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Will the EU's SPC manufacturing waiver weaken European pharma's IP?

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Paul Williams

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Despite dire warnings by the US Chamber of Commerce, the impact of the EU's SPC waiver won't be known for years, says Paul Williams of Lewis Silkin.

The US Chamber of Commerce has published its *International IP Index 2020*, a map of the IP ecosystems of 53 economies, representing over 90% of global gross domestic product (GDP). The index aims to provide a snapshot of each economy's overall IP ecosystem by evaluating its IP framework across 50 indicators, selected to represent the most effective IP systems.

Nine categories are scanned: patents, copyright, trademarks, design rights, trade secrets, commercialisation of IP assets, enforcement, systemic efficiency, and membership and ratification of international treaties.

Western European economies dominate the top 10 rankings, with the US (#1) and Japan (#6) the only exceptions. The UK ranks second, with a marginally increased score over last year, despite Brexit and (along with EU countries) a score reduction due to the introduction in July 2019 of the EU supplementary protection certificate (SPC) manufacturing waiver.

The IP Index also reviews trends and developments in the global IP environment. Developments from 2019 which are discussed are the US-China trade talks (culminating in the signing on January 15, 2020, of phase one of the Economic and Trade Agreement); whether IP standards are being undermined in international trade agreements; and the erosion of rights in IP-intensive industries.

Regarding the latter, the EU SPC manufacturing waiver is singled out for criticism. Under SPC Regulation (EC) No. 469/2009 it was not possible to manufacture, stockpile or export an active pharmaceutical ingredient or finished dosage form that fell within the scope of an SPC.

For EU generic and biosimilar manufacturers, this meant it was not possible to manufacture in the EU, either for export to countries where the basic patent had already expired and SPC-type patent extensions were not available or in preparation for "day-one" launch within the EU upon SPC expiry.

Waiver rules

The EU SPC manufacturing waiver (Regulation [EU] 2019/933) is intended to address these issues, by allowing generic and biosimilar manufacturers to make a medicine without the permission of the SPC holder: a) for export to a country outside the EU; and/or b) within the final six months of the SPC, to store to sell on the EU market once the SPC has expired.

"The manufacturing waiver certainly erodes the rights conferred by SPCs, but will generic and biosimilar manufacturers choose to take advantage of the waiver?"

Initially, the proposal was merely to permit manufacture for export, until it was noted that this would allow medicines to be manufactured for export and subsequently re-imported for day-one launch, but would not allow manufacture for storage for this purpose within the EU. Accordingly, manufacture for storage within the EU was also permitted.

The waiver came into effect on July 1, 2019, with immediate effect for SPCs applied for after this date. However, it does not apply to certificates which have taken effect prior to this date, and comes into effect only on July 2, 2022, for certificates which have been applied for before, but take effect after, this date.

For post-Brexit UK, the UK Intellectual Property Office has stated that it intends that the waiver will apply to manufacture in the UK for export outside the UK, and storage within the UK for day-one entry in the UK on expiry of the SPC.

In the *IP Index* the US Chamber of Commerce is highly critical of the SPC manufacturing waiver, arguing that it is likely to have a negative impact on the European biopharma industry, where IP

rights have been central to its success, and describing it as "highly damaging" and "a significant blow" to biopharma rights owners.

The logic of the European Commission's proposal is described as "highly dubious", and the claims of economic benefits are overstated, the index says.

It questions whether there is an actual export market and demand for European generic manufacturers, arguing that it is not clear what this market is or where the demand for generics manufactured in Europe would come from: in the markets being targeted, demand would most likely be met by local manufacturers, who are preferred partners, and the policy framework often actively discriminates against foreign manufacturers, through price preferences, import bans and increased taxation.

The conclusion is that rather than offering EU manufacturers a competitive advantage, the more likely outcome is that other economies will adopt similar policies, resulting in a "race to the bottom" in the erosion of IP standards.

Likely effects

Those are strong words, but are they justified? The manufacturing waiver certainly erodes the rights conferred by SPCs, but will generic and biosimilar manufacturers choose to take advantage of the waiver?

For example, during the transition period will EU-based generic and biosimilar manufacturers bide their time until existing SPCs have expired and the waiver fully enters into force? Alternatively, will they shift their manufacturing outside the EU during this period? Will SPC holders see any benefit in enforcing SPCs against a company that decides to take the risk of manufacturing for export/storage in the EU during the transition period, in the knowledge that EU courts are of course aware that the waiver will soon be coming fully into force, and the damage to their business is minimal?

The regulation contains safeguards for SPC holders against abuses of the manufacturing waiver, which the index does not discuss. Thus, generic and biosimilar producers (and their supply chain partners) wishing to rely on the waiver are required to provide information regarding their manufacturing plans both to the national patent offices of those member states where production and any first related acts will take place, and directly to the SPC holder.

On the face of it, the information to be provided does not seem to be a cause for concern: the name and address of the manufacturer; whether manufacture is for export or storage or both; the member states in which the manufacture and/or storage will be taking place; and the relevant SPC and marketing authorisation number(s).

However, the question arises as to what the SPC holder will do with the information: never before has this information been required to be provided by a generic or biosimilar manufacturer to an SPC holder.

Article 5(4) of the amended SPC regulation states: "The information provided to the certificate holder ... shall be used exclusively for the purpose of verifying whether the requirements of this regulation

have been met, and where applicable initiating legal proceedings for non-compliance."

However, when the information drops through the letterbox of the SPC holder, is it plausible that the in-house IP attorneys will not start searching the cupboards for other IP rights which are not subject to the SPC waiver and thus might be enforced, now that they know exactly where manufacture will be taking place?

Is it reasonable to believe that the manufacturing information will indeed be used "exclusively" to check compliance with the regulation?

In addition, amended article 11 of the SPC regulation states that the national patent office must publish the information provided to it by a manufacturer wishing to take advantage of the waiver, which will presumably serve to inform its competitors of its intention prior to producing the medicine (the information is to be provided three months prior to manufacture).

Then there is the restriction on manufacture for storage for day-one launch being waived only within the final six months before expiry of the SPC. Thus, any product which has a lead-time of greater than six months will not be able to take advantage of the waiver to achieve day-one launch.

Initially the European parliament proposed a two-year period, but the European Council reduced this to six months, with studies published by the European Commission identifying this as the mean term of delay to enter the EU market after the expiry of an SPC.

Accordingly, the manufacture of at least half the medicines in question will seemingly be penalised by the reduction of this term to six months, in particular generic and biosimilar products where both the active ingredient and the dosage form are manufactured within the EU.

Having said that, the regulation does require the European Commission to carry out an evaluation of the manufacturing waiver provisions by July 1, 2024 at the latest, and then again every five years in order to assess their impact, and in particular to determine whether the six-month period for stockpiling is sufficient to achieve the objective of day-one launch within the EU.

Thus, while any erosion of IP rights will obviously be of concern to rights owners, there are questions as to whether generic and biosimilar manufacturers will wish to take advantage of the SPC manufacturing waiver. The full impact of the waiver will be known only once it comes fully into force after the transition period and the years beyond.

Paul Williams is a partner and European and UK Chartered Patent Attorney at Lewis Silkin. He can be contacted at: paul.williams@lewissilkin.com