Deckblatt Übersetzung

Daten der Übersetzung:

Court/Gericht:	Bundesgerichtshof
Date of Decision / Datum der Entscheidung:	2017-07-11
Docket Number / Aktenzeichen:	X ZB 2/17
Name of Decision / Name der Entscheidung:	Raltegravir

FEDERAL COURT OF JUSTICE

IN THE NAME OF THE PEOPLE

JUDGMENT

X ZB 2/17

Pronounced on:
11 July 2017
Anderer
Judicial Secretary as
clerk of the Court
registry

In the preliminary injunction proceedings

Raltegravir

Patent Act Sec. 24, Sec. 85(1)

a) Whether the licence seeker has made unsuccessful efforts within a reasonable period of time to obtain from the patentee the consent to use the invention on reasonable commercial terms is to be assessed on the basis of the circumstances of the individual case.

b) A public interest in the grant of a compulsory licence for an active pharmaceutical agent may also exist if only a relatively small group of patients is affected. This is particularly true if this group would be at particularly high risk if the drug in question were no longer available.

c) A hesitant behaviour of the licence seeker shall be taken into account in the balancing of interests required under Sec. 85(1) Patent Act. However, such conduct does not automatically speak against the existence of a public interest.

d) The issue of a temporary injunction under Sec. 85(1) Patent Act does not require the additional requirements laid down in Sec. 935 or Sec. 940 Code of Civil Procedure.

Federal Court of Justice, judgment of 11 July 2017 - X ZB 2/17 - Federal Patent Court

ECLI:DE:BGH:2017:110717UXZB2.17.0

The X. Civil Senate of the Federal Court of Justice following the oral hearing on 11 July 2017 attended by the presiding judge Prof. Dr. Meier-Beck, the judges Gröning, Dr. Bacher, Dr. Deichfuß and the judge Dr. Kober-Dehm
ruled as follows:

The appeal against the judgment of the Third Senate (Nullity Senate) of the Federal Patent Court of 31 August 2016 is dismissed at the expense of the Respondent.

By operation of law

Facts of the case:

1 Since 2008, the Applicants have been marketing the drug Isentress in Germany, which contains the active agent Raltegravir and is used for the treatment of human immunodeficiency virus (HIV) infections.

2 The Respondent is the patentee of the European patent 1 422 218 (patent in dispute), granted with effect in the Federal Republic of Germany, which was applied for on 8 August 2002 and relates to an antiviral agent. The grant of the patent was published on 21 March 2012. The European Patent Office has maintained the patent in dispute as amended following opposition. The appeal against the decision is still pending.

3 In a letter dated 3 June 2014, the Respondent claimed from a company affiliated with the Applicants that Isentress falls within the scope of protection of Japanese patent 5 207 392, which belongs to the family of the patent in dispute. Subsequent negotiations on a worldwide licence agreement were unsuccessful.

4 With brief of 17 August 2015, the Respondent filed an action for patent infringement against the Applicants before the Düsseldorf Regional Court (4c 0 48/15) regarding the patent in dispute, *inter alia* requesting an injunction. The Regional Court has suspended litigation until the decision on the appeal pending before the European Patent Office is made. The immediate appeal filed by the Respondent against the suspension was unsuccessful.

5 With application dated 5 January 2016, the first Applicant claimed the grant of a compulsory licence from the Respondent on the patent in dispute. The second and third Applicants joined the proceedings later. The first instance has not yet decided on the action.

6 In a letter dated 7 June 2016, the Applicants applied for provisional permission to use the protected invention by means of a preliminary injunction.

7 After obtaining an expert opinion, the Patent Court rejected the Applicants' main request, which was not limited to individual forms of levy. Upon their auxiliary request, the Patent Court provisionally allowed them to distribute Isentress for the treatment of HIV-infected and AIDS patients in the four forms of supply already on

the market, as specified in the contested judgment. The Respondent challenges that decision with the appeal, which the Applicants are contesting.

Grounds of the decision:

8 The admissible appeal is not successful.

9 I. The Patent Court essentially justified its decision as follows:

10 The group company acting on behalf of the Applicants endeavoured to obtain consent to use the invention on reasonable commercial terms, within a reasonable period of time. The fact that it had only offered a one-off payment, which in the opinion of the Respondent was unreasonably low, did not call into question the seriousness of the efforts. Admittedly, in compulsory licence proceedings the legal status of the patent in dispute had to be assumed. However, in negotiations on the acquisition of a licence, a licence seeker may take into account his expectations regarding the validity.

