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Mini Review

Compulsory Licensing in the "Public Interest"

Johann Pitz*

Vossius and Partner Patentanwälte Rechtsanwälte mbB, München, Germany

***Corresponding Author:** Johann Pitz, Vossius and Partner Patentanwälte Rechtsanwälte mbB, München, Germany.

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Abstract

This overview on compulsory licensing in Europe/Germany demonstrates that patent law allows room to use patent protected technologies in the public interest.

Licence seekers faced with broad patents covering vital pharmaceuticals, gene patents and diagnostic methods may more often think about the possibility to request for compulsory licences. The mere possibility to get such a compulsory licence may encourage patentee and potential licensee to come to an agreement. Since there are no unified rules on compulsory licences in Europe it will be desirable to seek for a harmonized framework for compulsory licensing and guidance for a predictable enforcement environment.

Keywords: Compulsory Licensing; Public Interest

As a major principle of patent law, the non-authorized use of patent protected products and processes is considered to be an act of patent infringement with the consequence that the patent holder has the right to enforce the patent and request for injunctions to cease and desist against infringers. In the field of digital products using technical standards, as well as in the area of complex products and processes covered by hundreds of patents, this result may be inadequate and in contradiction to the gist of patent systems to promote research and development. Other concerns arise in the field of vital ingredients of pharmaceuticals and gene patents. Enforcement of patents with a broad scope in this area may limit the appropriate access to fundamental high quality products and methods instrumental to public health. Whereas the experimental use exemption in European Patent Law allows sufficient room for research activities in the area of patent protected technologies (see HR Jaenichen and J Pitz, "Research Exemption/Experimental Use in the European Union: Patents Do Not Block the Progress of Science", *Cold Spring Harbor Perspectives in Medicine*, published online November 6, 2014) the question how to allow commercial use of blocking patents in the field of health care is still under debate. This article considers the instrument of compulsory licensing in Europe/Germany in this context and provides an overview of the legal requirements based on recent case law.

Antitrust objection of compulsory licensing

In the public debate about patents, specifically in the field of new technologies related to digital and connected technologies and technical communication standards, the position has been taken that the grant of injunctions may be an inappropriate blocking of innovation which is in contrast to European antitrust Law. In the field of standard essential patents (SEPs) the European Court of Justice allowed in its decision Huawei Technologies v. ZTE (CJEU C 170/13) dated May 16, 2015 the use of such patents based on a fair and reasonable and non-discriminatory licence offer (so-called FRAND-defence). These SEPs are patents which cover standardized technology, therefore are necessarily used by products which comply with the standards and for which the patent owner have irrevocably declared their willingness to licence these SEPs on FRAND terms vis-à-vis the respective standard organization.

Following the requirements defined by the CJEU the SEP-holder is obliged to offer a licence on FRAND terms, including a fair and reasonable royalty calculation. In case the alleged infringer is not willing to accept the SEP-holders offer, a written counter offer has to be made.

This ruling of the CJEU has a strong impact on current and future SEP litigation and national courts. SEP owners will need to start reasonable licence negotiations with an alleged infringer. Only if the alleged infringer is unwilling to negotiate a licence of is unduly delaying the licence negotiations, the SEP owner will be able to successfully take legal action against the alleged infringer. The alleged infringer will further be able to contest infringement and attack the validity for the SEP without losing the right of demand a licence on reasonable and non-discriminatory terms from the SEP owner.

Compulsory licensing for public heath

With judgement dated August 31, 2016 the German Federal Patent Court (FPC) granted a compulsory licence in the field of pharmaceuticals and public health and authorized commercial use of a patent protected invention in the public interest [1].

The patent in suit covered the active ingredient Raltegravir, which is an antiviral compound to treat AIDS. The alleged infringer a US pharmaceutical company offered pharmaceutical products including Raltegravir and was therefore sued because of patent infringement by the patent holder, a Japanese company. As a strategy of defence the US company started a lawsuit before the FPC and requested in preliminary injunction proceedings the grant of a compulsory license (sec. 85 GPA). The FPC granted a compulsory licence based on "public interest". The decision was confirmed by the Federal Court of Justice (FCJ) in its judgement of July 11, 2017 on defendant´s appeal [2].

Statutory principles

According to Art. 5 A of the Paris Union Convention for the protection of industrial property, almost all countries of the European Union adopted legal rules which provide for the grant of compulsory licences. In addition, the convention on Trade-Related Aspects of Intellectual Property Rights (TRIPs) allows the grant of compulsory licences (Art. 31 TRIPs). In France, Belgium and Switzerland the instrument of compulsory licensing specifically for public health has been established. The legal basis for the grant of compulsory licences in the Federal Republic of Germany is found in sec. 24 paragraph 1 German Patent Act (GPA):

"The non-exclusive authorisation to commercially use an invention shall be granted by the Federal Patent Court in an individual case in accordance with the following provisions (compulsory licence) where

1. A licence 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

2. The public interest calls for the grant of a compulsory licence".

The grant of a compulsory licence is only admissible after patent grant. The purpose for which the compulsory licence was granted may limit its lifetime and extent.

The provision of sec. 24 GPA applies not only for German patents, granted by the German patent office but also for European patents registered for the Federal Republic of Germany [3].

Procedure for grant

The procedure for the grant of a compulsory licence is comparable to the procedure for revocation of patents [4]. The competent court is the Nullity Senate of the FPC [5]. In contrast to proceedings before the regular courts, the FPC investigates the factual situation on its own motion, without being bound by the pleadings of the parties. In particular, the public interest which is necessary for the grant of the compulsory licence is established by the court on its own motion [6].

