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

[*Certified translation from the German language*]

Reference work: yes

BGHZ: yes

BGHR: yes

[*Stamp*:] Received, 19 July 2016,
Jordan & Hall
Lawyers at the German Federal Court of
Justice [*Bundesgerichtshof – BGH*]

Pemetrexed

EPC, art. 69(1); Protocol on the Interpretation of Article 69 EPC, arts. 1, 2; German Patent Act [*Patentgesetz – PatG*], sec. 14

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

b) For this principle to be applicable, it is not sufficient that, as a result of statements in the description or for other reasons, an embodiment claimed by the patent constitutes a specific application of a more general solution principle and that, as a result of this knowledge, the person skilled in the art was able to discover further embodiments corresponding to this solution principle.

German Federal Court of Justice, judgment of 14 June 2016 – X ZR 29/15 –

Dusseldorf Court of Appeals [*Oberlandesgericht – OLG*]
District Court [*Landgericht*] of Dusseldorf

[*Certified translation from the German language*]

[*Stamp*:] Received, 19 July 2016,
Jordan & Hall
Lawyers at the German Federal Court of Justice

[*Coat of arms*]

GERMAN FEDERAL COURT OF JUSTICE

IN THE NAME OF THE PEOPLE

JUDGMENT

X ZR 29/15

Pronounced on:
14 June 2016
Anderer
Justice Officer as
Clerk of the Court
[*Justizangestellte als Urkundsbeamtin der Geschäftsstelle*]

in the matter of

Eli Lilly & Co., represented by its Chief Executive Officer,
Indianapolis (United States of America),

Plaintiff and Appellant,

- legal representative: Rechtsanwälte Jordan and Dr Hall -

versus

1. Actavis Group PTC ehf, represented by the chairman of the management board, Reykjavikurvegi 76–78, Hafnarfjordur (Iceland),

Defendant and Appellee,

- legal representative: Rechtsanwälte von Gierke and Prof. Dr Rohnke -

2. … ,

3. … ,

Defendants

Following the oral hearing held on 14 June 2016, Civil Panel X of the German Federal Court of Justice, through the Presiding Judge Prof. Dr Meier-Beck and the judges Gröning, Dr Bacher, Hoffmann and Schuster,

found as follows:

In response to the Plaintiff's appeal on questions of law, the judgment of the 2nd Civil Division of the Dusseldorf Court of Appeals of 5 March 2015 is set aside.

The matter is remanded to the appellate court for a new hearing and decision, also on the costs of the appeal on questions of law.

In the name of the law

Facts of the case:

1 The Plaintiff is the proprietor of European patent 1 313 508 (patent in suit), which has been granted with effect for the Federal Republic of Germany, was registered on 15 June 2001 and relates to the use of pemetrexed disodium in combination with vitamin B12 to inhibit tumour growth. Claim 1 reads as follows in the language of the proceedings:

> 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 Furthermore, the Plaintiff is a co-proprietor of European patent 432 677 and of supplementary protection certificate 12 2005 000 012, which relates to Pemetrexed and pharmaceutically acceptable salts thereof, which was granted in Germany for the period up to 10 December 2015 on the basis of European patent 432 677.

3 The Defendant under 1 (hereinafter: the Defendant) informed the Plaintiff by lawyers' letter dated 12 July 2012 that, after the expiry of the protection certificate, it intended to launch a medicinal product with the active agent pemetrexed dipotassium on the market as a generic drug containing the reference medicinal product Alimta, which is distributed by the Plaintiff and contains the active agent pemetrexed disodium.

4 The Plaintiff filed a cease and desist claim against the Defendant, its German distribution company and the latter's managing director. The District Court found against the Defendant in accordance with the alternative motion based on an infringement of the patent in suit by equivalent means, and dismissed the remainder of the complaint. The appellate court dismissed the complaint in its entirety. The Plaintiff objected to this by filing an appeal on questions of law which was permitted by the panel, and is contested by the Defendant.

Grounds for the decision:

5 The appeal on questions of law leads to the judgment under appeal being set aside and the matter being remanded to the appellate court.

6 I. The patent in suit relates to the use of pemetrexed disodium in combination with vitamin B12 to inhibit tumour growth in mammals.

