Milestones (07/2017)

The first German compulsory patent license ever - start of a new era?
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DE – Judgement of the Federal Supreme Court, dated 11 July 2017, docket no. X ZB 2/17

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In the decision 'Raltegravir' dated 11 July 2017, the Federal Supreme Court granted a compulsory patent license pursuant to § 24 German Patent Act. Interestingly, the license was granted on short track, i.e. in 'preliminary injunction proceedings' pursuant to § 85 German Patent Act. The Supreme Court's decision sets a milestone and marks German patent law history. This is due to the fact that no single compulsory license was ever successfully requested before. The last attempt, when the Federal Patents Court accepted such a request at first instance, was frustrated upon appeal by the Federal Supreme Court (cf. GRUR 1996, 190 – Polyferon). The important question is whether 'Raltegravir' marks a new era and thus paves the way for further compulsory licenses.

The facts underlying the Supreme Court's decision are as follows: 'Raltegravir' is an active compound used in the treatment of HIV-positive patients. The applicant for the compulsory license had already been offering its drug comprising 'Raltegravir' on the German market since 2008. The patentee of the patent in dispute had neither been producing drugs with this active compound nor marketing such drugs in Germany. In 2012, the patent in dispute was granted by the EPO and subsequently immediately opposed. The EPO's Opposition Division upheld the patent in dispute in amended form. As subsequent negotiations for a worldwide license failed, the patentee commenced infringement proceedings before the Düsseldorf District Court. The infringement proceedings were however stayed by the District Court, until the final decision of the EPO's Boards of Appeal. In January 2016, the applicant decided to file a complaint with the Federal Patents Court for a compulsory license pursuant § 24 German Patent Act. In addition thereto, the applicant requested a preliminary ruling that the use of the patent in dispute be allowed pursuant to § 85 German Patent Act. This request was accepted by the Federal Patent Court and confirmed by the Federal Supreme Court.

The Supreme Court's decision elaborates on the two requirements for a compulsory license pursuant § 24 German Patent Act:
Firstly, it is necessary that the applicant has tried without success for a 'reasonable period of time' to obtain a license under 'reasonable conditions'. This first requirement must be fulfilled at the end of the oral hearing. This allows the applicant to make a first request for a license even after the proceedings for a compulsory license have already started. However, a request made at the 'very last minute', just prior to the oral hearing, will not suffice. The request must further comprise 'reasonable conditions'. Insofar, it is acceptable that the applicant factors the validity of the patent in dispute in his offer, provided such 'discount' has a proper basis. In the case at hand, the High Court of Justice of England and Wales dismissed a parallel complaint due to the invalidity

of the UK counterpart of the patent in dispute (Arnold J, [2016] EWHC 2889 (Pat), margin. 355). In light of this background, the Federal Supreme Court accepted the applicant's standpoint, even though the patent had been maintained in amended form before the EPO. However, the Federal Supreme Court also made clear that mere fake negotiations are not acceptable. The same applies to a request that a compulsory license is only requested under the condition that the court will not fix an amount exceeding a certain upper limit (if the court deems such limit as being unsatisfactory). The Federal Supreme Court emphasized that, in the end, the license fee for a compulsory license corresponds to the fee for a non-exclusive license on market terms.

The second requirement is the 'public interest' for the grant of such a compulsory license. The Federal Supreme Court highlighted that there is no general definition for this requirement, and that each case must be considered separately. However, the Federal Supreme Court made clear that such 'public interest' requires special circumstances, since patent law has allocated exclusive rights to the patentee and that he could – as a general rule – freely decide how to exercise these rights. For drug cases, this leads to the following results: a 'public interest' can be successfully argued provided that the active compound at issue has certain therapeutic effects which the other active compounds available on the market do not provide; or that by using this active compound, negative side effects (which the other active compounds do induce) can be avoided. In this regard, it does not matter that the user group to which such considerations apply is small, given the fact that the hardships of such small group are huge.

Finally, the Federal Supreme Court held that a compulsory license could be granted in preliminary proceedings, even though the applicant acted hesitantly. This argument is convincing: whether a compulsory license is needed on an 'urgent' basis, depends on the 'urgency' with a view to the public interests at stake and not on the applicant's behavior.

Returning to the beginning: does 'Raltegravir' mark a new era? The answer is 'yes', but only for such cases which have implications on parties other than the patentee and the alleged infringer. In these situations, a 'compulsory license' is available if the other available technologies imply downsides for third parties that the patented technology does not have. Of course, the significance of such downsides plays a role. However, it seems that it will be sufficient to show that such downsides are in conflict with the German constitution and the European Convention on Human Rights. This means that not only pharma cases are eligible for 'compulsory licenses', but also all other cases where third-party human rights play a role (e.g. right to information, right to practice a profession, etc.).

A full copy of the decision can be found at:
http://juris.bundesgerichtshof.de/cgi-bin/rechtsprechung/document.py?Gericht=bgh&Art=en&az=X%20ZB%202/17&nr=79269

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