11 The Applicants had shown that the public interest requires the grant of a compulsory licence. In that regard, it could be left open whether Raltegravir could not be regarded as more advantageous in all respects than the other two, currently available, active agents from the group of integrase inhibitors (Elvitegravir and Dolutegravir). In the everyday practice of HIV/AIDS therapy, there is no general preference for certain active agents. Rather, the concept of individualised therapy suggested by the published guidelines is implemented, in which a combination of active agents from several groups is used for each patient depending on the individual circumstances. In view of this, not every HIV or AIDS patient is dependent on being able to be treated with Raltegravir at any time. There are, however, patient groups who need Raltegravir for the maintenance of treatment safety and quality. This applies above all to infants, children under twelve years of age and pregnant women, but also to persons who require prophylactic treatment due to the existing risk of infection, and to patients already treated with Isentress who are at risk of significant side effects and interactions when switching to another drug, especially patients treated for many years who, after several changes of therapy, could have been saved only by Raltegravir, the only integrase inhibitor available since 2007.

12 Urgency should only be based on the public interest concerned. The question of whether the Applicants had waited an unreasonably long time to apply for a preliminary injunction was therefore of no importance.

13 II. this assessment stands up to review in the appeal proceedings.

14 1. The patent court was right to consider it *prima facie* evident that the Applicants had sought consent to use the invention on reasonable commercial terms within a reasonable time period.

15 a) The Patent Court rightfully did not rely solely on the fact that, in the course of the compulsory licence proceedings, the Applicants declared their willingness to pay an appropriate licence fee.

16 aa) According to the case-law of the Federal Court of Justice on Sec. 24(1) Patent Act in the version applicable until 31 October 1998, the requirement then in force stating that the licence seeker may make an offer, as a condition of the proceedings that may be made up on during the proceedings.

17 To fulfil this obligation, it was sufficient for the licence seeker to declare its willingness to pay an appropriate licence in principle. It could not be required that it names an even or approximate amount, which the court later considers appropriate (BGH, decision of 5 December 1995 - X ZR 26/92, BGHZ 131, 247, 250 = GRUR 1996, 190, 191 f. - Interferon-gamma).

18 bb) According to the version of Sec. 24(1) No. 1 Patent Act applicable to the dispute and in force since November 1, 1998, it is, however, required that the licence seeker has unsuccessfully tried within a reasonable period of time to obtain from the patentee the consent of the patentee to use the invention on reasonable commercial terms.

19 Again, this condition does not necessarily have to be fulfilled at the time of the filing of the compulsory licence request, but, according to general principles, it is sufficient if it is fulfilled at the end of the oral hearing. However, it follows from the requirement that the effort must have extended over a reasonable period of time that it is not sufficient for the licence seeker to agree to pay an appropriate licence at the last minute during the proceedings. Rather, it must have attempted to reach

an agreement with the patentee on the granting of a licence over a certain period of time in a manner appropriate to the situation. What time period and what measures are required for this is a question of the individual case.

20 b) The Patent Court correctly concluded that the pre-litigation conduct of the company acting on behalf of the Applicants was not in line with the requirements of Sec. 24(1) No. 1 Patent Act with regard to the special features of the dispute (anymore).

21 However, the two offers made by the Applicants, each of which provided for a one-off payment that was lower than the remuneration expectations of the Respondent, gave little reason to expect that an agreement would be reached before the final conclusion of the opposition proceedings. Nevertheless, the Patent Court rightly did not regard the behaviour on the Applicants' side as mere sham negotiations. The different ideas of the parties regarding the total amount of the royalties to be paid cannot be regarded as unreasonable in a dispute, because the question whether the patent in dispute will prove to be legally valid could not be assessed with sufficient certainty even after the decision of the Opposition Division.

