Deckblatt Übersetzung

Daten der Übersetzung:

Court/Gericht:	Bundesgerichtshof
Date of Decision / Datum der Entscheidung:	2016-06-14
Docket Number / Aktenzeichen:	X ZR 29/15
Name of Decision / Name der Entscheidung:	Pemetrexed

Arbeitskreis
Patentgerichtswesen
in Deutschland e.V.

FEDERAL COURT OF JUSTICE

IN THE NAME OF THE PEOPLE

JUDGMENT

X ZR 29/15

Pronounced on:
14 June 2016
Anderer
Judicial Secretary as
Clerk of the court
registry

in the matter

Pemetrexed

EPC Art. 69(1); Protocol on the Interpretation of Article 69 EPC Art. 1, 2; Patent Act Sec. 14

a) As a rule, a patent infringement by equivalent means is to be denied if the description discloses several possibilities of how a certain technical effect can be achieved, but only one of these possibilities has been included in the patent claim (confirmation of Federal Court of Justice, judgment of 10 May 2011 - X ZR 16/09, BGHZ 189, 330 = GRUR 2011, 701 marginal no. 35 - Okklusionsvorrichtung; judgment of 13 September 2011 X ZR 69/10, GRUR 2012, 45 marginal no. 44 - Diglycidverbindung).

b) For the applicability of this principle, it is not sufficient that an embodiment claimed by the patent presents itself as a specific application of a more general solution principle due to information in the description or for other reasons and that the skilled person was able to find further embodiments corresponding to this solution principle due to this knowledge.

Federal Court of Justice, judgment of 14 June 2016 - X ZR 29/15 –
Higher Regional Court of Düsseldorf
Regional Court of Düsseldorf

ECLI:DE:BGH:2016:140616UXZR29.15.0

The X. Civil Senate of the Federal Court of Justice, following the oral hearing on 14 June 2016, attended by the presiding judge Prof. Dr. Meier-Beck, the judges Gröning, Dr. Bacher and Hoffmann as well as the judge Schuster

ruled that:

On appeal by the plaintiff, the judgment of the 2. Civil Senate of the Higher Regional Court of Düsseldorf of 5 March 2015 is set aside.

The matter is referred back to the Court of Appeal for a new hearing and decision, including on the costs of the appeal.

By operation of law

Facts of the case:

1 The plaintiff is the owner of European patent 1 313 508 (patent in suit), which was granted with effect for the Federal Republic of Germany, was filed on 15 June 2001 and relates to the use of pemetrexed disodium in combination with vitamin B12 to inhibit the growth of tumors. Claim 1 of the patent reads in method language:

> Use of pemetrexed disodium in the manufacture of a medicament for use in combination therapy for inhibiting tumor growth in mammals wherein said medicament is to be administered in combination with vitamin B12 or a pharmaceutical derivative thereof, said pharmaceutical derivative of vitamin B12 being hydroxocobalamin, cyano-10-chlorocobalamin, aquocobalamin perchlorate, aquo-10-chlorocobalamin perchlorate, azidocobalamin, chlorocobalamin or cobalamin.

2 The plaintiff is also co-owner of the European patent 432 677 and the supplementary protection certificate 12 2005 000 012 granted on the basis thereof in Germany for the period until 10 December 2015, which concerns pemetrexed and pharmaceutically acceptable salts thereof.

3 By letter from a lawyer dated 12 July 2012, the first defendant (hereinafter: defendant) informed the plaintiff that it intended to market a drug containing the active ingredient pemetrexed dipotassium after the expiration of the supplementary protection certificate, namely as a generic product with Alimta, the product containing the active ingredient pemetrexed disodium and marketed by the plaintiff, as a reference drug.

4 The plaintiff filed a claim for injunctive relief against the defendant, its German sales company and its managing director. The Regional Court found against the defendant in accordance with the alternative claim based on infringement of the patent in suit by equivalent means, and dismissed the remainder of the action. The Court of Appeal dismissed the action in its entirety. The plaintiff appealed against this decision in an appeal allowed by the Senate, which the defendant opposes.

Grounds of the decision:

5 The appeal leads to the reversal of the appellate judgment and to the remand of the case to the Court of Appeal.

6 I. The patent in suit relates to the use of pemetrexedisodium in combination with vitamin B12 to inhibit the growth of tumors in mammals.

7 1. The patent-in-suit explains that antifolates are among the best-studied classes of antineoplastic agents. They resulted in inhibition of one or more key enzymes for the biosynthesis of thymidine and purine by competing with reduced folate for binding of these enzymes. Examples of such antifolates include 5-fluorouracil, Tomudex®, Methotrexate®, Lometrexol, and pemetrexedisodium (Alimta®).

