

WIPO Circular C.8828 – Contribution to the preparation of a draft reference document on the exception of compulsory licence

I. Description of the Exception

1. Compulsory licences under patent law are governed by Section 24 of the German Patent Act (*Patentgesetz*):

Section 24 [Compulsory licence; withdrawal of the patent]

(1) 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.

(2) 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 under subsection (1) no. 1 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) Subsection (2) shall apply *mutatis mutandis* where a plant breeder cannot obtain or exploit a plant variety right without infringing an earlier patent.

(4) A compulsory licence under subsection (1) may be granted for a patented invention in the field of semi-conductor 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.

(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.

(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 which 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.

Section 24 of the Patent Act was revised by the Second Act Amending the Patent Act (2. *Patentgesetzänderungsgesetz*) of 16 July 1998 (Federal Law Gazette [*Bundesgesetzblatt*] p. 1827) and brought into line with the requirements of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), which, in Article 27(1), second sentence, and Article 31, contains minimum obligations for the protection of the patent proprietors to be observed when granting compulsory licences (*Bundestagsdrucksache* [Bundestag document] BT-Drs. 13/9971 p. 24). The Act Implementing the Directive on the Legal Protection of Biotechnological Inventions (*Gesetz zur Umsetzung der Richtlinie über den rechtlichen Schutz biotechnologischer Erfindungen*) (Directive 98/44/EC) of 21 January 2005 (Federal Law Gazette p. 146) also brought the requirements for a compulsory licence for dependent inventions and plant varieties into line with European law (cf. Sec. 24(2) and (3) Patent Act).

2. In addition to the compulsory patent licence governed by Section 24 of the Patent Act, a claim to the grant of a compulsory licence may also arise from competition law provisions (*Bundesgerichtshof* – BGH [Federal Court of Justice], judgement of 13 July 2004, ref: KZR 40/02, GRUR 2004, 966 – *Standard-Spundfass*; Hacker in: Busse/Keukenschrijver, 8th edition 2016, Sec. 24 marginal note 100).

3. For the European Union, a further legal basis for compulsory licences was created by Regulation (EC) No 816/2006 of 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems.

II. Objectives and Goals

The objective and goals of the compulsory licence exception is to protect the general public from the disadvantages of the monopoly position of a patent proprietor (Hacker in: Busse/Keukenschrijver, 8th edition 2016, Sec. 24 marginal note 15; Rinken in: Schulte, *Patentgesetz*, 10th edition 2017, Sec. 24 marginal note 5).

III. National Implementation

i) Compulsory licence pursuant to Section 24 of the Patent Act

1. General requirements (Sec. 24(1) Patent Act)

Pursuant to Section 24(1) of the Patent Act, the Federal Patent Court (*Bundespatentgericht*) grants a non-exclusive authorisation to commercially use an invention in an individual case, provided that the licence seeker has unsuccessfully attempted, within a reasonable period of time, to obtain permission from the proprietor of the patent to use the invention on reasonable commercial terms and the public interest calls for the grant of a compulsory licence.

a) A compulsory licence may be granted in respect of patents and supplementary protection certificates (Secs. 24(1), 16a(2) Patent Act). However, a requirement is that the patent has already been granted (Sec. 24(6), first sentence, Patent Act). The grant of a

compulsory licence shall not be permissible before the patent has been granted. If the patent proprietor has already granted a non-exclusive or exclusive licence for the patent to another licensee, this does not conflict with the grant of a compulsory licence (BGH, judgement of 5 December 1995, ref: X ZR 26/92, GRUR 1996, 190 – *Polyferon*)

b) Anyone can be a licence seeker. However, the licence seeker must be able and willing to use the invention commercially for his own account. (*Reichsgericht* [Imperial Court of Justice] judgement of 8 November 1913, ref: I 153/13, RGZ 83, 274; *Reichsgericht*, judgement of 26 November 1930, ref: I 295/28, RGZ 130, 360).

c) Pursuant to Section 24(1) no. 1 of the Patent Act, it is necessary that the licence seeker has unsuccessfully attempted within a reasonable period of time to obtain permission from the proprietor of the patent to use the invention on reasonable commercial terms.

This requirement does not necessarily have to be met by the date on which the action for a compulsory licence is brought; under general principles it suffices if it is met at the close of the oral hearing (BGH, judgement of 11 July 2017, ref: X ZB 2/17, GRUR (journal of the German Association for the Protection of Intellectual Property) 2017, 1017 – *Raltegravir*). However, from the requirement that the attempt must have extended over a reasonable period of time, it follows that it is not sufficient when the licence seeker declares his willingness to pay an appropriate licence “at the last minute” as it were during the proceedings. Rather, he must have attempted over a certain period of time, in a manner appropriate to the specific situation, to reach agreement with the proprietor of the patent on the granting of a licence (BGH judgement of 11 July 2017, ref: X ZB 2/17, GRUR 2017, 1017 – *Raltegravir*).