7 1. The patent specification in suit explains that antifolates represent one of the most thoroughly studied classes of antineoplastic agents. It also states that antifolates lead to the inhibition of one or several key enzymes for the biosynthesis of thymidine and purine by competing with reduced folates for binding sites of these enzymes. Examples of such antifolates are given as 5-fluorouracil, Tomudex®, Methotrexat®, Lometrexol and pemetrexed disodium (Alimta®).

8 Substantial toxicity, sometimes even resulting in a high mortality risk, is cited in the patent specification in suit as a factor limiting the development of such medicinal products. It is stated that folic acid and retinoid compounds such as vitamin A were used as a means of reducing toxicity. However, the patent specification in suit states, cytotoxic activity of antifolates remains cause for serious concern in the development of such medicinal products.

9 2. The patent specification in suit does not expressly state to which technical problem the patent in suit relates.

10 a) The appellate court formulated the object of the patent in suit as being to reduce the adverse toxic effects for patients that are caused by the administration of pemetrexed disodium as an antifolate, without adversely affecting therapeutic efficacy.

11 b) The appeal on questions of law objects to this formulation, stating that it is flawed. It takes the view that the appellate court should not have defined the problem underlying the patent in suit without first construing the patent claim.

12 This objection is unfounded.

13 aa) Pursuant to the rulings of the panel, the determination of the technical problem (the object) in nullity or opposition proceedings serves to locate the starting point of efforts undertaken by the person skilled in the art to enhance the prior art without having any knowing of the invention, in order to assess – during the subsequent and separate review of patentability – whether the solution proposed for the purpose of such enhancement was suggested by the prior art or not (German Federal Court of Justice, judgment of 11 November 2014 – X ZR 128/09, GRUR 2015, 356 margin no. 9 – *Repaglinid*). However, the purpose of this determination is not to decide in advance on the question of patentability (German Federal Court of Justice, judgment of 13 January 2015 – X ZR 41/13, GRUR 2015, 352 margin no. 16 – *Quetiapin*).

14 The same premises apply to infringement proceedings. In order to assess the question of whether the respective contested embodiment makes use of the patented teaching, it is necessary to establish – through construction of the patent claim – the extent to which the efforts by the person skilled in the art to enhance the prior art are specifically reflected in the patent claim (cf. for example German Federal Court of Justice, judgment of 24 July 2012 – X ZR 126/09, GRUR 2012, 1130 margin no. 9 – *Leflunomid*). The determination of the technical problem contributes to establishing what the invention actually achieves in this respect (cf. German Federal Court of Justice, judgment of 4 February 2010 – Xa ZR 36/08, GRUR 2010, 602 – *Gelenkanordnung*). It follows from this that, in the grounds for a decision, a court cannot postpone addressing the technical problem until it has construed the patent claim. There is, in fact, a certain interaction between the determination of the object and the construction of the patent claim. As a rule, it is thus expedient and necessary to reflect on the technical problem in advance. This is because both the meaning of the patent claim in its entirety and the contribution made by the individual features to the solution offered by the invention must be determined in the course of construction (cf. for example German Federal Court of Justice, judgment of 17 July 2012 – X ZR 117/11, BGHZ 194, 107 = GRUR 2012, 1124 margin no. 27 – *Polymerschaum I*). As a rule, this requires obtaining an initial idea of what the technical problem concerned is.

15 It would only be legally flawed to define the technical problem during this initial consideration in such a way that this constituted a decision in advance on how to construe the patent claim. Just like the remaining content of the patent specification, statements on the object of the invention that are contained in the patent specification must not lead to a narrowing of the material scope of the subject matter defined by the literal meaning of the patent claim (German Federal Court of Justice, judgment of 4 February 2010 – Xa ZR 36/08, GRUR 2010, 602 margin no. 27 – *Gelenkanordnung*; judgment of 17 July 2012 – X ZR 113/11, GRUR 2012, 1122 margin no. 22 – *Palettenbehälter III*). Furthermore, such statements must be disregarded even if the patent claim does not specify any means by which the object in question could be achieved (German Federal Court of Justice, judgment of 25 February 2014 – X ZR 84/12, margin no. 13). These principles also apply to a description of the object of the patent that is not contained in the patent specification. Any description of the object of the patent must therefore be reviewed in a subsequent step in order to establish whether it is consistent with the specifications of the patent claim that were determined by way of construction.