22 The Respondent's offer required that the licensee would withdraw all oppositions to the patent in dispute. The proposed licence agreement was thus intended to serve at the same time to settle the dispute about the validity of the patent in dispute. In this initial situation, it was not unreasonable for the Applicants to include its expectations regarding the outcome of the opposition proceedings or any subsequent nullity proceedings in its price expectations. Their chances of success may have been reduced to a certain extent by the partial maintenance of the contested patent by the Opposition Division. However, this decision did not exclude a more favourable assessment by the Technical Board of Appeal. The fact that the position of the Applicants is not hopeless was further confirmed by the - also challenged - decision of the High Court of Justice of England and Wales, which dismissed an infringement action based on the patent in dispute lacking patentability and insufficient disclosure of the invention (Arnold J, [2016] EWHC 2889 (Pat), margin 355).

23 In this initial situation, the Applicants were not obliged to further accommodate the Respondent's price expectations, which are based on the

permanent legal status of the patent in dispute, and to give themselves the opportunity to further attack the existence of the property right by concluding a licence agreement under the proposed conditions. Although the parties could have taken this interest into account by agreeing on a licence fee calculated on the assumption of the permanent validity of the patent, they could have left open to the Applicants the possibility of further attacks on the patent's validity. However, an inclination towards such an arrangement is not apparent from the Respondent's offers either.

24 c) The grant of the requested compulsory licence is also not precluded by the fact that the Applicants have announced a request in the main proceedings according to which the amount of the licence fee is to be limited to a specific one-off amount, or alternatively to a licence fee which is significantly lower than that envisaged by the Respondent.

25 aa) Contrary to the Applicants' view, however, this circumstance is not irrelevant simply because they did not submit their applications until the end of oral hearing in the main proceedings.

26 A preliminary injunction under Sec. 85(1) Patent Act is generally not possible if it can be expected that the action for the grant of a compulsory licence will be unsuccessful. The mere possibility that the prospects of success of the action could be improved by an amended application cannot, in principle, justify the issuance of an preliminary injunction.

27 bb) The Respondent is also correct in assuming that an action for a compulsory licence must be unsuccessful if the applicant indicates that it is seeking a licence only on condition that the licence fee fixed by the court does not exceed a certain maximum amount and the court considers that this amount is not sufficiently high.

28 Pursuant to Sec. 24(6) Sentence 4 Patent Act the patentee is entitled to a remuneration from the compulsory licensee which is appropriate under the circumstances of the case and considers the economic value of the compulsory licence. The court shall determine the amount of such remuneration when the compulsory licence is granted. In doing so, it is appropriate to be guided by the

royalty rate that would be agreed in a licence agreement under the circumstances of the individual case. In this context, it should be taken into account that the risk of revocation or nullification after the grant of a compulsory licence remains with the patentee. The royalties must therefore not be calculated according to the same criteria as in a contract in which the licensee undertakes to refrain from further attacks on the patent and must therefore expect that the obligation to pay the royalties will continue until the end of the term of the property right. The fact that the licence seeker retains the possibility of being released from the obligation to pay royalties for subsequent periods by a successful attack against the validity of the patent must in principle be considered by an appropriate increase in the licence fee. As a rule, the amount of the licence fees is therefore to be determined according to the same standards as the remuneration for a non-exclusive contractual licence to a patent with a validity that is to be regarded as secured.

29 cc) On the basis of the original requests and the requests in the proceedings for a preliminary injunction, the Applicants' requests are, however, not subject to any reservations in this respect.

30 In the request, the Applicants have left the amount of the licence fee to the discretion of the Court. In the grounds for the request, they stated that the Respondent's interest in exploitation could be fully satisfied by the Court setting an appropriate licence fee. In the oral hearing on the request for a preliminary injunction, they further stated that the previous offer of a licence did not constitute a maximum limit on the amount of a compulsory licence that might have to be paid; they were prepared to take a licence on reasonable commercial terms.

31 It is sufficiently clear from these statements that the grant of a compulsory licence is not only sought in cases where the royalty fixed does not exceed a certain limit.

32 The seriousness of these statements is not called into question by the announcement made in the oral hearing before the Patent Court, that an amended request with a royalty rate limited in amount will be filed as the main request if the Patent Court intends to decide on the amount of the royalty rate already in the present proceedings. This announcement does not indicate that the Applicants are unwilling to make higher payments if their proposed main request is unsuccessful.

33 dd) The amended applications announced by the Applicants for the main proceedings do not lead to a different assessment.

