

D YOUNG & CO **INTELLECTUAL** **PROPERTY**

European patent prosecution & litigation: Germany
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Slides and a recording of this webinar will be emailed to you later this week.

Webinar agenda

- Compulsory License in the Public Interest, Supreme Court decision “*Raltegravir*”
- (Allowed) repair versus (forbidden) new production, Supreme Court decision “*Electrophotographic photosensitive drum*”

Compulsory License under Sec. 24 GPA

Decision of the Federal Supreme Court of 11 July 2017 – Case No. X ZB 2/17 “Raltegravir”:

- a) Whether the licence seeker has within a reasonable period of time attempted unsuccessfully to obtain permission from the patent proprietor to use the invention on reasonable commercial terms and conditions must be evaluated based on the circumstances of the individual case.
- b) A public interest in the grant of a compulsory licence for a pharmaceutical substance 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.
- c) Hesitant behaviour on the part of the licence seeker must be taken into consideration in the balancing of interests required by Sec. 85(1) of the Patent Act. Such behaviour does not in and of itself argue against the presence of a public interest.
- d) The issue of an interim injunction under Sec. 85(1) of the Patent Act is not additionally subject to the requirements laid down in Sec. 935 or Sec. 940 of the Code of Civil Procedure.

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Sec. 24 Patent Act

(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.

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Sec. 24 Patent Act

(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. [...]**

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Sec. 85 Patent Act

(1) In proceedings for the grant of a compulsory licence the claimant may, at his request, be permitted to use the invention on the basis of a **preliminary injunction** if he substantiates that the requirements under section 24 (1) to (6) are fulfilled and that there is an **urgent need**, in the public interest, for the immediate grant of the permission.

(2) The issue of the preliminary injunction may be made dependent on the fact that the person making the request **provides a security** due to the imminent threat of disadvantages arising for the party opposing the request.

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- There had previously been only 1 published decision with which the Federal Patent Court had granted a compulsory license in main proceedings under sec. 24 GPA.
- The decision was revoked by the Supreme Court on appeal (decision of 05 December 1995, case no. X ZR 26/92 "*Polyferon*") for lack of public interest.
- In 1998 the statutory pre-action requirements for the license seeker have been raised.

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Why is there a need for a statutory compulsory licence in Germany?

- Under German law an injunction is an automatic consequence of a finding for patent infringement. There is generally no discretion for the court to find for infringement but reject the request for an injunction
- While in extreme cases an injunction may be denied for overriding interests, these interests can only be interests of the respondent, not third parties or the public
- A first instance injunction is immediately enforceable against a security bond during a pending appeal

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- Since 2008 the applicants have sold the medicine Isentress in Germany, which contains the substance raltegravir and is used to treat infection with the human immunodeficiency virus (HIV)
- The respondent is the proprietor of European patent No. 1 422 218 which concerns an antiviral drug. Upon opposition, the European Patent Office (EPO) upheld the patent in suit in a modified version. The respondent appealed
- In 2014 the respondent alleged patent infringement on an international basis. Subsequent negotiations on a worldwide licensing agreement remained inconclusive

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- In June 2014 the parties started to discuss possible infringement on an international level. Patent owner stated **willingness to grant license in principle** if certain conditions are fulfilled
- During the **12 months of negotiations** the applicant made two concrete offers, the best one being a one off payment 10 million dollar for a worldwide license. Respondent made on counter offer.
- There was no other product using raltegravir as an effective ingredient on the German market.

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August 2015	Infringement action filed in the High Court
January 2016	Appl. for compulsory license filed in Federal Patent Court
June 2016	Application to grant license by preliminary injunction (PI)
August 2016	Federal Patent Court grants PI and reserves determination of license fee for main decision
October 2016	Infringement action stayed pending EPO appeal
July 2017	Supreme Court rejects appeal against grant of PI
October 2017	EPO BoA revokes patent in suit
November 2017	Federal Patent Court decides the remainder of the case

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“within a reasonable period of time, unsuccessfully attempted to obtain permission from the proprietor of the patent to use the invention on [...]”

- What period of time and what measures are required is a matter of the individual case
- It suffices if the requirement is met at the close of the oral hearing
- However, it is not sufficient when the licence seeker during the proceedings, “at the last minute” declares its willingness to pay an appropriate licence.