8 The limiting factor for the development of such drugs in the patent specifications is the considerable toxicity, which sometimes even results in a high mortality risk. Folic acid and retinoid compounds such as vitamin A have been used as means to reduce toxicity. Nevertheless, the cytotoxic activity of antifolates continues to be a serious concern in the development of such drugs.

9 2. The patent specifications does not explicitly state which technical problem the patent in suit concerns.

10 a) The Court of Appeal formulated the task of the patent-in-suit as reducing the adverse toxic effects for the patient that would be caused by the administration of pemetrexed disodium as an antifolate without adversely affecting the therapeutic efficacy.

11 b) The appeal complains that this is incorrect. It argues that the Court of Appeal should not have defined the problem underlying the patent in suit without first interpreting the patent claim.

12 This complaint is unfounded.

13 aa) According to the case law of the Senate, the purpose of defining the technical problem (the task) in nullity or opposition proceedings is to locate the starting point of the skilled efforts to enrich the state of the art without

knowledge of the invention in order to assess, in the subsequent and separate examination for patentability, whether the solution proposed for it was suggested by the state of the art or not (Federal Court of Justice, judgment of 11 November 2014 X ZR 128/09, GRUR 2015, 356 marginal no. 9 - Repaglinid). On the other hand, it does not have the function of already making a preliminary decision on the question of patentability (Federal Court of Justice, judgment of 13 January 2015 - X ZR 41/13, GRUR 2015, 352 marginal no. 16 - Quetiapin).

14 Nothing else applies in principle to an infringement dispute. To assess the question of whether the respective challenged embodiment makes use of the patented teaching, it must be determined by interpreting the patent claim what concrete expression the efforts of the skilled person to enrich the state of the art have found therein (see only Federal Court of Justice, judgment of 24 July 2012 - X ZR 126/09, GRUR 2012, 1130 marginal no. 9 Leflunomid). The determination of the technical problem contributes to the elaboration of what the invention actually accomplishes in this sense (cf. Federal Court of Justice, judgment of 4 February 2010 Xa ZR 36/08, GRUR 2010, 602 - Gelenkanordnung). It follows from this that a court may not deal with the technical problem in the reasons for a decision only after it has interpreted the patent claim. Rather, determination of the problem and interpretation of the patent claim interact to a certain extent. Accordingly, as a rule it is expedient and necessary to consider the technical problem in advance. Within the scope of the interpretation, both the meaning of the patent claim in its entirety and the contribution that the individual features make to the performance result of the invention must be determined (see only Federal Court of Justice, judgment of 17 July 2012 - X ZR 117/11, BGHZ 194, 107 = GRUR 2012, 1124 marginal no. 27 - Polymerschaum I). This usually requires a preliminary orientation as to which technical problem is concerned.

15 It would only be legally erroneous to define the technical problem within the scope of this first consideration in such a way that a preliminary decision on the interpretation is made. Information contained in the patent specification regarding the task of the invention must - just like the remaining content of the patent specification - not lead to a factual narrowing of the subject matter defined by the literal sense of the patent claim (Federal Court of Justice, judgment of 4

February 2010 - Xa ZR 36/08, GRUR 2010, 602 marginal no. 27 - Gelenkanordnung; judgment of 17 July 2012 - X ZR 113/11, GRUR 2012, 1122 marginal no. 22 - Palettenbehälter III). Moreover, they must also be disregarded if the patent claim does not specify any means by which the objective in question could be achieved (Federal Court of Justice, judgment of 25 February 2014 - X ZR 84/12, marginal no. 13). These principles also apply to a task description that is not expressly included in the patent specification. Each task description must therefore be examined in a subsequent step to determine whether it is consistent with the definitions of the patent claim determined by interpretation.

16 bb) Against this background, the contested decision does not reveal any legal error.

17 In view of the interactions shown between the determination of the task and the interpretation of the patent, the task could possibly also be defined in a first step to the effect that the adverse toxic effects of the antifolate used are to be reduced without adversely changing the intended effects. However, the contested decision would only be legally erroneous from this point of view if the Court of Appeal had drawn conclusions for the interpretation of the patent in suit from the narrower definition it had chosen.

18 There are no indications of such circular reasoning in the judgment under appeal. On the contrary, the Court of Appeal consistently took into account in its interpretation that a reduction in toxicity is also possible with other antifolates.