34 It is not easy to see from the language of these requests whether the Applicants are seeking a compulsory licence even if the licence fee set by the Patent Court exceeds the maximum limit specified in the request. In this situation, however, it would be up to the Patent Court to work towards clarification.

35 The Applicants made this clarification at the oral hearing before the Senate by stating that, in any event, the entirety of their requests is not aimed at ensuring that the compulsory licence is granted only up to a certain maximum amount. Thus, the Patent Court is not prevented from granting the compulsory licence by fixing the licence fee it considers appropriate even if it exceeds a maximum amount specified by the Applicants. The Applicants are not prevented from seeking a lower licence fee by means of an appeal.

36 2. The Patent Court has rightly considered that the public interest requires the grant of a compulsory licence in the event of a dispute.

37 a) Whether the public interest requires the grant of a compulsory licence shall depend on the circumstances of the individual case

38 The legal term "public interest" used in Sec. 24(1) No. 2 cannot be paraphrased in a generally applicable manner. The question whether there is a public interest requiring the grant of a compulsory licence must rather be answered by weighing all circumstances relevant to the individual case and the interests involved. In this context, it must be taken into account that the legal system grants the patentee an exclusive right, the exercise of which it alone may in principle determine. Therefore, the public interest can only be affected if special circumstances are added which cause the unrestricted recognition of the exclusive right and the interests of the patentee to be negated because the interests of the general public require the exercise of the patent by the licence seeker (BGH, judgment of 5 December 1995 - X ZR 26/92, BGHZ 131, 247, 251 et seq. = GRUR 1996, 190, 192 - Interferon-gamma).

39 In application of these principles, a public interest requiring the grant of a compulsory licence can be affirmed if a drug for the treatment of serious diseases has therapeutic properties which the drugs available on the market do not possess or do not possess to the same extent, or if undesirable side effects are avoided during its use, which must be accepted when the other therapeutic agents are administered (BGHZ 131, 247, 256 f. = GRUR 1996, 190, 193 - Interferon-gamma). In contrast, a compulsory licence cannot be granted if the public interest can be satisfied with other, essentially equivalent alternative preparations (BGHZ 131, 247, 254 = GRUR 1996, 190, 193 - Interferon-gamma).

40 b) Against this background, the Patent Court has rightly held that there is a public interest in the continued availability of Raltegravir for the treatment of infants and children up to the age of 12.

41 aa) According to the findings of the Patent Court, Raltegravir is the only integrase inhibitor that is eligible for combination therapy with two nucleoside reverse transcriptase inhibitors for infants aged between four weeks and three months in Germany.

42 The only alternative to Raltegravir for this patient group would be the non-nucleoside reverse transcriptase inhibitor nevirapine. However, this is not considered safe in terms of its hepatotoxicity and is not recommended in the guidelines of the US Department of Health and Human Services for first-line therapy. For children aged two years and older, other alternatives include protease inhibitors such as lopinavir. However, these require the use of a booster, which leads to an increased risk of interactions.

43 In infants and children, alternative therapies are also associated with particular risks because the viral load typically increases rapidly due to the immature immune system and the growing lymphatic system, so that there is a comparatively higher risk of death and little time remains for changes in therapy.

44 bb) The appeal does not provide any concrete evidence to cast doubt on the completeness or accuracy of these findings.

45 Contrary to the opinion of the appeal, the assessment of the Patent Court is not called into question by the fact that the guidelines of the Paediatric

European Network for Treatment of AIDS (PENTA) for the year 2015 do not generally recommend Raltegravir, but only describe it as a first-choice agent for rare cases.

46 The Patent Court has taken this aspect into account. Its conclusion that there is nevertheless a public interest in the availability of Raltegravir for the group of patients in question is neither contradictory nor open to objection on any other grounds.

47 In the PENTA recommendations, the rather cautious assessment with regarding Raltegravir is justified by the fact that the data situation is not yet sufficient. The toxicity of other active agents is cited as a reason which could nevertheless speak in favour of the use of this active agent in individual cases. The Patent Court has also attached central importance to this aspect. In addition, it rightly considered the recommendations and approvals specifically applicable to Germany to be particularly important, because the requested compulsory licence relates exclusively to acts of use relevant to Germany.

48 cc) A public interest in the availability of Raltegravir cannot be denied because the patient group in question is rather small and currently only a small proportion of the patients concerned are treated with Raltegravir.

