Kluwer Patent Blog

Analysing the use of the SPC waiver provisions and its reach outside the EU

Ji?í Slavík (European Patent Attorney | Senior IP Manager at Adalvo) · Monday, October 17th, 2022

Just over 2 years after the SPC waiver Regulation (EU) 2019/933 (amending the Regulation (EC) No 469/2009) entered into force (1 July 2019), and only a few months after the end of the transitional provisions for application of the SPC waiver under Art. 5(10) of the Regulation (2 July 2022), I have decided to follow up on my previous post on the SPC manufacturing and stockpiling waiver provisions. Previously, I summarized the practical implementation of the SPC waiver provisions among the majority of the 27 EU offices shortly after the amended Regulation entered into force. The current post focuses on the use of the SPC waiver provisions by generic manufacturers, and on the reach of those provisions outside of the EU.

European Union

Focusing first on the biggest markets, at least two notifications were published in **Germany** in relation to SPCs for sugammadex (Synthon – included CZ as the Member State in which the first related act prior to making is to take place, see further below) and sitagliptin (Denk Pharma). It is also quite easy to search for either new notifications or any updates thereof *via* the expert search on DPMA website, by selecting the appropriate tag under the legal/procedural status (VST).

Probably the highest number of notifications and their updates were published in **Spain**. Notifications were filed with respect to SPCs relating to sugammadex, sitagliptin, sitagliptin/metformin, vildagliptin, vildagliptin/metformin, rivaroxaban and ticagrelor and the manufacturers involved were Galenicum, Farmhispania, Biogaran, Normon Labs, Liconsa Labs, Kern Pharma, Cinfa Labs, Pensa Pharma, Alter Labs and Merck. The details for each notification and updates are included among the documents in the on-line register for each SPC. It is also possible to easily search for the waivers using advanced search function within the Official Gazette, in volume II (*Invenciones*), section C (*Certificados complementarios de Protección*) and subsection 14.0.0.14 (*Otras anotaciones*).

France has not yet received any notification[1]. It was previously reported that said notifications will be published in the Official Bulletin (part 6.1) and directly in the on-line register for each SPC. **Italy** has previously mentioned that it will provide a separate table on its website, where the SPC waiver notifications will be published. However, as no such notification has been received, there is no table available[1]. **Ireland** already provides an easily accessible separate list of SPC waiver notifications received by the Office, from which it visible that at the time of conducting this

research no notification has been received. No notification has been received in **the Netherlands**[1]. It has been previously reported that the Netherlands Patent Office will publish notifications in the Official Gazette and in the on?line register, as part of each SPC file.

Several notifications for either storing and/or export have been published in **Portugal** in relation to SPCs for sitagliptin (Alfred E. Tiefenbacher), sitagliptin/metformin (Alfred E. Tiefenbacher, Axunio Pharma, Bluepharma and Axapharm), vildagliptin (Mylan, Bluepharma, Alfred E. Tiefenbacher, Zydus and Rivopharm) and vildagliptin/metformin (Alfred E. Tiefenbacher, Mylan, Bluepharma and Rivopharm). It is worth mentioning that the Portuguese on-line register includes only a note for an observation received in the list of miscellaneous documents for each SPC. Details of the notification is available in the IP Bulletin which is published daily (in a separate section for SPC waiver notifications). So, the Portuguese notices are not easily searchable.

No notification has been published in the Official Journal in **Slovakia** (published bi-monthly). Previously, it was reported that the on-line register will only include a general note in the protocol of the on-line file of each SPC for the notification. No SPC waiver notification has been received in **Austria**[1]. Any such notification will be published in the Austrian Patent Gazette (under the SPC section). Also, among the Baltic states (**Latvia**, **Lithuania,** and **Estonia**) no Office has thus far received a notification[1].

Similarly, none of the Offices in the Nordic countries have so far received a SPC waiver notification[1]. The **Danish Office** has mentioned that it is currently implementing the publication means for the SPC waivers. It is therefore not possible to access the notifications on its website for now. In **Finland**, the notifications will be accessible either electronically *via* the PatInfo database for each specific SPC or in the Patent Gazette (under part D). **Sweden** unfortunately reported that there is no easy way to search for the notifications – it previously stated that the information will be published in the Swedish Patent Gazette, but will not for the time being be available in the on-line database (Svensk Patentdatabas) for each corresponding SPC. Iceland and Norway are discussed further below as they are not part of the EU.

Turning further to several EU member states with important local generic manufacturers, we find more examples of the use of the SPC waiver. Several notifications and updates thereof were identified in **Poland** in relation to 4 different SPCs – sitagliptin (Adamed and Polpharma), rivaroxaban (Polpharma), ticagrelor (Polpharma) and apixaban (Polpharma).

At least one SPC waiver notification for export & storing was published in the Official Bulletin in the **Czech Republic** for sugammadex SPC by Synthon (corresponds to the SPC waiver published in Germany, as noted above).

On the other hand, no SPC waiver notifications were received in **Hungary**[1]. The Hungarian Office confirmed that the information from the waiver will be included in the Gazette (in the SPC part, as diverse publications) and that the same information will be available in the on-line database for each respective SPC (under the other procedures part).