16 bb) In light of this, no error of law is apparent in the decision under appeal.

17 In view of the interactions shown between the determination of the object and the construction of the patent, the object could, in a first step, potentially also be defined in such a way that the adverse toxic effects of the antifolate used are to be reduced without adversely altering the desired effects. However, in this respect, the decision under appeal would be legally flawed only if the appellate court had drawn conclusions for the construction of the patent in suit from the narrower definition chosen by it.

18 No signs of such circular logic are evident in the decision under appeal. In fact, in its construction, the appellate court consistently took into account the fact that a reduction in toxicity is also possible in the case of other antifolates.

19 3. In order to solve the problem, the patent in suit proposes a use, the features of which can be broken down as follows:

1. Pemetrexed disodium is used in the manufacture of a medicament.

2. The medicament is to be used in a combination therapy for inhibiting tumour 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, acetocobalamin, chlorocobalamin, or cobalamin.

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

21 II. The appellate court essentially gave the following grounds for its decision:

22 According to the literal meaning of feature 1, the use of pemetrexed disodium is necessary. This term refers to a specific chemical compound, namely the disodium salt of the antifolate pemetrexed. For the person skilled in the art – a team comprising an oncologist and a pharmacologist – there is no indication from the patent specification in suit that the patent claim is based on different terminology to that used in the patent specification in suit. In fact, the description states that the antifolate to be used in the invention is pemetrexed disodium (Alimta). Furthermore, the remainder of the description refers – with one exception – consistently to pemetrexed disodium, often followed in brackets by the name of the product distributed by the Plaintiff (Alimta), and not to pemetrexed. Pemetrexed is mentioned merely in connection with a study known in the prior art with regard to the effects of folic acid. Moreover, that pemetrexed disodium exclusively means the compound in question and not derivatives of pemetrexed in general is confirmed by the fact that, with regard to the active agent vitamin B12 to be used in combination and the binding agent provided for in claim 2, the patent in suit claims protection not only for the specific compound, but also for

derivatives. In light of this, function-based construction cannot lead to a different conclusion. The finding that the antifolate effect of pemetrexed is a decisive factor does not justify extending claim 1 beyond its unambiguous wording. The same applies to the fact that the weight information provided in the description of the exemplary embodiments relates to pemetrexed. The definition of the term "antifolate" contained in the description is likewise clear and unambiguous. The fact that the term "pemetrexed disodium" must be understood literally is also confirmed by the comments made by the examiner during the grant procedure; the examiner objected to previous claim versions that provided for the use of an antifolate (or pemetrexed) in feature 1 on the grounds that the originally filed documents only disclosed the use of pemetrexed disodium as forming part of the invention.

23 Pemetrexed dipotassium cannot be regarded as an equivalent means. In this respect, it is irrelevant whether pemetrexed dipotassium has the same effect and whether its use as a replacement means was obvious to the person skilled in the art. In any case, there is a lack of parity because the patent claim specifies a single chemical compound, although the person skilled in the art can only infer from the patent specification in suit in its entirety that the invention can be successfully implemented with any antifolate. An embodiment is excluded from the patent's scope of protection if it is disclosed or at least discoverable by the person skilled in the art, but the reader of the patent specification must assume that the embodiment – for whatever reasons – was not intended to be protected. In this context, it cannot make any difference whether alternative solution variants are noted in a detailed list or are specified collectively using superordinate generic terms, so to speak. In the latter scenario, however, only those replacement means that were already known on the priority date are generally excluded from equivalent protection. 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. Moreover, the discrepancy between the description and claim 1 reflects the course of the grant procedure. It is not acceptable for protected subject matter that the applicant deliberately dropped in the course of the examination procedure to subsequently again be covered by patent protection in the infringement proceedings. Any other approach irresponsibly undermines the aspect of legal certainty. The patent proprietor is not

allowed to impose on its competitors the task and the risk of correctly defining the patent's scope of protection.

24 With the contemplated distribution, the Defendant does not infringe the patent in suit indirectly either. Although the contested embodiment is administered by means of infusion and the infusion solution contains sodium ions, this does not mean that pemetrexed disodium is used at any point to manufacture a medicinal product.

