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SPC rules harmonization: EU and Ukraine

Alona Kiriak (ELC Group) · Monday, October 17th, 2016

To ensure the continued development of medicinal products which are the result of enormous R&D costs the supplementary protection certificate ('SPC') was introduced into EU law in 1993 with the entry into force of the SPC Regulation (Council Regulation (EEC) No 1768/92).

After the Ukraine's declaration of independence, hard work on adopting new legislation began to enable the functioning of a market economy. Even though the Ukrainian law "On Protection of Rights to Inventions and Utility Models" came into force on July 1, 1994, the concept of SPCs was still missing in Ukraine at that time. A mechanism comparable to the EU SPC appeared in Ukraine only on June 1, 2000, with the entry into force of a new law (repealing the law of 1994). It took the Ministry of Education and Science of Ukraine two more years to adopt a detailed instruction on where, when, and how to apply for an extension of the term of protection of a medicinal product.

From the early 2000s, the respective mechanisms in the EU and Ukraine were similar. Nevertheless, the name "supplementary protection certificate" was never used in the Ukrainian legislation before the execution of the EU-Ukraine Association Agreement in 2014 (see hereafter). The duration of the additional protection remains the most striking difference in the legal regime of SPCs in the EU and Ukraine in spite of all harmonization efforts.

The SPC Regulation (Regulation No 469/2009 as well as its predecessor in 1992), provides in Article 13 that the SPC shall have effect for the 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, reduced by a period of five years. In any event, the duration of the certificate may not exceed five years. Thus, if the period between the patent application date and the date of the first market authorisation is 7 years, one should reduce it by 5 years, and the resulting duration of the SPC is 2 year. The condition that the duration of a certificate may not exceed five years serves to safeguard all interests in the public health sector.

The Ukrainian Instruction "On prolongation of the patent protection of the invention that is subject to an administrative authorisation procedure" repeats the language of the SPC Regulation, but for the part where the period between the patent application date and the date of the first market authorisation shall be reduced by a period of five years. Therefore, in the same situation as described above, where the period between the patent application date and the date of the first market authorisation is 7 years, Ukrainian authorities will not reduce it by 5 years. Instead, the condition of "not-more-than-5-years" applies. Thus, in the very same situation as described above, the duration of the additional protection in Ukraine will be 5 years.

The EU-Ukraine Association Agreement has introduced a new way to calculate the duration of SPCs. This agreement contains an Article 220 named “Supplementary protection certificate” which details, inter alia, the duration of the SPC:

Article 220:

1. The Parties recognise that medicinal and plant protection products protected by a patent on their respective territory may be subject to an administrative authorisation procedure before being put on their market. They recognise that the period that elapses between the filing of the application for a patent and the first authorisation to place the product on their respective market, as defined for that purpose by the relevant legislation, may shorten the period of effective protection under the patent.
2. The Parties shall provide for a further period of protection for a medicinal or plant protection product which is protected by a patent and which has been subject to an administrative authorisation procedure, that period being equal to the period referred to in paragraph 1 [of this Article], reduced by a period of five years.

These provisions are operational since January 1, 2016, when the provisional application of the Agreement took effect. Article 220 introduces that the term of protection is reduced by a period of five years.

Unlike other Association Agreements signed by the EU with Eastern Partnership countries – Moldova and Georgia – the EU-Ukraine Association Agreement does not contain the condition that the duration of SPC may not exceed five years. The three Association Agreements are analogous; they were negotiated and signed almost simultaneously. However, the Association Agreements with both Moldova and Georgia limit the maximum term of additional protection to 5 years in Art. 314(3) and Art. 186(3) respectively. Under the EU-Ukraine Association Agreement supplementary protection can be obtained for more than five years if the first market authorisation was granted more than ten years after the patent application date. Thus, the EU-Ukraine Association Agreement is more favorable to research-based pharmaceutical companies, but clashes with provisions of Art. 13 of the SPC Regulation, which does contain the 5 years limitation.

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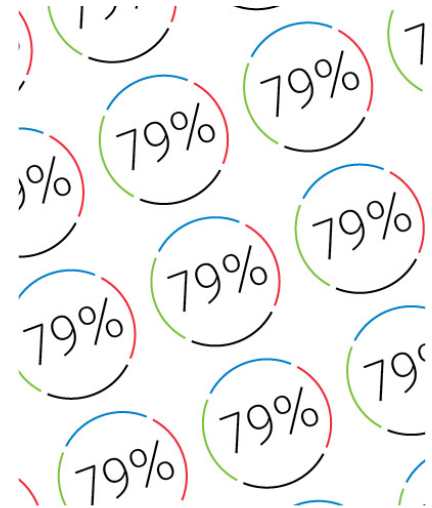
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