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EU Council seeks to further justify SPC "Manufacturing Waiver" on grounds already rejected by WTO

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As discussed in our blog of 30 May 2018, the EU Commission has proposed an amendment to Regulation (EC) 469/2009 concerning the supplementary protection certificate for medicinal products ("SPC Regulation") aimed at introducing a "manufacturing for export exception." The purpose of the amendment is to allow the manufacture of generic and biosimilar medicines within the EU for export to countries where there are no patent rights in force. The proposal included some "safeguards" aimed at assuring transparency (for example, prior notice to the national authority that granted the SPC) and preventing re-entry of the exported products into the EU market (basically stamping an "EU export" logo to the outer packaging).

One of the issues raised by the proposal is whether or not it is compatible with the obligations assumed by both the EC and its Member States in the context of the TRIPS Agreement. In the Explanatory Memorandum that sought to justify the proposal, the Commission simply took it for granted that the "Manufacturing Exception" was in line with the TRIPS Agreement. Hence, it wrote that "The proposal is consistent with existing international trade agreements, such as the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) between members of the World Trade Organization as well as those free trade agreements that the EU has concluded with non EU-countries and that include supplementary protection-like provisions." However, no reasons were given to justify the alleged "consistency".

The Explanatory Memorandum cited in footnote 25 a long study commissioned from the Max Planck Institute by the EU Commission, where the author of the relevant chapter wrote that "Article 27 TRIPS provides for specific features that define the subject matter of a patent, and distinguish the latter from other categories of rights covered by the Agreement. Thus it can be argued that because SPC do not conform to the defining elements of patents under TRIPS, they are not subject to the specific obligations relating to the latter." As readers will have noted, this brief statement is not very enlightening either. In fact, this narrow construction of the obligations derived from the TRIPS Agreement contrasts with the wide views that the EU Commission defended successfully before the WTO Dispute Settlement Body against the U.S. in the *U.S. Section 211 Appropriations Act* case (2002). In that case, the WTO Appellate Body, among other aspects, endorsed the EU Commission's view in that the list of IP rights mentioned in the TRIPS Agreement is not a closed list ("numerus

clausus"). So, if one may paraphrase the expression used in the aforementioned study, *it can also be argued* that because the TRIPS Agreement generally applies to "patent rights" (not only to those derived from "patents"), all types of patent rights (including those derived from "patent restoration term" instruments such as SPCs) fall within the realm of the TRIPS Agreement.

The EU Commission proposal has now been considered by COREPER (Permanent Representatives Committee), which last Wednesday published the mandate for negotiations with the European Parliament based on a text that contains some amendments to the initial text proposed by the Commission. For example, the COREPER suggests that the Exception be inserted in Article 5 ("Effects of the Certificate") instead of in Article 4 ("Subject matter of protection"). In addition, the "maker" would have to notify its intention of manufacturing for export not only to the authority that granted the SPC but also to the SPC holder. Also, the prior notice is extended from 28 days to 3 months. Furthermore, the "maker" will also have to notify any changes (for example, countries of destination) in the initial plan. Another change is the introduction of a "standard form" (Annex I) aimed at simplifying the "notification" obligations. These amendments, most of which were already suggested by the Committee of Legal Affairs of the European Parliament last October, represent a clear improvement, which will, to some extent, alleviate the monitoring burden that the text proposed by the Commission would have brought.

Another improvement introduced by COREPER is that the "EU Export" logo will have to be affixed not only to the outer packaging but also "where feasible, to its immediate packaging." Hopefully, this amendment will make it more difficult to circumvent the EU "re-entry" prohibition.

On the TRIPS Agreement point, the text proposed by the COREPER has introduced an amendment in Recital (11) that suggests that the EU Council has tried to further justify compliance with Articles 27, 28 and 30 of the TRIPS Agreement. Article 30 reads as follows:

"Exceptions to Rights Conferred

Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties."

Although, as mentioned, the EU Commission appears to consider that SPCs are not subject to the TRIPS Agreement, just in case, it introduced the following text in Recital (11) of the initial proposal:

"By limiting the scope of the exception to making for the purpose of export outside the Union and acts strictly necessary for such making or for the actual export itself, the exception introduced by this Regulation will not unreasonably conflict with normal exploitation of the product in the Member State where the certificate is in force, nor unreasonably prejudice the legitimate interests of the certificate-holder, taking account of the legitimate interests of third parties."

The COREPER appeared to feel the need to go an extra mile and added the text in italics to Recital (11):

"By limiting the scope of the exception to making for the purpose of export outside the Union and acts strictly necessary for such making or for the actual export itself, the exception introduced by this Regulation will not unreasonably conflict with normal exploitation of the product *or medicinal product containing that product* in the Member State where the certificate is in force, *namely with the core exclusive right of the certificate holder to make that product for the purpose of placing it on the Union market during the term of the certificate*. In addition, the certificate should not unreasonably prejudice the legitimate interests of the certificate-holder, taking account of the legitimate interests of third parties."

The amendment proposed by the COREPER seems to take the view that some of the rights enshrined in Article 28 of the TRIPS Agreement (prevent others from making, using, offering for sale, selling or importing the products for these purposes) are at the "core" whereas other rights would be at the "periphery" of the array of patent rights mentioned in Article 28. This view was rejected by the WTO Dispute Settlement Body in its panel of 17 March 2000 (*EC v. Canada, patent protection for pharmaceutical products* case), where it rejected this very same argument, which had been raised by Canada in response to the complaint filed by the EU Commission. In particular, in paragraphs 7.34-7.35 the panel reached the following conclusions:

"7.34 In the Panel's view, the question of whether the stockpiling exception is a "limited" exception turns on the extent to which the patent owner's rights to exclude "making" and "using" the patented product have been curtailed. The right to exclude "making" and "using" provides protection, additional to that provided by the right to exclude sale, during the entire term of the patent by cutting off the supply of competing goods at the source and by preventing use of such products however obtained. With no limitations at all upon the quantity of production, the stockpiling exception removes that protection entirely during the last six months of the patent term, without regard to what other, subsequent, consequences it might have. By this effect alone, the stockpiling exception can be said to abrogate such rights entirely during the time it is in effect.

7.35 In view of Canada's emphasis on preserving commercial benefits before the expiration of the patent, the Panel also considered whether the market advantage gained by the patent owner in the months after expiration of the patent could also be considered a purpose of the patent owner's rights to exclude "making" and "using" during the term of the patent. In both theory and practice, the Panel concluded that such additional market benefits were within the purpose of these rights. In theory, the rights of the patent owner are generally viewed as a right to prevent competitive commercial activity by others, and manufacturing for commercial sale is a quintessential competitive commercial activity, whose character is not altered by a mere delay in the commercial reward. In practical terms, it must be recognized that enforcement of the right to exclude "making" and "using" during the patent term will necessarily give all patent owners, for all products, a short period of extended market exclusivity after the patent expires. The repeated enactment of such exclusionary rights with knowledge of their universal market effects can only be understood as an

affirmation of the purpose to produce those market effects."

All in all, for the reasons explained in this blog, the text introduced by COREPER in Recital (11) will not help alleviate the inconsistency of the proposal with the obligations derived from the TRIPS Agreement.

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