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German Federal Court of Justice confirms the compulsory license granted by way of a preliminary injunction for the AIDS drug Isentress; the EPO Board of Appeal then revokes the European patent (German Federal Court of Justice, judgment dated July 11, 2017 – *"Raltegravir"* – docket no. X ZB 2/17, GRUR 2017, 1017 // EPO, TBA 3.3.01, file no. T 1150/15, decision dated October 16, 2017)
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In its judgment, the German Federal Court of Justice dismisses the appeal of the patent proprietor and also substantially follows the German Federal Patent Court with respect to the grounds for its decision. By revoking the patent, the Board of Appeal deprives the compulsory license of its basis.

Facts and circumstances

The parties Merck Sharp & Dohme/MSD (US) (hereinafter: Merck for all companies of the group) and Shionogi are pharmaceutical companies competing in the field of antiviral agents for the treatment of AIDS. Both simultaneously conducted research on a group of agents inhibiting the enzyme integrase and thus counteracting proliferation of the human immunodeficiency virus (HIV). This group also includes the agent nowadays known as Raltegravir. In August 2002, these works resulted in application of European patent no. 1 422 218 by Shionogi and in October 2002 in another application by the Italian Merck subsidiary. The patent for Merck was granted in 2006, the one of Shionogi in 2012.

At the end of 2007, Merck was granted approval for its drug Isentress, which contains Raltegravir as active ingredient, and started distributing the product. Shionogi is present on the market with two drugs which act as integrase inhibitors and are also covered by the patent. In June 2014, Shionogi asserted against a company of the Merck group that Isentress fell within the scope of protection of its Japanese patent, which belonged to the patent family of European patent no. 1 442 218. This was followed by more than one year of negotiations on a global license, which, however, remained unsuccessful due to different opinions on the amount of the royalty. In August 2015, Shionogi filed an infringement complaint and asserted claims for injunctive relief, *inter alia*, against Merck. The Regional Court of Düsseldorf stayed the infringement proceedings until the rendering of a decision in the opposition appeal proceedings. Upon appeal of the Plaintiff, the stay was upheld by the Higher Regional Court.

At the beginning of January 2016, Merck filed a complaint requesting a compulsory license before the German Federal Patent Court. Following the objection of Shionogi, Merck requested that it be granted permission to use Raltegravir preliminarily, i. e. before a decision is rendered in the principal proceedings, by way of a preliminary injunction.

After the patent had been granted to Shionogi, Merck filed an opposition. In the proceedings before the Opposition Division, the Opponent asserted that limitations of claim 1 which had already been made in the grant procedure had not been originally disclosed and therefore violated the prohibition of adding subject-matter. The Opposition Division did not agree with this and maintained the patent in a limited version.

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The decision of the German Federal Court of Justice

1. Admissibility of the request

Pursuant to Sec. 85 German Patent Act (*PatG*), in pending proceedings for the grant of a compulsory license, the plaintiff may be allowed by way of a preliminary injunction to exploit a patented invention if it demonstrates to the satisfaction of the Court that the requirements of Sec. 24 German Patent Act for the grant of a compulsory license are being met and that an immediate grant is urgently required in the public interest.

The patent proprietor asserted that the request was inadmissible as Merck had not made genuine and sustainable efforts to obtain a license on reasonable commercial terms and conditions. The German Federal Court of Justice does not agree with this from a procedural point of view in the first place. It distinguishes between the admissibility of the complaint for compulsory license, where the refusal of a license by the patent proprietor is a procedural requirement that can be met subsequently, and the preliminary injunction proceedings, where the substantiation of all requirements of Sec. 24 German Patent Act cannot be a mere requirement of admissibility, similar to the requirement of urgency, which is to be substantiated as well. Therefore, the efforts required by Sec. 24 (1) German Patent Act to obtain a license on reasonable commercial terms and conditions had to be examined in the context of allowability within a reasonable period of time.

2. Allowability of the request

2.1 Unsuccessful efforts to obtain a license

The examination of the required efforts to obtain a license is the first focus of the decision. First of all, the German Federal Court of Justice points out that the required efforts do not have to be necessarily made prior to the complaint for compulsory license. However, it is not sufficient if the plaintiff agrees to pay a reasonable royalty virtually at the last minute.

The negotiations had failed because the parties had different opinions on the royalty amount, which, according to the judgment, differed considerably. According to reports on the proceedings, Merck offered 10 million US dollars as a global one-off payment, whereas Shionogi considered a royalty of 10 % of the turnovers generated with Isentress reasonable, stating that the global turnovers amounted to approximately 1.5 billion US dollars per year. Because of these extremely diverging positions, Shionogi considered Merck's offer to be entirely inappropriate and not genuine.

