SPC Manufacturing Waiver

The subject of the supplementary protection certificate (SPC) has already been featured in a number of our publications. The essential basic information about SPC can be found in one of the first entries in our series “Patents Without Secrets” (No. 7/2020 — available only in Polish language). We have also covered for you the case-law of the CJEU clarifying the conditions for granting of SPCs (the judgments in Royalty Pharma and Santen cases, see: WTS Legal Reports No. 11/2020 and No. 12/2022, respectively).

This time, we would like to examine **the institution of the SPC Manufacturing Waiver — which can be considered as an intrusion into the scope of protection that a patent holder (or their successor) enjoys on the grounds of an SPC.** In this Report we indicate when the application of the waiver will be possible and what conditions a maker who wants to invoke it has to fulfill. We present the current practice that has developed in Poland in this area. We also aim to bring to your attention certain controversies involving the interpretation of the regulation that a maker intending to use the waiver should take into consideration.

SPC: basic information

Let us remind you that a supplementary protection certificate, as an institution of the EU law, is mostly regulated by **Regulation (EC) No 469/2009 of the European Parlia-**

ment and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products.

Pursuant to Art. 5, the certificate shall confer the same rights as conferred by the basic patent and shall be subject to the same limitations and the same obligations. It shall be granted either to the holder of the basic patent or their successor in title (Art. 6). The regulation, when demarcating the scope of protection, states that it shall extend only to the product covered by the authorisation to place the corresponding medicinal product on the market and for any use of the product as a medicinal product that has been authorised before the expiry of the certificate (Art. 4).

The key role of the SPC is **to provide the extension of the duration of protection.** The certificate is valid for a time equal to the period that elapsed between the date on which the application for a basic patent was lodged and the date of the first authorization to place the product on the market in the Community, reduced by the period of 5 years (Art. 13(1)). The duration of the certificate may not exceed 5 years (Art. 13(2)). The regulation provides for an exception in case of studies conducted in compliance with an agreed pediatric investigation plan where it is possible to extend the duration of protection by 6 months (Art. 13(3)).

Such strengthening of the protection of medicinal products was justified by a diagnosis that due to the time-consuming nature of the necessary research (a long time lapses between the filing of a patent application and obtaining the authorization to place the product on the market), the actual duration of the protection is not sufficient to cover the investment. The SPC is, therefore, supposed to serve as a compensation for individuals and entities conducting pharmaceutical research and prevent situations where it would be more beneficial for them to relocate outside the EU. **Nevertheless, the strengthening of the protection of the patent holder by allowing them to file for an SPC, had some unintended consequences.**

The rationale behind the waiver

As a result of the introduction of the SPC, **the makers of generics and biosimilars established in the EU found themselves in an especially disadvantageous position.** They were not able to make generics and biosmiliars for purpose of export to third-country markets in which the protection did not exist or had expired, nor for the purpose of storing them for a period before the expiry of the certificate. **The makers from outside of the EU were not bound by similar restrictions,** therefore, the competition did not take place on the level playing field.

The solution to this problem has been proposed in **Regulation (EU) 2019/933 of the European Parliament and of the Council of 20 May 2019 amending Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products.** Through that legal instrument the manufacturing waiver has been introduced.

The preamble explicitly states that such an intervention is necessary to avoid the threat to viability of makers of generics and biosimilars established in the Union. The gravity of the problem is underscored by the statement in the Preamble that the effective functioning of the internal market is at risk and the effects of such a situation can be a decrease in investments and hampering of job creation within the EU. The aim of the regulation has been defined as "to promote the competitiveness of the Union, thereby enhancing growth and job creation in the internal market and contributing to a wider supply of products under uniform conditions" (Preamble, para. 8). It is not only supposed to support the pharmaceutical sector, but above all promote the general interest of the Union by increasing medicines' accessibility to patients.

In a report from a study commissioned by the European Commission we can find estimates that the introduction of the waiver would result in generating, i.a., additional net sales for the EU pharmaceutical industry amounting to €9.5 billion, 25,000 additional jobs, and saving in the European healthcare system of €3.1 billion (see: Charles River Associates, *Assessing the economic impacts of changing exemption provisions during patent and SPC protection in Europe*).