It depends on the circumstances of the individual case, what period of time and what measures are required for this purpose (BGH, judgement of 11 July 2017, ref: X ZB 2/17, GRUR 2017, 1017 – *Raltegravir*).

d) In addition, a requirement for the grant of a compulsory licence, pursuant to Section 24(1) no. 2 of the Patent Act, is that the grant of such a licence is in the public interest.

The term “public interest” is an indefinite term that must be given concrete meaning by case law (BGH, judgement of 5 December 1995, ref: X ZR 26/92, GRUR 1996, 190 – *Polyferon*). There can be no universally valid definition of this term (BGH, judgement of 5 December 1995, ref: X ZR 26/92, GRUR 1996, 190 – *Polyferon*; BGH, judgement of 11 July 2017, ref: X ZB 2/17, GRUR 2017, 1017 – *Raltegravir*). The question of whether a public interest requiring the grant of a compulsory licence is present must instead be answered by weighing all circumstances that are relevant in the individual case and the interests concerned (BGH, judgement of 11 July 2017, ref: X ZB 2/17, GRUR 2017, 1017 – *Raltegravir*).

Since the grant of a compulsory licence represents a significant encroachment on the patent holder’s legal and constitutionally protected exclusive rights, the balancing of interests must be subjected to the principle of reasonableness (BGH, judgement of 5 December 1995, ref: X ZR 26/92, GRUR 1996, 190 – *Polyferon*).

Public interest cannot be established merely on the basis of the exclusive position enjoyed by the patent holder, even if the latter enjoys an actual monopoly on the market. The law confers on the patent holder an exclusive right, the exercise of which, as a rule, he alone may decide on. For this reason, public interest can only be affected if there are particular circumstances that subordinate the unrestricted recognition of the patent holder's exclusive right and interests to the interest of the general public in the exploitation of the patent by the party seeking a licence. Only then is there justification for a major impairment of the patent holder's rights against his will in the form of a compulsory licence (BGH, judgement of 5 December 1995, ref: X ZR 26/92, GRUR 1996, 190 – *Polyferon*; BGH, judgement of 11 July 2017, ref: X ZB 2/17, GRUR 2017, 1017 – *Raltegravir*).

Particular circumstances that justify the assumption of public interest, in addition to the abusive exploitation of patent right, may also include other circumstances of a technical, economic, socio-political and medical nature (BGH, judgement of 5 December 1995, ref: X ZR 26/92, GRUR 1996, 190 – *Polyferon*; BGH, judgement of 13 July 2004, ref: KZR 40/02, GRUR 2004, 966 – *Standard-Spundfass*).

In applying these principles, a public interest prescribing the grant of a compulsory licence can be confirmed when a medicament used to treat serious illnesses displays therapeutic characteristics that the medicaments available on the market do not possess, or not in the same degree, or when its use avoids undesirable side effects that must be accepted with the administration of the other therapeutic medicines (BGH, judgement of 5 December 1995, ref: X ZR 26/92, GRUR 1996, 190 – *Polyferon*; BGH, judgement of 11 July 2017, ref: X ZB 2/17, GRUR 2017, 1017 – *Raltegravir*). A public interest can exist even when only a relatively small group of patients is affected. This is the case in particular when this group would be exposed to an especially high risk if the medicament in question were no longer available. (BGH, judgement of 11 July 2017, ref: X ZB 2/17, GRUR 2017, 1017 – *Raltegravir*). However, a compulsory licence in a pharmaceutical cannot be granted if the public interest can be satisfied with other more or less equivalent alternative products. (BGH, judgement of 5 December 1995, ref: X ZR 26/92, GRUR 1996, 190 – *Polyferon*).

2. Requirements in special cases (Sec. 24(2) to (5) Patent Act)

a) For dependent inventions for which a patent has been granted, the grant of a compulsory licence is facilitated by Section 24(2) of the Patent Act by dispensing with the requirement of public interest under Section 24(1) no. 2 of the Patent Act. 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 he 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 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 (Sec. 24(2), first sentence, Patent Act). The same applies under Section 24(3) of the Patent Act where a plant breeder cannot obtain or exploit a plant variety right without infringing an earlier patent.

