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Patentanwälte Rechtsanwälte mbB

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Compulsory Licence in the urgent public interest

1. The new case law of the Federal Court of Justice (FCJ) and the Federal Patent Court (FPC)

In its recent judgement dated August 31, 2016 (GRUR 2017, 373 – Isentress) the FPC granted a compulsory licence for the medical use of the patent protected active ingredient Raltegravir, which is offered and distributed by the pharmaceutical company Merck Sharp & Dohme / MSD (US) as antiviral agent for the treatment of AIDS. The pharmaceutical company Shionogi competing with Merck in the respective field filed an infringement complaint and asserted claims for injunctive relief against Merck. The latter filed in 2016 a request with the FPC to grant a compulsory licence by way of a preliminary injunction (§ 85 GPA). The FPC affirmed allowability of the request and acknowledged the necessary public interest in the grant of a compulsory licence. The decision was confirmed by the FCJ in its judgement of July 11, 2017 on Shionogi's appeal (GRUR 2017, 1017 – Raltegravir).

2. Guidelines for the granting of a compulsory licence:

The decision of the FCJ provides the following criteria for the granting of a compulsory licence:

- a) The public interest within the meaning of § 24 (1) GPA is a legal expression which cannot be circumscribed in a generally valid fashion and is subject to constant change. A public interest cannot be justified according to the exclusivity position of the patentee, even if the latter has an actual monopoly in the market. Rather, the public interest plays a role only when particular circumstances exist, which favour a less restrictive view of the normally exclusive right and interest of the patentee, because the public need demands the exploitation of the patent by the licence seeker.
- b) Whether or not the prerequisite public interest exists depends on the circumstances and is decided by weighing the protectable interests of the patentee with the public interest. Since the grant of a compulsory licence signifies a considerable intervention in the statutory exclusivity rights (protected by constitutional law) of the patentee, it is necessary to observe the principle of proportionality. Thus, a compulsory licence can principally not be awarded in respect of a pharmaceutical product if the public interest can be satisfied by other, more or less equivalent alternatives.
- c) Even if alternative therapies with equivalent active ingredients are available it can be in the public interest to avoid the risks of a change in therapy in cases where patients have been successfully treated with a drug which includes the patent protected ingredient (here Raltegravir). The urgent public interest is given where a group of patients with HIV (including women, babies, children

- and patients treated successfully with Raltegravir for a long time) require Raltegravir further on and cannot switch to another drug without significant health risks.
- d) The public interest can also be present if only relatively small groups of patients are affected.
 - e) The requirement of § 24 GPA that the applicant for a licence has to make genuine efforts to obtain a licence on reasonable commercial terms has to be considered based on the circumstances of the individual case. It is sufficient to confirm the willingness to pay adequate licence fees whereas it is not required to present a specific fair reasonable and unconditional licence fee offer. The requirements for the FRAND objection based on antitrust law are not applicable for the compulsory licence based on § 24 GPA.
 - f) Pursuant to § 85 (1) GPA a preliminary injunction may be issued if the immediate grant of the licence is urgently required in the public interest. The procedural urgency in the sense of § 935, 940 German Code of Civil Procedure is not required because not the interest of the applicant but the public interest is decisive. Insofar, the licence seeker's hesitation to conduct with filing the preliminary injunction request is less important and cannot per se speak against the required public interest.

3. Outlook

In this decision, the FCJ specified the prerequisites for the grant of compulsory licences based on former case law (FCJ, GRUR 1996, 199 – Interferon-gamma), clarifying that a FRAND offer is not necessary for a successful claim. The FCJ confirmed for the first time the grant of a compulsory licence by the FPC and provided clear principles for the determination of "public interest". Licence seekers may now refer to reliable precedents and may consider more often the possibility to seek for compulsory licences even in preliminary injunction proceedings. Since there are no unified rules on compulsory licences for the future Unitary Patents, these guidelines will also have to be respected by the Unitary Patent Court as far as the German territory is concerned.

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