49 A public interest may also exist if only a relatively small group of patients is affected. This is particularly true if this group would be at particularly high risk if the drug in question were no longer available. In the case of infants and children up to 12 years of age, the Patent Court has affirmed the existence of these conditions without error.

50 The Patent Court did not need to deal with the question whether the small size of this patient group should be taken into account by a corresponding limitation of the content of the compulsory licence, because it affirmed a public interest also with regard to other patient groups which cannot be delimited in a practicable way by abstract criteria.

51 c) The Patent Court was also right to affirm a public interest in the continued availability of Raltegravir for the treatment of pregnant women.

52 aa) According to the findings of the Patent Court, Raltegravir is currently considered and recommended as the preferred therapy for pregnant women.

53 The particular advantage of raltegravir is the rapid reduction of viral load, which minimizes the risk of HIV transmission to the child. Alternative agents are not explicitly recommended for use in pregnancy. Their use would be associated with particular risks in view of the greater risk of side effects, especially in pregnant women. Furthermore, fertility-damaging effects have been observed with the active ingredient efavirenz.

54 bb) Contrary to the view of the appeal, these findings are not called into question by the statements of the court expert, according to which, on the basis of the current German guidelines, a protease inhibitor or a non-nucleosidic reverse transcriptase inhibitor can be considered as an alternative to Raltegravir and the last German-Austrian guidelines published in 2014 do not contain an unrestricted recommendation for Raltegravir due to the then still smaller data basis.

55 Notwithstanding these circumstances, the court expert, whose assessment the Patent Court has endorsed in this respect, has described Raltegravir as the preferred therapy for pregnant women in practice. The objection raised by the Appellant that it is not clear on what reliable information this conclusion is based does not give rise to any concrete doubts as to its accuracy.

56 Contrary to the opinion of the appeal, the Patent Court did not assume that other active agents would have stronger side effects, especially in pregnant women. Rather, it considered these substances to be particularly risky for pregnant women because of the generally greater risk of side effects. There are no specific indications that give rise to doubts as to the correctness of this conclusion.

57 d) The same applies to the prophylactic treatment of patients in the event of an acute risk of infection, e.g. due to an unintentional needle insertion by medical personnel.

58 aa) According to the findings of the Patent Court, Raltegravir is currently the only recommended active agent for this patient group in Germany for a

combination treatment. A recommendation by the American International Antiviral Society in favour of Dolutegravir, on the other hand, is not based on clinical tolerance studies.

59 (bb) This finding is not called into question by the fact that the current guidelines of the Center for Disease Control (TWeV35) recommend a combination treatment using Dolutegravir and list Darunavir and Ritonavir as alternatives.

60 These recommendations state that there is not sufficient evidence to recommend a particular medication as particularly effective for post-exposure prophylaxis. The recommendations contained in the guidelines are therefore based on experience in the treatment of HIV-infected patients (TWeV35 p. 30).

61 This is in line with the findings of the Patent Court that the recommendations made in US guidelines are not based on clinical studies and does not contradict, but rather supports the accuracy of these findings.

62 cc) The fact that the forensic expert recommended treatment with Dolutegravir or Darunagravir in a professional journal (HIV&More 4/2016, p. 26, TWeV36) does not lead to a different assessment.

63 This recommendation refers to the special constellation that the index patient, from whom the risk of transmission emanates, has a multidrug-resistant HI virus and is treated with raltegravir, as the response to the complaint has correctly pointed out on the basis of the same publication (HIV&More 4/2016, p. 12, RW6). The court expert justified his treatment proposal with the consideration that the recommended combination of active substances should still be effective, if possible, even in the case of resistance mutations that had occurred under raltegravir. The fact that he did not recommend raltegravir for this constellation seems logical, but does not cast doubt on his assessment that this active substance is particularly suitable in cases without the complication mentioned.

64 e) The Patent Court has rightly affirmed a public interest also regarding patients who would be forced to change therapy if Raltegravir was no longer available.

65 aa) According to the findings of the Patent Court, a change of therapy is always associated with the risk of new side effects or interactions or even failure of the therapy. In addition, there is the risk that, in the event of failure, a return to Raltegravir is no longer possible for medical reasons and that further alternatives are only available to a limited extent.

66 bb) These findings support the conclusion of the Patent Court that there is a public interest in the continued availability of Raltegravir to patients already treated with it.