When the waiver will apply

The essential changes introduced by the Regulation have affected in particular Art. 5. The provision determining the effects of the certificate, which used to consist of just a single sentence, has been considerably expanded. New Section 2 stipulates that **the certificate shall not confer protection against certain acts which would otherwise require the consent of the holder of the certificate.**

We can identify **two categories of acts** covered by the waiver: **the making of a product, or a medicinal product containing that product, for the purpose of export to third countries and the making for the purpose of storing it** (so as to be able to place the product on the market in the Member States after the expiry of the certificate). The possibility to invoke the waiver in the latter situation is temporarily limited: such acts cannot be undertaken earlier than 6 months before the expiry of the SPC.

It must be remarked that **the waiver extends also to related acts**. When it comes to the export to third countries, any related act that is strictly necessary for the making of the product in the Union or for the actual export shall be excluded from the scope of protection. As for the storing, it is permissible to carry out any related acts that are strictly necessary for the making of the product or for the actual storing — under the condition that such acts are carried out no earlier than 6 months before the expiry of the certificate.

The preamble in paragraph 11 specifies also **in what cases the waiver will not apply:**

- Placing a product, or a medicinal product containing that product, which is made for the purpose of export to third countries or for storing with a view to EU day-one entry, on the market of a Member State where certificate is in force, either directly or indirectly after export;
- Re-importation of such a product, or medicinal product containing that product, into the market of a Member State in which a certificate is in force;
- Any act or activity carried out for the purpose of import of products, or medicinal products containing those products, into the Union merely for the purposes of repackaging and re-exporting;
- Storing of products, or medicinal products containing that products, for any purposes other than those set out in the Regulation.

It should be noted that the Regulation provides as well an autonomous definition of the maker as an individual who is entitled to invoke the waiver. The maker has been defined as the person, established in the Union, on whose behalf the making of a product, or a medicinal product containing that product, for the purpose of export to third countries or for the purpose of storing, is carried out (Art. 1(f)). For their actions not to constitute an infringement of the protection that the patent holder or their successor enjoys on the grounds of the SPC, the fulfillment of certain further conditions is required.

The obligations of the maker

First, the Regulation imposes on the maker intending to use the waiver **an obligation to provide specific information.** The maker has to fulfill that obligation no later than 3 months before the start date of the making or no later than 3 months before the first related act prior to that making (whichever is the earlier). The information has to be notified to the certificate holder and the competent industrial property office of the Member State which granted the basic patent (or on whose behalf it was granted) and in which the authorization to place the product on the market was obtained.

The information to be provided by the maker shall comprehend:

- The name and address of the maker;
- An indication of the purpose of the making: export / storing / both export and storing;
- The Member State in which the making and, if applicable, also the storing is to take place (as well as the Member State in which the first related act, if any, prior to that making is to take place);
- The number of the certificate granted in the Member State of making (and the number of the certificate granted in the Member State of the first related act, if any, prior to that making);
- For medicinal products to be exported to third countries, the reference number of the marketing authorization, or the equivalent of such authorization, in each third country of export, as soon as it is publicly available (Art. 5(5)).

One of the attachments to the Regulation (Annex I-a) is **the standard form that the maker has to use when submitting the notification** (Art. 5(6)). The maker is obliged to notify the changes in the information listed above before the changes take effect (Art. 5(2)(c)). What is particularly important, if making takes place in more than one Member State, the notification will be required in each Member State.

The Regulation stipulates that the information provided to the certificate holder shall be used exclusively for the purposes of verifying whether the requirements of the Regulation have been met and, where applicable, initiating legal proceedings for non-compliance (Art. 5(4)).

Second, the Regulation lays down **a due diligence standard that the maker is expected to comply with**. They shall provide certain information also to persons with whom they have a contractual relationship and who perform acts covered by the waiver. It concerns mostly persons within their supply chain, including the exporter and the person carrying out the storing. These persons have to be fully informed and aware of the fact that the acts they carry out are subject to the provisions of the Regulation (i.e., that the waiver applies to them), and that the placing on the market, import or re-import of the product made for the purpose of export or the placing on the market of the product made for the purpose of storing could infringe an SPC where, and for as long as, the certificate applies (Art. 5(9)).

