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The Bolar exemption: the need for agreement

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There is no uniform interpretation of the scope of the Bolar exemption in Europe, but a CJEU opinion harmonising the issue may be on the way, says Rafal Witek.

In recent months, we've had the opportunity to analyse the final decisions of the courts in Poland and Germany on the *Astellas v Polpharma* case interpreting the range of the Bolar exemption in Europe (for earlier details of the case click here).

In the case, Polish company Zakłady Farmaceutyczne Polpharma SA (Polpharma) produced an active pharmaceutical ingredient (API) which it offered it to other companies, and in particular to a German company Hexal AG, claiming the API was being offered only to allow them to carry out

whatever activities were necessary to obtain marketing approval (MA) for a generic product.

The plaintiff, Astellas Pharma Inc, sued Polpharma for infringing its German and Polish patents protecting the API offered by Polpharma. Polpharma argued that its activities did not infringe Astellas' patent because they were covered by the Bolar exemption defined in both Polish law (Article 69.1.[iv] IPL) and German law (§11 Nr. 2b PatG).

Poland

The Polish courts of first and second instance decided that Polpharma's activities were of a strictly commercial nature and were not conducted to obtain MA for itself. As a result, its actions were not considered to be covered by the exception defined in Article 69.1.(iv) IPL. Polpharma was labelled a patent infringer even though the client that bought the API, Hexal, actually applied for MA and the subsequent order volume confirmed the nature of the activities planned by the customer. These circumstances, however, were deemed irrelevant in the case concerning the allegation of patent infringement by Polpharma.

In the appeal proceedings, Polpharma asked for directions on the following question from the Court of Justice of the European Union (CJEU): "Is the manufacture of patented substances permissible under Article 10(6) of Directive 2004/27/EC if the privileged purpose is conducted by a third party? And, if the answer is yes, what conditions must be fulfilled by a third party so that the supply falls within the requirements of the directive?"

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In October 2013, the Polish Supreme Court (Sygn. akt IV CSK 92/13) confirmed the position of the lower instance courts and held that the production and/or offering of the API by third parties that had not directly applied for their own MA should be considered patent infringement and not covered by the scope of the exception defined in Article 69.1.(iv) IPL.

Moreover, the Supreme Court refused to refer the case to the CJEU for a preliminary ruling on its interpretation of the Bolar exemption.

Germany

Generally, the decision of the court of first instance in Germany was in line with the decisions of the Polish courts. However, the court of appeal, the Düsseldorf Higher Regional Court, took into consideration the importance of the decision for the development of generic drugs in Europe.

As a result, the following questions were submitted to the CJEU for a preliminary ruling (Case C-661/13):

1. Is Article 10(6) of Directive 2001/83/EC to be interpreted as meaning that the exclusion from patent protection also applies to acts of provision by which a third party for purely commercial reasons offers or supplies to a manufacturer of generic medicinal products a patent-protected active substance which that generic pharmaceutical undertaking has planned to use for conducting studies or trials for a MA under medicinal product law as provided for in Article 10(6)?

2. If yes:
(a) Does the third party's enjoyment of the exemption depend on the manufacturer of generic medicinal products supplied by him actually using the provided active substance for exempted studies or trials under Article 10(6) of Directive 2001/83/EC? Does the exclusion from patent protection apply in such a case even where the third party has no knowledge of the intentions of his customer to use the active substance for purposes covered by the exemption and has also not satisfied himself in this regard?

Or, in order for the third party to enjoy the exemption, does it matter only that at the time of his act of provision he can legitimately assume on the basis of all the circumstances (for example, the focus of the undertaking supplied, the small quantity of the active substance provided, the imminent expiry of the patent protection for the active substance in question, experiences as to the customer's reliability) that the generic pharmaceutical undertaking supplied will use the active substance provided exclusively for exempted trials or studies in the context of a MA?

(b) Must the third party, in connection with the performance of his act of provision, take measures of his own to ensure that the active substance is actually used by his customer only for exempted trials or studies, and do the measures to be taken by him differ according to whether the patent-protected active substance is only offered or also supplied?

Comments

Despite the fact that the decision issued by the Supreme Court is a final decision in Poland and is not subject to appeal, we assume that if a different view is expressed by the CJEU then that will be taken into consideration as 'superior' in future Polish court rulings.

In view of the divergent positions adopted by the courts in Poland and Germany, the need to harmonise the interpretations of Article 10(6) of Directive 2001/83/EC becomes obvious.

We assume that the expected CJEU opinion will take into account the intention expressed in Article 10(6) of Directive 2001/83/EC, and that activities commonly practised today in the pharmaceutical industry relating to the outsourcing of API production will be considered to be "the consequential practical requirements" mentioned in the article.

Aside from the legal importance of the expected CJEU opinion, it will also have an important

influence on the European economy. The adoption of a restrictive interpretation of the Bolar exemption in Europe would have a very negative influence on public healthcare financing and the development of the industry in Europe. The ban on API production outsourcing would become a serious barrier to the introduction of generic products in Europe. At the same time, it would force the production of most known APIs and related inventive activities to be relocated beyond Europe.

We hope that all this will not persuade the patentee to take legal action to avoid the CJEU opinion being issued.

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