In return, Section 24(2), second sentence, of the Patent Act gives the patent proprietor the right to 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.

b) For the grant of a compulsory licence for a patented invention in the field of semiconductor technology the applicable requirements are extended compared to Section 24(1) of the Patent Act: In addition to the requirements of Section 24(1) of the Patent Act, a compulsory licence for a patented invention in the field of semiconductor technology may only be granted pursuant to Section 24(4) of the Patent Act, 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.

c) Section 24(5) of the Patent Act specifically governs the case of insufficient domestic supply: 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 Section 24(1) of the Patent Act, may be granted to ensure an adequate supply of the patented product on the German market. Import is thus equivalent to the use of the patent in Germany.

3. Granting of the compulsory licence

a) Content of the compulsory licence

The compulsory licence is always a non-exclusive licence, not an exclusive licence (Sec. 24(1) Patent Act). The scope of the compulsory licence must be determined in the judgement. It may be granted subject to limitations, for example, only for a certain period of time or a certain territorial scope or only in respect of the main claim but not in respect of the subclaims of the patent (Sec. 24(6), second sentence, Patent Act; BT-Drs. 13/9971 p. 24). The compulsory licence may also be made dependent on certain conditions, i.e. on certain obligations (Sec. 24(6), second sentence, Patent Act; BT-Drs. 13/9971 p. 24).

b) Remuneration

Pursuant to Section 24(6), fourth sentence, of the Patent Act, the proprietor of the patent is entitled to remuneration from the holder of the compulsory licence, which is equitable in the circumstances of the case and takes into account the economic value of the compulsory licence. The amount of this remuneration must be fixed by the court when granting the compulsory licence. It would seem appropriate to take the licensing fee that would be agreed on in the circumstances of the respective individual case in a licensing agreement as a guideline for this amount. As a rule, the amount of the licensing fees must be determined according to the same standards as the remuneration for a non-exclusive contractual licence for a patent whose validity must be considered as secure (BGH, judgement of 11 July 2017, ref: X ZB 2/17, GRUR 2017, 1017 – *Raltegravir*).

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 is entitled to require a corresponding adjustment, pursuant to Section 24(6), fifth sentence, of the Patent Act.

However, if the persons applying for a compulsory licence have made use of a provisional permission to use the invention granted to them in injunction proceedings, they must pay the legally specified remuneration for the duration of this (provisional) licence grant even if the patent is revoked during the course of the (main action) of the compulsory licence proceedings in which the decision is still pending (Federal Patent Court, judgement of 21 November 2017, ref: 3 Li 1/16 (EP), GRUR 2018, 803 – *Isentress II*)

c) Withdrawal of the compulsory licence

The proprietor of the patent can require withdrawal of the compulsory licence if the circumstances upon which the grant of a compulsory licence was based no longer apply and if their recurrence is improbable (Sec. 24(6), sixth sentence, Patent Act).

d) Proceedings

Proceedings on account of the grant or withdrawal of the compulsory licence, or on account of the adjustment of the remuneration for a compulsory licence determined by court judgement is initiated by filing an action. The action shall be directed against the proprietor of the patent entered in the Register or against the holder of the compulsory licence (Sec. 81(1), first and second sentences, Patent Act). The proceedings for the grant of the compulsory licence are governed by Sections 81 et seqq. of the Patent Act. Pursuant to Section 66(1) no. 2 of the Patent Act, the Nullity Board of the Federal Patent Court shall have first instance jurisdiction and the Federal Court of Justice shall have jurisdiction in appellate proceedings pursuant to Section 110(1) of the Patent Act.

In case of special urgency, the claimant may, at his request, be permitted to use the invention on the basis of an injunction if he substantiates that the requirements under Section 24 of the Patent Act are fulfilled and that there is an urgent need, in the public interest, for the immediate grant of the permission (Sec. 85(1) Patent Act).

e) Transfer

In order to prevent abuse, the transfer of the compulsory licence in respect of a patent is only allowed together with the business which is involved in exploiting the invention pursuant to Section 24(7), first sentence, of the Patent Act. In the case of Section 24(2) of the Patent Act, the 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, pursuant to Section 24(7), second sentence, of the Patent Act, only together with the patent with a later filing or priority date (*Mes, Patentgesetz*, 4th edition 2015, Sec. 24 marginal note 42).

ii. Compulsory licence under competition law

Irrespective of the requirements of Section 24 of the Patent Act, a claim to the grant of a licence may also come about as a result of competition law provisions (BGH, judgement of

