crowell moring

Legal Analysis of the Rights Conferred by Supplementary Protection Certificates

14 June 2018

The purpose of the present legal analysis is to consider whether, in the context of supplementary protection certificates ("SPCs"), a stockpiling waiver is in accordance not only with the applicable EU legislative framework but also the free trade agreements ("FTAs") the European Union negotiates with third countries, particularly the EU-Canada Comprehensive Economic and Trade Agreement ("CETA"). This analysis concludes that the introduction of a SPC stockpiling waiver would contravene neither the applicable EU legislative framework nor the European Union's obligations to its trading partners under the FTAs.

1. EU Legislative Framework Applicable to SPCs

The European Commission published on 28 May 2018 its legislative proposal amending certain aspects the SPC Regulation ("Proposal").[1] In particular, the Proposal expands upon the subject matter of protection under Article 4 and includes amendments introducing a manufacturing waiver enabling EU generics companies to produce in the European Union, subject to detailed reporting conditions, SPC-protected drugs for sale in third countries. However, it does not allow for stockpiling in view of placing the product on the EU market the day after expiry of the SPC ("EU day-1 launch"), and imposes anti-diversion measures under which import or re-import of the product into the European Union of the drugs produced under the manufacturing waiver is not allowed. Furthermore, the waiver would apply only to newly granted SPCs. Effectively, generics companies thus still can only perform some limited activities for purposes of obtaining a marketing authorization.[2]

Significantly, the creation of a SPC stockpiling waiver and allowing for EU day-1 launch would not permit generics companies to commercialize their products in markets protected by SPCs. Originator companies' marketing exclusivity for the product covered by the SPC beyond the useful life of its patent would thus be fully preserved. This is in keeping with the fundamental purpose of SPCs, which, from the start, the Commission intended "specifically to ensure that research-based industry has a market exclusivity of sufficient length to permit recovery of their investments."[3]

As the Commission has noted, SPC protection is not without limits: "The certificate does not protect the expired patent in its entirety. It protects only the product authorized to be placed on the market."[4] This is reflected in SPC Regulation Article 4, which provides that the

[1] Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products, COM(2018) 317 final (28 May 2018) ("Commission Proposal").
[2] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (as amended). The scope of what is permitted in this context under Article 10(6) (the "Bolar Exemption") varies from Member State to Member State.
[3] Proposal for a Council Regulation (EEC) concerning the creation of a supplementary protection certificate for medicinal products, COM(90) 101 final - SYN 255 (11 Apr. 1990) at para. 25.
[4] Id. at para. 13.

protection conferred by a SPC is limited to the product authorized for marketing. It is precisely this strong link between a SPC and marketing exclusivity that has led the Commission to acknowledge consistently the *sui generis* nature of SPCs as distinct intellectual property ("IP") rights from patents.[5]

The marketing exclusivity feature of SPCs has also been recognized by the Court of Justice of the European Union ("CJEU") in *Novartis AG v Actavis UK Ltd*, in which the CJEU held in relevant part that: "*Articles 4 and 5 of Regulation (EC) No 469/2009 … must be interpreted as meaning that … a supplementary protection certificate granted for that 'product' enables its holder, after the basic patent has expired, to oppose the marketing by a third party of a medicinal product containing that product for a use of the 'product', as a medicinal product, which was authorised before that certificate expired*."[6]

This principal characteristic of SPCs, granting an additional period of marketing exclusivity, is further confirmed in the international trade context by official EU submissions to the World Trade Organization ("WTO"). In its 2017 Trade Policy Review, the European Union specifically described SPCs as providing an additional period of market exclusivity of up to five years for medicinal and plant protection products resulting from any patentable inventions.[7] The European Union further suggested that the introduction of a SPC manufacturing waiver could be achieved without curtailing SPC protection.[8]

Accordingly, from the inception of the SPC Regulation to the latest EU pronouncements in international fora on the issue, the European Union has maintained the position that the main aim of a SPC is to allow originators to recoup their investments through extended marketing protection. In this context, a SPC manufacturing waiver that allows generics companies to manufacture and stockpile, but not to commercialize, their products in markets protected by SPCs respects the rights strictly conferred to originator companies by SPCs.