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“unsuccessfully attempted to obtain permission from the proprietor of the patent to use the invention on reasonable commercial terms and conditions”

- The mechanism set out by the CJEU in standard essential patent cases does not apply
- It was sufficient for the licence seeker to declare its fundamental willingness to pay an appropriate licence fee;
- It could not be demanded that the applicants name precisely or approximately the amount that the court later deems appropriate

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“The public interest calls for the grant of a compulsory licence”

Legal Principles:

- Whether the public interest calls for the grant of a compulsory licence must be answered by weighing all circumstances that are relevant in the individual case and the interests concerned
- The public interest can only be affected when special circumstances arise that outweigh the unlimited recognition of the exclusive right and the interests of the patent proprietor because the interests of the public necessitate the exercise of the patent by the licence seeker

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- A public interest can be confirmed when a medicament used to treat serious illnesses displays therapeutic characteristics that the drugs 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 drugs
- A compulsory licence cannot, on the other hand, be granted when the public interest can be satisfied by substituting other, essentially identical drugs

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Considerations for a Compulsory License:

- Continued availability of raltegravir for treating infants and children under 12 years of age
- In infants and children, alternative treatment attempts also entail special risks because the viral load typically increases quickly due to the not yet fully developed immune system and the still-growing lymphatic system, resulting in a comparatively higher risk of fatality, which leaves little time for modifications to the treatment
- A public interest in the availability of raltegravir cannot be denied solely on grounds that the patient group in question tends to be small and at the moment only a small portion of the affected patients is being treated with raltegravir

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- Public interest in the further availability of raltegravir for the treatment of pregnant women
- Public interest the prophylactic treatment of patients in the case of an acute risk of infection, for instance in medical personnel due to an accidental needle prick
- Public interest in respect of patients who would be forced to change their long term treatment and risk serious side effects if raltegravir were no longer available

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Balancing the Patent Owner's Interests:

- Raltegravir was approved several years before the grant of the patent and has meanwhile come into widespread use
- The respondent is thus deprived of the chance given by the applicants being excluded from competition to increase its revenue with the other medicaments covered by the patent that it sell
- This consequence does not seem out of proportion considering the serious risks for an undetermined number of patients, especially considering that the opponent is willing to enter into a licensing agreement and that its legitimate financial interests can be sufficiently accounted for by the acceptance of an appropriate license fee

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“There is an urgent need, in the public interest, for the immediate grant of the permission”

- The urgency requirement (1 – 2 months) for preliminary injunctions in patent infringement proceedings does not apply.
- Hesitant behaviour on the part of the licence seeker must be taken into consideration but does not in itself exclude public interest.

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“remuneration being equitable in the circumstances of the case and taking into account the economic value of the compulsory licence”

The Federal Patent Court had deferred the setting of a license fee to the main proceedings and in November 2017 decided as follows, applying the principles stated in the Supreme Court decision:

- a license fee must be paid for the use despite the revocation of the patent in suit by EPO BoA for the time between the grant of the licence and the revocation of the patent

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- By giving the security in form of a bank guarantee, as ordered in the preliminary injunctions, the applicant indicated that the continued use took place under the preliminary compulsory license
- Starting point: what would reasonable parties have agreed on?
License rates common in the industry
- The fact validity proceedings can continue after the grant of a compulsory license must lead to an increase in the license fee
- The compulsory license is not an exclusive license

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- Usual bracket for license fees for pharmaceuticals: 5 – 15% of the net revenues
- Result: 4% of the net revenues. Licensee only gets “bare” patent licences and has to undertake substantial R&D efforts to get to product stage and also uses own patents in the marketed product.

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Is the compulsory license a new arrow in the quiver of defendants in pharmaceutical cases to avoid dire consequences of (i) the German injunction regime, (ii) the German bifurcated system?

Federal Patent Court, decision of **6 September 2018**, case no. 3 LiQ 1/18 (EP), „*Praluent / Repatha*“ denied the grant of a compulsory license because the applicant

- Did not seek license for a reasonable time
- Did not offer commercially reasonable terms
- Could not prove public interest

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November 2017	Stay of pending infringement proceedings, validity doubtful
December 2017	EPO OD preliminary opinion: likely to uphold patent
February 2018	Infringement proceedings resumed in light of EPO opinion
June 2018	Attorney letter seeking license
Juli 2018	Court application to grant compulsory license + PI
6 September 2018	Oral hearing re PI in the Federal Patent Court
11 September 2018	Trial in the infringement proceedings

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- Applicants sell a cholesterol reducing drug
- Respondent sells competing drug
- Respondent had made it clear in previous parallel litigation that it is generally not interested in granting a license, save extraordinary circumstances
- Applicants had offered a license fee of 2% of net revenues in Germany

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“within a reasonable period of time, unsuccessfully attempted to obtain permission from the proprietor of the patent to use the invention on [...]”

