"The First Year of SPC in Poland: A Tentative Summary"

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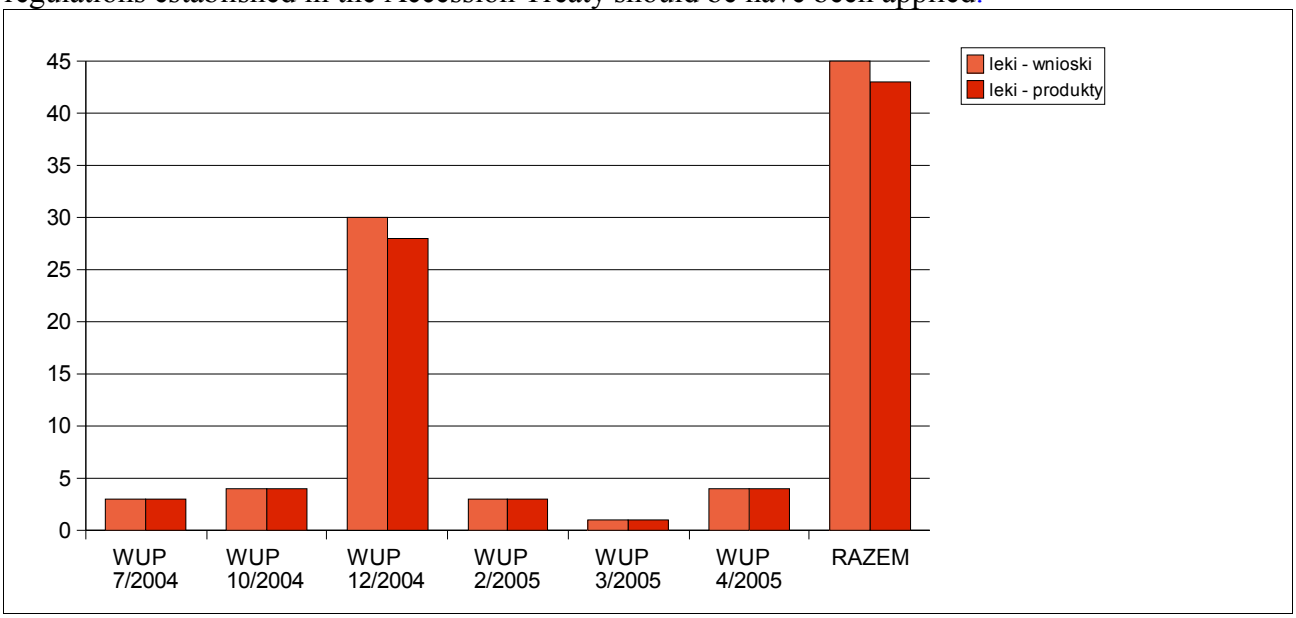
1. Introduction

