

Merck Sharp and Dohme Limited v Shionogi and Co Limited
German Federal Court of Justice

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Case summary

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Introduction

In *Merck Sharp and Dohme Limited (hereinafter MSD) v. Shionogi (2017)*, the German Federal Court of Justice, the country's highest civil and criminal court, confirmed for the first time ever a compulsory license granted in preliminary proceedings for an HIV medicament. Although permitted under TRIPS, compulsory licensing of patents has been used only rarely in Germany and throughout Europe. Article 31 of the TRIPS Agreement provides the multilateral minimum standards for the non-voluntary or compulsory licensing of patent rights. As the term indicates, a compulsory license is the authorization to use a patented invention without the consent of the patent holder. The TRIPS Agreement leaves Members the discretion to determine the substantive grounds for authorizing compulsory licenses. This understanding was confirmed by the 2001 *Doha Declaration on the TRIPS Agreement and Public Health*, which states, *inter alia*, that

“Each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.”¹

Recourse to compulsory licensing typically occurs when governments perceive that patent holders have not satisfied the market demand for a given product by supplying sufficient quantities at prices that broad sectors of the public can afford.²

The TRIPS Agreement leaves WTO Members the freedom to designate the authority to issue a compulsory license; this can be a government agency or a court. According to Article 31 TRIPS, the decision to grant a compulsory license shall be subject to judicial review or other independent review by a distinct higher authority. Article 31 TRIPS lays down a number of procedural requirements that the granting authority needs to take into account. For instance, the seeker of the license, in principle, must conduct negotiations with the patent holder regarding the agreement on a voluntary license, prior to the granting of the compulsory license. Also, the patent holder shall be paid equitable remuneration, taking into account the economic value of the compulsory license.

Depending on national law, a situation comparable to the grant of a compulsory license may arise in the context of patent infringement litigation. The United States Supreme Court in 2006 decided that in the case of a confirmed patent infringement, the patent holder does not have an

¹ Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2 of 20 November 2001, at paragraph 5(b). Available at https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm.

² See UNCTAD, ‘Using Intellectual Property Rights to Stimulate Pharmaceutical Production in Developing Countries: A Reference Guide’, United Nations, New York and Geneva, 2011, p. 122 (hereinafter UNCTAD Reference Guide), available at https://unctad.org/en/docs/diaepcb2009d19_en.pdf.

automatic right to a permanent injunction against the infringer, but may have to tolerate the continued use of the patented invention in exchange for monetary damages.³

The present brief analyzes how the German Federal Court of Justice addressed compulsory licensing under German patent law, where the request for a compulsory license was used in preliminary proceedings as a defense against alleged patent infringement.

The facts

The plaintiff, MSD, is a U.S. pharmaceutical company that manufactures and sells an HIV medication called 'Isentress' in Germany since 2008. 'Isentress' encompasses the antiretroviral Raltegravir as active ingredient.

The defendant, the Japanese pharmaceutical company Shionogi, held a European patent for the antiviral drug with the compound Raltegravir with effect for Germany (contested patent).

In June 2014, Shionogi notified MSD that the drug 'Isentress' was falling within the scope of protection of the contested patent. Licensing discussions ensued amongst the two parties. At the time of the discussions, MSD was the only company offering medication with the antiviral agent Raltegravir in Germany.

In August 2015, as negotiations on a global license agreement remained unsuccessful, Shionogi, unwilling to accept a one-off payment offer in the amount of 10 million USD, sued MSD for patent infringement before the District Court of Düsseldorf (4c O 48/15).⁴ Shionogi had also started parallel proceedings for infringement in numerous jurisdictions; MSD, on its turn, had initiated opposition proceedings in patent offices to revoke the aforementioned patent.

In response, MSD brought an action in 2016 for issuance of a compulsory license before the Federal Patent Court⁵ based on section 24 of the German Patent Act (PatG). In addition, MSD requested the grant of a compulsory license by way of a preliminary injunction pursuant to section 85 PatG.

³ *EBay Inc. et al. v. MercExchange, L.L.C.*, Supreme Court of the United States, 547 U.S. ____ (2006). In this decision, the Supreme Court did not specifically refer to compulsory or non-voluntary licensing but analyzed the case in the context of whether or not to grant a permanent injunction. In a post-*EBay* case, the Court of Appeals for the Federal Circuit (i.e. a specialized intellectual property court in the United States) disagreed whether the award of an ongoing royalty for continuous patent infringement is similar to the granting of a compulsory license. See *Paice LLC v. Toyota Motor Corp.*, Nos. 06-1610, -1631 (Fed. Cir. Oct. 18, 2007), available at [https://scholar.google.ch/scholar_case?case=11258567835887748472&q=Paice+LLC+v.+Toyota+Motor+Corp.&hl=en&as_sdt=2006&as_vis=1#r\[13\]](https://scholar.google.ch/scholar_case?case=11258567835887748472&q=Paice+LLC+v.+Toyota+Motor+Corp.&hl=en&as_sdt=2006&as_vis=1#r[13]). The majority view distinguished awards of ongoing royalties from compulsory licenses, as the former are only available to the particular defendant of the case at hand. By contrast, a compulsory license is generally open to any interested party that meets the conditions laid down in the license (paragraph 1313, footnote 13 of this decision). The minority view, by contrast, stated that "calling a compulsory license an 'ongoing royalty' does not make it any less a compulsory license." (Paragraph 1316 of this decision, by Judge Rader).