19 3. In order to solve the problem, the patent in suit proposes a use whose features can be divided as follows:

1. Pemetrexed disodium is used for the preparation of a medicament.

2. The medicament is for use in combination therapy to inhibit tumor growth in mammals.

3. The medicament is to be administered in combination with vitamin B12 or a pharmaceutical derivative thereof.

4. The pharmaceutical derivative of vitamin B12 is

hydroxocobalamin, cyano-10-chlorocobalamin, aquocobalamin perchlorate, aquo-10-chlorocobalamin perchlorate, azidocobalamin, chlorocobalamin or cobalamin.

20 According to the description of the patent in suit, the administration of vitamin B12 leads to a reduction of methylmalonic acid present in the body. Why this effect is important for the reduction of toxicity is not shown.

21 II. The Court of Appeal gave the following main reasons for its decision:

22 According to the literal sense of feature 1, the use of pemetrexed disodium is required. This term designates a specific chemical compound, namely the disodium salt of the antifolate pemetrexed. For the skilled person, a team consisting of an oncologist and a pharmacologist, there was no indication from the patent specification in suit that the patent claim was based on a different linguistic usage. Rather, the description states that the antifolate for use in the invention is pemetrexed disodium (Alimta). With one exception, the description also consistently refers to pemetrexed disodium - often with a reference in parentheses to the product Alimta marketed by the plaintiff - and not to pemetrexed. Pemetrexed is mentioned only in connection with a state of the art study on the effects of folic acid. The fact that pemetrexed disodium refers exclusively to the compound in question and not to derivatives of pemetrexed in general is further confirmed by the fact that the patent in suit claims protection for the active ingredient vitamin B12 to be used in combination and for the binder provided for in patent claim 2 not only for the specific compound but also for derivatives. Against this background, a function-oriented interpretation could not lead to a different result. The finding that the antifolate effect of pemetrexed was decisive did not justify extending claim 1 beyond its unambiguous wording. The same applied to the fact that the weight data in the description of the embodiments referred to pemetrexed. The definition of the term "antifolate" contained in the description was also clear and unambiguous. That the term "pemetrexed disodium" was to be understood literally was further confirmed by the opinion of the examiner in the grant proceedings, who had objected to earlier claim versions which had provided for the use of an antifolate

or of pemetrexed in feature 1 on the grounds that only the use of pemetrexed disodium was disclosed as belonging to the invention in the documents originally filed.

23 Pemetrexeddicalium could not be regarded as an equivalent agent. It was irrelevant whether it had the same effect and whether its use as a replacement agent had been obvious to the skilled person. In any case, equivalence was lacking because the patent claim was limited to a single chemical compound, although the skilled person could only take the message from the patent specifications as a whole that the invention could be successfully carried out with any antifolate. An embodiment is excluded from the scope of protection of the patent if it is disclosed or can in any case be found by a skilled person, but the reader of the patent specification must assume that - for whatever reason - it was not intended to be protected. In this respect, it could make no difference whether alternative solution variants were noted in a detailed list or whether they were named collectively, as it were, using superordinate generic terms. In the latter case, however, only those substitutes were excluded from equivalence protection which were already known on the priority date. This applies to pemetrexed dipotassium because European patent specification 432 677 discloses that pemetrexed can also be used in the form of a potassium salt. The discrepancy between the description text and patent claim 1 also reflected the course of the granting procedure. It was not acceptable to include in the patent protection subjects which the applicant had deliberately dropped during the examination procedure. Any other handling would irresponsibly neglect the aspect of legal certainty. The patent proprietor should not burden competitors with the task and the risk of correctly defining the scope of protection of the patent.

24 The defendant also did not indirectly infringe the patent in suit with the distribution it was considering. It is true that the challenged embodiment is administered by infusion and that the infusion solution contains sodium ions. However, it does not follow from this that pemetrexedisodium is used at any time for the preparation of a medicament.

25 III. This assessment does not stand up to legal scrutiny in two decisive respects.

26 1. Without error of law, the Court of Appeal reached the conclusion that the term "pemetrexed disodium" is not to be interpreted in the sense of "pemetrexed".

27 a) The appeal complains that the Court of Appeal defined the requirements for a function-oriented interpretation too narrowly.

28 This complaint is unfounded.

29 With reference to the judgment of the court of first instance, the Court of Appeal stated that a function-oriented interpretation is in principle required, but may not lead to a spatially and physically defined feature being reduced to its mere function, because otherwise the boundary between literal and equivalent use would be dissolved.

30 This is in accordance with the case law of the Senate. It is true that the patent in suit is not concerned with a device, but - to which we shall return (III 3 a) - with the protection of a substance for a specific purpose in the form of a claim to use; accordingly, it is not the spatially and physically defined features and their function that are important, but the material properties. In this respect, however, the same principles apply. Even in the context of such a use claim, there may be limits to a purely functional understanding of the relevant material compound in the context of claim interpretation.