Third, **the maker shall label medicinal products made for the purpose of export to third countries.** A logo in the form set out in Annex -I shall be affixed to the outer packaging of the product. Whenever it is possible, it shall be also placed on the immediate packaging (Art. 5(2)). The logo shall appear in black and in such a size as to be sufficiently visible (see below).

Publication of the information provided by the maker

Under Art. 11(4) of the amended regulation, **the competent industrial property office of the Member State which granted the basic patent** (or on whose behalf it was granted) **and in which the authorization to place the product on the market was obtained, shall publish, as soon as possible, the information listed in Art. 5(5), together with the date of notification of that information.** The same applies to the changes of the information in question. This obligation is justified in the Preamble by the need to ensure transparency (para. 14).

It shall be added that the industrial property office may charge a fee for the notifications if such a requirement has been adopted by a given Member State (Art. 12(2)).

The practice in Poland

The fact that the manufacturing waver has been introduced into the EU legal system through a regulation has some important consequences. **The provisions concerning that matter shall be binding in their entirety in all Member States, without any need for their transposition.** A question could be raised whether every regulation would always be appropriate for direct application if there in the lack of implementing provisions adopted on the level of individual Member States. In the judgement of 11 January 2001 in the case C-403/98 *Azienda Agricola Monte Arcosu Srl v. Regione Autonoma della Sardegna Organismo Comprensoriale,* the Court of Justice confirmed that in certain cases some provisions of regulations might necessitate, for their implementation, the adoption of measures of application by the Member States. **It appears that in Polish law,** even though the provisions of the Regulation satisfy the criteria of direct applicability, **there remains certain**

space for more clear and precise rules governing the procedure concerning the notifications by the maker.

Under current law, **the publications are made by the Patent Office of Poland (PPO)**. The information submitted by the maker is presented in the PPO's official gazette: **Patent Office News (WUP)** in the rubric "Announcements not published in other independent publications". The current practice of the PPO is to publish the information within a month after its submission (due to some technical reasons and also taking into consideration the publication frequency of WUP). Meanwhile, the EU lawmaker has indicated that the publication shall be made as soon as possible.

As of this moment, there are no legal provisions in Poland that would constitute a basis for charging the maker a fee for the notification. The Regulation of the Council of Ministers of 8 September 2016 amending the regulation on fees related to the protection of inventions, utility models, industrial designs, trademarks, geographical indications, and mask works has not been updated, therefore it does not address the fee for the notification that Regulation 2019/933, adopted later, refers to.

The controversies regarding the interpretation of the Regulation

In certain cases, we might be dealing with acts whose qualification as related acts that are covered by the manufacturing waiver, would raise some considerable difficulties. As the matter is governed by the EU law, it is the CJEU that is competent to interpret relevant provisions, not industrial property offices of distinct Members States. **The institution of the manufacturing waiver is still relatively novel, therefore, no practice has developed that might be helpful in clarifying certain more controversial issues.**

It is worth pointing out the problem that can arise in the context of the interpretation of the scope of the related acts. The related acts are defined in paragraph 9 of the Preamble as acts strictly necessary for the making or for the actual export or the actual storing, where such acts would otherwise require the consent of a certificate holder. Subsequently, the Preamble offers an exemplary list of such acts: the Regulation mentions possessing; offering to supply; supplying; importing; using or synthesising an active ingredient for the purpose of making a medicinal product; or temporary storing or advertising — for the exclusive purpose of export to third-country destinations. This reservation of the exclusive purpose of export turns out quite confusing. Would, for instance, importing for the purpose of storing qualify as a related act? On the one hand, if it is an act strictly necessary for the use of the manufacturing waiver, the conditions laid down in the definition would be fulfilled. Moreover, the list in the Preamble cannot be considered exhaustive — there can exist other types of related acts besides those mentioned expressly by the Eu-

ropean lawmaker. On the other hand, however, an argument can be made that such an explicit stipulation that these acts shall be allowed only if they are carried out for the purpose of export to third-country destinations means that *a contrario* the same acts carried out for the purpose of storing would fall beyond that scope.

Considering the scarcity of practice as well as the lack of available binding interpretation, we are faced with ambiguity that requires extensive caution when invoking the manufacturing waiver in case of certain kinds of related acts.