Nevertheless, the German Federal Court of Justice found that the conduct prior to the proceedings had (still) met the requirements of Sec. 24 (1) German Patent Act with respect to the particular circumstances of the case. The German Federal Court of Justice considered it significant that according to Shionogi's position Merck should withdraw all oppositions and thus the license agreement should simultaneously settle the disputes over the validity of the patent. The validity is uncertain since diverging decisions have been rendered in

the first instance in England and before the EPO. Merck was allowed to consider this in its price expectations and was not obliged to meet the price expectations of the patent proprietor, which were based on a permanent existence of the patent.

In the main proceedings, Merck had left the royalty of the compulsory license at the discretion of the court and later announced a specified request for a one-off payment, and for a turnover license rate as an auxiliary request. The German Federal Court of Justice concedes to the patent proprietor that a complaint for compulsory license has to remain unsuccessful if the complaint is made under the condition that a certain royalty is not exceeded, and the court does not consider this amount sufficiently high. This is because the royalty is to be set by the court when the compulsory license is granted. However, the German Federal Court of Justice concludes that the case is different here because Merck had explained that the previous license offer had not constituted an upper limit and that it was willing to take a license on reasonable commercial terms and conditions. The German Federal Court of Justice further states that the German Federal Patent Court had to clarify the requests in the principal proceedings, if necessary. In the oral proceedings before the German Federal Court of Justice, Merck explained that the requests in their entirety were aimed at the compulsory license also being granted if the royalty considered reasonable by the German Federal Patent Court exceeded the maximum amount mentioned by Merck.

2.2 Public interest in the grant of a compulsory license

As a starting point, the German Federal Court of Justice emphasizes the exclusive right of the patent proprietor to solely decide how the invention is used: the interests of the patent proprietor are less important than the public interest only if under the particular circumstances of the individual case, public interests require use of the patent by the license seeker. This is, for example, the case if a medicine for the treatment of severe diseases has therapeutic properties which the drugs available on the market do not have at all or not to the same extent, or if it avoids undesired side effects that have to be taken into account in connection with the other therapeutic agents. On the other hand, a compulsory license is unjustified as a matter of principle if the public interest can basically be met with other, alternative substances.

According to the factual findings of the German Federal Patent Court based on the expert opinion of the court expert and the parties expert opinions, the German Federal Court of Justice confirms the public interest in the continued availability of Raltegravir for the treatment of babies and children as well as pregnant women, and for the prophylactical treatment of patients in cases of acute risk of infection. Public interest can also be present if only relatively small groups of patients are affected. The German Federal Court of Justice considers it particularly important that Isentress has been on the market for several years and is distributed on a large scale. In the end, it is irrelevant whether the particular problems stated by the German Federal Patent Court regarding the change from Raltegravir to

the two other available integrase inhibitors give rise to public interest.

In any case, the general risks of a change in therapy give rise to considerable public interest in the continued availability of Raltegravir in the first place.

The German Federal Court of Justice recognizes that in many individual cases, alternative treatment methods may be considered which have relatively high chances of success. However, in all affected groups, this is opposed by the considerable risk of severe side effects or interactions or treatment failures. The German Federal Court of Justice considers this risk unacceptable. Both for patients who are already being successfully treated with Raltegravir and for patients for whom Raltegravir is the preferred treatment method, it is not about obtaining a new alternative therapy, the benefit of which cannot be conclusively assessed, but about continued access to a therapy option which has been established for years and used with success.

The German Federal Court of Justice does not consider it unreasonable that Shionogi is deprived of the chance to increase its turnovers with its drugs, which are also covered by the patent, because Merck is not eliminated as a competitor, especially since the latter is willing to pay royalties and the justified financial interests of the patent proprietor can thus be met.

The German Federal Court of Justice does not consider it necessary to limit the authorization of use to particular groups of patients. It is not possible to describe, based on abstract criteria, the patient group for which public interest is to be affirmed, as such a limitation would require an individual medical forecast in certain patients.

In addition, the German Federal Court of Justice holds that it has been substantiated that immediate grant of the authorization of use seems urgently required in the public interest. If the request for a preliminary injunction is dismissed, but the complaint in the principal proceedings should prove to be well-founded later on, an indefinite number of patients would have to face a change in therapy or an alternative first-line therapy with considerable risks and possibly severe consequences. If use is temporarily permitted, but the complaint in the principal proceedings should prove to be unfounded later on, the patent proprietor may miss out on financial benefits. In the particular situation of the dispute, this consequence is to be considered clearly less severe, because the legitimate financial interests of the patent proprietor can be sufficiently met by a reasonable royalty.