⁴ In Germany, questions regarding patent infringement and validity are dealt with by different courts (bifurcated system). The district courts have jurisdiction over infringement, whereas the Federal Patent Court decides on validity. For more information, see figure 1 "Courts and offices involved in German patent cases" in *Patent Litigation in Germany*, p. 12, available at <https://preubohlig.de/wp-content/uploads/2019/07/PatentLitigationHoppe.pdf>.

⁵ The Federal Patent Court is a specialized IP court composed of judges with both legal and technical training and dealing with industrial property rights, such as patents, trademarks and designs. It is also the competent court to issue compulsory licenses (Section 24 PatG). The Federal Patent Court's decisions can be appealed to the Federal Court of Justice (Section 100 *et seq.* PatG).

In its ruling on 31 August 2016, the Federal Patent Court granted MSD a ‘preliminary’ compulsory license.⁶ This decision was confirmed by the Federal Court of Justice⁷ on 11 July 2017. At that time the contested patent was still under opposition before the European Patent Office’s Technical Board of Appeal.⁸

The legal issues

This case revolved around the two cumulative conditions for obtaining a compulsory license set out in section 24 (1) PatG. The grant of a compulsory license requires that : (1) the party seeking a license unsuccessfully tried during a reasonable period of time to obtain the consent from the patent holder to use the invention on reasonable commercial terms and conditions (Section 24 (1) No. 1 PatG); (2) the public interest at stake must demand the grant of the compulsory license (Section 24 (1) No. 2 PatG).

With regards to the reasonable efforts of the license seeker to receive the patentee’s consent, the Federal Court of Justice held that this requirement must be met at the close of the oral hearing; it does not need to be fulfilled by the date on which the action for a compulsory license is brought before the Patent Court. However, the Federal Court of Justice stressed that it is not sufficient for the license seeker to start these efforts just prior to the oral hearing, as a last-minute resort.

In addition, the Federal Court of Justice pointed out that it depends on the particular circumstances of each case, what period of time and what measures are required to fulfill the obligation to seek a license.⁹

It is noteworthy to mention that the Federal Patent Court, in its ruling on 31 August 2016, emphasized that the principles established for granting a compulsory license under German anti-trust law are not applicable under section 24 (1) PatG. According to the Federal Patent Court, German anti-trust law provides that a patent holder in a dominant market position that receives a fair and non-discriminatory offer for a voluntary license, which already includes the essential licensing terms such as the fee, has no right to reject such offer. A rejection constitutes an abuse of its dominant position under German competition law. In other words, a fair and sufficiently detailed offer for a license triggers the license seeker’s entitlement to a compulsory license under German anti-trust law. By contrast, under German patent law, the compulsory license can only be granted by the Federal Patent Court and cannot be triggered by the license seeker’s offer. While it is necessary under patent law that the license seeker attempted to obtain a license over a reasonable period of time, the content of the patent license offer does not have

⁶ German Federal Patent Court, judgment of 31 August 2016, 3 LiQ 1/16 (EP), available (in German) at http://www.rechtsprechung-im-internet.de/jportal/portal/t/19ke/page/bsjrsprod.psml?pid=Dokumentanzeige&showdoccase=1&js_peid=Trefferliste&documentnumber=1&numberofresults=10908&fromdoctodoc=yes&doc.id=MPRE135990964&doc.part=L&doc.price=0.0&doc.hl=1#focuspoint.

⁷ The Federal Court of Justice is the final instance in patent infringement and validity proceedings.

⁸ A granted European patent is protected under national law in each of the contracting States of the European Patent Convention designated in the application. Similarly, a revoked European patent is no longer enforceable in the countries concerned.

⁹ See UNCTAD Reference Guide, p. 128, which suggests that “[i]n cases regarding the production of life-saving drugs, negotiations for a voluntary license may be considered unsuccessful after a shorter period of time than in other cases”, citing a negotiation period of 90 days as an example of a reasonable period of time.

to meet the elevated requirements for a compulsory license under anti-trust law, such as fairness and non-discrimination, including a fair and reasonable fee.¹⁰

In the case at hand, the Federal Court of Justice found MSD's offer to pay 10 million USD for a global license sufficient and declined any evidence of fake negotiations. The parties had been negotiating a license for about a two-year period and an improved offer could not be expected given the enormous difference between the parties' expectations.