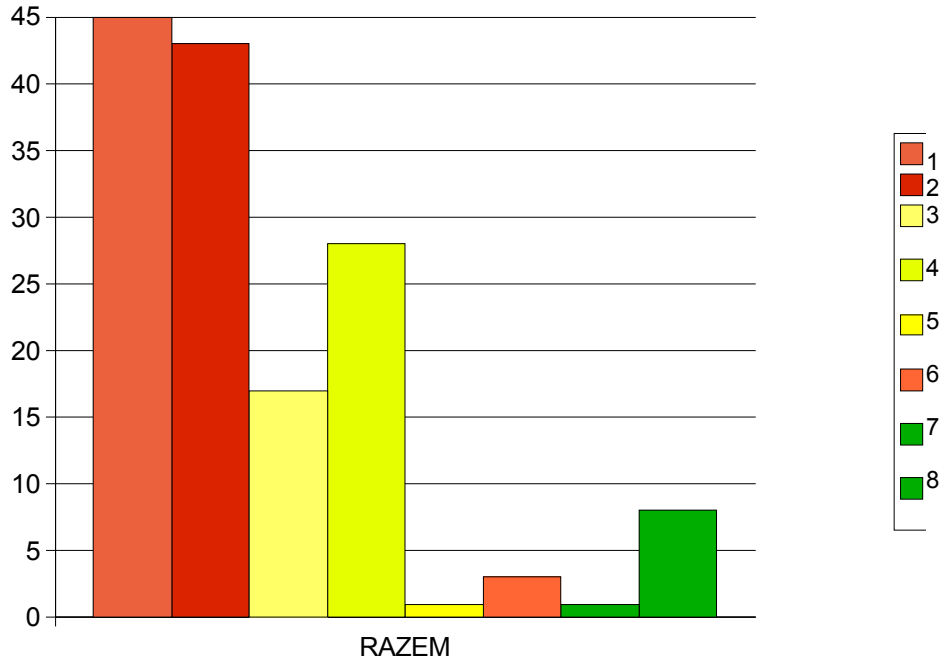
With Poland's accession to the EU in May of 2004, regulations allowing the acquirement of supplementary protection certificates (SPCs) for therapeutic products took effect in our country. These regulations allow the owners of patents involving innovative drugs to prolong patent protection for even up to five years. The particular principles of granting an SPC are defined in the Directive of the Council (EEC) 1768/92 (hereinafter "the Directive") and the respective regulations contained in the Polish Industrial Property Act of June 30, 2000 (hereinafter "IPA"). Of particular significance in the first months of introducing SPCs in our country were also the respective transitional provisions contained in the Accession Treaty, in which the wording of Art. 19 of the Directive was established for Poland.
We invite you to become acquainted with our attempt to summarize the first year of Poland's experience regarding the introduction of SPCs as well as a discussion of the most important legal problems accompanying this process.

2. Applications for the granting of SPCs submitted in Poland

Information concerning applications for the granting of SPCs in Poland is published by the Patent Office of the Republic of Poland (UPRP, Urząd Patentowy RP) in the Patent Office News (WUP, Wiadomości Urzędu Patentowego). To date, i.e. August 8, 2005, information on 45 applications for the granting supplementary protective rights (hereinafter "published applications") have been published (issues WUP 7/2004 - WUP 6/2005), these involving 43 different pharmaceutical products (complete documentation of these applications can be found at http://www.wtspatent.pl/download, accessible to clients of WTS). Only three of these applications concern products which obtained their first authorization for market introduction after May 1, 2004, whereas in the case of the remaining 40 therapeutic products, because of the dates of issuance of the first authorizations for market introduction, we have to do with applications to which transitional regulations established in the Accession Treaty should be have been applied.



Initial analysis of these decisions leads us to conclude that most of them do not fulfill the formal requirements set forth in the above regulations.



1 - SPC applications (drugs)
2 - number of products related to filed SPC applications (drugs)
3 - first authorization granted before 2000
4 - Polish authorization granted before 5/2004
5 - patent issued after May 1, 2004
6 - application submitted after the deadline
7 - first authorization after May 1, 2004
8- other: no formal errors found

3. The most serious obstacles in granting SPCs concerning the applications published by the Polish Patent Office (UPRP)

The most serious formal errors observed in the published applications are discussed below.

3.1. Products introduced on the Polish or EU markets before January 1, 2000, may not apply for an SPC in Poland.

Seventeen of the SPC applications published by the UPRP concern pharmaceutical products which obtained their first authorizations for market introduction before January 1, 2000. Such products are not within the domain defined in Art. 19 of Directive 1768/92 in the version adopted for Poland in the Accession Treaty and may not apply for an SPC in our country.

Let us try to analyze the legal bases which justify the above statement in detail. In this case, the transitional regulations apply, in particular:

- the Act of June 6, 2002, amending the Act of June 30, 2000, the Industrial Property Act (Polish Journal of Laws No. 108, 2002), in particular the changes in Art. 2 of the IPA contained in it, establishing that:

"Article 2

(Act of 6 June 2002 amending the Act of 30 June 2000 Industrial Property Act – Polish Journal of Laws No. 108/2002)

1. A supplementary protection right may be granted for an active ingredient or combination of active ingredients, which at the date of the accession of the Republic of Poland to the European Union are protected by a valid basic patent and for which the first authorisation to place them on the market on the territory of the Republic of Poland or of the European Union has been obtained prior to the date of the accession of the Republic of Poland to the European Union, however no earlier than the date of 1 January 2000.

