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Changes to draft EU legislation introducing an export manufacturing waiver to SPCs

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A consolidation and modernization of Europe's intellectual property framework, featuring a "recalibration" of patent and SPC protection and possibly the creation of a unitary SPC title – those were the ambitious aims set out in the European Union's single market strategy adopted in 2015. This was followed by a comprehensive evaluation of the legal aspects of the SPC system and its economic impact, which gave reason to believe that the groundwork for a fundamental reform had been laid.

Yet, what has since materialized is a far cry from anything resembling an ambitious reform of the current SPC system. The European Commission rather chose to press ahead with a narrowly focused legislative proposal aiming merely at introducing an "export manufacturing waiver", with the objective of promoting the competitiveness of the European generics and biosimilar industry. The corresponding Commission proposal for a regulation amending Regulation (EC) 469/2009 on SPCs for medicinal products (COM(2018) 317 final) was issued on 28 May 2018 and has already been discussed on this blog.

Significant changes to the regulation proposed by the Commission have now been put forward in a draft report of the European Parliament's Committee on Legal Affairs published on 30 October 2018 (PDF), which was debated in a Committee meeting on 20 November 2018 (a video recording of this meeting can be viewed here). Most notable among the proposed changes are the following aspects:

- A person intending to manufacture an SPC-protected medicinal product for the exclusive purpose of export to a third country outside the EU will be required not only to notify the respective national patent office in each EU member state where the manufacture should take place, but will also be required to directly inform the SPC holder of his intention in writing.
- These obligations apply not only to the intention to manufacture a protected medicinal product but also to any subsequent changes (e.g., regarding the target countries for export), which must likewise be notified to the respective national patent office(s) and directly to the SPC holder.
- The national patent office(s) and the SPC holder must be notified no later than three months before the start date of the intended manufacture (rather than merely 28 days in advance, as envisaged in the original Commission proposal).
- A standard form (contained in a new annex) must be used for the notification to the competent national patent office(s).
- Confidential or commercially sensitive information notified to the competent national patent

office(s) should not be published, and such information will not need to be provided to the SPC holder either.
- The export manufacturing exemption will apply to all SPCs for which the underlying basic patent expired on or after 1 January 2023.

These changes proposed by the Committee on Legal Affairs of the European Parliament, if enacted, will constitute a considerable improvement of the safeguards for SPC holders against abuse of the export manufacturing waiver.

In particular, the obligation of a generics or biosimilar producer to directly inform the SPC holder, rather than encumbering the latter with the burden to actively monitor the relevant publications of the national patent offices of all EU member states, rectifies one of the most apparent shortcomings of the original Commission proposal. The extension of the corresponding deadline for notification to three months before the start date of the intended manufacture is likewise reasonable and provides SPC holders with the necessary time to assess whether the conditions to benefit from the export manufacturing exemption are fulfilled.

Moreover, the establishment of a transitional regime that couples the applicability of the export manufacturing exemption to the expiration date of the basic patent underlying an SPC is a sensible approach, as it ensures a uniform legal situation for all SPCs coming into force after 1 January 2023, including all the various national SPCs for a given product that are based on the same European patent and the same earliest marketing authorization. This is an improvement over the transitional rules envisaged in the original Commission proposal, which tie the applicability of the export manufacturing exemption to the grant date of the respective SPC and thereby predictably entail an unnecessary legal fragmentation: Since the length of the SPC grant proceedings typically differs greatly between the different EU member states, it is quite common that the simultaneous filing of SPC applications for the same product in the various EU member states, relying on the same European patent and the same earliest marketing authorization, may result in the grant of SPCs in some member states in a matter of months whereas parallel SPCs in other member states may only be granted many years later – with the consequence that the export manufacturing waiver may not even apply uniformly to all parallel national SPCs of the same family under the transitional regime originally proposed by the Commission.