31 In the "Spannschraube" decision cited by the appeal, the Senate stated that the interpretation of a feature must be based decisively on its purpose as expressed in the patent specification (Federal Court of Justice, judgment of 2 March 1999 - X ZR 85/96, GRUR 1999, 909, 911 Spannschraube). It cannot be inferred from this that specifications contained in the patent claim concerning the spatial-physical or - as here - material design of a feature must always take a back seat. In the case decided at that time, it was rather a matter of the fact that a certain aspect - namely the question in which way a washer must be "inserted" between a flange and a screw head - had not been explicitly defined in the patent claim. In this initial situation, the Senate did not consider it an error of law that the Court of Appeal, in a function-oriented interpretation, had come to the conclusion that the insertion had to be effected by a linear movement.

32 In the decision "Staubsaugersaugrohr" (vacuum cleaner suction tube), also cited by the appeal, the Senate stated that a function-oriented interpretation is appropriate at any rate if the wording of the patent claim does not essentially permit a fixed understanding (Federal Court of Justice, order of 12 October 2004 - X ZR 176/02, GRUR 2005, 41, 42 - Staubsaugersaugrohr). This does not contradict the approach taken by the Court of Appeal and is consistent with the view expressed shortly before in the literature and cited by the Regional Court that spatial-physical definitions may not be completely disregarded (Meier-Beck, GRUR 2003, 905, 907).

33 The decision of the Court of Appeal remains within this framework. The Court of Appeal did not reject an interpretation based exclusively on function in the case in dispute solely on the basis of what it considered to be the unambiguous wording of the claim, but rather because it considered the aspects it had previously dealt with, which in its opinion speak in favor of a close orientation to the wording, to be decisive. This does not reveal any error of law.

34 In particular, the Court of Appeal took into account the aspects pointed out by the appeal, namely that the tumor-inhibiting effect emanates solely from the pemetrexedione and that the disodium salt is dissolved before being administered to a patient, so that the ionic compound dissolves. Contrary to the opinion of the appeal, it does not necessarily follow from these aspects that the indication "pemetrexed disodium" contained in the patent claim must be interpreted beyond its wording. The circumstances considered decisive by the Court of Appeal, in particular the uniform use of language within the patent specification, its consistency with the wording of the patent claim and the fact that pharmaceutical derivatives are also expressly claimed for vitamin B12 and other substances, rather speak decisively in favor of taking the patent claim at its word in this respect.

35 b) The appeal complains that the Court of Appeal based its interpretation of the patent in suit on documents from the grant proceedings.

36 In doing so, it also fails to show any legal error relevant to the decision.

37 aa) The appeal claims that the selective consideration of documents

from the grant procedure is in conflict with the case law of the Senate.

38 This is incorrect.

39 As the Court of Appeal correctly pointed out, according to the case law of the Senate it is permissible to use statements made by the applicant in the grant procedure as an indication of how the skilled person understands the subject matter of the patent (Federal Court of Justice, judgment of 5 June 1997 - X ZR 73/95, NJW 1997, 3377, 3380 - Weichvorrichtung II). Nothing else applies to statements made by the examiner.

40 However, such indications cannot be used without further ado as the sole basis for interpretation. However, no legal errors in this respect can be inferred from the contested judgment. On the contrary, the Court of Appeal only used the statement of the examiner, according to which the mention of pemetrexed disodium did not disclose the more general term "pemetrexed", as additional confirmation for its interpretation based on other aspects.

41 bb) The appeal complains that the Court of Appeal disregarded the plaintiff's argument that the examiner's statement did not allow any conclusions to be drawn as to the understanding of the skilled person because it was based on the strict concept of disclosure of the European Patent Office, which was simply guided by the wording of the documents.

42 This complaint is also unfounded.

43 It is true that the Court of Appeal did not expressly deal with the aforementioned aspect in more detail. However, in view of the comprehensive reasoning on which the Court of Appeal based its interpretation of the patent in suit, it seems impossible that the Court of Appeal would have reached a different result if it had taken this aspect into account.

44 As already mentioned, the Court of Appeal used the statement of the examiner only as additional confirming circumstantial evidence. If it had regarded this statement not as an indication of the expert's understanding but merely as a statement of a legal opinion, it would not have been permitted to attribute to it an indicative effect in the present context, either in one direction or

in the other. However, according to the assessment of the Court of Appeal, which is free of errors of law, all remaining aspects also speak in favor of the result of interpretation which the Court of Appeal considered to be correct.