Literature and Precedents

The pros and cons of compulsory licences in respect of patents are widely discussed in legal literature and precedents [7]. Whereas some authors see the compulsory licence as necessary commercial instrument, there are others who are afraid of an erosion of the patentee´s exclusive right which is an incentive for innovation. However, there is agreement that there must be an exceptional regulation in favour of the public interest, in order to avoid prejudicial effects of the exclusivity rights for individual cases.

The expression "public interest" within the meaning of sec 24 paragraph 1 sentence 1 GPA is an indeterminate legal expression which has to be interpreted by the precedents.

In the older case law, a public interest in favouring a compulsory licence grant was assumed if the exploitation of the property right by the licensee appeared to be necessary for the improved supply of the domestic market [8], for the prevention of industrial shutdowns or large-scale dismissals [9], for the promotion of public health [10], or to ensure the uninterrupted supply of electric power [11]. However, because of changing opinions, these grounds can no longer be relied upon for as the definite determinants of the public interest nowadays [12].

The Polyferon case

Only a small number of compulsory licence proceedings have been initiated since the foundation of the FPC in 1961. For the first time a compulsory licence was granted with judgement of the Federal Patent Court dated June 7, 1991 [13]. At that time, the FPC granted a compulsory licence and acknowledged the public interest in the medical use of the patented active substance human immune interferon. Using human immune interferon, the petitioner manufactured a pharmaceutical product (polyferon) for the treatment of chronic polyarthritis and obtained approval, under the pharmaceuticals law, for application of the product. In this case, the FPC granted a compulsory licence having regard to the public interest in the medical use of the pharmaceutical use in the form of polyferon, which is dependent upon the dominant substance patent in respect of human immune interferon.

The Raltegravir case

For the second time in its history, the FPC granted a compulsory licence with judgement of August 31, 2016, which was confirmed by the FCJ in appeal proceedings [14].

The FCJ provided the following guidelines for the grant of compulsory licences:

- The public interest within the meaning of sec. 24 paragraph 1 GPA is a legal expression which has to be determined case by case. Circumstances which favour a less restrictive view of the exclusive right and interest of the patentee may rectify the exploitation of the patent by the licence seeker.
- The definition of the prerequisite public interest is based on weighing of protectable interests of the patentee with the public interest. In this context the principle of proportionality has to be respected. If the public interest can be satisfied by other, more or less equivalent pharmaceutical products, a compulsory licence cannot be awarded.
- Even if there are alternative therapies with patent free equivalent active ingredients 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) may establish the required public interest. In the case decided by the FPC the urgent public interest was approved because a group of patients with HIV (including women, babies, children and patient treated successfully with Raltegravir for a long time) required Raltegravir further on and could not switch to another pharmaceutical product without substantial health risks.
- The public interest can also be approved in cases, where not the whole population but only a relatively small group of patients is affected.
- The applicant for a licence has to make serious efforts to obtain a licence on reasonable commercial terms. In contrast to the FRAND-defence it is not required to present a specific fair reasonable and unconditional licence fee offer on order to get the compulsory licence based on sec. 24 GPA.
- According to sec 85 paragraph 1 GPA a compulsory licence may be granted by way of a preliminary injunction.

The FCJ specified the prerequisites for the grant of compulsory licences based on former case law of the FPC [15] and established clear guidelines for the determination of "public interest".

Conclusion

Patent law and courts in Europe/Germany allow room to use patent protected technologies in specific cases where the grant of injunctions would contradict public interest. In the field of standard essential patents the Court of Justice of the European Union opened the door for antitrust objections of compulsory licensing. Recent case law of the Federal Patent Court and the Federal Court of Justice in Germany approved the grant of compulsory licences. Licence seekers faced with broad patents covering vital pharmaceuticals, genes and diagnostic methods may refer to such precedents and consider more often the possibility to seek for compulsory licences, even in preliminary injunction proceedings, in favour of "public health". Since there are no unified rules on compulsory licences in Europe it will be desirable to seek for a harmonized framework for compulsory licensing and guidance for a predictable enforcement environment. Even if compulsory licences are not applied for frequently the mere possibility of adopting compulsory measures provides an incentive for an agreement between patentee and potential licensees in the respective fields.

Bibliography

1. GRUR 2017, 373 – Isentress.
2. GRUR 2017, 1017 – Raltegravir.
3. Art. 2 paragraph 2, Art. 74 EPC.
4. cf. sec. 81 Patent Act.
5. sec. 110 Patent Act.
6. Benkard/Rogge/Kober-Dehm, Patentgesetz, 11th edition sec. 24, marginal No. 14 et seq.
7. Ballhaus, Mitt. 1961, 182; Schade, Mitt 1964, 101; Horn, Mitt. 1970, 184; Schatz, GRUR Int. 1968, 273; Segade, GRUR Int. 1973, 95 and 123; Preu in: 10 Jahre Bundespatentgericht 1971, 239; Tetzner, GRUR 1973, 62; Greif, GRUR Int. 1981, 731; Pfanner, GRUR Int. 1985, 357.

8. Reichsgericht, Decisions in Civil Cases 39, 50.

9. Reichsgericht, Decisions in Civil Cases 118, 115, Reichsgericht, Decisions in Civil cases 143, 223, 226.

10. cf. Reichsgericht, Decisions in Civil cases 126, 226; Reichsgericht, Mitt. 1935, 343; Reichsgericht, GRUR 1935, 877, 878.

11. Reichsgericht, GRUR 1936, 604, 605.

12. Federal Court of Justice, judgement dated December 5, 1995, loc. cit., 190, 192.

13. GRUR 1994, 98 - compulsory licence.

14. GRUR 2017, 1017 - Raltegravir.

15. FCJ, GRUR 1996, 199 - Interferon-gamma.

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