2. Applications for the granting of supplementary protection rights in the cases referred to in paragraph (1) may be lodged within 6 months of the date of the accession of the Republic of Poland to the European Union."

and

- the appropriate provisions contained in the Accession Treaty, in particular Appendix II, the Company Act, introducing, among others, changes to the Directive of the Council of the EEC 1768/92 including the supplementary Art. 19a containing, among others, transitional provisions concerning Poland, establishing that:

"Article 19a

Additional provisions relating to the enlargement of the Community

Without prejudice to the other provisions of this Regulation the following shall apply:

(h) any medicinal product protected by valid basic patent and for which the first authorisation to place it on the market as a medicinal product was obtained after 1 January 2000 may be granted a certificate in Poland, provided that the application for the certificate is lodged within six months starting no later than the date of accession;"

From these provisions results that supplementary protection certificate may not be granted to products which obtained their first authorization for market introduction before January 1, 2000.

In accordance with the content of Art. 2 of the IPA, one must regard the earliest authorization granted anywhere on the territory of the EU states or in Poland as the first authorization for market introduction. As the provision cited above defining the wording of Art. 19 of the Directive contained in the Accession Treaty may appear unclear, it is worth discussing here additional circumstances facilitating the interpretation of this provision.

An unambiguous interpretation of this provision results, among others, from a comparison of the content of the provision concerning Poland and provisions applying to other countries accessing to the EU at the same time, in which a separate regulation was adopted. For example, it was established with regard to Slovenia that only authorizations granted in that country are to be taken into consideration, which was clearly expressed in the respective provision of the Treaty:

"(i) any medicinal product protected by valid basic patent and for which the first authorisation to place it on the market as a medicinal product <u>was obtained in Slovenia</u> prior to the date of accession may be granted a certificate, provided that the application for the certificate is lodged within six months of the date of accession, including in cases where the period provided for in Article 7(1) has expired;"

The lack of a similar special regulation in the provisions concerning Poland allows us to conclude that the date of the "first authorization to place it on the market" given, spoken of in the version of Art. 19a of the Directive of the Council (EEC) 1768/92 accepted in the Accession Treaty with regard to Poland, is "the date of the first authorization to place it on the market in the Community" applied to determine the duration of the supplementary protective rights in accordance with Art. 13 of the Directive, whereby “the Community” is here to be understood as the states belonging to the EU on May 1, 2004, that is on the day when the directive of the Council took effect on Polish territory. Only this kind of interpretation allows maintaining a uniform duration of an SPC on the territory of the Community.

Confirmation of such an interpretation may be found in rulings of the European Court of Justice (ECJ), in particular in decision number ECJ C-110/95 handed down in the case of Yamanouchi Pharmaceutical Co. Ltd. v. the Comptroller-General of Patents, Designs, and Trademarks. In its verdict, the ECJ referred to the time limits connected with authorizations for market introduction and stated that the reference to the first authorization for market introduction in the Community aims at establishing the duration of an SPC, and one date for the whole EU assures uniformity of the time of duration of the SPC in the whole Community. The existence of a national authorization to introduce a therapeutic product to the market is, however, a necessary condition for obtaining an SPC in the given country.

The justification of the correctness of a direct application of the remaining regulations of the Directive of the Council (EEC) 1768/92 is also contained in the first sentence of Art. 19a, which, introducing the transitional provisions, states:

> *"19a Without prejudice to the other provisions of this Regulation, the following shall apply:"*

From this one must conclude that the remaining provisions of the Directive which have not been modified in the transitional provisions, and therefore in particular Art. 13, should be applied in accordance with their current wording. Thus the date of obtaining authorization to introduce a product on the market mentioned in Art. 19a (h) is the date of the first authorization to introduce the product on the market in the Community, as spoken of in Art. 13.

Justification for such a position may also be found in the decision of the ECJ of December 11, 2003, in case number C-127/00 Hässle AB v. Ratiopharm GmbH concerning the invalidation of an SPC issued to the company Hässle in Germany. In its verdict the European Tribunal of Justice referred to the time limits connected with authorizations to allow market introduction in light of the transitional provisions determined for Germany in Art. 19 of the Directive, which established that in that country, supplementary protective rights may be granted for products which obtained their first authorization for sale on the territory of the Community after January 1, 1988.