45 c) The appeal claims that the Court of Appeal should also have included the statements made by the applicant in the grant proceedings in its assessment.

46 In doing so, it does not demonstrate a procedural error.

47 The plaintiff did assert this argument in the present legal dispute. However, it cannot be inferred from the fact that the Court of Appeal did not expressly deal with it that the Court of Appeal disregarded an essential aspect of its reasoning. The plaintiff's statement at issue in the grant proceedings is identical in substance to its legal argumentation in the infringement proceedings. The Court of Appeal dealt with this in detail.

48 2. Contrary to the opinion of the Court of Appeal, an infringement of the patent in suit by equivalent means cannot be denied by recourse to the principles developed by the Senate regarding the selection decision.

49 a) According to the established case law of the Senate, infringement of a patent by equivalent means can only be affirmed if the considerations which the skilled person must make in order to find a modified means as objectively having the same effect are oriented to the meaning of the technical teaching protected in the patent claim (Federal Court of Justice, judgment of 12 March 2002 - X ZR 168/00, BGHZ 150, 149, 154 = GRUR 2002, 515, 517 - Schneidmesser I; judgment of 14 December 2010 - X ZR 193/03, GRUR 2011, 313 marginal no. 35 - Crimpwerkzeug IV).

50 aa) Orientation to the patent claim requires that the patent claim in all its features not only forms the starting point, but also the decisive basis for the considerations of the skilled person (Federal Court of Justice, judgment of 29 November 1988 - X ZR 63/87, BGHZ 106, 84, 90 et seq. = GRUR 1989, 205, 208 - Schwermetalloxidationskatalysator; judgment of 12 March 2002 - X ZR 168/00, BGHZ 150, 149, 154 = GRUR 2002, 515, 517 - Schneidmesser I). If, when viewed objectively, the patent is limited to a narrower version of the claim

than would be required by the technical content of the invention and in relation to the state of the art, those skilled in the art may trust that the protection is correspondingly limited. The patent proprietor is then precluded from subsequently claiming protection for something which he has not had placed under protection. This applies even if the skilled person recognizes that the effect according to the invention as such (in the narrower sense described above) could be achieved beyond the scope of protection provided in the patent claim (Federal Court of Justice, judgment of 12 March 2002 - X ZR 168/00, BGHZ 150, 149, 159 = GRUR 2002, 515, 518 - Schneidmesser I). Therefore, an embodiment is excluded from the scope of protection of the patent which may be disclosed or at least discoverable by a skilled person, but which the reader of the patent specification must assume - for whatever reasons - was not intended to be protected (Federal Court of Justice, judgment of 10 May 2011 - X ZR 16/09, BGHZ 189, 330 = GRUR 2011, 701 marginal no. 36 Okklusionsvorrichtung; judgment of 13 September 2011 - X ZR 69/10, GRUR 2012, 45 marginal no. 44 - Diglycidverbindung).

51 As the Senate understands it, this criterion corresponds to the third of the three so-called improver or protocol questions which the UK courts have consistently used to assess whether an embodiment which is not covered by the primary, literal or contextually detached wording of the patent claim nevertheless falls within the scope of protection of the patent. According to this case law, such an embodiment, even if the variation has no substantial influence on the effect according to the invention and this circumstance was obvious to the skilled person, does not fall within the scope of protection of the patent if it can be inferred from the patent claim from the point of view of a skilled person that the conformity with the primary wording is one of the essential requirements of the invention (similarly already for national patents: Catnic Components Ltd v Hill & Smith Ltd [1982] RPC 183 para. 242 f.; fundamental to Art. 69 EPC: Improver Corporation v Remington Consumer Products Ltd (Hoffman J), [1990] FSR 181 para. 289, cited in the two decisions concerning the patent-in-suit here, Actavis UK Ltd & Ors v Eli Lilly & Company, [2014] EWHC 1511 (Arnold J), para. 92 [to that extent not in GRUR Int. 2015, 52]; [2015] EWCA Civ 555 (Floyd LJ), para. 46).

52 bb) For cases in which the patent claim is based on a selection decision between different possibilities, the Senate has concretized the requirement of orientation on the patent claim to the effect that the considerations of the skilled person on possible variations must also be in line with this selection decision (Federal Court of Justice, judgment of 10 May 2011 - X ZR 16/09, BGHZ 189, 330 = GRUR 2011, 701 marginal no. 35 Okklusionsvorrichtung). Therefore, a patent infringement by equivalent means is generally to be denied if the description discloses several possibilities how to achieve a certain technical effect, but only one of these possibilities has been included in the patent claim (Federal Court of Justice, judgment of 10 May 2011 - X ZR 16/09, BGHZ 189, 330 = GRUR 2011, 701 marginal no. 35 - Okklusionsvorrichtung; judgment of 13 September 2011 X ZR 69/10, GRUR 2012, 45 marginal no. 44 - Diglycidverbindung).