2. The EU Charter of Fundamental Rights

In the Explanatory Memorandum to its Proposal, the Commission specifically addresses the Charter of Fundamental Rights of the European Union ("Charter") by stating that: "*The proposal fully respects fundamental rights and observes the rights, freedoms and principles set out in the Charter*," especially the rights to property (Article 17), of access to health care (Article 35), and to conduct a business (Article 16).[9] However, Recital 22 of the Proposal itself is more limited in its language and scope, referring more generally to respect for the Charter and citing only the right to property under Article 17 of the Charter as warranting "*confining the exception to certificates granted on or after a specified date after entry into force of this Regulation and by imposing certain conditions on the application of the exception*."[10] This approach is unwarranted. In fact, a full SPC manufacturing waiver, including stockpiling for export and EU day-1 launch without unnecessary and unjustified

[5] Id. at para. 20.
[6] *Novartis AG v Actavis UK Ltd*, Case C-442/11 (9 Feb. 2012), at para. 23 (emphasis added).
[7] *See* WT/TPR/S/357/Rev.1 (13 Oct. 2017), at p. 211.
[8] *See* WT/TPR/M/357/Add.1 (6 Nov. 2017), at p. 98 (noting that the Commission is considering the introduction of a SPC manufacturing waiver without curtailing SPC protection in the EU).
[9] Commission Proposal Explanatory Memorandum at 12-13.
[10] Commission Proposal Recital 22 at 18.

limitations, would ensure a high level of protection of IP rights pursuant to the Charter while achieving a better balance with the other fundamental rights of access to health care and to conduct a business.

Whether the adoption of a full manufacturing waiver without limitations is in line with EU fundamental rights must also be assessed in light of Article 52(1) of the Charter. As interpreted by the jurisprudence of the CJEU, Article 52(1) establishes three cumulative conditions to assess whether a limitation on the exercise of fundamental rights complies with EU law. Specifically, the limitation must have a legal basis, must refer to an objective of general interest recognized as such by the European Union, and may not be excessive (i.e., it must be necessary and proportional to the aim sought, and the substance of the right or freedom at issue must not be impaired).

The adoption of a full manufacturing waiver without limitations would fulfil the three cumulative conditions of Article 52(1) of the Charter as interpreted by EU courts. First, the waiver would be established by law in the SPC Regulation. Second, it would refer to objectives of general EU interest, namely the rights of access to health care (Article 35) and to conduct a business (Article 16), which have the same constitutional rank as the right to property. Third, the limitation would not be excessive and would not jeopardize the full enjoyment by originators of the market exclusivity granted under the SPC (i.e., the *sui generis* right to intellectual property protected under Article 17(2)).[11]

In its current form, including unnecessary and unjustified limitations, the Proposal fails to strike a balance between the right to property and the rights of access to health care and to conduct a business. The Proposal, as reflected in Recital 22, is significantly imbalanced in favor of the right to property, despite EU legal precedents recognizing the need to strike a balance between IP rights under Article 17(2) and the freedom to conduct a business under Article 16.[12] The exclusion of EU day-1 launch, the imposition of unnecessary anti-diversion measures, and the failure to apply the waiver to existing SPCs are particularly egregious in this context and extremely difficult to justify in light of the fundamental right of generics companies to conduct a business and EU citizens' fundamental right of access to health care.