> *"Article 19*
>
> *Transitional provisions*
>
> *1. Any product which, on the date on which this Regulation enters into force, is protected by a valid basic patent and for which the first authorisation to place it on the market as a medicinal product in the Community was obtained after 1 January 1985 may be granted a certificate.*
>
> *In the case of certificates to be granted in Denmark and in Germany, the date of 1 January 1985 shall be replaced by that of 1 January 1988."*

In the above matter, the SPC issued in Germany for the product of the company Hässle was then annulled in consideration of an existing authorization for the sale of this same product which was

issued in France before the date of January 1, 1988, defined in Art. 19 of the Directive. Appealing this decision, Hässle tried to argue that one of the conditions of obtaining an SPC on the basis of Art. 19 is an authorization spoken of in Art. 2 (b) and (d), i.e. the first authorization granted in that country in which the application was made (i.e. an authorization granted in the Federal Republic of Germany after the date defined in Art. 19). The ECJ saw this position as ineffective. In the opinion of the Tribunal, the expression "first authorization (...) in the Community" used in Art. 1 par. 1 means the first authorization granted "in any of the Member States". Therefore only one authorization, that is the oldest authorization granted in the Member States of the Community, comes into consideration.

The cases discussed of applications submitted to the UPRP present a situation analogous to that of case C-127/00 of Hässle AB v. Ratiopharm GmbH, which was the subject of the decision of the ECJ cited above. In these cases there were authorizations granted on the territory of the Community before the date of January 1, 2000, stipulated in the transitional provisions for Poland.

In summary it must be said that supplementary protective rights acknowledged by the UPRP based on the transitional provisions cited above should be limited to products fulfilling the remaining conditions, for which first authorizations to introduce a product on the market of the Republic of Poland or the European Union was obtained no earlier than January 1, 2000. However, in the cases cited, the first authorizations to introduce these products on the market were granted before January 1, 2000, in each case.

3.2. Polish authorizations for market introduction granted before May 1, 2004, may not be the basis for granting an SPC based on the provisions of Directive 1768/92.

Twenty-eight SPCs applications published by the UPRP indicate the authorization granted before May 1, 2004, as Polish authorization for market introduction. In view of the transitional provisions contained in the Accession Treaty, these applications do not fulfill the conditions stipulated in Art 3 (b) of Directive 1768/92.

Let us attempt to analyze the legal basis justifying the above statement in detail. In light of the prevailing regulations, these decisions, first of all, do not fulfill the demand stipulated in Art 3 letter b) of the Directive of the Council (EEC) No. 1789/92 of June 18, 1992.[1] According to this regulation, certification is issued if, in the Member State in which the application is submitted, on the day of submission of the mentioned application a valid authorization for the sale of the therapeutic product had been granted in accordance with the appropriate directive 65/65/EEC or 81/851/EEC.

Authorizations granted in Poland before May 1, 2004, on the basis of regulations unadjusted to Community pharmaceutical directives[2] do not fulfill the condition stipulated in Art 3 (b) of the Directive. That "old" national authorizations do not fulfill this condition is clearly testified by the fact that Poland had to obtain a transitional period to re-register drugs in order to bring their authorizations into agreement with EU law. Although on the strength of the decisions establishing the transitional period, "old" authorizations remain valid to the time they are prolonged in accordance with the *acquis* and the schedule indicated in the register contained in Supplement A to

[1] Justification for the correctness of directly applying the remaining regulations of the Directive of the Council (EEC) 1768/92 to products defined in the transitional provisions defined in Art. 19 is provided in the first sentence of Art. 19a, which, introducing the transitional provisions, states "19a Without prejudice to the other provisions of this Regulation, the following shall apply:".

[2] This especially concerns regulations in effect prior to the time the law, the Pharmaceutical Law, took effect. Indeed, the law of October 10, 1991, about pharmaceuticals, medical materials, pharmacies, wholesalers, and Pharmaceutical Inspection (Journal of Laws No. 105, item 452, with later amendments) lost force on the day the Pharmaceutical Law took effect (October 1, 2002); however, applications for authorization for sale could be submitted in accordance with the regulations during the period to June 30, 2003, and processed according to the prior regulations. See Art. 19 par. 2 of the Law of September 6, 2001, Journal of Laws No 126, item 1382, with later amendments.

