Germany

Legal basis

Section 24 Patent Act (*Patent Gesetz*, hereinafter PatG).

Section 24(2) and (3) PatG was amended in order to implement the Biotech Directive.

EU Regulation 816/2006 did not lead to a change in Section 24 PatG, as the content of Section 24 PatG was deemed to be in line with the Regulation.

Grounds for applying for a licence

According to Section 24(1) PatG, it must be demonstrated that:

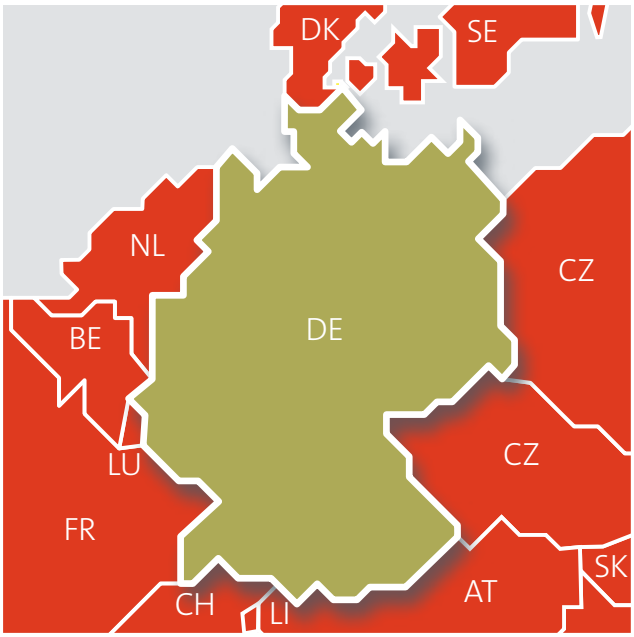
(1) the applicant has tried, within a reasonable period of time, unsuccessfully to obtain permission from the proprietor of the patent to use the invention on reasonable commercial terms and conditions;

(2) the public interest calls for the grant of a compulsory licence.

When the applicant has a dependent patent, Section 24(2) PatG adds to the abovementioned requirements:

> *"Where a licence 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, he shall be entitled, in respect of the proprietor of the patent with the earlier filing or priority date, to the grant of a compulsory licence from the proprietor of the patent if:*
>
> *1. the condition* [set out in Sect. 24(1)(1) PatG] *is fulfilled; and*
>
> *2. his own invention demonstrates an important technological advance of substantial economic significance compared to that of the patent with the earlier filing or priority date."*

The proprietor of the patent can require the licence seeker to grant him a cross-licence on reasonable terms and conditions for the use of the patented invention with the later filing or priority date.



> *"(3) Section 24(2) PatG shall apply mutatis mutandis where a plant breeder cannot obtain or exploit a plant variety right without infringing an earlier patent."*

A special clause applies to the field of semiconductor technology. Here it is mandatory that the compulsory licence is granted only to overcome anti-competitive practices pursued by the proprietor of the patent. These practices have to be established in court or administrative proceedings according to Section 24(4) PatG:

> *"A compulsory licence under subsection (1) may be granted for a patented invention in the field of semiconductor technology only where this is necessary to eliminate those anti-competitive practices pursued by the proprietor of the patent which have been established in court or administrative proceedings."*

Further special requirements are set out in Section 24(5) to (7) PatG:

> *"(5) Where the proprietor of the patent does not apply the patented invention in Germany or does not do so predominantly, compulsory licences in accordance with Subsection (1) may be granted to ensure an adequate supply of the patented product on the German market. Import shall thus be equivalent to the use of the patent in Germany.*

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(6) The grant of a compulsory licence in respect of a patent shall be admissible only after the patent has been granted. The compulsory licence may be granted subject to limitations and made dependent on conditions. The extent and the duration of use shall be limited to the purpose for which the compulsory licence was granted. The proprietor of the patent shall be entitled to remuneration from the proprietor of the compulsory licence, such remuneration being equitable in the circumstances of the case and taking into account the economic value of the compulsory licence. Where, in relation to recurrent remuneration payments due in the future, there is a substantial change in the circumstances which governed the fixing of the amount of remuneration, each party shall be entitled to require a corresponding adjustment. Where the circumstances upon which the grant of a compulsory licence was based no longer apply and if their recurrence is improbable, the proprietor of the patent can require withdrawal of the compulsory licence.

(7) A compulsory licence in respect of a patent may be transferred only together with the business that is involved in exploiting the invention. A compulsory licence in respect of an invention which is the subject matter of a patent with an earlier filing or priority date may be transferred only together with the patent with a later filing or priority date."

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General procedure

The Federal Patent Court (*Bundespatentgericht*) is competent to grant a compulsory licence. The applicant must apply for a compulsory licence before the Federal Patent Court, either as part of the main proceedings or with a preliminary injunction (Section 85 PatG).

The court must apply Section 24(6) PatG, which states that the compulsory licence may be subject to limitations and can be dependent on conditions. Those limitations and conditions should be in line with the purpose of the compulsory licence.