Finally, the German Federal Court of Justice deals with the question of the significance of the fact that the applicant was aware for some time in advance of the facts and circumstances on which the request for a preliminary injunction is based. For assessing the question whether a provisional ruling by way of preliminary injunction is necessary, the conduct of the applicant may be relevant. If the request was filed hesitantly, this might indicate that the interest of the applicant in a provisional settlement is not sufficiently strong for justifying a preliminary injunction. The principles otherwise applying to a preliminary injunction, however, cannot be adduced without limitation for a decision pursuant to Sec. 85 German Patent Act.

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Pursuant to Sec. 935 and Sec. 940 German Code of Civil Procedure (*ZPO*), a preliminary injunction may only be issued if otherwise realization of a party's right is made impossible or considerably more difficult or a party has to face unreasonable disadvantages. On the other hand, pursuant to Sec. 85 (1) German Patent Act, a preliminary injunction may be issued if the immediate grant of the authorization is urgently required in the public interest. In connection with the question whether sufficient public interest is present, the license seekers own conduct is usually significantly less important than for the question whether its own interests are compromised. This does not generally exclude taking into account hesitant behavior of the license seeker in the balancing of interests prescribed by Sec. 85 (1) German Patent Act.

However, it cannot be readily assumed in this respect that such behavior speaks against the presence of public interest. The German Federal Court of Justice does not recognize any particular circumstances suggesting a different assessment in the dispute. It states that the requirements of Sec. 935 and Sec. 940 German Code of Civil Procedure are not necessary for issuing a preliminary injunction pursuant to Sec. 85 German Patent Act, because in the present case, not the interest of the applicant but public interest is material. Moreover, the conduct of the applicant is not abusive of process. Although Merck could have filed the request for preliminary injunction considerably earlier, it nevertheless seems far-fetched that the defense possibilities of the patent proprietor would have been negatively affected.

The decision of the Board of Appeal

After the Board had discussed the matter, the revocation of the patent was pronounced at the end of the oral proceedings in the opposition appeal proceedings. The written decision is not yet available. The following emerges from the course of the oral proceedings:

The definitions in the formula for the active agent used for producing a drug for treating viral diseases according to claim 1 of the main request were already limited in the grant procedure in several regards with respect to the original documents, in particular:

- 3 substituent groups XYZ were each limited to one selection;

- 2 of 5 groups were limited for the R1 substituent;

- Rb1 = amine was selected from a list.

Shionogi argued that for the narrower meaning for XYZ, "singling out" had already been disclosed in the original documents, namely in combination; therefore, only one admissible selection from a list remained, as well as deletion of meanings, which was also admissible.

In contrast, Merck held the opinion that the individualized definitions of X, Y and Z each already constituted a selection and that the deletion of meanings for R1 was inadmissible for the reason alone that more than one meaning had been deleted. Therefore, all things considered, an inadmissible multiple selection was present.

As a result, the Board arrived at the conclusion that the person skilled in the art had not been able to derive the formula in the limited version from the original documents. The relevant considerations in detail will only emerge from the written decision. In any case, it is to be expected that the grounds for this decision, enlarging the case law rendered up to now and discussed in detail, will provide further guidance on dealing with the narrow disclosure concept of the EPO in the case of multiple limitations of claimed subject matters to preferred and particularly preferred embodiments, especially if they correlate with a selection from a list.

Comments

The German Federal Court of Justice had to assume that the patent is valid. Its decision terminated the preliminary proceedings; however, this was not the case with the dispute in the principal proceedings, where a decision was still to be rendered particularly on the issue of a reasonable royalty. The compulsory license relation terminated upon retroactive revocation of the patent. Payment obligations for an interim use based on the compulsory license of course continue to exist, which is why the case is possibly not yet concluded.

Prior to the success in the opposition appeal proceedings, Merck had already prevailed in the first instance in England. There, the Patents Court decided in respect of added-subject matter in favor of the proprietor but held the patent invalid due to lack of enablement and inventive step (Merck Sharp and Dohme v Shionogi, [2016] EWHC 2989 (Pat)).

The compulsory license had been laying dormant for decades in Germany. The German Federal Patent Court granted a compulsory license on one single occasion more than 25 years ago. Following an appeal of the patent proprietor, the German Federal Court of Justice negated the necessary public interest and set the decision aside (German Federal Court of Justice GRUR 1996, 190 – *Interferon Gamma*). The German Federal Patent Court never granted a permission to use the invention by way of a preliminary injunction. The Raltegravir dispute has raised public awareness of the compulsory license.

The circumstances of the legal dispute are not commonplace and do not allow for conclusions on chances of success in other constellations. However, the possibility of a compulsory license will increasingly be taken into account in entrepreneurial considerations. The German Federal Court of Justice has shown that the compulsory license is not only of theoretical significance. At the same time, it has supplemented the previous sparse case law and thus clarified the possibilities of action for the parties participating in such a dispute.