53 b) Contrary to the opinion of the Court of Appeal, the latter requirements are not met in the case in dispute.

54 aa) As the appeal rightly asserts and as the Court of Appeal did not fail to recognize in its approach, the starting point of the dispute is different from the cases on which the decisions "Occlusion Device" and "Diglycid Connection" were based.

55 In these cases, (at least) two specific embodiments were indicated in the description of the patent with which the effect according to the invention could be achieved, and in each case only one of these embodiments was reflected in the patent claim. In the case in dispute, only one embodiment is disclosed in the patent specification. It is indeed stated in the description that the invention relates generally to the use of antifolate drugs by administration of a methylmalonic acid reducing agent such as vitamin B12. However, only the use of pemetrexed disodium is shown as a specific embodiment of this invention.

56 bb) The Court of Appeal assumes that the disclosure of a genus of chemical compounds has the same legal effects as the listing of all compounds belonging to the genus and already known as such on the priority date.

57 This is in contradiction with the recent case law of the Senate.

58 According to this case law, the ability of a skilled person to prepare, with the aid of known methods and his other expertise, a greater or lesser number of individual compounds falling within a disclosed structural formula may not be equated with the disclosure of these individual compounds. Rather, the individual compounds represent, at least regularly, useful applications of the technical information given to the skilled person by the disclosure of the structural formula or otherwise of a more general formula. By their communication, the individual compounds falling thereunder are not disclosed as such. In order to make them "available" to the skilled person in the sense of the novelty test, further information is generally required, in particular regarding their individualization (Federal Court of Justice, judgment of 16 December 2008 - X ZR 89/07, BGHZ 179, 168 = GRUR 2009, 382 marginal no. 28 - Olanzapin; judgment of 10 September 2009 - Xa ZR 130/07, GRUR 2010, 123 marginal no. 31 - Escitalopram).

59 In the case in dispute, pemetrexeddicalium is not expressly named in the patent specifications. The fact that it is an antifolate and belongs to the same group as pemetrexed disodium is not sufficient, according to the case law cited, to regard it as disclosed by the patent specification in suit. Special circumstances which could indicate that the skilled person nevertheless reads this compound, as it were, have not been established.

60 cc) Contrary to the opinion of the Court of Appeal, the principle developed in the decision "Occlusion Device" cannot be transferred to the constellation of the dispute already if the use of pemetrexed dipotassium instead of pemetrexed disodium is suggested by the patent specification in suit.

61 As already explained above, the above-mentioned principle is admittedly based on the more general consideration that an embodiment is excluded from the scope of protection of the patent if it is disclosed or in any case discoverable by the skilled person, but the reader of the patent specification must assume that - for whatever reasons - it was not intended to be protected. However, as the appeal correctly points out, the Senate has established the principle itself only for the constellation that the patent specification itself discloses several possible embodiments. An extension to embodiments, which could be found on the basis of the information in the patent specification, on the other hand, would

be going too far, if only because findability is a basic prerequisite for the affirmation of equivalence and the use of modified means could consequently never lead to a patent infringement.

62 dd) On the other hand, it does not necessarily follow from this that the affirmation of a selection decision is absolutely excluded in the case constellation to be assessed here.

63 From the content of the patent specification or from other circumstances relevant for the interpretation it may result in individual cases that the focus on a single compound from a group of substances, which are classified as suitable in the description without further differentiation, is based on a selection which excludes the inclusion of further compounds belonging to the group in the scope of protection of the patent. This can be considered, for example, if the compound included in the patent claim has a special property compared to other compounds of the disclosed group, which is important for the realization of the function according to the invention. However, this is a question of the individual case for which no general rules can be established.

64 ee) No generally valid conclusions can be drawn from a comparison between the valid version of the patent and the (published) application or any earlier versions of the property right either. Therefore, it is not necessary for the assessment of the dispute to decide whether such documents may be taken into account in the interpretation of the applicable version of a patent.

65 (1) If the patent proprietor at a certain stage of the proceedings claims protection for a group of compounds, but later has worded the patent claims in such a way that their literal sense now covers only a single compound, this may indicate in individual cases that he has excluded the remaining compounds from the claim for protection. Then there is room for the application of the principle already mentioned that the patent proprietor may not subsequently claim protection for something which he has not had protected by means of the legal concept of equivalence.