67 This is not contradicted by the fact that the Patent Court has not made any findings on the question under which specific circumstances and with what probability serious side effects or even therapy failure are to be expected. The Patent Court has rightly affirmed a public interest already because every patient is exposed to a corresponding risk by a legally enforced change of therapy. This risk may not be too high. Nevertheless, it cannot be considered negligible.

68 In this context, it is important to note that the drug marketed by the Applicants had already been approved for several years at the time the patent was granted and, according to the parties' submissions, had been used to a considerable extent. On the other hand, the consequences of therapy failure can be extremely serious. In this situation, the interest of patients already successfully treated with Raltegravir in continuing their treatment is particularly important. For these patients, it is not a question of being provided with a new treatment alternative that offers more or less good prospects of better therapeutic success, but rather of having to change a treatment that may have been successfully carried out for years and accept all the risks involved.

69 Against this background, it can be left open whether the special problems mentioned by the Patent Court in connection with the conversion from Raltegravir to Dolutegravir or Elvitegravir or adhesion problems caused by side effects can also constitute a public interest. Even if this were to be denied, the

general risks of a change of therapy alone would result in a considerable public interest in the continued availability of Raltegravir.

70 f) The same applies to patients who have been treated for many years and who, after several therapy changes due to resistance mutations that have already occurred, could only be saved by treatment with Raltegravir.

71 According to the findings of the Patent Court, such patients can now at least consider switching to Dolutegravir. However, this group of patients is particularly exposed to the risks associated with a change in therapy. In view of this, there is a particularly strong public interest in enabling this group to continue treatment with Raltegravir.

72 g) On this basis, the Patent Court has rightly concluded that the public interest requires the grant of a compulsory licence to the extent granted.

73 Based on the findings of the Patent Court, it is to be expected that even in those patient groups in which there is a particularly high level of interest in the continued availability of Raltegravir, alternative treatment methods with relatively high chances of success will be considered in many individual cases. However, for all affected groups risks of serious side effects, interactions or therapy failure are not inconsiderable. This risk affects all patients of the groups in question equally, because it is only possible to predict to a limited extent in which individual persons it will occur. This uncertainty is all the more burdensome for those affected because, according to the current state of knowledge, they are dependent on lifelong treatment and failure of the therapy can be associated with serious consequences, even death.

74 This risk seems unacceptable, especially as Raltegravir had already been approved for several years at the time of patenting and has since been widely used. For patients who have already been successfully treated with Raltegravir, as well as for patients for whom Raltegravir is the preferred treatment option, it is not a question of obtaining a new therapy alternative whose benefit cannot be conclusively assessed, but rather of continuing to have a therapy option that has been established for many years and has been used successfully.

75 In view of all this, the public interest in the continued availability of raltegravir is of such great importance that the interest of the respondent in a sole decision on the use of the protected invention to the extent awarded by the patent court must take a back seat. The respondent is thus deprived of the opportunity to increase sales of the drugs it sells, which are also covered by the patent, due to the elimination of competition from the applicants. However, this consequence does not appear disproportionate in view of the serious risks for an undetermined number of patients, especially since the respondent is prepared to license the product and its justified financial interests can be adequately taken into account by granting an appropriate license fee.

76 h) The Patent Court was right not to limit the granted permission to certain groups of patients.

77 However, as the Patent Court did not fail to recognise, it cannot be excluded that there are patients for whom reasonable alternatives to treatment with Raltegravir are available. According to the findings of the Patent Court, it is not possible to predict in advance, based on abstract criteria, whether the existing risk of virologic failure or of side effects and interactions of possible alternative drugs will be realised in individual cases. In addition, even initial treatment without Raltegravir is associated with comparable risks for the other affected patient groups.

