

# Germany - Compulsory license for an HIV/AIDS drug

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In a judgment in preliminary proceedings the Bundespatentgericht (German Federal Patent Court) granted the pharmaceutical company Merck the right to use European patent EP 1 422 218 and to continue sales of the AIDS drug Isentress in Germany. It is the first time in its 55-year history that the Bundespatentgericht granted a compulsory patent license in preliminary proceedings. The written judgment in the preliminary proceedings is now available (BPatG 3 LiQ 1/16 (EP)). The main action concerning Merck's request for a compulsory license is still pending.

Following an independent expert opinion the Bundespatentgericht concluded that there is an urgent public interest in the continued availability of the drug which exceeds the interest of the patent proprietor in its monopoly right. In particular certain groups of patients with HIV or AIDS require the drug with the active ingredient Raltegravir for medical reasons. These include in particular pregnant women, babies and children, and patients that have taken HIV treatment for a long time and cannot switch to other medication without significant health risks. The judges also took into consideration that the risk of infection for third parties decreases when the viral load is effectively reduced. Merck is currently the only company that offers medication with the antiviral agent Raltegravir for an antiviral therapy of HIV and AIDS in Germany.

The patent proprietor, Japanese pharmaceutical company Shionogi, sued Merck in 2015 for patent infringement before the Landgericht Duesseldorf (District Court) and requested an injunction (LG Düsseldorf 4c O 48/15) after the license

negotiations between the parties had failed. Several Merck companies then filed a request for a compulsory license acc. to sec. 24 German Patent Act. In addition they requested a preliminary decision which allowed them to continue distribution of the drug Isentress in Germany. They argued that they are willing to take a license on reasonable and customary terms and that their previous license offer corresponds to such terms.

The compulsory license acc. to sec. 24 German Patent Act is awarded by an official act of a public authority if there is a prevailing public interest. It has different requirements than the FRAND/compulsory license defence based on antitrust law as confirmed by the Bundespatentgericht in the decision. In the action on the merits, the court will also have to determine the main license terms, including the royalty, if it grants the compulsory license.

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