 65% were granted (65); approximately 20% were rejected; and a decision has yet to be issued regarding 15 applications.

The examination board's decision can be appealed before the RPTO Board of Appeal within three months from notification.

Further, the appeal board's decisions may be challenged before the Bucharest Court of Law within 30 days from notification; further appeal is possible before the Bucharest Court of Appeal, whose decisions are final and irrevocable.

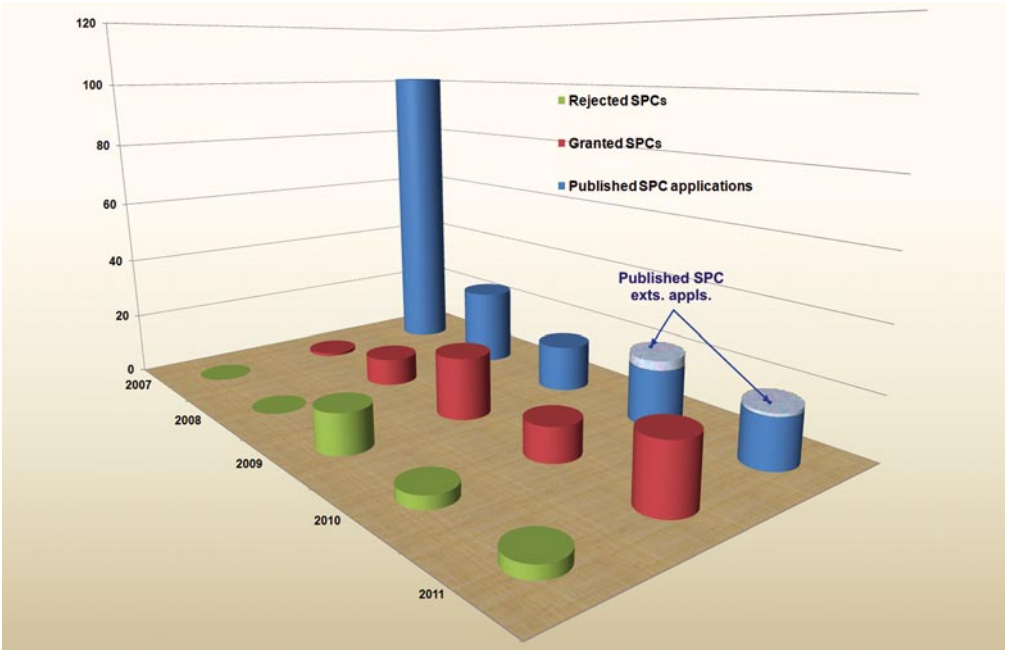

Figure 1. Overview of Romanian SPC applications filed and granted and/or rejected between 2007 and 2011 (based on data published in the *Official Bulletin of Industrial Property – Inventions*)

Significant case law

First market authorisation for a medicament filed before January 1 2000, which is not in accordance with directive

One of the issues that repeatedly arises in SPC-related case law originates from the interpretation of the transitory provisions regarding first market authorisation of a product.

Thus, the transitional provisions (Article 19(j) of Regulation 1768/92 for medicinal products and Article 19(l) of Regulation 1610/96 for plant protection products), state that: "any medicinal/plant protection product protected by a valid basic patent and for which the first authorization to place it on the market as a medicament/plant protection product was obtained after January 1 2000 may be granted a certificate in Romania. In cases where the period provided for in Art. 7(1) has expired, the possibility of applying for a Certificate shall be open for a period of six months starting no later than the date of accession (January 1 2007)."

These provisions have been interpreted by SPC applicants, the RPTO, courts and intervening third parties (producers of generics) in two conflicting ways.

One interpretation considers that the term 'first authorisation' should have a meaning consistent with the rest of the regulations – that is, it should be read as being in accordance with Article 3(b) of the regulations: "a valid authorization to place the product on the market as a medicinal product granted *in accordance with Directive 65/65/EEC or Directive 81/851/EEC*, as appropriate." (Emphasis added.)