25 III. This assessment does not stand up to legal scrutiny in respect of two decisive points.

26 1. Free of errors of law, the appellate court concluded that the term "pemetrexed disodium" cannot be construed to mean "pemetrexed".

27 a) The appeal on questions of law raises the objection that the appellate court defined the prerequisites for function-based construction too narrowly.

28 This objection is unfounded.

29 With reference to the first-instance judgment, the appellate court stated that function-based construction is necessary as a rule, but must not mean that a feature defined in spatio-physical terms is reduced to its mere function, because otherwise the boundary between literal and equivalent use would cease to exist.

30 This is consistent with the panel's rulings. It is true that the subject matter of the patent in suit is not a device, but is – as will have to be addressed below (III 3 a) – substance protection that is intended for a specific purpose and that takes the form of a use claim; thus, the relevant factor cannot be spatio-physically defined features and their function, but the properties of the substance. However, the same principles apply in this respect. Even with regard to such a use claim, when construing the claim, there may be limits to a purely functional understanding of the relevant compound substance.

31 In the "*Spannschraube*" decision referred to in the appeal on questions of law, the panel stated that the construction of a feature must hinge on its purpose as expressed in the patent specification (German 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 on the spatio-physical or – as in the case at hand – design of a feature in terms of its substance must always be subordinate. In fact, the case decided on at the time concerned the fact that a particular aspect – namely the question of how a washer must be "inserted" between a flange and a screw head – was not explicitly specified in the patent claim. In light of this, the panel did not deem it legally flawed that, in its function-based construction, the appellate court concluded that insertion must take place by way of a linear motion.

32 In the "*Staubsaugersaugrohr*" decision also referred to in the appeal on questions of law, the panel stated that function-based construction was in any case appropriate if the wording of the patent claim did not, in itself, substantially permit a clearly defined understanding (German Federal Court of Justice, decision of 12 October 2004 – X ZR 176/02, GRUR 2005, 41, 42 – *Staubsaugersaugrohr*). This does not contradict the approach taken by the appellate court and is consistent with the view expressed in the literature shortly beforehand and cited by the District Court that spatio-physical specifications must not be completely disregarded (Meier-Beck, GRUR 2003, 905, 907).

33 The decision of the appellate court is within these bounds. In the legal dispute at hand, the appellate court rejected an exclusively function-based construction not solely due to the claim wording, which it considered to be unambiguous, but because it regarded as decisive the aspects that were previously addressed by it and that, in its view, argue in favour of basing construction closely on the wording. This does not indicate any errors of law.

34 In particular, the appellate court took into account the aspects set out in the appeal on questions of law that the tumour-inhibiting effect stems solely from the pemetrexed ion and that the disodium salt is dissolved in a solution before it is administered to a patient, with the result that the group of ions dissolves. Contrary to the view taken in the appeal on questions of law, these aspects do not necessarily

mean that the term "pemetrexed disodium" contained in the patent claim must be construed beyond its wording. Rather, the facts deemed decisive by the appellate court, in particular the consistent terminology within the patent specification, the conformity of the terminology with the wording of the patent claim and the fact that pharmaceutical derivatives are also expressly claimed for vitamin B12 and other substances decisively argue in favour of taking the patent claim at its word.

35 b) The appeal on questions of law raises the objection that the appellate court based its construction of the patent in suit on documents from the grant procedure.

36 In raising this objection, the appeal on questions of law likewise does not identify an error of law that is relevant to the decision.

37 aa) The appeal on questions of law asserts that the selective consideration of occurrences from the grant procedure contradicts the panel's rulings.

38 This is incorrect.

39 As the appellate court correctly demonstrated, it is permissible, pursuant to the panel's rulings, to use statements made by the applicant during the grant procedure as an indication of how the person skilled in the art understands the subject matter of the patent (German Federal Court of Justice, judgment of 5 June 1997 – X ZR 73/95, NJW 1997, 3377, 3380 – *Weichvorrichtung II*). The same applies to statements made by the examiner.

40 However, such indications cannot be readily used as the sole basis for construction. Nevertheless, errors of law in this respect are not apparent from the judgment under appeal. In fact, the appellate court used the examiner's statement, according to which the reference to pemetrexed disodium does not mean that the more general term "pemetrexed" is disclosed, merely as additional confirmation of its construction that is based on other aspects.