66 (2) However, the assumption that with the concretization of the claim all other compounds belonging to the disclosed group are excluded from

protection can only be considered under certain conditions.

67 It may be justified in individual cases if a comparison of the different claim versions, taking into account the other contents of the corresponding application or patent specification, shows sufficiently clearly that the specification was made in order to delimit the subject matter of the patent from the state of the art and thus to avoid doubts as to patentability. If this is the case, the affirmation of a selection decision is generally not excluded even if the concretization would not have been necessary when viewed objectively, because the reasons for refraining from including certain embodiments are generally irrelevant according to the case law shown above.

68 If the specification was made with regard to formal requirements - again irrespective of whether these requirements objectively existed - or if it is not sufficiently clear for what reason it was made, on the other hand, a selection decision in the above sense cannot generally be assumed. Insofar as the patent claim is given a relatively narrow wording, for example for reasons of claim clarity or to avoid an inadmissible extension, no compelling conclusions can be drawn therefrom for the question of infringement by equivalent means, if only because these two aspects are not of direct importance for equivalence. As a rule, the question of claim clarity cannot arise because it is only a question of whether the use of a certain means of substitution is to be regarded as equivalent, and for this purpose it is in principle irrelevant whether other equivalent means of substitution can be considered. The question of whether an embodiment is disclosed in the originally filed documents as belonging to the invention is also generally of no significance, because an exchange means can also be equivalent if it is disclosed neither in the application nor in the patent, but was suggested to the skilled person by the state of the art.

69 c) In the case in dispute, the orientation to the patent claim cannot be denied on the basis of the findings made by the Court of Appeal.

70 aa) As the Court of Appeal correctly pointed out, pemetrexeddicalium is not listed as a possible substitution agent in the patent specification in suit. The fact that in the patent specification all antifolates are classified as suitable for use according to the invention, and the conclusion resulting at least indirectly

therefrom that this also applies in principle to all pemetrexed compounds, cannot in itself support the assumption of a selection decision for the reasons stated above.

71 bb) Nothing else applies to the fact that in the application the plaintiff claimed protection for the use of any antifolate in combination with any methylmalonic acid reducing agent.

72 The comparison of the two versions does not provide sufficient information as to the reason for the concretization to pemetrexedisodium as well as vitamin B12 and its derivative. The content of the granting file, which was additionally referred to by the Court of Appeal, indicates that it was based on formal considerations. Thus, the assumption of a selection decision is not justified for the reasons outlined above.

73 cc) The protection of legal certainty for third parties does not necessarily require the exclusion of pemetrexeddicalium from the scope of protection of the patent in suit.

74 Legal certainty for third parties is of considerable importance according to Art. 1 sentence 3 Protocol on the Interpretation of Article 69 EPC. However, according to this provision, the interests of the patent proprietor must also be taken into account. According to Art. 1 sentence 3 of the Protocol, the conflicting interests are to be appropriately balanced, combining adequate protection for the patent proprietor with sufficient legal certainty for third parties. According to Art. 2 of the Protocol, due consideration shall also be given to those elements which are equivalents of the elements mentioned in the patent claims.

75 In view of this, the inclusion of an embodiment in the scope of protection of a patent cannot be refused merely because the patent proprietor has failed to give his patent a version in which the embodiment would be covered by the literal sense of the patent claim. The consequence associated with the inclusion of equivalents, i.e. that legal transactions cannot accurately and conclusively assess the scope of protection of the patent in every respect on the basis of the claim wording alone, cannot lead to a different assessment, if only because according to Art. 69 EPC the description and drawings are to be used for the

interpretation of the patent claim.

76 dd) Contrary to the view of the defendant, the orientation to the patent claim cannot be denied solely because the term "pemetrexed disodium" represents an exact circumscription for a certain chemical compound whose degree of detail is comparable to that of a numerical indication.

77 (1) According to the case law of the Senate, an unambiguous numerical indication in principle conclusively defines and limits the protected subject matter in this respect. However, this does not exclude that the skilled person considers a certain degree of vagueness to be compatible with the technical meaning of a numerical indication. Whether and to what extent this is to be affirmed depends on the circumstances of the individual case (Federal Court of Justice, judgment of 12 March 2002 - X ZR 168/00, BGHZ 150, 149, 156 f. = GRUR 2002, 515, 518 - Schneidmesser I).

78 (2) In principle, nothing else applies to the indication of a substance name or a chemical formula.

79 In individual cases, such a designation may have the same degree of concretization as a numerical designation. This may mean that substances which do not fall under this definition are not covered by the literal sense of the patent claim. However, just as in the case of numerical indications, all this does not justify without further ado the conclusion that the use of a compound having the same effect and detectable by the skilled person is not oriented to the meaning of the patent claim.

