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It takes Two to Bolar – European courts have excluded third party manufacturers from scope of Bolar exemption

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The Regional Court in Dusseldorf and the Higher Regional Court in Gdansk have ruled in June and July 2012 that the Bolar exemption and the experimental-use exemption only apply to the testing entity and that a third party's manufacturing and selling to the testing entity is not exempted.

The so-called Bolar exemption was introduced into European patent law via Art. 10 (6) of Directive 2004/27/EC. It exempts those activities from patent infringement that are necessary to conduct trials for drug approval since such trials and studies could otherwise only be conducted after patent expiry and this would artificially prolong the lifetime of the drug patent:

"Conducting the necessary studies and trials with a view to the application of paragraphs 1, 2, 3 and 4 and the consequential practical requirements shall not be regarded as contrary to patent rights or to supplementary protection certificates for medicinal products."

Most European countries implemented this provision more or less verbally into their national laws. While the provision only applies in some countries to generic applications (e.g. the Netherlands and UK), in other countries the scope has been extended to applications for innovative drugs as well (e.g. Germany, France and Belgium). However, all of the new laws shared the legal uncertainty that arose from the Directive's vague wording, i.e. it remained unclear what actually constitutes "consequential practical requirements". It was clarified in the legislative process on European level that the testing entity shall be allowed to manufacture the patented substance itself for its trials and studies, but it still remained unclear whether the substance could also be manufactured and sold by a third party manufacturer without infringing the patent. The same uncertainty existed with regard to the experimental use exemption.

Surprisingly, this question did not arise in litigation in Europe and only remained a subject of speculation in legal literature. Now, however, two decisions have come down that shed some light on this issue. The one was issued by the Regional Court in Dusseldorf (Judgment of July 26, 2012, docket 4a O 282/10) and the other by the Higher Regional Court in Gdansk (Judgment of June 26, 2012 docket IX GC 76/11).

The story behind the decisions is quickly told: A Polish manufacturer of active pharmaceutical ingredients placed advertisements for an active ingredient protected by a substance patent on his own website and in well-renowned pharmaceutical magazines such as SCRIP and Generics Bulletin. The patentee sued the Polish API manufacturer in Poland and Germany as these two

markets were addressed. It turned out that the API manufacturer had sold several kg of the API to different generic companies, among others in Germany. The line of defense by the API manufacturer was that all its activities were exempted by the Bolar exemption since its customers were going to use the API only for testing purposes. The manufacturer also stated that it would be allegedly indispensable for the generic industry to receive supplies from third party manufacturers since many generic companies would not be in a position to manufacture the API themselves. They would therefore be excluded from making use of the exemptions, and the provision would entirely fail its purpose.

Both courts have clearly rejected this line of argumentation and have held that these sales are a clear-cut case of patent infringement. In the Polish case the judgment has already been confirmed on appeal.

The Regional Court in Dusseldorf found particularly clear words in this regard:

“The balance which Sec. 11 German Patent Act [including the Bolar and Experimental Use Exemption] wants to achieve between the interests of the patentee and the public would be jeopardized to the detriment of the patentee and would therefore be inequitable if supply by third parties would be privileged according to Sec. 11 No. 2 or 2b) of the German Patent Act only because the customer can invoke these privileges. In cases where the third party cannot be seen as a co-organizer of the trials and studies and does thereby not have a genuine interest in these trials and studies, the main interest of the third party will be the turnover generated by the supply business and thereby the commercial exploitation of the invention.”

The Regional Court also clearly rejected the argument by the defendant that the involvement of an API manufacturer would have to be accepted because it is a common practice in the industry:

“Nobody is prevented from conducting trials and studies and to this end from providing the necessary means and substances by manufacturing or importing them. It is possible that individual companies are not able to do so themselves and that in the case of the generic industry the manufacturers of generics receive a large part of the active substances from third parties and do not manufacture them themselves. These factors however lie within the responsibility of the individual company and should not harm the patentee […].”

Both the Regional Court Dusseldorf and the Higher Regional Court Gdansk have clarified that a supplier cannot rely on the exemptions only because its customer uses the purchased item exclusively for experimental or Bolar purposes as this would lead to free trade with protected substances. These decisions thereby provide a long awaited clarification and have clearly strengthened the position of the patentee.

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