

Kluwer Patent Blog

The missing basic patent: Specific Mechanism expands scope of protection during the lifetime of an SPC

Thomas Musmann (Rospatt Osten Pross) · Wednesday, November 11th, 2015

by Dr. André Sabellek

In a recent judgment the Higher Regional Court of Düsseldorf (OLG Düsseldorf) had to deal with the application of the “Specific Mechanism” for parallel imports of pharmaceuticals if those pharmaceuticals are protected by a supplementary protection certificate (SPC) (judgment of August 6, 2015, court docket: 2 U 21/15 – Ezetimib, <<http://www.duesseldorfer-archiv.de/?q=node/6461>>).

The background of this case is the “Specific Mechanism” which constitutes an exception to the principle of exhaustion. The Specific Mechanism is codified in the Treaties of Accession of the member states which joined the EU since 2004 (new member states). The Mechanism effects that a parallel importer who imports pharmaceuticals from a new member state into a territory where the product falls under the protection of a patent or SPC cannot refer to the principle of exhaustion if the patent or SPC was applied for at a point in time at which a similar protection could not be obtained in the respective new member state for legal reasons.

In the present case, the claimant sought for a preliminary injunction against the defendant who planned to import a pharmaceutical from Croatia to Germany. One active substance of this pharmaceutical was protected in Germany by a European Patent that had expired in September 2014. The patent protection was prolonged by an SPC until 2017. The proprietor had applied for the SPC already in 2003. At that point in time, there was no SPC-like instrument in Croatia. An SPC protection in Croatia is only available since July 2013 when Croatia joined the EU. The invention had never been protected by a patent or SPC in Croatia.

The court of the first instance, the Regional Court of Düsseldorf (LG Düsseldorf) had rejected the claimants request for a preliminary injunction. It argued that the claimant had missed the opportunity to apply for a patent in Croatia. Hence, the claimant shall not be allowed to benefit from the inability to obtain an SPC when it has not even created the necessary conditions for an SPC by applying for a patent in Croatia.

The OLG overruled the court of the first instance and granted the preliminary injunction. It argued that the wording of the Specific Mechanism in the Treaty of Accession of the Republic of Croatia is unambiguous. The day when the SPC was applied for is a key date: If the SPC as a legal construction was not available in Croatia at this very day, the importer cannot refer to the principle

of exhaustion.

The court also mentions an astounding consequence of this legal interpretation: A parallel importer could be allowed to import a pharmaceutical from a new member state where the product is not protected by a patent into a territory where a patent is in force, because the proprietor missed the opportunity to apply for a patent in the new member state. But as soon as the patent protection expires and an SPC comes into force, the parallel importer would have to stop importing the product if the SPC as a legal construction was formerly not available in the new member state.

Moreover, the court confirmed that, although the SPC refers to a specific product, the scope of protection of the SPC is not limited to the active substance or to the combination of active substances that are present in the respective product. Instead of that, the scope of protection of the SPC is identical to the scope of protection of the patent the SPC refers to. Thus, if the patent protects a specific substance and the SPC refers to the “mono-product” which has this substance as the only active ingredient, any pharmaceutical that combines the protected substance with other active ingredients also falls under the scope of protection of the SPC.

Dr. André Sabellek, B.Sc.

rospatt osten pross– Intellectual Property Rechtsanwälte

To make sure you do not miss out on regular updates from the Kluwer Patent Blog, please subscribe [here](#).

Kluwer IP Law

The **2022 Future Ready Lawyer survey** showed that 79% of lawyers think that the importance of legal technology will increase for next year. With Kluwer IP Law you can navigate the increasingly global practice of IP law with specialized, local and cross-border information and tools from every preferred location. Are you, as an IP professional, ready for the future?

Learn how **Kluwer IP Law** can support you.

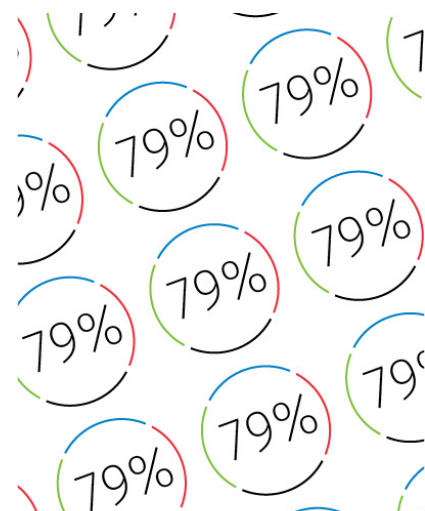
79% of the lawyers think that the importance of legal technology will increase for next year.

Drive change with Kluwer IP Law.

The master resource for Intellectual Property rights and registration.



Wolters Kluwer



2022 SURVEY REPORT
The Wolters Kluwer Future Ready Lawyer
Leading change

This entry was posted on Wednesday, November 11th, 2015 at 3:52 pm and is filed under [European Union](#)

You can follow any responses to this entry through the [Comments \(RSS\)](#) feed. Both comments and pings are currently closed.