Moreover, the Federal Court of Justice considered that the uncertain validity of a patent can be taken into consideration in the license negotiations. In the present case, diverging decisions on the patent validity were rendered by the High Court of Justice of England and Wales¹¹ and the European Patent Office's Opposition Division¹². Since the enforceability of the European patent was not clear, the offer by MSD of a single payment for patent use was considered as justified.

While this first requirement for obtaining a compulsory license was of low concern in this case, as urgency was elicited and prior negotiations took place for two years, the second one, regarding the 'public interest', is typically more difficult to prove. As the Federal Court of Justice held, the question whether or not the public interest outweighs the patent owner's interest in the exclusive exploitation of the patent is a matter of a case-by-case analysis. The license seeker's interest is however irrelevant as a compulsory license is only granted on the ground of public interest.

Moreover, the Federal Court of Justice relied on its interpretation of the 'public interest' developed in the *Polyferon*-case, holding that a 'public interest' prescribing the grant of a compulsory license can exist when "a medicament treats a serious disease which cannot be treated by an equivalent product or only with considerable side effects."¹³ The Court added that the public interest can also be present when only a relatively small group of patients is affected.¹⁴

In the present case, as confirmed by an expert, certain groups of patients, including infants, children and pregnant women with HIV and AIDS, strongly rely on Isentress with the compound Raltegravir for their treatment. The consequences of a switch to other medication would be of considerable impairment with significant health risks. Therefore, the Federal Court of Justice concluded that there was a predominant public interest that the only available drug containing the compound Raltegravir remains available to the HIV-infected or/and patients with AIDS. It considered that a change in therapy by replacing Isentress with another equivalent alternative drug was not tolerable considering the potential life-long side or adverse effects due

¹⁰ Paragraphs 56-58 of the 31 August 2016 decision. Paragraph 58: "Accordingly [i.e. in patent law], the jurisprudence and the literature only require the license seeker's principal willingness to take the license under conditions that are adequate and in line with customary business practice, without the need to specify directly or approximately the sum that subsequently the court will consider adequate." (translation by the authors).

¹¹ *Merck Sharp and Dohme Limited v Shionogi*, High Court of England and Wales (Arnold J), 25 November 2015, Neutral Citation Number [2016] EWHC 2989 (Pat).

¹² Shionogi's European patent was the subject of opposition proceedings and subsequently to appeal proceedings before the EPO. While the patent was maintained at first instance in amended form in 2015, it was finally revoked by the Technical Board of Appeal on 11 October 2017 (T 1150/15).

¹³ German Federal Court of Justice, judgment of 5 December 1995, X ZR 26/92 (*Polyferon*).

¹⁴ German Federal Court of Justice, judgment of 11 July 2017, X ZB 2/17, paragraph 49: "A public interest is also given when only a relatively small group of patients is affected. This is particularly true if this group were exposed to great endangerment in case the medicine in question would no longer be available." (translation by the authors).

to a forced switch to another medicament. Thus, the public interest outweighed Shionogi's interest in its monopoly right to exclusive exploitation of the contested patent.

Finally, the Federal Court of Justice held that a compulsory license can be granted in preliminary proceedings if there is an urgent need, in the public interest, for the immediate grant of the authorization pursuant to section 85 PatG in conjunction with section 24 PatG. Such 'urgency' was confirmed in the present case. According to the Federal Court of Justice, if the request for a compulsory license is denied in preliminary proceedings but approved in main proceedings, an undefined number of patients would have had to change their treatment with all the risks this entails. If however a compulsory license is granted in preliminary proceedings but it is later shown that it should not have been granted, the patent owner may only face some financial loss, a consequence regarded as significantly less serious by the Federal Court of Justice.

In conclusion, since all the requirements of sections 24 and 85 PatG were met, the Federal Court of Justice confirmed the decision of the Federal Patent Court to grant a compulsory license to MSD in preliminary proceedings.

Three months after the ruling by the Federal Court of Justice, the European Patent Office's Technical Board of Appeal on 11 October 2017 revoked the contested patent.¹⁵ On 21 November 2017, the German Federal Patent Court in the main proceedings regarding the compulsory license decided that despite the revocation of the patent, MSD was obliged to pay a license fee of 4% of the net sales value of Isentress to Shionogi for the duration of the preliminary compulsory license.¹⁶ Finally, on 20 December 2017 the District Court of Düsseldorf rejected Shionogi's claim of patent infringement.¹⁷

Points of significance

- This case illustrates the significance of public interest considerations related to access to an essential HIV drug by a relatively small group of patients in a preliminary proceeding for a compulsory license.
- The present decision was taken by a German court, a country known for its robust protection as well as its effective enforcement of patent rights.
- The case is not only highly exceptional since only few compulsory licenses have been granted so far in Germany, but also because the grant occurred in preliminary proceedings. The Federal Court of Justice considered the potential damage for patients in case the compulsory license would not have immediate effect to be greater than the potential financial damage for the patent holder in case the compulsory license should not have been granted.