41 bb) The appeal on questions of law raises the objection that the appellate court ignored submissions by the Plaintiff, according to which the examiner's statement does not allow any conclusions as to the understanding of the person skilled in the art, because this statement is based on the European Patent Office's strict definition of disclosure, which is based simply on the wording of the documents.

42 This objection is also unfounded.

43 It is true that the appellate court did not explicitly address the aforementioned aspect in detail. However, in view of the extensive grounds on which the appellate court based its construction of the patent in suit, it appears in any case impossible that the appellate court would have reached a different conclusion if it had taken this aspect into account.

44 As already mentioned, the appellate court used the examiner's statement merely as an additional confirming indication. Had the appellate court regarded this statement not as an indication of the understanding of the person skilled in the art, but merely as a statement of a legal opinion, the appellate court would not have been permitted, in the present context, to accord the statement indicative effect in favour of one argument or the other. However, according to the appellate court's assessment, which is free of errors of law, all remaining aspects also support the construction result deemed by the appellate court to be correct.

45 c) The appeal on questions of law asserts that the appellate court should have also included in its assessment the statements made by the applicant during the grant procedure.

46 In asserting this, the appeal on questions of law does not identify any procedural errors.

47 It is true that the Plaintiff asserted this argument in the present legal dispute. However, the fact that the appellate court did not explicitly address this argument does not allow the conclusion that the appellate court ignored a significant aspect of the Plaintiff's argumentation. The statement in question made by the Plaintiff during the

grant procedure is, in substance, consistent with its legal argumentation in the infringement proceedings, which the appellate court addressed in detail.

48 2. Contrary to the appellate court's view, an infringement of a patent in suit by equivalent means cannot be dismissed by referring to the principles developed by the panel regarding the selection decision.

49 a) Pursuant to the established legal practice of the panel, infringement of a patent by equivalent means must be deemed to have been committed only if the considerations that the person skilled in the art must make in order to regard a modified means as objectively having the same effect are based on the meaning of the technical teaching protected in the patent claim (German 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 margin no. 35 – *Crimpwerkzeug IV*).

50 aa) Basing such considerations on the patent claim requires that the patent claim, in all its features, forms not only the starting point, but also the decisive basis for the considerations of the person skilled in the art (German Federal Court of Justice, judgment of 29 November 1988 – X ZR 63/87, BGHZ 106, 84, 90 f. = 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, from an objective point of view, the patent is restricted to a narrower version of the claim than would be necessary based on the technical content of the invention and taking into account the prior art, experts may rely on protection being restricted accordingly. The patent proprietor is then prevented from subsequently claiming protection for something that it did not have protected. This applies even if the person skilled in the art realises that the effect according to the invention as such (in the narrower sense set out above) could be achieved beyond the scope protected in the patent claim (German 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 patent's scope of protection if such embodiment may be disclosed or in any case discoverable by the person skilled in the art, but the reader of the patent specification must assume from the embodiment that – for whatever reasons – it was

not supposed to be protected (German Federal Court of Justice, judgment of 10 May 2011 – X ZR 16/09, BGHZ 189, 330 = GRUR 2011, 701 margin no. 36 – *Okklusionsvorrichtung*; judgment of 13 September 2011 – X ZR 69/10, GRUR 2012, 45 margin no. 44 – *Diglycidverbindung*).

51 According to the panel's understanding, this criterion corresponds to the third of the three so-called improver or protocol questions used by the British courts in their established legal practice in order to assess the question of whether an embodiment that is not covered by the primary, literal or context-independent wording of the patent claim nevertheless falls within the patent's scope of protection. Pursuant to this legal practice, such an embodiment does not fall within the patent's scope of protection – even if the modification has no significant influence on the effect according to the invention and this fact was suggested to the person skilled in the art – if, from the perspective of the person skilled in the art, it must be inferred from the patent claim that conformity with the primary wording is one of the essential requirements of the invention (previous similar cases involving national patents: Catnic Components Ltd vs Hill & Smith Ltd [1982] RPC 183 margin no. 242 f.; fundamental in respect of art. 69 EPC: Improver Corporation vs Remington Consumer Products Ltd (Hoffman J), [1990] FSR 181 margin no. 289, cited in the two decisions relating to the present patent in suit: Actavis UK Ltd & Ors vs Eli Lilly & Company, [2014] EWHC 1511 (Arnold J), margin no. 92 [not in GRUR Int. 2015, 52]; [2015] EWCA Civ 555 (Floyd LJ), margin no. 46).