3. Stockpiling in Canada and the United States

In fact, Canada and the United States thus far have achieved a better balance between the rights of SPC holders and generics companies. Canada has introduced a SPC manufacturing waiver in its domestic law[13] and allows generics companies to pursue a broad range of activities linked to regulatory approval efforts under the Bolar Exception, including the possibility of stockpiling drug inventory. In the United States, the legislative history of the Drug Price Competition and Patent Term Restoration Act ("Hatch-Waxman Act") confirms the intent to provide prompt public access to generics upon expiry of a SPC. This goal is best fulfilled by interpreting broadly, in accordance with court precedents, the Act's Safe Harbor

[11] *See* Commission Proposal Explanatory Memorandum at 5, stating "*this proposal leaves SPC protection fully intact as regards placing products on the EU market. SPC holders will keep their market exclusivity in Member States during the full SPC protection term*." (emphasis added)
[12] *See, ex pluribus*, Judgment of 16 February 2016, *SABAM, C-360/10,* published in the electronic Reports of Cases (Court Reports - general), paras. 39-44.
[13] *See* Canadian Patent Act Section 115.

provision. Generics companies in the United States can thus pursue a similarly broad range of activities, including possibly stockpiling, aimed at securing regulatory approval and market access without undue delay.

4. SPC Provisions in EU FTAs

In recent years, the European Union has begun to include deep and comprehensive IP chapters in the FTAs it has negotiated and concluded with some of its most significant trading partners. These chapters usually cover a broad range of IP rights, including patents and, most notably, SPCs. In fact, SPC clauses are included in the FTAs already in force with Canada, Colombia/Ecuador/Peru, South Korea and Ukraine, as well as in other preferential trade arrangements for which negotiations have been concluded or that are awaiting ratification/signature by the parties (i.e., Japan, Singapore and Vietnam).

For example, the IP chapter of the EU-South Korea FTA provides as follows:

> *2. The Parties shall provide, at the request of the patent owner, for the extension of the duration of the rights conferred by the patent protection to compensate the patent owner for the reduction in the effective patent life as a result of the first authorisation to place the product on their respective markets. The extension of the duration of the rights conferred by the patent protection may not exceed five years.*[14]

The FTAs between the European Union and Colombia/Ecuador/Peru, Japan, Singapore, Ukraine and Vietnam all include the same or similar broad wording regarding the provision of SPC protection.[15]

However, CETA goes further in defining SPCs. CETA Article 22.27 on SPCs is entitled "Sui generis protection for pharmaceuticals" and, in line with the separate nature of this IP right, provides for the possibility of a SPC export waiver for pharmaceuticals. Specifically, Paragraph 9 of Article 22.27 allows for each party to "*limit the scope of the [SPC] protection by providing exceptions for the making, using, offering for sale, selling or importing of products for the purpose of export during the period of protection*." As noted above, Canada has effectively implemented this export waiver by introducing a SPC manufacturing waiver in its domestic law.

As a result, EU generics companies will be at a severe competitive disadvantage in relation to their Canadian counterparts unless the European Union aligns its SPC legislation with that of Canada. Therefore, the Commission has emphasized the importance of a level playing field as follows: "*[O]ften overlooked is the fact that a level playing field between the EU and Canada will ensure a fairer and more favourable competitive environment for the important European generics industry, which will no longer be disadvantaged vis-à-vis its Canadian counterparts*."[16]

---

[14] EU-South Korea FTA, Article 10.35.
[15] *See* EU-Colombia/Ecuador/Peru FTA, Article 230(4); EU-Japan FTA, Article 14.35; EU-Singapore FTA, Article 10.31; EU-Ukraine FTA, Article 220; EU-Vietnam FTA, Article 8.3.
[16] *See* European Commission Factsheet, "The EU'S Free Trade Agreement with Canada and its Intellectual Property Rights Provisions," available at http://trade.ec.europa.eu/doclib/docs/2012/august/tradoc_149866.pdf.

It is particularly important to recall the fundamental function of SPCs in this context (i.e., to grant an additional period of marketing exclusivity). Specifically, Paragraph 8 of CETA Article 22.27 reiterates the language of SPC Regulation Article 4, providing in relevant part that "*the sui generis protection shall extend only to the pharmaceutical product covered by the marketing authorization*."

The recent FTAs agreed between the EU and its trading partners thus recognize and enact SPC protection. However, the parties remain free to tailor the scope of SPCs in accordance with their domestic legislation and policy priorities (i.e., the FTAs establish an obligation of results rather than an obligation of means). Accordingly, parties could consider a variety of SPC provisions, so long as they do not contravene the basic purpose of SPCs to provide an additional period of marketing exclusivity.