¹⁵ See UNCTAD's case summary of *Merck & Co., Inc. vs. Shionogi & Co., Ltd*, European Patent Office Technical Board of Appeal, decision of 11 October 2017, T 1150/15, soon available in the Intellectual Property and Public Health Case Law database under <https://unctad.org/ippcaselaw/>. The original decision is available (in English) at <https://www.epo.org/law-practice/case-law-appeals/recent/t151150eu1.html>.

¹⁶ German Federal Patent Court, judgment of 21 November 2017, 3 Li 1/16 (EP), available (in German) at http://www.rechtsprechung-im-internet.de/jportal/portal/t/19ke/page/bsjrsprod.psml?pid=Dokumentanzeige&showdoccase=1&js_peid=Trefferliste&documentnumber=1&numberofresults=10908&fromdoctodoc=yes&doc.id=JURE189019376&doc.part=L&doc.price=0.0&doc.hl=1#focuspoint.

¹⁷ District Court of Düsseldorf, judgment of 20 December 2017, 4c O 48/15, see (in German) <https://www3.hhu.de/duesseldorfer-archiv/?p=7477>.

- The judgment of 31 August 2016 relating to MSD’s drug Isentress is only the second decision in which the German Federal Patent Court granted a compulsory license. The first example of a compulsory license being granted by German courts referred to the medicine ‘Polyferon’ for rheumatoid arthritis in the early 1990s.¹⁸ It was granted in the main proceedings. The decision was however subsequently overturned on appeal by the Federal Court of Justice, which concluded that the removal of the medicine ‘Polyferon’ from the market would still leave the patients with another drug, which was considered a valid alternative for the treatment of the disease.
- The Federal Patent Court confirmed that a license seeker’s offer for a voluntary license plays a different role under German competition law as compared to patent law. Under German competition law, a patentee in a dominant position cannot refuse a fair, non-discriminatory and sufficiently detailed offer for a license by an interested party. The refusal of such offer is considered an abuse of a dominant position and directly entitles the interested party to a compulsory license (with a broader aim of ensuring competitive markets and protecting “consumers’ welfare”¹⁹). By contrast, under German patent law, which applied to the case at hand, the compulsory license can only be granted by the Federal Patent Court on the ground of public interest and cannot be triggered by the license seeker’s offer. As the Federal Patent Court itself determines the final terms of the license, such as the exact amount of remuneration, the offer made by the license seeker in order to justify a compulsory license does not need to be as detailed as an offer that triggers a compulsory license under competition law.
- The present case seems to have confirmed one important consideration for adjudicating public interest in the context of a request for a compulsory license, i.e. when “a medicament treats a serious disease which cannot be treated by an equivalent product or only with considerable side effects”.²⁰ Accordingly, in the *Sanofi v. Amgen (2019)* case²¹, the Federal Patent Court (as confirmed by the Federal Court of Justice) rejected a compulsory license on public interest grounds, *inter alia* because patients still had access to medicines considered similar to the one for which a compulsory license had been requested.

Key words

License agreement, compulsory license, public interest, public health, balancing public and patent owner’s interests, preliminary proceedings/injunction, German Federal Court of Justice, German Federal Patent Court, specialized IP court.

Available at

<http://juris.bundesgerichtshof.de/cgi-bin/rechtsprechung/document.py?Gericht=bgh&Art=en&az=X%20ZB%202/17&nr=79269>
(only in German)

More information in English at below source:

¹⁸ German Federal Court of Justice, judgment of 5 December 1995, X ZR 26/92 (Polyferon).

¹⁹ This may be inferred from Article 102 of the Treaty on the Functioning of the European Union (dominant position) and similar provisions under German competition law.

²⁰ German Federal Court of Justice, judgment of 5 December 1995, X ZR 26/92 (Polyferon).

²¹ German Federal Court of Justice, judgment of 4 June 2019, X ZB 2/19, available (in German) at <http://juris.bundesgerichtshof.de/cgi-bin/rechtsprechung/document.py?Gericht=bgh&Art=en&az=X%20ZB%202/19&nr=98248>.

- <https://www.twobirds.com/en/news/articles/2017/uk/ils/german-federal-patent-court-grants-compulsory-licence-for-hivmedicament>