As reported earlier, **Slovenia** publishes the manufacturing notifications in a separate list, from which it is visible that two SPC waiver notifications and two further updates were received in relation to the sitagliptin SPC by local generic manufacturers (Lek and Krka).

At least two SPC waiver notifications for storing were published by the Office in **Greece**, in relation to vildagliptin and vildagliptin/metformin SPC by Pharmathen. The published SPC waivers are available both in the on-line register for each respective SPC and in the Patent Bulletin (separate chapter for said notifications is included in the general Part C of the Patent Bulletin).

Malta provides a separate list of notifications received by the Office. However, at the time of conducting this research, no SPC waiver notification was listed. In **Romania**, at least one SPC waiver notification for storing was published in the IP Bulletin (Invention Patents section, SPC part in Annex no. 1) for sitagliptin SPC by Gedeon Richter Romania. No notification has been received in **Bulgaria**[1]. The Office is still in the process of implementing its local provisions for publication of the SPC waivers. No SPC waiver notification has been received in **Croatia**[1]. The Office noted that it is not possible to search for the waivers on the DZIV website, but an interested party can submit a request to the Office to provide such information. However, each notification will be associated with the relevant SPC and visible in the on-line register.

Countries outside the European Union

The **United Kingdom** is not part of the EU anymore, however, the amended SPC Regulation that entered into force on 1 July 2019 was retained as a domestic UK law following Brexit, and was further amended in order to work correctly within the UK territory[2]. The most important change is the territorial scope of the manufacturing waiver for export – whereas the EU SPC waiver provisions allow for manufacturing in an EU member state for export into the UK (as a third country outside the EU, if there is no corresponding UK SPC in-force), the UK SPC waiver provisions allow for manufacturing in the UK for export only outside the UK, the Isle of Man and the EU member states (see also box 5 of the Patents Form SP5, used for the SPC manufacturing waiver notifications in the UK). The dates applicable to the transitional provisions under Art. 5(10) of the Regulation remain the same. It is worth noting that thus far there have been no notifications in in the UK[1].

The Regulation (EU) 2019/933 was adopted by the EU Parliament and Council with EEA relevance. Even though it does not extend automatically to the **EEA/EFTA member states**, the process of incorporating the SPC waiver provisions into the EEA Agreement is well underway[3]. The entry into force of this amendment requires fulfilment of certain legislative requirements, which may take some time. As a comparison, it took almost 10 years for the current SPC Regulation (EC) No 469/2009, which entered into force in the EU on 6 July 2009 (repealing the former SPC Regulation (EEC) No 1768/92), to be incorporated into the EEA Agreement and enter into force on 1 June 2018[4].

[5]

Iceland, independently of the foreseen amendments to the EEA Agreement, adopted the SPC waiver provisions last year by amending Art. 65a of its Patents Act No. 17/1991 after enacting Act No. 1460/2021, which entered into force on 1 July 2021[6]. Further to that, Art. 69a of the revised Regulation on Patents No. 477/2012 was amended by Regulation No. 224/2022, in force as of 31 January 2022[7]. As the Icelandic SPC waiver provisions entered into force quite soon after the EU Regulation itself, they included similar, yet shorter transitional provisions as compared with the EU ones. As of 2 July 2022, the waiver applies to SPCs entering into force on 1 July 2021 and later, if an SPC application has been filed prior to that date. A notable difference lies in the export provisions, which apply to products to be exported to countries outside of the EEA where a product or a medicinal product containing that product no longer enjoys or has never enjoyed SPC protection. Iceland has not yet received any SPC waiver notifications[1] (these will be published in the Gazette).

In **Norway**, the process for incorporating the SPC waiver provisions into the Norwegian Patents Act Section 62a, following the amendment of Annex XVII of the EEA Agreement, is still pending[8]. From the consultation letter published by the Ministry of Justice and Public Security[7], it is apparent that some adjustments will have to be made regarding the transitional provisions for the applicability of the SPC waiver in view of the time when the EEA Joint Committee's decision comes into force (see page 10, third paragraph of the consultation letter).

Switzerland, in general, shall take account of the EU regulations (hence including the SPC waiver amendments) in view of Art. 140*l* (2) of the Federal Patents Act. The discussion relating to the introduction of the SPC waiver provisions was initiated by a parliamentary request *"SPC-Waiver: Auch die Schweiz braucht eine Lösung zum Erhalt der Wettbewerbsfähigkeit der Generika herstellenden Pharmaindustrie"**[9]*. The Federal Council has so far responded that it would endeavour to bring the Swiss regulations on SPCs in-line with the European law. Therefore, the introduction of the SPC waiver provisions in Switzerland does not seem to be imminent for now. In view of the patent union between Liechtenstein and Switzerland, **Liechtenstein** (which neither has its own patent law nor a patent office) does not grant any SPCs (in accordance with Decision of the EEA Joint Committee No 92/2017[3]). Therefore, the amended SPC Regulation does not apply to Liechtenstein (see also the third recital *ibid.*[3]) and it will follow the Swiss approach.