- Denied
- Only 3 weeks between first approach and filing of court application
- Only 2.5 months between first approach and oral hearing
- Offer by attorney correspondence must allow for more time than direct communication between parties
- If the respondent has previously expressed that it is unwilling to grant license to competitors in principle, the applicants will have to allow for more time for negotiations

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“unsuccessfully attempted to obtain permission from the proprietor of the patent to use the invention on reasonable commercial terms and conditions”

- First approach only offered a license fee of 2%
- Offer also insisted on continuing with validity proceedings
- EPO preliminary opinion should have been reason for the applicant to reconsider its commercial offer (which was initially based on the assumption that the patent was invalid)

Compulsory License under Sec. 24 GPA

“The public interest calls for the grant of a compulsory licence”

- Based on the evidence the court had doubts that applicant’s drug has the superior effects claimed by the applicant
- Reduction of death rate shown by studies not significant
- Even the applicant’s own expert expressed doubts as to effectiveness
- Applicant could not show that there is no equivalent substitute on the market. Onus of proof lies with applicant
- Mere lack of willingness of patients to change therapeutic product is not enough for public interest (as opposed to expected severe side effects in case of a change of therapy)

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Conclusions:

- Compulsory license remains to be the last resort
- Applicants must show to the court that they acted in good faith and did everything to resolve the matter out of court and in due time
- Any attempt to mix own commercial interest with the interests of the public must fail

Repair vs Infringing New Production

German Supreme Court decision of 24 October 2017, case no. X ZR 57/16 “*Electrophotographic photosensitive drum*” regarding the alleged infringement of the German part of EP 2 087 407:

- *Patent owner sells printers and spare / replacement parts*
- *Defendant takes original process cartridges, replaces the image drum in the drum unit and sells the refurbished cartridges to users of the patents owner’s printers*
- *High Court and Court of Appeal found for patent infringement, Supreme Court overturned and dismissed the complaint*

Repair vs Infringing New Production

*Claim 1: „An **electrophotographic photosensitive drum unit (B)** **usable with a main assembly of an electrophotographic image forming apparatus**, the main assembly including **a driving shaft (180)** to be driven by a motor, having a rotational force applying portion, wherein said electrophotographic drum unit is dismountable from the main assembly in a dismounting direction substantially perpendicular to an axial direction (L3) of the driving shaft, said **electrophotographic drum unit comprising**:*

*i) an electrophotographic photosensitive **drum (107)** having a photosensitive layer (107b) at a peripheral surface thereof, said electrophotographic photosensitive drum being rotatable about an axis (L1) thereof;*

*ii) a **coupling member (150)** rotatable about an axis (L2) thereof, engageable with the driving shaft (180) to receive a rotational force, from the rotational force applying portion, for rotating said electrophotographic photosensitive drum (107) said coupling member is provided at an axial end of said electrophotographic photosensitive drum (107) such that said coupling member (150) is capable of taking a rotational force transmitting angular position substantially co-axial with said axis (L1) of said electrophotographic photosensitive drum (107) for transmitting the rotational force for rotating said electrophotographic photosensitive drum (107) to said electrophotographic photosensitive drum (107) and a disengaging angular position in which said coupling member (150) is inclined away from the axis (L1) of said electrophotographic photosensitive drum (107) from said rotational force transmitting angular position for disengagement of the coupling member (150) from the driving shaft (180), wherein said electrophotographic drum unit (B) is adapted such that when said electrophotographic drum unit (B) is dismounted from the main assembly in the dismounting direction substantially perpendicular to the axis (L1) of said electrophotographic photosensitive drum (107) said coupling member (150) moves from said rotational force transmitting angular position to said disengaging angular position.“*

Repair vs Infringing New Production

*Claim 1: **Electrophotographic drum unit** comprising [...]*

(i) an electrophotographic photosensitive drum [...];

(ii) a coupling member [...]

*Claim 25: A **process cartridge** having an electrophotographic drum unit according to any of the preceding claims [...]*

*Claim 29: An **electrophotographic image forming apparatus** comprising:*

(i) a main assembly including a driving shaft, to be driven by a motor, having a rotational force applying portion; and

(ii) an electrophotographic photosensitive drum unit according to claim 1.

Repair vs Infringing New Production

The patent owner and plaintiff produces toner cartridges comprising

- a drum unit with an image drum,*
- a flange, and*
- a coupling member*

(so-called process cartridges) and distributes the cartridges as original equipment and consumables for the copiers and printers the plaintiff offers.