The court also has the discretion to determine the amount for the remuneration accorded to the patent owner. As a starting point, a court would consider a "usual" licence. However, it shall be taken into account that the risk of revocation or invalidity stays with the patentee. Therefore, if a comparison to a licence agreement in which a licensee would refrain from attacking the patent cannot be made, the criteria for determining the reasonable royalty can be different. Hence the remuneration payable for the compulsory licence shall be reasonably higher than a usual non-exclusive licence.

The Federal Court of Justice (*Bundesgerichtshof*, hereinafter FCJ) has recently provided guidance on how to apply the requirements set out in the PatG:

(i) It is sufficient that the applicant has tried to obtain permission by the end of the oral hearing. However, the potential licensee must have tried to compromise with the patentee over a certain period of time. Therefore, it is not sufficient for the potential licensee to only declare his will to take a licence at the last minute, meaning during the proceedings.

The term "reasonable conditions" also suggests that mere mock negotiations are not sufficient. The court may however decide at its own discretion how far the range of offers and counteroffers can be spread. The FCJ explicitly states that the potential results of an invalidity proceeding against the patent can be taken into account when assessing the reasonableness of the offers. It is not necessary for the applicant to give a specific number – this will ultimately be set by the court. It is sufficient that the applicant declare that they are willing to pay a reasonable licence fee.

(ii) The term "public interest" can, according to a recent decision of the FCJ, not be described in general. Whether or not the public interest calls for a compulsory licence is always a question of the particular facts of the case. Therefore, special circumstances need to be present. According to the case law of the FCJ, public interest exists if a medicine to treat serious illnesses has specific therapeutic characteristics that comparable medicines do not have, or not to the same extent. Furthermore, public interest can exist if the use of such a medicine leads to a reduction of side effects that would have been suffered when prescribing/using different medicines. However, public interest cannot exist if there is a similar treatment possible with a different medicine.

(iii) In the special situation that the applicant asks the FCJ for a compulsory licence by way of a preliminary injunction, then it is not the interests of the parties that need to be weighed against each other but the interest of the patentee to exert his exclusive position against the above-described public interest. The interest of the applicant is of no relevance as the compulsory licence will be granted to the applicant so that he can use the licence for the public interest.

Appeal/review

The decision of the Federal Patent Court may be appealed before the FCJ.

Statistics and jurisprudence

There have been two cases in Germany concerning compulsory licences, one case where the compulsory licence was not granted and, more recently, one where it was.

BGH - GRUR 1996, 190 (192) – Interferon-gamma/Polyferon: not granted
In this case, the Federal Patent Court granted the compulsory licence. However, on appeal the FCJ denied it as all requirements were not fulfilled.

More specifically, the FCJ declined the public interest argument. The patentee had a patent on the active ingredient Interferon-gamma. The applicant found a new use of this active ingredient for the treatment of rheumatoid arthritis. The applicant was even granted a patent for that specific use. This patent was however dependent on the patentee's interferon-gamma patent, so that the patentee could demand from the applicant to cease and desist from offering medicine for that specific use. The applicant was furthermore granted an authorisation for the medicine Polyferon, which was the embodiment of the specific use that the applicant discovered.

In its decision, the FCJ found that neither the fact that a patent had been granted for a new use of the active ingredient nor the authorisation as a medicine could constitute a public interest. Furthermore, the FCJ stated that the patentee was also exploring the use of Interferon-gamma to treat rheumatoid arthritis. The FCJ also came to the conclusion that there were other medicines available which could be used in a similar way as Polyferon. It was not sufficiently proven by the applicant that Polyferon was the only available medicine for any subset of patients. Therefore, the FCJ denied the existence of a public interest and rejected the claim for a compulsory licence.

BGH GRUR 2017, 1017 Rn. 22 f. – Raltegravir: compulsory licence granted (in preliminary injunction proceedings)
This is the first case in which a compulsory licence granted by the Federal Patent Court was upheld by the FCJ. In addition, it was granted in preliminary injunction proceedings.

The applicant distributes the medicine Isentress that includes the active ingredient Raltegravir. This medicine can be used for the treatment of HIV. The patentee claimed that Raltegravir falls under the scope of protection of their patent and started infringement proceedings. The patentee also offers a medicine for the treatment of HIV that falls under the scope of the patent. Parallel to the infringement proceedings, the parties talk about worldwide licences. After the infringement complaint was filed, the applicant filed a complaint with the Federal Patent Court to obtain a compulsory licence (as a main action). After the applicant filed the main action, they later filed the request in addition as a preliminary injunction request.

The FCJ decided that the applicant had requested a licence from the patentee on reasonable terms, especially since the applicant had claimed a compulsory licence and requested the Court to set the licence fee. Furthermore, the applicant had stated that previous licence offers did not present a maximum value for a compulsory licence. The applicant would have accepted any licence fee the court set. Therefore, the first requirement according to Section 24(1) PatG was fulfilled.

The FCJ went on to state that there was a public interest in the continued availability of a medicine for HIV, even though only a small group of patients would have been affected (second requirement). The court determined that there was a considerable risk of serious side effects, interaction or therapy failure for the patients if they had to change the medicine. This would have been the case had the patentee been successful with their infringement suits and the applicant would have had to stop selling Raltegravir. In that case, all patients undergoing treatment with Raltegravir would have had to change the treatment to different medicines with a considerable risk of side effects. The FCJ therefore confirmed that the public interest condition was met.

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