Conclusion and further outlook

In conclusion, the use of the SPC waiver within the EU is objectively and gradually growing, and companies have started filing the mandatory notifications at the national offices (and supposedly to the SPC owners as well, as required). Some countries' offices are still not fully prepared for handling the receipt of these notifications and no court decisions have yet been rendered on this matter. It is too early to say whether these provisions will become widely used or not – the EU Commission will carry out an official evaluation of the SPC waiver provisions no later than in July 2024, in order to assess whether the objectives of those provisions have been achieved (as set out in Art. 21a of the Regulation). Until then, we may see further countries outside of the EU/EEA adopting similar provisions in their national patent laws. This would not be surprising because the EU, while concluding Free Trade Agreements with third countries, often mandates them to adopt SPC-like provisions prolonging the patent term. When this is viewed parallel to the adopted SPC waiver export provisions available to EU manufacturers, third countries that do not implement similar exemptions may very well put their own local manufacturers at a disadvantage in relation

to preparations for day?1 launch on their respective markets (subject to the relevant national patent laws). It is worth remembering that even before the EU implemented the SPC waiver provisions, and presumably because of the prior WTO dispute between EU and Canada[10], the CETA agreement allowed parties to provide exceptions from infringement during the period of such *sui generis* protection for export purposes only[11]. Subsequently, this export exemption has been implemented into the Canadian patents act[12].

In **Serbia** (one of the current EU candidate countries), amendments were made to its patent law in December last year, harmonizing it with the EU's amended SPC Regulation and introducing the SPC manufacturing waiver provisions effective as of 2 July 2022[13]. **Kosovo** published its new law on patents on 20 January 2022. The new law ensures that Kosovo's SPC provisions are no longer dependant on its accession to the EU. It also introduces the SPC manufacturing waiver provisions[14]. It is yet to be seen how these provisions will work in practice.

Interestingly, in **Israel**, where the entitlement, duration and validity of Patent Term Extensions is linked to a selected 'reference patent' in the 'reference country' (including a granted SPC in certain European countries), a proposal introducing manufacturing and stockpiling waiver provisions (specifically referring to the Regulation (EU) 2019/933) is being heavily discussed in the parliament and between the relevant stakeholders[15].

****

[1] This information has been confirmed directly by the respective national industrial property office.

[2] Amendments made as set out in the Schedule of the Intellectual Property (Amendment etc.) (EU Exit) Regulations 2020 [https://www.legislation.gov.uk/uksi/2020/1050/schedule/made]

[3] Decision of the EEA Joint Committee No 197/2022 of 10 June 2022 amending Annex XVII (Intellectual property) to the EEA Agreement [https://www.efta.int/media/documents/legal-texts/eea/other-legal-documents/adopted-joint-committee-decisions/2022%20-%20English/197-2022.pdf]

[4] The legislative process and related documents for incorporating the Regulation (EC) No 469/2009 into the EEA Agreement [https://www.efta.int/eea-lex/32009R0469]

[5] This logo will apply to products exported from the EFTA states, once the Regulation has been incorporated into the EEA Agreement

[6] Act No. 1460/2021 amending Patents Act No. 17/1991 [https://api.hugverk.is/media/nyqbmieu/patents-act-w-14602021.pdf]

[7] Regulation on Patents No. 477/2012, amended by Regulation 224/2022 [https://api.hugverk.is/media/0aqofeep/ens_b_nr_477_2012_w2242022.pdf]

[8] The legislative process and related documents for implementing the Regulation (EU) 2019/933 in Norway [https://www.regjeringen.no/no/dokumenter/horing–gjennomforing-av-forordning-eu-2019933-i-patentloven/id2681060/]

[9] *SPC-Waiver: Auch die Schweiz braucht eine Lösung zum Erhalt der Wettbewerbsfähigkeit der Generika herstellenden Pharmaindustrie* [https://www.parlament.ch/de/ratsbetrieb/suche-curia-vista/geschaeft?AffairId=20195334]

[10] WTO DISPUTE SETTLEMENT DS114: Canada — Patent Protection of Pharmaceutical Products [https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds114_e.htm]

[11] Sub-sec. E, Art. 20.27(9), Comprehensive Economic and Trade Agreement (CETA) between Canada and the European Union [https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:22017A0114(01)]

[12] Sec. 115(2) of Patent Act (R.S.C., 1985, c. P-4) [https://laws-lois.justice.gc.ca/eng/acts/p-4/fulltext.html]

[13] Art. 1 and 7 of the Law on Amendments to the Law on patents no. 123/21 [https://www.zis.gov.rs/o-zavodu/dokumenta/zakoni-i-propisi/]

[14] Art. 93.3-10 of the Law No. 08/L-059 for patents [https://kipa.rks-gov.net/Page.aspx?id=1,54]

[15] https://en.globes.co.il/en/article-patents-law-change-pits-drug-innovators-against-generics-cos-1001422594

To make sure you do not miss out on regular updates from the Kluwer Patent Blog, please subscribe here.

This entry was posted on Monday, October 17th, 2022 at 9:28 am and is filed under European Union, SPC
You can follow any responses to this entry through the Comments (RSS) feed. Both comments and pings are currently closed.