Appendix XII of the Accession Act, that is December 31, 2008, whichever is earlier,[3] this does not change the fact that to the time of renewal they may not be recognized as granted in accordance with the EU directives mentioned.

In addition, one cannot find in the transitional provisions concerning Poland contained in Art. 19 of the Directive grounds for issuing SPCs for pharmaceutical products allowed for sale based on pharmaceutical legislation in force in Poland. For comparison, one must observe that solutions applied in connection with the accessions of Austria, Finland, and Sweden involved "equalization" of the national authorizations granted in the countries mentioned during the period preceding accession to authorizations spoken of in Art. 3 (b) of the Directive. On the strength of the Act of Accession of 1994 in Art. 3 (b) of the Directive, decisions given in accordance with the goals of Art. 19 par. 1, an authorization granted in accordance with the national law of Austria, Finland, or Sweden is regarded as an authorization granted in accordance with Directive 65/65/EEC or Directive 81/851/EEC.[4]

In contrast, analogous solutions were not applied with regard to Poland (and the other new members of the Community), which means that there was no ruling on the basis of which national authorizations could be treated, in particular in deciding on SPCs, as granted in accordance with both directives (currently 2001/83/WE and 2001/82/WE).

In summary, one must state that supplementary protective rights acknowledged by the UPRP based on the transitional provisions cited above should be limited only to products which, fulfilling the remaining conditions, possess an authorization for market introduction in the Republic of Poland granted in accordance with Directive 65/65/EEC or Directive 81/851/EEC.

However, in the case of the products discussed there are no authorizations for their introduction for sale in Poland granted in accordance with the cited directives of the Community.

3.3. Products introduced for sale during the transitional period may apply for an SPC in Poland under the condition that a valid basic patent existed on the day the Republic of Poland obtained membership in the European Union.

In the case of one of the decisions concerning SPCs published by the UPRP, a basic patent was approved several days after May 1, 2004. At the same time, the first authorization to introduce the product for sale, which was also indicated in the application for issuing the SPC, was granted after January 1, 2000, and before May 1, 2004, i.e. during the so-called "transitional period". However, in accordance with the content of Art. 2 of the IPA cited above, supplementary protective rights may be granted on the active substance or the combination of such substances which, on the day the Republic of Poland acquired membership in the European Union, were protected by basic patent and for which a first authorization for market introduction in the Republic of Poland or the European Union was obtained during the transitional period.

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[3] See points 4 and 5 of chapter 1 of Appendix XII to the Accession Act (appendix No. 1 of the Journal of Laws of 2004, No. 90, item 864, vol. II, pp. 391-392). The provision concerning Directive 2001/83/WE is worded: "As an exception to the requirements concerning quality, safety, and effectiveness established in Directive 2001/83/WE, authorizations to place pharmaceutical products on the market which are found within the register (in supplement A to this Appendix in the version presented by Poland in one language version) issued by force of Polish law before the day of accession shall remain valid to the time of their prolongation in accordance with the *acquis* and schedule indicated in the register referred to above, or December 31, 2008, whichever is earlier. Without prejudice to the regulations of title III, chapter 4 of the Directive, authorizations to place a product on the market included by this exception do not make use of reciprocal recognition in the Member States." An analogous regulation concerns Directive 2001/82/WE (point 5, chapter 1, Appendix XII to the Accession Act).

[4] This decision, added as the second sentence of Art. 3 letter b), runs: "*For the purpose of Article 19 (1), an authorization to place the product on the market granted in accordance with the national legislation of Austria, Finland or Sweden is treated as an authorization granted in accordance with Directive 65/65/EEC or Directive 81/851/EEC, as appropriate.*"

3.4. Applications for an SPC involving products introduced for sale before May 1, 2004, must be submitted to the UPRP before October 31, 2004.

Three of the applications published by the UPRP concern products introduced for sale during the so-called "transitional period" were submitted to the UPRP after October 31, 2004. This is not in accordance with the content of Art. 19a of Directive 1768/92 `cited above in the version established for Poland in the Accession Treaty, according to which applications involving products during the transitional period must be submitted within six months from the day of Poland's entry into the European Union, i.e. no later than October 31, 2004.