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COMPULSORY PATENT LICENSE FOR PROTECTED ACTIVE SUBSTANCES FOR INDIVIDUALIZED THERAPIES

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In a recent decision ("Raltegravir"), the German Federal Court of Justice (FCJ) has for the first time confirmed a compulsory patent license granted by the German Federal Patent Court (FPC) in first instance in a preliminary injunction proceeding. The compulsory license permits the preliminary manufacture and the (further) distribution of the antiretroviral HIV/AIDS medicament Isentress (active ingredient: Raltegravir), which has been distributed in German since 2007. Only once before, the FPC had granted a compulsory license for a patent-protected active substance (Interferon-gamma) for the treatment of a severe disease. However, this decision was later lifted by the FCJ in its Polyferon decision due to the lack of public interest in the grant of a compulsory license.

The recent decision rendered in a preliminary injunction proceeding offers interesting approaches, which may enhance the importance of compulsory patent licenses in the future. After the board of appeal of the European Patent Office (EPO) revoked the underlying compulsory license patent in mid-October, it is unlikely that the FCJ will again deal with the request for compulsory license in main proceedings.

REQUIREMENTS FOR A COMPULSORY PATENT LICENSE

German patent law stipulates in Sec. 24. Para. 1 of the German Patent Act (GPA) the grant of a compulsory license under the following requirements:

i. a license seeker has, within a reasonable period of time, unsuccessfully attempted to obtain permission from the proprietor of the patent to use the invention on reasonable commercial terms and conditions; and

ii. the public interest calls for the grant of a compulsory license.

Alternatively, a compulsory license may be considered under the requirements of Sec. 24 para. 2 of the GPA if a license seeker cannot exploit an invention for which he holds protection under a patent with a later filing or priority date without infringing a patent with an earlier filing or priority date. However, this pathway for granting a compulsory license was not assessed by the FCJ in the Raltegravir decision (BGH GRUR 2017, 1017 - Raltegravir).

In Raltegravir, the decision was furthermore rendered in a preliminary injunction proceeding based on Sec. 85 para. 1 of the GPA. Accordingly, the FPC may grant a compulsory license on the basis of an injunction if the license seeker substantiates that the aforesaid requirements for the grant of a compulsory license are fulfilled and that there is an urgent need in the public interest for the immediate grant of the permission. The FCJ held that these requirements are fulfilled.

WHICH STANDARD OF "SINCERE EFFORT" APPLIES TO THE LICENSE SEEKER?

In its recent decision, the FCJ clarifies that a license seeker must have attempted over a certain period of time and in a way that reasonably suits the concerned situation to come to an agreement with the patentee on the grant of a license. This is a case-by-case decision. Ultimately, it comes down to the sincerity of the respective efforts. Here, one can only request from the license seeker to strive for a license under conditions, which a reasonable and commercially acting third person in his stead would be willing to accept.

Generally, it may be sufficient if these requirements are fulfilled only before the end of the oral proceedings for a compulsory license. Here, the FCJ points out that it is, however, not sufficient if the license seeker declares a general willingness to pay a reasonable royalty to begin with only "at the last minute" of the proceedings.

Correlation between the content and the duration of negotiations

Whether the license seeker attempted to obtain a license over a "reasonable period of time", primarily also depends on the content of the (counter-)offer and the type of conduct of negotiations. There is a correlation between these two requirements. Therefore, as the FCJ indicates, further negotiations cannot be expected from the license seeker if, for example, the (counter-)offers highly deviate from each other and if an agreement cannot be expected.

Significance of the validity of the patent in suit

The validity of the patent in suit is not decisive in the context of compulsory license proceedings. However, plausible doubts about the validity of the patent in suit may affect the royalty. For example, the license seeker may factor in any prospects of success in opposition proceedings or in potential subsequent nullity proceedings with his (counter-)offer. This is all the more true if the patentee's offer provides that the license seeker may not challenge the validity of the patent.

The license seeker may defer the royalty amount to the discretion of the court

The license seeker is not required to provide the amount of remuneration in his claim, which he considers appropriate, but may defer this to the discretion of the court. Thus, the general willingness of the license seeker to accept the license under conditions (and in particular the royalty), which are later considered appropriate by the court, is sufficient. A request by the license seeker that the royalty to be determined by the court shall not exceed a certain maximum may be rejected, in case the court considers this maximum insufficient.

The standards of compulsory antitrust license and of antitrust objection of compulsory license do not apply to the patent license offer

Furthermore, the FPC emphasizes in its first instance decision that the standards of compulsory antitrust license and of antitrust objection of compulsory license do not apply to the patent license offer (BPatG GRUR 2017, 373, 377 - Isentress). Thus, also the principles of the decision of the Court of Justice of the European Union (CJEU) regarding the requirements of compulsory licensing of standard essential patents (SEPs) and the rigid offer-acceptance system developed by the CJEU in Huawei (EuGH GRUR 2015, 764 - Huawei/ZTE) basically do not apply to the application and grant proceedings for a (preliminary) compulsory patent license. The FCJ did not comment further on these questions.

The acknowledgement of liability for damages and obligation to render accounts is not necessary

Since the principles of compulsory antitrust license do not apply to the patent license offer, according to the FPC, it is not required for a patent license offer to contain an acknowledgement of liability for damages and an obligation to render accounts.

The provision of security by the license seeker is not always mandatory

According to the FPC, an explicit offer of security by the license seeker during license negotiations is at least not required if the economic strength of the license seeker or rather of its group company in terms of global turnover is generally known and if, in

proportion to that, the turnover of the drug to be licensed in Germany is very low. Furthermore, an offer of security may also not be expected if the negotiating parties at no time have even come close to the royalty amount.