80 (3) Contrary to the view of the defendant, the fact that the description of the patent-in-suit (para. 22) expressly states that the antifolate for use in the invention is pemetrexed disodium does not lead to a different assessment.

81 It is true that these statements in the description support and confirm the assessment that the term "pemetrexedisodium" used in the patent claim is to be understood in the general technical sense, i.e., as an exact scientific definition of a particular chemical compound. However, the use of such a definition is not sufficient for the reasons mentioned to be able to deny an orientation to the patent claim. A further definition can neither be inferred from the definition

contained in the description of the patent in suit nor from the term in the patent claim itself, which is characterized in more detail by the definition.

82 (3) The Court of Appeal also erred in law in denying contributory patent infringement.

83 a) According to the case law of the Senate, the subject matter of a patent claim directed to the use of a substance for the treatment of a disease is the suitability of the substance for a specific medical purpose and thus ultimately an inherent property of the substance (Federal Court of Justice, order of 5 October 2005 - X ZB 7/03, BGHZ 164, 220 = GRUR 2006, 135 - Arzneimittelgebrauchsmuster). This corresponds in substance to a purpose-related substance protection as expressly provided for by Sec. 3(4) Patent Act and Art. 54(5) EPC in the version applicable since 13 December 2007. This applies irrespective of whether the wording of the patent claim is directed to the protection of the substance for a specific purpose, to the use of the drug or to its preparation for a specific purpose (Federal Court of Justice, order of 25 February 2014 - X ZB 5/13, BGHZ 200, 229 = GRUR 2014, 461 marginal no. 17 - Kollagenase I).

84 Nothing else applies to claims directed to the use of the substance for the manufacture of a medicament in accordance with the earlier legal practice of the European Patent Office. This special claim version, called Swiss type claim, took into account the fact that the use of a substance for the treatment of a disease was not amenable to patenting in the opinion of the European Patent Office. The solution chosen instead, namely to direct the protection to the use for the manufacture of a medicament, does not change the fact that, in substance, a particular property of the substance is protected, which is also inherent in the manufactured medicament.

85 A different assessment would not result even if Swiss type claims were understood according to their wording as claims directed to the protection of a manufacturing process. Based on such an understanding, a drug manufactured according to the protected process would have to be regarded as a direct process product, which may also only be offered, marketed and used by the patent proprietor for the protected purpose according to Sec. 9 No. 3 Patent Act.

As a result, this also led to a substance protection limited to the intended use.

86 b) The decision of the Court of Appeal is in conflict with these principles.

87 The Court of Appeal left open whether the medicinal product, which the defendant intends to market is to be dissolved in a saline solution before administration and whether a mixture of pemetrexediones and at least twice as many sodium ions is produced in the process. It considered the plaintiff's arguments in this regard to be irrelevant, if only because the patent claim was directed to the use of the disodium salt for the preparation of a medicament.

88 In doing so, the Court of Appeal failed to take into account the fact that even such a claim version grants limited substance protection. An infringement of the patent in suit cannot be rejected solely on the basis of this claim version. Rather, insofar as a mixture of pemetrexediones and at least twice as many sodium ions is to be regarded as pemetrexedisodium within the meaning of claim 1, and such a mixture is prepared prior to the intended administration of the medicament which the defendant wishes to market, indirect patent infringement must be affirmed - in accordance with the decision of the Court of Appeal for England and Wales handed down after the judgment of appeal (Floyd LJ, [2015] EWCA Civ 555, paras. 74-92).

89 IV. The case is not ready for final judgment.

90 The Court of Appeal expressly left open whether the use of pemetrexeddicalium should be regarded as a like product and whether it was discoverable as such by the skilled person. The assessment of these two questions - the second of which the UK courts have answered in the negative (Arnold J, [2014] EWHC 1511, paras 120-128 [to that extent not in GRUR Int. 2015, 52]; Floyd LJ, [2015] EWCA Civ 555, paras 62-71) - requires additional factual findings.

91 The Court of Appeal will also have to clarify the questions it left open regarding contributory patent infringement, insofar as this aspect should still be relevant in the further course of the proceedings, despite the defendant's statement in the meantime before the UK courts that it intends to market the

drug for administration in a dextrose solution (Arnold J [2016] EWHC 234).

Meier-Beck Gröning Bacher

Hoffmann Schuster

Previous instance:
Regional Court of Düsseldorf, judgment of 3 April 2014 – 4b O 114/12 –
Higher Regional Court of Düsseldorf, judgment of 5 March 2015 – I-2 U 16/14 –