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You must Bolar alone: Polish Supreme Court confirms exclusion of third-party manufacturers from the Bolar exemption

Thorsten Bausch (Hoffmann Eitle) · Thursday, November 7th, 2013

In a decision handed down on October 23, 2013, the Polish Supreme Court confirmed that the Bolar exemption does not cover activities by third-party manufacturers, i.e. supplying active ingredients for studies and trials to be conducted by third-party generic manufacturers (court docket: IV CSK 92/13). Parallel proceedings in Germany are pending.

We have reported before in this [blog on two previous decisions](#) relating to the same litigation complex regarding the infringement of the Astellas' substance patent for Solifenacin by a Polish manufacturer of active ingredients. The Regional Court Dusseldorf (decision of July 26, 2012, 4a O 282/10) and the Court of Appeal in Gdansk (decision of June 26, 2012, I ACa 320/12) held that supplying infringing products to a third party does not fall under the Bolar exemption, even if said third party should use these products for activities covered by the Bolar exemption.

By rejecting the Cassation Appeal against the judgment of the Court of Appeal in Gdansk, the Polish Supreme Court has now confirmed the interpretation of the Bolar exemption applied by the lower instance courts in Poland and also in Germany, i.e. that the Bolar exemption (and in Germany also the experimental-use exemption) only applies to the entity conducting the experiments or trials, and does not allow infringing acts committed by third-party suppliers or manufacturers.

The European Bolar exemptions have been implemented in the national patent laws in accordance with the respective provision in the European Directive 2004/27/EC, which reads:

“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.”

The facts behind the case are as follows:

In late 2010, Astellas discovered that a Polish manufacturer of active pharmaceutical ingredients (API) had placed advertisements for an active ingredient protected by Astellas' substance patent on its company website and in pharmaceutical magazines such as SCRIP and Generics Bulletin. Astellas sued the manufacturer in Poland and in Germany on the grounds of patent infringement in late 2010/early 2011 since at least these two markets were involved. In the course of the Polish

proceedings, it was discovered that the manufacturer had in addition offered and already sold the protected API to generic companies all over the world, including a generic company in Germany. In its defense, the manufacturer mainly argued that all of its activities were covered by the Bolar exemption as its customers would only be using the API for the studies and trials required for obtaining market approval. Only in Germany was the argument also extended to the experimental-use exemption. The reason for not using this argument in Poland seems to be that under Polish patent law the scope of the experimental-use exemption is very limited and would not have safeguarded the third-party manufacturer. The experimental-use exemption may only be applied in Poland to scientific and not to commercially motivated research.

The defendant argued in both the Polish and the German proceedings that the use of third-party suppliers was indispensable for the generic industry and should therefore be exempted as a “consequential practical requirement”. Since small or medium-sized generic companies are not always in a position to manufacture the active ingredient themselves, the purpose behind the Bolar exemption would not be met if these companies could not be supplied by third-party manufacturers.

The Regional Court Dusseldorf and the Court of Appeal in Gdansk both clearly rejected this argument and ruled that the Bolar exemption (and the experimental-use exemption) is only available to the testing entity itself which has a genuine interest in either obtaining market approval for the drug candidate or in obtaining the new information which results from the research.

In Germany, the case is pending in an appeal before the Higher Regional Court Dusseldorf and a decision is expected early next year.

In Poland the proceedings advanced at a faster pace. After the appeal was decided in June 2012, the manufacturer filed for cassation proceedings at the Supreme Court in November 2012. The Polish system of civil courts only includes two instances and therefore the decision of the Court of Appeal in Gdansk was final. The application for a cassation to the Supreme Court is an extraordinary remedy and only in rare cases admitted by the Supreme Court. Most likely since this case had received a lot of attention also in Poland, the Supreme Court, however, accepted the case.

On October 23, the Supreme Court delivered its verdict. The written grounds will probably be available in about a month. In essence, the bench, in the oral presentation of the basic motives of the verdict, held that the Bolar exemption has to be interpreted narrowly because it is an exception to the rule of patent protection. Therefore, according to the wording of Article 69 section 1 item 4 of the Polish Industrial Property Law, only that entity that actually applies for market approval may conduct the trials and studies necessary for this goal and benefit from the exemption. Also, sales by a third-party manufacturer may not be considered as “consequential practical requirement” only because such sales might be convenient from an economic perspective. The presiding judge in particular based this interpretation on the European background of the norm. The European Directive 2004/27/EC on which the Bolar exemption is based does not indicate anywhere in its wording or legislative history that activities by third parties should be covered as well.

In addition to the foregoing, the Supreme Court supported the view that the term “offering” as used in Industrial Property Law has a broader meaning than “an offer” in the understanding of civil law. An activity qualifies as an offer if it constitutes an inducement to sales, i.e. advertising, etc. would also be covered. This interpretation is in line with the understanding of the term “offer” in most

European jurisdiction but the matter had been controversial under Polish law and has now been clarified by the Supreme Court.

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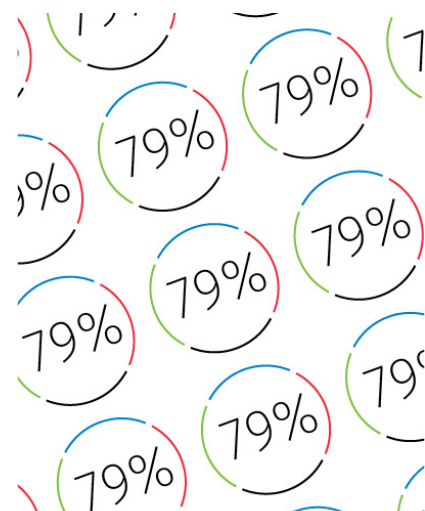
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