52 bb) With regard to scenarios in which the patent claim is based on a decision to select between various options, the panel further defined the requirement that the patent claim be used as a basis to the effect that the considerations of the person skilled in the art regarding potential modifications must also be consistent with this selection decision in particular (German Federal Court of Justice, judgment of 10 May 2011 – X ZR 16/09, BGHZ 189, 330 = GRUR 2011, 701 margin no. 35 – *Okklusionsvorrichtung*). This is why, as a rule, there is no patent infringement by equivalent means if the description discloses several possibilities as to how a particular technical effect can be achieved, but only one of these possibilities is included in the patent claim (German Federal Court of Justice, judgment of 10 May 2011 – X ZR 16/09, BGHZ 189, 330 = GRUR 2011, 701 margin no. 35 – *Okklusionsvorrichtung*;

judgment of 13 September 2011 – X ZR 69/10, GRUR 2012, 45 margin no. 44 – *Diglycidverbindung*).

53 b) Contrary to the appellate court's opinion, the requirements referred to above are not met in the dispute at hand.

54 aa) As correctly asserted in the appeal on questions of law, and as the appellate court likewise did not fail to recognise in its initial approach, the starting point of the dispute at hand differs from the cases underlying the "*Okklusionsvorrichtung*" and "*Diglycidverbindung*" decisions.

55 In these cases, the description of the patent listed (at least) two specific embodiments which could be used to achieve the effect according to the invention and, in both cases, only one of these embodiments was included in the patent claim. In the dispute at hand, only one embodiment is disclosed in the patent specification. It is true that the description states that the invention generally relates to the use of antifolate drugs by administering a methylmalonic acid lowering agent such as vitamin B12. However, only the use of pemetrexed disodium is mentioned as a specific embodiment of this invention.

56 bb) The appellate court assumes that the disclosure of a class of chemical compounds has the same legal effects as a listing of all compounds that form part of this class and are already known as such on the priority date.

57 This contradicts the panel's more recent rulings.

58 According to these rulings, the fact that the person skilled in the art, using known methods and his expert knowledge, is able to produce a greater or smaller number of individual compounds which are attributable to a disclosed structural formula must not be equated with the disclosure of these individual compounds. In actual fact, the individual compounds, at least as a rule, constitute practical applications of the technical information provided to the person skilled in the art by the disclosure of the structural formula or any other more general formula. The provision of such formulas does not constitute a disclosure of the individual compounds covered that are

attributable to such formula as such. In order to make them available to the person skilled in the art for the purpose of the examination of novelty, further information – in particular on their customisation – is usually required (German Federal Court of Justice, judgment of 16 December 2008 – X ZR 89/07, BGHZ 179, 168 = GRUR 2009, 382 margin no. 28 – *Olanzapin*; judgment of 10 September 2009 – Xa ZR 130/07, GRUR 2010, 123 margin no. 31 – *Escitalopram*).

59 In the dispute at hand, pemetrexed dipotassium is not mentioned explicitly in the patent specification in suit. Pursuant to the established legal practice referred to, the fact that pemetrexed dipotassium is an antifolate and forms part of the same group as pemetrexed disodium is not sufficient for it to be considered disclosed in the patent specification in suit. Particular circumstances which could indicate that the person skilled in the art would nevertheless infer this compound have not been determined.

60 cc) Contrary to the appellate court's opinion, the principle developed in the "*Okklusionsvorrichtung*" decision cannot be applied to the scenario in the dispute at hand simply because the use of pemetrexed dipotassium instead of pemetrexed disodium is suggested by the patent specification in suit.