5. SPC Stockpiling Waiver Not Contrary to EU Law or FTAs

There do not appear to be any compelling arguments according to which the inclusion of a SPC stockpiling waiver would contravene either the applicable EU legal framework or the specific SPC provisions included in EU FTAs.

First, the relevant EU FTA provisions contain an obligation for parties to enact SPC protection while leaving the same parties a certain degree of freedom on how to implement such protection in practical terms. Therefore, the relevant EU FTA provisions do not explicitly prevent the European Union from adopting a manufacturing waiver.

Second, the introduction of a full SPC manufacturing waiver would in no way impair the rights of the European Union's trading partners under the applicable FTAs. These third countries would maintain their current ability to market generic drugs in the European Union immediately after the expiry of a SPC. The enactment of a manufacturing waiver within the European Union thus would not discriminate against these trading partners. On the contrary, it would level the playing field between EU and third-country generics companies.

Third, EU trading partners could not legitimately claim that the introduction of a full SPC manufacturing waiver in EU legislation would contravene FTA provisions simply by arguing that a SPC shall confer to its holder the same rights enjoyed under the basic patent. Whether the SPC confers to its holder the same rights enjoyed under the basic patent must be interpreted in light of the Bolar Exemption and the *sui generis* nature of the SPC protection itself, which essentially aims to provide originator companies with market exclusivity to recoup investments. As discussed above, a full SPC manufacturing waiver does not impair the ability of a holder to benefit from market exclusivity.

Finally, an EU FTA partner cannot invoke the agreement's SPC clause to oppose to manufacturing or stockpiling in the EU of generics for export to its country following SPC expiry. At the moment SPC protection expires in the EU FTA partner country, generics could be sold legitimately in such country from a third-country or other domestic sources. For a FTA partner country to read the SPC clauses contained therein as preventing manufacturing or stockpiling of generics only from the EU would represent a blatant

discrimination and thus a violation of relevant most-favored-nation ("MFN") and national treatment rules of the WTO.

In accordance with the fundamental WTO precept of MFN treatment, WTO Members must accord immediately and unconditionally to the nationals of all other Members any advantage, favor, privilege or immunity granted by a Member to the nationals of any other country. This is valid with respect to goods under Article I of the General Agreement on Tariffs and Trade ("GATT"), and with respect to the protection of intellectual property under Article 4 of the Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS"). Similarly, in accordance with the fundamental WTO precept of national treatment, under GATT Article III and TRIPS Article 3 WTO Members must accord to the nationals of other Members treatment no less favorable than that they accord to their own nationals. Therefore, any disparity in the treatment of domestic versus third-country generics companies under the EU FTAs could give rise to challenges under the dispute settlement processes of the WTO.

6. Conclusion

The introduction of a full manufacturing waiver, including stockpiling for export and EU day-1 launch without unnecessary or unjustified limitations and applicable to all existing and future SPCs, would contravene neither the applicable EU legislative framework nor the European Union's obligations to its trading partners under the FTAs. From the SPC Regulation's inception to the latest EU pronouncements in international fora on the issue, the Commission has recognized that SPC protection is not without limits.

In fact, the introduction of a full manufacturing waiver is necessary to strike a genuine balance among the EU fundamental rights to property, health care access and the conduct of a business. Canada and the United States have come closer to achieving such a balance through broader interpretations of relevant statutes and the Bolar Exception or Safe Harbor to allow for the possibility of stockpiling in view of day-1 launch. This disparity leaves EU generics companies unable to compete with their international counterparts.

Accordingly, the introduction of a full manufacturing waiver would ensure a level playing field between the EU generics industry and its third-country competitors. While not affecting in any way the rights of originator companies or impairing the rights of EU trading partners under the applicable FTAs, a manufacturing waiver covering both export and EU day-1 launch is needed to ensure the full economic benefits are derived within the European Union and globally from the activities of EU generic and biosimilar medicines companies.

* * *