13 July 2004, ref: KZR 40/02, GRUR 2004, 966 – *Standard-Spundfass*; Hacker in: Busse/Keukenschrijver, 8th edition 2016, Sec. 24 marginal note 100). This is particularly the case if the refusal to grant a licence or the enforcement of the patent constitutes an abuse of a market-dominating position or an unfair restraint or discrimination on the part of a market-dominating undertaking (Art. 102 Treaty on the Functioning of the European Union, Secs. 19, 20 Act against Restraints of Competition [*Gesetz gegen Wettbewerbsbeschränkungen*]) (BGH, judgement of 13 July 2004, ref: KZR 40/02, GRUR 2004, 966 – *Standard-Spundfass*; CJEU, judgement of 16 July 2015, C-170/13, GRUR 2015, 764 – *Huawei Technologies/ZTE*; Hacker in: Busse/Keukenschrijver, 8th edition 2016, Sec. 24 marginal note 100).

It should be noted that the exercise of an exclusive intellectual property right forms part of the rights of the proprietor of such a right. Consequently, the exercise of the exclusive right, even if it is the act of an undertaking holding a dominant position, cannot in itself constitute an abuse of a dominant position. However, the exercise of an exclusive right linked to an intellectual property right by the proprietor may, in exceptional circumstances, involve abusive conduct (CJEU, judgement of 16 July 2015, C-170/13, GRUR 2015, 764 – *Huawei Technologies/ZTE*). Therefore, the scope for objective justification of unequal treatment of would-be licensees must also be fundamentally broad. Stricter requirements can however be considered if, besides the market domination achieved by virtue of the patent, additional circumstances exist in light of which the unequal treatment endangers the freedom of competition that the Act Against Restraints of Competition aims to protect. Which circumstances these are cannot be determined conclusively for all imaginable types of cases (BGH, judgement of 13 July 2004, ref: KZR 40/02, GRUR 2004, 966 – *Standard-Spundfass*).

The importance of the compulsory licence under competition law is shown in particular by the supreme court decisions of the Federal Court of Justice (BGH) and the European Court of Justice (CJEU) (BGH, judgement of 13 July 2004, ref: KZR 40/02, GRUR 2004, 966 – *Standard-Spundfass*; BGH, judgement of 6 May 2009, ref: KZR 39/06, GRUR 2009, 694 – *Orange-Book-Standard*; CJEU, judgement of 16 July 2015, C-170/13, GRUR 2015, 764 – *Huawei Technologies/ZTE*).

iii. Compulsory licence pursuant to Regulation (EC) no. 816/2006

Another legal basis for compulsory licences was created by Regulation (EC) no. 816/2006 of the European Parliament and of the Council of 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems. This Regulation establishes a procedure for the grant of compulsory licences in relation to patents and supplementary protection certificates concerning the manufacture and sale of pharmaceutical products, when such products are intended for export to eligible importing countries in need of such products in order to address public health problems (Art. 1 Regulation (EC) no. 816/2006).

IV. Challenges Faced by Member States in its Implementation

V. Results of its Implementation

The compulsory licence under patent law has so far been of little practical relevance. For a long time, there has only been one case in which the Federal Patent Court granted a compulsory licence, but this decision was reversed by the Federal Court of Justice. (BGH, judgement of 5 December 1995, ref: X ZR 26/92, GRUR 1996, 190 – *Polyferon*). In 2017, there was another case involving the grant of a compulsory licence by the Federal Patent Court, which was confirmed by the Federal Court of Justice (BGH, judgement of 11 July 2017, ref: X ZB 2/17, GRUR 2017, 1017 – *Raltegravir*). The cases decided so far relate to pharmaceuticals.

i. Federal Court of Justice (*Bundesgerichtshof*), decision of 5 December 1995, ref: X ZR 26/92, GRUR 1996, 190 – *Polyferon*

In this case, the Federal Patent Court (*Bundespatentgericht*) had originally granted a compulsory licence for the first time. However, the Federal Court of Justice subsequently reversed this decision and did not grant the compulsory licence, since the public interest argument was declined.

The action for the grant of a compulsory licence concerned a patent on a polypeptide with interferon-gamma (INF-gamma) properties. The plaintiff found a new use of the patented substance as an active ingredient for the treatment of rheumatoid arthritis and had also been granted a patent for that specific use. At the time, it produced the only medicine approved in Germany to contain the active ingredient INF-gamma, which was marketed under the name “Polyferon”. The use patent was dependent on the substance patent. The patentee therefore requested that Polyferon not be manufactured and offered, particularly since the patentee was developing its own medicine for the treatment of rheumatoid arthritis on the basis of the INF-gamma for which it held a patent.

By judgement of 7 June 1991, the Federal Patent Court ruled that, taking into account the public interest in the medical use of the medicine “Polyferon”, a compulsory licence should be granted as long as no other medicine with an active substance of the patented active ingredient with the same or better active properties was approved.