61 It is true that, as already set out above, the principle referred to is based on the more general consideration that an embodiment is excluded from the patent's scope of protection if it is disclosed or at least discoverable by the person skilled in the art, but the reader of the patent specification must assume that the embodiment – for whatever reasons – was not intended to be protected. However, as is correctly stated by the appeal on questions of law, the panel established this principle as such solely for the scenario in which the patent specification itself discloses several possible embodiments. In contrast, extending this principle to cover embodiments which were discoverable on the basis of the statements in the patent specification would go too far for the reason alone that discoverability is a basic requirement for establishing the existence of equivalence and the use of modified means could therefore never result in a patent infringement.

62 dd) On the other hand, this does not necessarily mean that it is simply out of the question to deem that the case scenario to be assessed here entails a selection decision.

63 In the individual case, it is possible that the content of the patent specification or other circumstances relevant to the construction may mean that the focus on a single compound from a group of substances, which are classified as suitable in the description without any further differentiation, is based on a selection which rules out the inclusion of other compounds that form part of the group in the patent's scope of protection. This may be the case, for example, if the compound included in the patent claim has a particular property compared to other compounds of the disclosed group which is relevant to the realisation of the function according to the invention. However, this is a question which must be raised in the individual case and for which it is not possible to establish general rules.

64 ee) Nor is it possible to draw generally applicable conclusions from a comparison between the applicable version of the patent and the (published) application or any previous versions of the IP right. This is why the assessment of the dispute at hand does not require a decision as to whether such documents may be taken into account when construing the applicable version of a patent.

65 (1) If the patent proprietor claims protection for a group of compounds at a certain stage of the proceedings, but has subsequently worded the patent claims in such a way that their literal meaning covers one individual component only, this may be an indication, in the individual case, that the patent proprietor deleted the other compounds from the application for protection. This leaves room for applying the aforementioned principle which stipulates that the patent proprietor may not use the legal concept of equivalence to subsequently claim protection for something for which it did not seek protection.

66 (2) However, the assumption that adding further details to the claim version means that all other compounds forming part of the disclosed group are excluded from protection is possible under certain conditions only.

67 This assumption may be justified in the individual case if it becomes sufficiently clear from a comparison of the different claim versions, taking into account the further content of the respective application and/or patent specification, that the further details were added to differentiate the subject matter of the patent from the prior art, thereby preventing doubts regarding patentability. If this is the case, it is not, as a rule, out of the question to deem that there is a selection decision, even if it would not have been necessary to provide further details based on an objective assessment, because the reasons why certain embodiments are not included are generally irrelevant pursuant to the established legal practice set out above.

68 If the further details were added in view of formal requirements – again, irrespective of whether these requirements objectively existed – or if it is not sufficiently clear why these details were added, a selection decision in the sense set out above can, as a rule, not be assumed. If the patent claim is worded comparatively narrowly, for example for reasons of the clarity of the claim or to avoid an inadmissible extension, it is not possible to draw obligatory conclusions regarding the question of an infringement by equivalent means for the reason alone that these two aspects are not directly relevant to equivalence. As a rule, the question of the clarity of the claim cannot be raised, because the only decisive aspect is whether the use of a certain replacement means must be deemed as par (equivalent) and because, in this respect, it is generally irrelevant whether there are other conceivable equivalent replacement means. The question of whether an embodiment is disclosed in the originally filed documents as forming part of the invention is generally likewise irrelevant, because a replacement means can be on a par (equivalent) even if it is not disclosed either in the application or in the patent, but was suggested to the person skilled in the art by the prior art.

69 c) On the basis of the findings of the appellate court, it cannot be said that, in the dispute at hand, the patent claim was not used as a basis.

70 aa) As correctly stated by the appellate court, pemetrexed dipotassium is not mentioned in the patent specification in suit as a potential replacement means. For the reasons set out above, the fact that in the patent specification in suit all antifolates are generally classified as being suitable for use according to the invention, and the

conclusion to be drawn at least indirectly in this regard that this generally also applies to all pemetrexed compounds, are not sufficient to support the assumption of a selection decision.

71 bb) The same applies to the fact that in the application the Plaintiff applied for protection of the use of any antifolate in combination with any methylmalonic acid lowering agent.

72 The comparison of the two versions does not provide sufficient insight as to the reason for the specification of pemetrexed dipotassium and vitamin B12 and its derivative. The content of the prosecution file to which the appellate court also referred points to the conclusion that formal considerations were the reason behind the aforementioned specification. Thus, for the reasons set out above, the assumption of a selection decision is not justified.