78 Against this background, the restriction of the authorisation proposed by the Respondent at the hearing to distribution for the treatment of pregnant women, infants and children under 12 years of age and patients for whom Isentress is absolutely necessary in order to achieve a viral load of less than 50 RNA copies per millilitre or in whom all therapy alternatives are contraindicated is also out of the question. It can be left open whether the group of patients in respect of whom there is a public interest in the continued availability of Raltegravir is fully circumscribed by these abstract criteria. Even if this were to be affirmed, the criteria that a certain viral load cannot be reached in any other way or that all therapy alternatives are contraindicated would in any case be unsuitable for a practicable delimitation because they would require an individual medical prognosis in patients with suspected infection and, depending on the individual case, also in other constellations. On the one hand, this would have the consequence that the dispute as to whether the Applicants are entitled to distribute Isentress would be shifted to

a later infringement dispute for an unspecified number of individual cases. On the other hand, an indeterminable number of patients would be exposed to an additional risk if, when preparing a therapy proposal, the attending physician had to fear that, in the event of a misjudgment, he might possibly be sued for participation in a patent infringement.

79 3. The Patent Court has also rightly considered it to be credible that the prompt granting of the licence is urgently required in the public interest.

80 a) The reasons for the public interest in the grant of a compulsory licence set out above also make it urgent, in the event of a dispute, to grant the licence as soon as possible.

81 Of central importance in this context is also the fact that Raltegravir has been available on the market for many years and is widely used, and that a change of therapy would be associated with serious risks for an undefined number of patients. On the one hand, this circumstance gives rise to a high probability that the Applicants will be successful in the main proceedings with their request for the grant of a compulsory licence. In addition, it makes the issuance of an preliminary injunction appear urgently necessary, also on the basis of an assessment of the consequences.

82 If the application for a preliminary injunction were to be rejected, but the action in the main proceedings should later prove to be well-founded, an unspecified number of patients would be threatened with a change of therapy or an alternative initial therapy with all the risks and possibly serious consequences described above. If the Applicants are provisionally allowed to use the drug, but the main action later proves to be unfounded, the Respondent may lose financial benefits. In the particular situation of the dispute, this consequence is to be regarded as much less serious because the legitimate financial interests of the Respondent can be sufficiently taken into account by an appropriate licence fee.

83 (b) The Patent Court was right not to attach any decisive importance to the fact that the facts on which the Applicants base their application for an injunction had become apparent some time before the application was filed.

84 aa) However, the conduct of the Applicants may be relevant for the assessment of whether interim measures are necessary.

85 This applies not only in constellations in which the grounds for a request for disposition are generally not required, due to special regulations such as Sec.12(2) Act against Unfair Competition, but in the entire scope of application of Sec. 935 and Sec. 940 Code of Civil Procedure (cf. Mayer in BeckOK ZPO, 24th edition, § 935 margin 16; Drescher in MünchKomm-ZPO, 5th edition, § 935 margin 18; Vollkommer in Zöller, ZPO, 31st edition, § 940 margin 4; Feddersen in Teplitzky, Wettbewerbsrechtliche Ansprüche und Verfahren, 11th edition, chapter 54 margin 24; Singer in Ahrens, Wettbewerbsverfahrensrecht, 8th edition, Chapter 45 margin 58; KG, MDR 2009, 888; OLG Hamm, NJW-RR 2016, 1112 margin 33; OLG Nürnberg, NJW-RR 2014 1452 margin 35; OLG Stuttgart, NJW-RR 2016, 932 margin 74; left open in BGH, decision of 7 December 2006 - IX ZR 253/03, margin 4). This is based on the consideration that a hesitant application or conduct of proceedings may indicate that the applicant's interest in a provisional arrangement is not sufficiently great to justify issuing a preliminary injunction.

86 bb) However, as the Patent Court has correctly pointed out, these principles cannot be fully relied upon for a decision under Sec. 85 Patent Act.

87 According to Sec. 935 and Sec. 940 Code of Civil Procedure, a preliminary injunction may only be issued if the realisation of a party's right would otherwise be thwarted or made considerably more difficult or if a party would be threatened with unreasonable disadvantages. Pursuant to Sec. 85(1) Patent Act, however, a preliminary injunction may be issued if the public interest urgently requires the permit to be granted as soon as possible. In connection with the question whether there is a sufficient public interest, the licence seeker's own conduct is usually of considerably less importance than for the question whether his own interests are endangered. This does not generally exclude the possibility of taking into account a hesitant behaviour of the licence seeker when weighing up the interests required under Sec. 85(1) Patent Act. In this context, however, it cannot be assumed without further ado that such conduct is contrary to the public interest. Special circumstances which might suggest a different assessment in the case of a dispute have neither been mentioned nor are otherwise apparent.

