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Compulsory license: Merck may AIDS drug thanks Hogan Lovells resell

The Federal Patent Court has broken new ground: the first time in its 55-year history it ranked this week in summary proceedings, a compulsory license to use a patent on. This now has the Japanese pharmaceutical company Shionogi US drugmaker Merck at its European patent (EP 1422218) grant (Az. 3 LiQ 1/16). This protects the HIV drug raltegravir. Merck may initially redistribute its HIV drug Isentress.



Miriam Gundt

The patent judges justified their decision with an urgent public interest, after they had obtained an expert opinion. It considers Isentress was needed by certain groups of HIV-infected or with AIDS patients for medical reasons. This can not switch to other products with no significant health risks. This applies in particular for pregnant women, infants and children and many years against HIV treated people. The judges also considered that an effective reduction of viral load Decrease a possible risk of infection for others.

The drug Raltegravir is a called integrase inhibitor. He does not cure infected humans, but prevents the HIV virus propagated in the body by blocking the incorporation of viral DNA into the human cell. Shionogi has a patent on the drug since 2012 Design. Meanwhile, with Dolutegravir and Elvitegravir two similar drugs on the market.

The dispute between Shionogi and Merck had ignited after the Japanese had in 2002 applied for a patent, that includes raltegravir. This was granted in 2012 by the European Patent Office and held in the wake of the appeals of Merck stood. The Americans had almost the same time developed a patent with a narrow scope for raltegravir and the first company to ever get an authorization in the United States of 2007. Isentress is now widespread in HIV patents and is approximately in the treatment of pregnant women, newborns and newly infected advantageous.

Merck offered ten million dollars for the license



Christian Lederer

Shionogi sued Merck 2015 the Landgericht Dusseldorf for violating an injunction (Az. : 4c O 48/15). By contrast, Merck defended a compulsory license.

The proprietary compulsory license under Section 24 Patent Act, unlike the currently much discussed antitrust compulsory license be granted if the licensee has tried unsuccessfully to obtain a license on reasonable terms, but the public interest is given - for example, for a smooth health care.

The Patent Court saw it now proved that Merck had made a corresponding license offer. In the course of the trial it was revealed that Merck had offered ten million dollars for a worldwide license. That was too little Shionogi. The Japanese had also defended the fact that associated with Dolutegravir and Elvitegravir two treatment alternatives available. To increase the pressure, Merck had pulled the extremely rare urgent application for a compulsory license under Section 85 Patent Law during the process.

For the first time compulsory license in summary proceedings

The dispute is not over yet with the recent ruling. Shionogi is now open to the appeal to the Federal Patent Court. It also remains to the Japanese nor the principal proceedings. On September 13, the LG Dusseldorf also negotiated the injury question.

After JUVE information yesterday's decision is only the second in the history of the Federal Republic, in which a compulsory license has been granted. The first time was the responsible Federal Patent Court this step in 1995 called Polyferon judgment. That it has chosen this emergency procedure, is new. Compulsory licenses are not requested frequently, usually it takes not to judgment, because comparing the parties beforehand.

Representatives Shionogi **Taylor Wessing** (Munich): Dr. Christian Lederer (Lead), Dr. Sabine Rojahn, Dr. Anja Lunze; Associate: Dr. Jan Rector shek **Isenbruck Bösl Hörschler** (Munich): Dr. Fritz Lahrtz, Dr. Sandra Zinner (patent attorneys)

Representatives Merck **Hogan Lovells** (Dusseldorf): Miriam Gundt (Lead), Dr. Andreas von Falck, Prof. Dr. Thomas Dünchheim (Public Law); Associates: Dr. Stephan Dorn, Kerstin Jonen (both patent law), Antje Sadowski (Public Law) **Abitz & Partner** (Munich): Dr. Jan Morf (patent attorney)

Federal Patent Court, 3rd Senate
Walter Schramm (Presiding Judge)

Background: Both process teams involved are considered well versed in drug cases. Taylor Wessing has thereby a very present practice for Asian companies, especially from Japan. The mandate was her plotted by Shionogi basis of recommendations. Hogan Lovells and Merck combine longstanding client relationships. (Mathieu Klos)

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