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Federal Supreme Court Confirms Compulsory License by Way of a Preliminary Injunction

Thomas Musmann (Rospatt Osten Pross) · Thursday, August 31st, 2017

In March our partner Hetti Hilge reported on a preliminary injunction by which the Federal Patent Court granted Merck an interlocutory compulsory license for Merck's HIV drug Isentress in the light of Shionogi's Raltegravir patent EP 1 422 218 ([link](#)).

The compulsory license has now been confirmed in the second instance PI proceedings by the Federal Supreme Court (BGH), which just issued its written decision (verdict of 11 July 2017, docket No. X ZB 2/17, [link](#)).

The Federal Supreme Court's decision sets precedents on the following legal issues:

1) Reasonable Efforts to Receive Patentee's Consent

According to Sec. 24 (1) No. 1 German Patent Act (PatG), the party seeking a license has to prove unsuccessful efforts during a reasonable time period to receive patentee's consent to use the invention. The BGH holds that it is not sufficient if the party seeking a license starts these efforts only in the course of the litigation, so to say as a last-minute resort.

2) Relevance of the Validity of the Patent in the Context of these Efforts

The BGH confirms that the party seeking a license may take the uncertain validity of the patent into consideration when it makes its efforts to get the patentee's consent. In the case at hand, Merck was allowed to offer a comparatively low lump sum license fee to the patentee in return for a license and in return for a withdrawal of its opposition against the patent because the opposition division of the EPO had previously limited the claims of the patent in its first instance decision; the appeal was still pending. In this context, the BGH also took into account that the UK court had held the patent invalid in a parallel infringement case.

3) Public Interest Demanding the Compulsory License

According to Sec. 24 (1) Nr. 2 PatG, the public interest must demand that the compulsory license be granted. The BGH confirms that such public interest can also be present if only a relatively small group of persons is reliant on the licensed product. In the specific case, at least babies, children under 12 and pregnant women would have been exposed to a high health risk if Isentress would have been removed from the German market.

4) Urgency Requirements

According to Sec. 85 (1) PatG, an interlocutory compulsory license can be granted by way of a preliminary injunction if the party seeking a license can plausibly demonstrate the prerequisites of Sec. 24 (1) PatG and if the public interest needs to be fulfilled on an urgent basis. The BGH clarifies that these prerequisites are preclusive and that no additional prerequisites according to the general laws on civil procedure (ZPO) have to be met, namely the danger of irreparable harm for the applicant.

The BGH also explains that a hesitant behavior on the side of the party seeking a license only has minor relevance for the urgency requirement according to Sec. 85 (1) PatG – contrary to cases where the applicant requests preliminary injunctive relief. Sec. 85 (1) PatG mainly refers to the public interest and not to the economical interest of the party seeking a license. A hesitant behavior on the applicant's side prior to his application can only give limited clues on whether or not a compulsory license is in the public interest and whether the public interest needs to be fulfilled on an urgent basis.

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