In its “Polyferon” judgement of 5 December 1995, the Federal Court of Justice recognised that rheumatoid arthritis is such a serious disease that, for reasons of medical care, there may be a public interest in the continued availability of a certain medicine with improved therapeutic options to the patients concerned. However, at the time, from the point of view of the Federal Court of Justice, it had not yet been found with certainty that there were significant improvements in the therapeutic possibilities for rheumatoid arthritis as a result of “Polyferon” as compared with traditional medicaments. In addition, Polyferon was not the only available medicine for any of the affected (sub)groups of patients, and it was very expensive compared to other known medicines. Accordingly, the Federal Court of Justice declined the public interest argument and – contrary to the previous ruling of the Federal Patent Court – did not recognise the claim to a compulsory licence.

ii. Federal Court of Justice, decision of 11 July 2017, ref: X ZB 2/17, GRUR 2017, 1017 – *Raltegravir*

This is the first case in which a compulsory licence granted by the Federal Patent Court has been upheld by the Federal Court of Justice. With reference to the public interest, a preliminary injunction to use the invention granted by the Federal Patent Court pursuant to Section 85(1) of the Patent Act was confirmed. In addition to the public interest argument, it was debated whether the applicants had made sufficient efforts in the previous unsuccessful negotiations in order to obtain a licence from the defendant under normal commercial conditions.

The applicants consist of a number of European companies belonging to an American group. They have distributed the medicine Isentress® for the treatment of infection with the human immunodeficiency virus (HIV) in Germany since 2008. It contains the active ingredient Raltegravir. The defendant is the proprietor of a European patent called “Antiviral Agent” granted with effect for Germany and also distributes a medicine for the treatment of HIV that falls under the scope of protection of the aforementioned patent.

In June 2014, the defendant asserted to the applicants’ Japanese sister company that “Isentress®” fell within the scope of protection of a Japanese patent, a member of the same family as the patent in suit. Under certain conditions, however, the patentee was willing to license the patent family of the disputed patent. Subsequent negotiations on a worldwide licensing agreement remained inconclusive. In August 2015, the defendant filed an infringement action against the applicants before the Regional Court of Düsseldorf. The infringement proceedings were stayed, because at that time, an appeal was still pending before the Board of Appeal of the European Patent Office.

In 2016, the applicants filed an action for the grant of a compulsory licence for the patent in dispute and later requested an interim injunction authorising them to provisionally use the protected invention.

In its assessment of the applicants' efforts to obtain a licence, the Federal Patent Court stated that the perspective of the licence seeker had to be taken into account. In order to be regarded as sufficient in the normal commercial sense, the offer does not have to meet the requirements for a compulsory licence under competition law. The licence seeker may also take into account circumstances which, in his view, call into question the validity of the corresponding patent. Against the background of the unsuccessful licence negotiations for a worldwide licence, the offer of a one-off payment of 10 million US dollars was made by the applicants, but it fell a long way short of the defendant's expectations. The court held that the offer should be assessed in the light of a decision not yet finally taken in the opposition proceedings and that the efforts of the applicants should not be regarded as mere sham proceedings (Note: In fact, the patent in dispute was later revoked by the Board of Appeal of the European Patent Office on 11 October 2017).

The Federal Patent Court also stated that there was a public interest in the continued availability of the active substance Raltegravir. Even though probably not every HIV or AIDS patient was dependent on being treated or on being able to be treated with Raltegravir, there were patient groups that needed medicine containing the active substance Raltegravir in order to maintain safety and quality of treatment, in particular to avoid serious side effects and interactions. The associated reduction of the viral load would also protect the general public from new infections.

In its judgement of 31 August 2016, the Federal Patent Court therefore provisionally permitted the applicants to use the invention protected by the contested patent and to market the medicine Isentress® in the four forms of administration already available on the market.

This decision was confirmed by the Federal Court of Justice in its “Raltegravir” decision of 11 July 2017. In particular, it confirmed the grant of a temporary injunction, since Raltegravir had been available on the market for many years and had found widespread use. Thus, for a large number of patients, a change in therapy would be associated with serious risks.

Regardless of the small number of compulsory licence proceedings, when assessing the importance of the legal regulation, it must be taken into account that the general possibility of a compulsory licence *per se* will promote the willingness to conclude licence agreements (Rogge/Kober-Dehm in: Benkard, *Patentgesetz*, 11th edition 2015, Sec. 24 marginal note 4; Rinke in: Schulte, *Patentgesetz*, 10th edition 2017, Sec. 24 marginal note 5).