Regrettably, however, the current proposals of the Committee on Legal Affairs do not require generics or biosimilar manufacturers to affix the “EU export” logo to *both* the outer packaging *and* the immediate packaging of the medicinal product destined for export. Such a measure could be very helpful in preventing unlawful reimports.

It remains to be seen how the draft regulation establishing the export manufacturing waiver will further “evolve” as it passes through the European legislative process, and when it may eventually be enacted. As a next step, the Committee on Legal Affairs will vote on the above-discussed draft report (after considering potential further amendments) in a meeting scheduled for 23 and 24 January 2019, and the report will then be put to a plenary session of the European Parliament. The Parliament will subsequently engage with the European Commission and the Council via the “trilogue” procedure in order to reach provisional agreement on the draft regulation introducing the export manufacturing waiver, which could still happen in spring 2019. In view of the upcoming European elections in May 2019, however, any unforeseen delay (think Brexit) could risk a standstill at least until after the newly elected European Parliament resumes work and the new European Commission is inaugurated. The further legislative progress of the export manufacturing

waiver will be covered on this blog.

Dr. Alexa von Uexküll *and* ***Oswin Ridderbusch****, both partners at the IP-specialized law firm Vossius & Partner, are the editors of the new handbook "European SPCs Unravelled: A Practitioner's Guide to Supplementary Protection Certificates in Europe" published by Wolters Kluwer in November 2018.*

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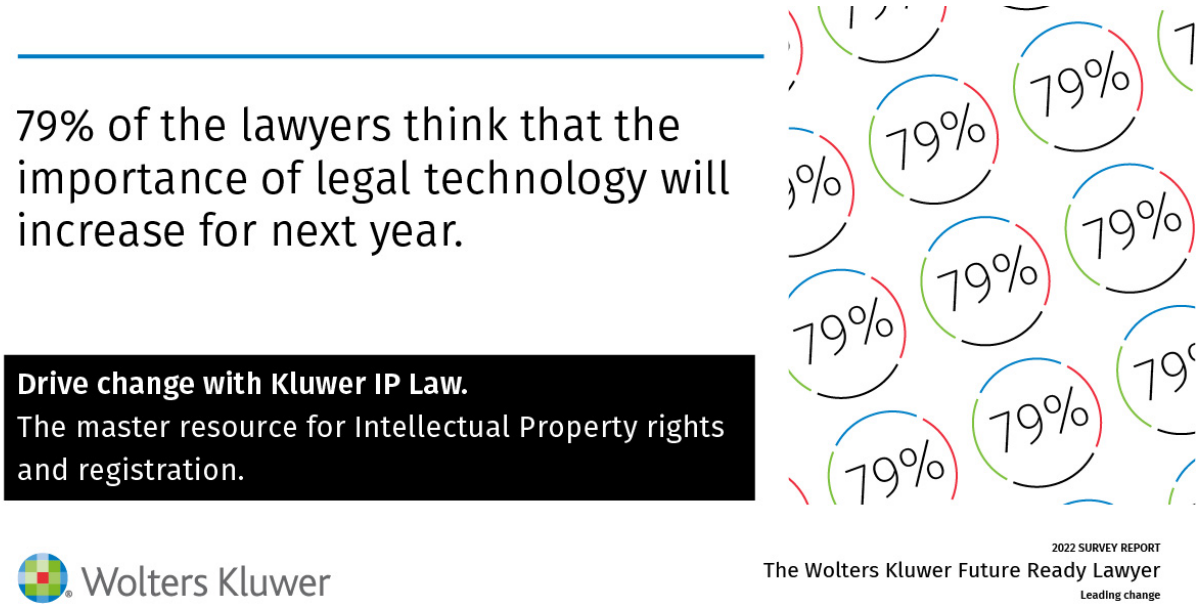

This entry was posted on Wednesday, November 28th, 2018 at 8:45 am and is filed under Biologics, European Union, Generics, Legislation, Pharma, SPC
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