SPC developments in the last year

In the wake of the major changes instituted by the EU creating export and stockpiling waivers during supplementary protection certificate (SPC) term, it was not surprising that Her Majesty's Government generated UK rules to implement this new legislation during the course of the year. In line with the UK's Brexit amendments to SPC law, to retain basing term calculation on the first marketing authorisation (MA) to issue in the UK or EU/EEA, the EU states were not defined as third countries to which export is permitted under the waiver legislation. At the time of writing no national patent office seems to have received any notification under the waiver. It will be interesting to see if UK generic industry finds the waiver attractive once it comes fully into operation in 2022.

Further changes followed at the end of the year to adapt the SPC application process to the different medicines regulatory schemes that will operate in Great Britain and Northern Ireland from 2021. Applicants will need to file within six months of the later of patent grant and the first MA to issue, be that an authorisation from the European Medicines Agency that covers Northern Ireland, or an MA from the Medicines Health Regulatory Authority that covers Great Britain. When the second of those MAs issues, applicants then have a six month period to communicate that to the UK Intellectual Property Office (UK IPO) so the territorial applicability of the SPC can be expanded. Monitoring MA grants from the Medicines and Healthcare products Regulatory Agency will be important for applicants under the new regime.

Those legal niceties show the complexities of adapting the UK's SPC legislation with Brexit. IP Federation members (often via other trade associations or individually) were very much involved in providing technical input to the UK IPO and other government departments to ensure the changes reflected both IP policy and worked effectively in practice. Maintaining a robust SPC regime is important to the UK life sciences industry which is a significant industrial sector domestically and is one that the Government is keen to grow with its research agenda. Ensuring similar protections are written into free trade agreements with other countries would be a success for UK industry.

This has also been the last year during which the UK courts can make references for interpretation to the Court of Justice of the European Union (CJEU). No case remains pending from the UK in this area. There were, though, two major decisions from the CJEU that helped clarify aspects of the Regulation.

In *Royalty Pharma Collection Trust* C-650/17, the court reiterated the rules on the interpretation of Article 3(a) of the Regulation, defining what it means for a

product to be protected by a basic patent. The court seemed surprised to have received another reference on this issue thinking it had provided the final answer in *Teva v Gilead* C-121/17. It seems that if the claims of a patent expressly name the product that should be an end to the matter. If they do not the patent should be analysed to understand whether the skilled person, in the light of the patent and general knowledge, considers the product to be specifically identifiable. However, that will not be the case where the product was developed after patent filing through an independent inventive step.

CJEU references are, of course, the product of keen legal minds paid to tease away what the law means for rights that are valued sometimes in the billions of pounds. It will be no surprise if cases continue to arise under this article, at least before national courts, turning on what information is part of the 'general knowledge' of the skilled person. In neither case did the CJEU explicitly confine this knowledge to the 'common general knowledge', and there are some indications that the whole prior art was what was meant. It will be interesting to see how this plays out.

A second issue, which is more likely to be referred, is what is meant by an independent inventive step. Does this occur whenever a new patent is obtained covering the product? Or does it only happen when there is a further patent by an unconnected proprietor? Was this judgment intended as a back-door route to try to stifle third party SPC applications? There is no consensus on what this test means.

The second case was rather simpler. In *Santen* C-673/18, the ruling of *Neurim* C-130/11 was reversed. Under Article 3(d) of the Regulation, when considering which was the first marketing authorisation for a product, no account is taken of any use limitations, be they of subject, as in *Neurim* where there was a change from sheep to humans, nor of indication, that a new disease is treated does not give standing for a new SPC.

It is interesting to see the CJEU reverse itself, which may suggest that where the CJEU finds their earlier cases have tied a Gordian knot they will follow Alexander's example and start again with a more consistent ruling. That said, the ruling itself is disappointing to innovative industry. Repurposing old medicines is often held up as a way in which new treatments can be brought rapidly to patients. This judgment closes down an avenue of protection by which such treatments could have been incentivised. One cannot help but feel an opportunity to adapt the law to medical advances was lost.

With the subsequent withdrawal of the *Novartis* reference (C-354/19), we head to the end of the year with no references pending at the CJEU. 2021 may therefore be a quieter year on the SPC front.

On 25 November 2020, the EU released its IP action plan. In regard to SPCs it pleasingly considered that the system generally works well. The main issue of concern raised was the fragmented nature of obtaining SPCs through national offices. SPC owners would welcome a more coordinated way of obtaining SPCs through a single virtual granting office, perhaps attached to the EPO. Such an office might carry out the preliminary stages of examining an SPC and then send to

national patent offices to grant or refuse, or grant centrally. In the latter case appeals could lie to the court where the applicant is domiciled or, if they are not located in the EU, to the court where the marketing authorisation holder is domiciled. It will be interesting to see how legislation for such an office is developed, and IP Federation members will continue to provide input so that a system useful for all interested parties results.

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