Repair vs Infringing New Production

The defendant and alleged infringer

- *sells reprocessed process cartridges in Germany, which can be used instead of the applicant's original cartridges;*
- *for reprocessing, the defendant uses used cartridges that were originally placed on the market by the applicant;*
- *the defendant replaces the used picture drum and, if necessary, the flange with new, not identical parts deriving from the applicant. From these components as well as an original coupling element the defendant creates a functional drum unit, which it installs in the used cartridge*

Repair vs Infringing New Production

Section 9 German Patent Act:

The patent shall have the effect that the proprietor of the patent alone shall be entitled to use the patented invention within the scope of the law in force. In the absence of the consent of the proprietor of the patent, any third party shall be prohibited from

*1. **producing**, offering, putting on the market or using **a product which is the subject-matter** of the patent, or from either importing or possessing such a product for the purposes referred to;*

Repair vs Infringing New Production

The Doctrine of Exhaustion of Patent Rights:

- The exclusive right deriving from a patent that concerns a product is exhausted with respect to such copies of the protected product that have been put into circulation by the patent holder or with his consent
- The lawful purchaser of such a copy is entitled to **use it as intended**, to sell it to third parties or to offer to sell it to third parties for one of these purposes
- The intended use also includes the **maintenance and re-establishment of usability** if the function or performance of the specific copy is impaired or terminated in whole or in part through wear and tear, damage or for other reasons

Repair vs Infringing New Production

Limitations of the Doctrine of Exhaustion of Patent Rights:

- a re-establishment of usability is not given if the measures taken no longer maintain the **identity of the copy put into circulation** but have the effect of in fact making a new patented product
- If the original product loses its identity there is no exhaustion and the measures taken are considered a making of a new product which infringes the patent

Repair vs Infringing New Production

Distinguishing between Repair and New Product:

requires a balancing of legitimate interests, taking into account

- the individuality of the patented product,
- of the protected interests of the patent holder in the commercial exploitation of the invention on the one hand and
- those of the purchaser in the unhindered use of the specific product according to the invention that has been put into circulation on the other hand.

Repair vs Infringing New Production

- Offering or supplying replacement components only constitutes patent infringement if the lawful purchaser of the protected product, by replacing these components, goes **beyond the limits of intended use** and makes a new total product according to the invention
- This is assessed in a 2-step process:

Question 1: *is the replacement of the component in question is **in the opinion of the trade** usually to be expected during the working life of the protected product?* If the answer is no => patent infringement, if the answer is yes => go to question 2

Question 2: *are the technical effects of the invention reflected precisely in the replaced components and for this reason the replacement of these components implements a second time **the technical or commercial advantage of the invention**?* If the answer is yes => patent infringement. If the answer is no => no patent infringement

Repair vs Infringing New Production

What is the correct reference point for the 2-step test? The component claimed in the patent claim enforced in court or the product sold to customers?

Appeal Court: the point of reference is always the component claimed in the patent claim in suit. Here: the drum unit (not the process cartridge)

⇒ Is the replacement of the electrophotographic photosensitive **drum** a new production of a electrophotographic photosensitive drum **unit**?

Supreme Court: agreed

Repair vs Infringing New Production

Replacement of the drum to be expected in the opinion of the trade?

Appeal Court:

- The real opinion of the trade cannot be determined because members of the trade can only buy process cartridges not separate drum units
- Therefore a **normative** trade opinion must be determined (based on fictitious reasonable members of the trade)
- The normative opinion sees the replacement of the drum in the drum unit as the making of a new unit not least because the value of the drum amounts to 70% of the value of the drum unit

Repair vs Infringing New Production

Supreme Court:

- A trade opinion can only form with regard to a product sold in the market. Here: printers and process cartridges. Not drum units.
- Relying on a normative / fictitious trade opinion is not appropriate
- Instead the sole remaining differentiating criteria is whether the replaced component implements a second time the technical or commercial advantage of the invention

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Supreme Court:

- The decisive question therefore is whether the technical effects of the claimed invention are reflected in the replaced parts (i) image drum and / or (ii) flange
- Image drum and flange are state of the art and the patent claim in suit does not provide for additional features
- The effects of the claimed inventions lie exclusively with the coupling member which is not replaced by the respondent

Repair vs Infringing New Production

Conclusions:

- Original manufacturers have apparently tried to improve their position against third party suppliers of replacement / spare parts by directing patent claims to smaller and smaller components within the overall device
- This follows the logic of past case law according to which it can be assumed that the higher the economic value of the replacement part within the component protected by the patent claim, the likelier it is that the members of the trade see this as a new product and not as maintenance or repair
- The Supreme Court makes it clear that this strategy will not work in cases where the replacement part makes no contribution to the patented invention

Repair vs Infringing New Production

Outlook:

- In a related case, where the claim in suit was also directed to the drum unit the respondent disassembled original process cartridges, sorted out all damaged / used up components and rebuilt new cartridges from the remaining components, including coupling members.
- High Court and Court of Appeal found that the identity of the initial process cartridge and the drum unit was no longer preserved, rejected exhaustion and found for patent infringement (however, again based on a normative trade opinion)
- The further appeal against this judgment is currently pending and it remains to be seen if the Supreme Court will continue to strengthen the position of third party spare and replacement parts over those of the OEM.

Questions and future webinars



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