WHICH STANDARDS APPLY TO THE "PUBLIC INTEREST"?

The FCJ stresses once more that a compulsory license may only be granted if "public interest" demands the use of the patent by the license seeker. The question, under which requirements there is public interest in the grant of a compulsory license specifically to the concerned license seeker, depends on the circumstances of the individual case and is to be decided by weighing the legitimate interests of the patentee against all aspects affecting the essential interests of the general public.

Individual suitability of an active substance for a relatively small patient group may constitute public interest

Already in its Polyferon decision, the FCJ clarified the requirements for the assumption of public interest for medical care reasons (BGH GRUR 1996, 190, 193 - Polyferon): a medicament for the treatment of a severe disease must have therapeutic properties, which the substances available on the market do not have or not to the same extent, or if at its use undesired side effects can be avoided, which at the administration of the other therapeutics had to be accepted up to now. Ultimately, in its Polyferon decision, the FCJ denied the public interest in a compulsory license, because the license seeker was not able to prove a therapeutically necessary and beneficial improvement of the treatment of the concerned disease (rheumatoid arthritis) with Polyferon neither generally nor specifically for a certain sub-group of patients in comparison to existing therapeutic options.

In the present Raltegravir decision, detailed comparisons of the properties and effects of the active substances used for HIV/AIDS were not decisive for the question of public interest in the further availability of the patent-protected active substance. Rather than that, the individual superiority of Raltegravir for the HIV treatment of certain relatively small groups of patients and medical experiences with the drug, according to which there is no general preference of certain active substances, were essential. Actually, according to the FCJ, it is not required that every patient has to rely on being (able to be) treated with the concerned medicament any time. This is all the more true if certain patient groups were exposed to a particularly high risk in case the concerned medicament was not available anymore. In the particular case, the FCJ found that Raltegravir, in individual cases, fulfills these criteria in any case particularly in the treatment of infants, children under the age of 12 and pregnant women.

The approach of the FCJ had mainly clinical reasons, which can particularly be found in the modern concept of highly differentiated and individual HIV therapy:

- A main difficulty in the treatment of HIV by the administration of a single substance (monotherapy) may be the development of resistances against that HIV medicament. Therefore, in the standard regimen of the so called "highly active antiretroviral therapy" (HAART) generally "drug cocktails" consisting of individual combinations of three antiretroviral active substances out of five different drug classes (abbreviated: (N(t)RTI, NNRTI, PI, EI and INI) are administered to patients (combination therapy). Raltegravir is an approved representative of the drug class of INIs.
- From the medical perspective, the antiretroviral active substances are generally regarded as equal. There is no general preference or recommendation of certain antiretroviral active substances for the use in combination therapies. The selection of the active substances is made according to factors to be assessed individually, such as side effects, co-morbidities, co-medication, drug interactions, stage of the immune deficiency, genetic barriers, life style and treatment adherence. The availability of medicaments out of each drug class is therefore indispensable.

Precisely this was different in the previous Polyferon decision where (at least at that time) there were demonstrably general recommendations for certain existing first choice drugs for the treatment of rheumatoid arthritis. In contrast to that, Polyferon, like further already existing drugs with similar therapeutic benefits, was rather allocated to the second line therapy.

Potential risks of switching ongoing treatments may indicate public interest

Moreover, in the view of the FCJ, public interest is also supported by the fact that by maintaining further effective treatment with Raltegravir (e.g. to avoid potential therapy failure by drug switching) a reduction of the viral load can be achieved and, thereby, at the same time, the general public can be protected from new infections. Here, it was of particular importance that the concerned medicament, at the time of grant of the patent, had been already approved for several years and is administered by physicians in Germany to a significant extent. In contrast to that, according to the findings of the FCJ in the Polyferon decision, the active substance Interferon-gamma (at that time) had no significance for the treatment of the concerned disease from a medical point of view. Furthermore, the treatment concept of rheumatoid arthritis provided for frequent drug switches anyway.

No limitation of the compulsory license to specific groups of patients

In its decision, the FCJ explicitly refuses to limit the compulsory license to certain patient groups since this would shift the dispute about the right to use the patent for an undetermined number of patients to the subsequent infringement dispute.

CONCLUSION

The decision is of significant importance and proves that the request for a compulsory license may be contemplated as a strategy on a case-by-case basis to ensure the further distribution of an allegedly patent-infringing product. Even following the Raltegravir decision, the proof of public interest in a compulsory license will only rarely succeed. This proof may now, however, be easier insofar as the therapy concept for the concerned disease is highly differentiated and individualized and, according to the applicable medical guidelines and/or medical experiences, the patent-protected active substance is, at least for a relatively small group of patients, in a particular therapeutic way suitable and necessary for the further treatment in the individual case.

This would apply all the more if the active substance is approved for several years, if it is in use in clinical practice to a significant extent and in case a potentially risky therapy switch can be avoided through a compulsory license. In contrast to that, the transmissibility of the concerned disease, such as HIV, may not necessarily be decisive.

With the advance of personalized medicine, where therapeutic concepts are not exclusively based on the diagnosis of a disease, but are very specifically adapted to the individual (e.g. genetic, molecular and/or cellular) characteristics of patients and their diseases as well as with the advance of the division of patients into smaller and smaller individual (sub)groups (e.g. due to different mutations in the tumor tissue), the importance of compulsory patent licenses as a defense in patent litigation may grow as well.

In case you have any questions, please do not hesitate to contact us.

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