88 cc) Contrary to the opinion of the appeal, the issue of a preliminary injunction under Sec. 85(1) Patent Act does not additionally require the conditions laid down in Sec. 935 or Sec. 940 Code of Civil Procedure.

89 Pursuant to Sec. 99(1) Patent Act, the provisions of the Code of Civil Procedure are in principle to be applied mutatis mutandis in proceedings before the Patent Court. However, with regard to the requirements for the issuance of a preliminary injunction, Sec. 85(1) Patent Act contains a special provision which, due to its meaning and purpose, must be regarded as conclusive.

90 (1) As the Patent Court has not failed to recognise, however, the provisional permission to use an invention leads to a sensitive encroachment on the legal position of the patentee, which may only take place if a comprehensive balancing of interests shows that the interests of the person entitled to an undisturbed exercise of his exclusive right must take second place in the individual case with regard to clearly predominant interests of third parties. As a standard of comparison, however, Sec. 85(1) Patent Act - in contrast to Sec. 935 or Sec. 940 Code of Civil Procedure - does not specify the interests of the licence seeker, but the public interest. Thus, contrary to the opinion of the appeal, the requirements for the issuance of a preliminary injunction are not mitigated, but modified in such a way that a decision favourable to the licence seeker can only be considered in exceptional cases.

91 (2) The cumulative application of Sec. 935 or Sec. 940 Code of Civil Procedure would contradict the purpose of Sec. 24 and 85 of the Patent Act.

92 Both under Sec. 24 and 85 of the Patent Act, the decisive factor is whether the permission of use is required in the public interest. The enforcement of this interest is in the hands of the private licence seeker - in contrast to an order of the Federal Government under Sec. 13 Patent Act. The rights to grant a compulsory licence and to grant provisional permission to use the work are granted to the private licence seeker. However, it is not allowed to use the information in its own interest, but only to safeguard the public interest. Consequently, neither Sec. 24 nor Sec. 85 Patent Act stipulate that the licence seeker must have a personal interest in the grant of a licence or provisional permission. Admittedly, a licence seeker will usually not assert these rights for altruistic reasons. However, if this

happens in individual cases, it would be contrary to the stated purpose to reject the request because there is no personal interest. Therefore, the question whether the licence seeker has a personal interest cannot be of any importance in principle.

93 dd) Contrary to the view expressed in the appeal, the Applicants' conduct does not lead to the rejection of their application for abuse of rights.

94 However, there is some evidence to suggest that the Applicants would have had the reasonable opportunity to bring the action for the grant of a licence and the application for a preliminary injunction much earlier. However, the course of the first instance proceedings, which can be seen from the files, does not show that the late filing of the application has significantly impaired the Respondent’s possibilities of defence or the Patent Court's ability to make findings.

95 It is true that the presiding judge of the Patent Court rejected a request by the Respondent to postpone the date of the oral proceedings, which had been set at two and a half months in advance. In view of the fundamental urgency of an injunction procedure, however, the time period mentioned seems appropriate for a proper defence, especially since the respondent had been aware of the request in the main action for a long time and the relevant issues are similar in many areas. In addition, the Patent Court - notwithstanding Sec. 294(2) Code of Civil Procedure - obtained a written opinion in preparation for the hearing, and asked the court experts and allowed both sides to interrogate him. Against this background, it seems far-fetched that the Respondent would have had more extensive possibilities of defence available to it if the Applicants had filed their request earlier.

96 c) Contrary to the view taken in the appeal, the fact that the Respondent is unable to enforce its injunction through the courts due to the suspension of the infringement proceedings pending the decision on the appeal before the European Patent Office does not prevent the issue of a preliminary injunction.

97 This procedural situation puts the Applicants in a de facto position to continue to expel Isentress. However, if the legal viewpoint of the Respondent is correct, this is a continuation of a patent infringement, based on which the

Applicants have to expect far-reaching sanctions. Against this background, the urgency of the Applicants' request to put the continued distribution of their drugs on a sound legal basis cannot be denied.

98 III. The decision on costs is based on Sec. 122(4) and 121(2) Patent Act and Sec. 97(1) Code of Civil Procedure.

Meier-Beck Gröning Bacher

Deichfuß Kober-Dehm

Previous instance:
Federal Patent Court, decision of 31 August 2016 - 3 LiQ 1/16 (EP) -