Following this line of thought, if a producer obtained market authorisation in Romania before January 1 2000, which was not (and could not have been at the time) in accordance with Directive 65/65/EEC (relating to pharmaceuticals) or Directive 81/851/EEC (relating to veterinary medicinal products), this market authorisation is not an 'authorisation' as provided for by the regulations and cannot be taken into account as the first market authorisation when filing an SPC application. Consequently, an SPC application would be allowable based on a subsequently filed market authorisation, filed after January 1 2000 and in accordance with Directives 65/65/EEC or 81/851/EEC. Such an authorisation – even if not strictly a 'first' authorisation – is still the first authorisation according to the directives.

An alternative interpretation of the same text takes the opposite approach – that is, the term 'first authorisation' is thought to mean the absolute first authorisation, regardless of whether this complies with the directives.

The arguments in favour of this line of thought (adopted by the RPTO and producers of generics) make reference to the purpose of an SPC for medicinal and plant protection products: to provide compensation for the period when

exploitation of a patent is not possible due to the procedures for obtaining market authorisation for such products. Consequently, it has been argued that market authorisation obtained before January 1 2000, while not being in accordance with the directives, nevertheless did enable the product onto the market in Romania, and therefore the product does not merit an SPC.

In practice, in such cases the RPTO has consistently adopted the second line of interpretation and rejected SPC applications which have a first market authorisation in force since before January 1 2000, even though this market authorisation did not comply with Directive 65/65/EEC. The outcome of all the appeals lodged against such decisions were equally consistent: the RPTO appeal board has validated the examining division's decisions and upheld the rejection decisions.

Many of these cases went further and the appeal decisions were challenged before the Bucharest Court of Law. The court was consistent in granting the SPCs, thus adopting a position in favour of SPC applicants. Consequently, the RPTO was obliged to grant the SPCs.

Some of these decisions to grant were, in turn, challenged by the producers of generics and/or the RPTO. Over time, many of the litigated SPCs expired, so at present only a few are still subject to court proceedings.

In such cases, it is expected that the decisions of the European Court of Justice (ECJ) in *Synthon v Merz* (C-195/09) and *Generics v Synaptech* (C-427/09) will play a role. These decisions stated that "a product which was placed on the market in the EU Community... before obtaining a MA in accordance with Council Directive 65/65/EEC as amended may not be the subject of a supplementary protection certificate".

Romania was not a member of the European Union until January 1 2000 and therefore not party to the EU market, so the wording of these decisions does not apply to the letter; however, the reasoning of these decisions is still expected to be taken into account in further decisions by Romanian courts.

SPC application for combination of two active substances rejected by RPTO Board of Appeal

One case with an interesting evolution is that of an SPC application filed by Novartis AG (CH) in 2007 for a combination of two active substances. In 2010 the examination board rejected the SPC application on the grounds that an SPC granted for a combination of two active substances would extend the protection conferred by a basic Romanian patent (granted only for one of these two active substances), violating the provisions of Article 3(a) of Regulation 1768/92 (concerning the creation of a SPC for medicinal products). The market authorisation used by the applicant in the SPC application was issued for the combination of the two active substances.

In the opposition procedure, a generics production company was also registered as an intervening party as an opponent to the granting of the SPC application.

The opposition procedure lasted almost two years, with several oral proceedings meetings. The applicant attempted to postpone the appeal board's final decision until the ECJ had resolved the *Medeva* case, as it wanted the appeal board to take into account the ECJ's answers to preliminary questions raised by the Court of Appeal of England and Wales in that case.

The members of the appeal board retained the ECJ's interpretation of Article 3(a): "The article 3 letter a) of the EC Regulation 469/2009 has to be considered in the sense that it is against the granting by the authorized institutions in the field of industrial property of a member state, of a SPC related to active principles that are not mentioned within the claims of the basic patent considered by the SPC application."

Consequently, the appeal board rejected the SPC application based on Article 18 of Regulation 469/2009 and Article 53 of the Patent Law (64/1991, as amended and republished), maintaining the examination board's decision to refuse the granting of the SPC on the grounds that the application did not fulfill the provisions of Article 3(a) of Regulation 469/2009.

The applicant did not appeal the Board of Appeal's decision to the courts.

The RPTO is generally guided by the decisions related to SPCs taken by the ECJ.

Conclusion

Romanian court jurisprudence in this area remains weak and existing cases have not yet been finally and irrevocably resolved. *iam*

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