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SPC Exceptions: a new trade front with president Trump?

Miquel Montañá (Clifford Chance) · Thursday, June 13th, 2019

Over the last few months, SPC *aficionados* have been expecting the birth of what is known as the "SPC Manufacturing Exception" proposed by the European Commission. Readers will remember that in May 2018, the European Commission proposed an amendment to Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products ("the SPC Regulation"), whereby the manufacture for export of medicinal products still protected by SPCs in force would be excluded from patent infringement. Surprise surprise, the text finally approved by the EU Legislator, which was published in the Official Journal of the European Union on 11 June 2019, has brought two babies into the world instead of one. In addition to the "Manufacturing Exception", the text finally approved has also introduced the "Stockpiling Exception" that will allow "the making, no earlier than six months before the expiry of the certificate, of a product, or a medicinal product containing that product, for the purpose of storing it in the Member State of making, in order to place that product, or medicinal product containing that product, on the market after the expiry of the corresponding certificate."

The new Exceptions will apply to SPCs that are applied for on or after 1 July 2019. They will also apply to SPCs that have been applied for before 1 July 2019 and which take effect on or after that date. They will not apply to SPCs that take effect before 1 July 2019.

The final approval of the "Stockpiling Exception" is a striking example of the evolution over the last 30 years of the priorities that guide the EU's Legislature. Whereas in 1992, when the SPC Regulation was introduced, and in the following years, the promotion of R&D ranked very high in the EU's political agenda, this long-term goal has now been engulfed by the throat of populism. But as the Rt. Hon. Professor Sir Robin Jacob highlighted in the conclusions of the paper given one decade ago at the Presentation of the Directorate-General of Competition's Preliminary Report of the Pharma-sector inquiry: "The big truth is that if you damage the income stream of research companies, you are going to imperil future research at the expense of European – indeed world – citizens. Yes, you will save money now, but at the cost of fewer future medicines."

It is remarkable that the EU Legislator has dared to introduce the "Stockpiling Exception" into EU law bearing in mind that, on 19 December 1997, it was the very same EU Commission that successfully sued Canada before the Dispute Settlement Body ("DSB") of the World Trade Organisation ("WTO") for having approved that very same Exception. The WTO's DSB, endorsing the arguments mastered by the EU Commission, came to the conclusion that the "Stockpiling Exception" approved by Canada was contrary to the obligations of patent protection

imposed by the TRIPS Agreement. The legal grounds used in that decision show that neither the "Manufacturing Exception" nor the "Stockpiling Exception" are compatible with the obligations of patent protection derived from the TRIPS Agreement.

In fact, a report from a researcher of the Max Planck Institute for Innovation and Competition commissioned by the EU Commission for the purpose of "reinforcing" the legal flank, openly admitted that if the "Manufacturing Exception" was framed as a exception of the obligations of "patent" protection, it would be contrary to the TRIPS Agreement. The researcher sought to get around such contradiction alleging that the obligations of "patent" protection imposed by the TRIPS Agreement would supposedly not apply to SPCs. In our opinion, this interpretation steps into rather dangerous territory, as the TRIPS Agreement's obligations of protection, as a rule, apply during the entire term of protection of the IP right at hand, notwithstanding the fact that in some WTO Members, the term of that very same IP right may be longer than in other Members. Also, it does not seem to take into account that the protection obligations imposed by the TRIPS Agreement do not only apply to "patents" but also to "patent rights" (see, for example, article 27). Such interpretation would have formidable consequences. It would mean, for example, that whereas during the initial 20-year term inventors could not be discriminated against (article 27), as from the day after expiry of the initial 20-year term, the WTO, whose cornerstone has been the principle of non-discrimination since the coming into force of the GATT in October 1947, would now become a jungle of discrimination. For instance, patent owners, just like in the early days (I should say *very* early days) could be forced to manufacture the patented product "domestically" (i.e. "domestic manufacturing requirement"). Really?

The incompatibility of the new Exceptions introduced by the amendment to the SPC Regulation under the watch of the WTO is so obvious that it begs the question as to whether on the other side of the Atlantic, it will be interpreted as an invitation to President Trump to open up a new trade front with the EU.

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