73 cc) The protection of legal certainty for third parties does not necessarily require pemetrexed dipotassium to be excluded from the patent in suit's scope of protection.

74 While, pursuant to art. 1 sentence 3 of the Protocol on the Interpretation of Article 69 EPC, legal certainty for third parties is of considerable importance, this provision also stipulates that the patent proprietor's interests must also be taken into account. Pursuant to art. 1 sentence 3 of the Protocol, the conflicting interests must be weighed up in a way that combines fair protection for the patent proprietor with a reasonable degree of legal certainty for third parties. Pursuant to art. 2 of the Protocol, due account shall be taken in this regard of any element which is equivalent to an element specified in the claims.

75 In view of the foregoing, the inclusion of an embodiment in a patent's scope of protection cannot be refused solely because the patent proprietor failed to word its patent in a way that the embodiment would be covered by the literal meaning of the patent claim. The consequence of including equivalents that it is not possible for the relevant public to evaluate the patent's scope of protection in an entirely exact and conclusive manner on the basis of the claim wording alone, cannot lead to a different

assessment for the reason alone that, pursuant to art. 69 EPC, the description and the drawings must be used to construe the patent claim.

76 dd) Contrary to the Defendant's opinion, it cannot be stated that the patent claim was not used as basis solely because the term "pemetrexed disodium" constitutes an exact description of a certain chemical compound whose degree of detail is comparable to a numeric value.

77 (1) Pursuant to the panel's established legal practice, an unambiguous numeric value conclusively defines and delimits the protected subject matter in this respect. However, this does not preclude the person skilled in the art from considering a certain inaccuracy to be compatible with the technical meaning of a numeric value. If and to what extent this must be deemed to be the case depends on the circumstances of the individual case (German 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, the same applies when specifying a substance designation or a chemical formula.

79 In the individual case, such a designation may have the same degree of detail as a numeric value. As a result, substances which do not fall within this definition may not be covered by the literal meaning of the patent claim. As in the case of numeric values, all this does not readily justify the conclusion that the use of an equivalent compound that is discoverable by the person skilled in the art is not based on the meaning of the patent claim.

80 (3) Contrary to the Defendant's view, the fact that it is stated explicitly in the description of the patent in suit (para. 22) that the antifolate for use in the invention is pemetrexed disodium cannot lead to a different assessment.

81 It is true that these statements in the description support and confirm the view that the term "pemetrexed disodium" used in the patent claim must be understood in a general technical sense, i.e. as an exact scientific definition of a certain chemical compound. However, for the reasons stated, the use of such a definition is not

sufficient in order to deem that the patent claim would not be used as a basis. It is not possible to determine anything more than this either from the definition contained in the description of the patent in suit or from the term in the patent claim itself which is further defined by the definition.

82 3. The appellate court's ruling that there is no indirect patent infringement is also legally flawed.

83 a) Pursuant to the panel's established legal practice, the subject matter of a patent claim that is aimed at the use of a substance for treating an illness is the suitability of the substance for a specific medical purpose and thus, ultimately, an inherent property of the substance (German Federal Court of Justice, decision of 5 October 2005 – X ZB 7/03, BGHZ 164, 220 = GRUR 2006, 135 – *Arzneimittelgebrauchsmuster*). In substance, this corresponds to substance protection intended for a specific purpose as expressly provided for in sec. 3 para. 4 *PatG* and art. 54(5) EPC in the version applicable since 13 December 2007. This applies regardless of whether the patent claim, according to its wording, is aimed at substance protection intended for a specific purpose, at the use of the drug or at the latter's preparation for a specific purpose (German Federal Court of Justice, decision of 25 February 2014 – X ZB 5/13, BGHZ 200, 229 = GRUR 2014, 461 margin no. 17 – *Kollagenase I*).

84 The same applies to claims which, in accordance with the previous legal practice of the European Patent Office, are aimed at the use of the substance for manufacturing a drug. This particular type of claim referred to as a Swiss type claim took into account that, in the opinion of the European Patent Office, the use of a substance for treating an illness was not patentable. The alternative solution chosen, namely to direct the protection at the use for manufacturing a drug, cannot change the fact that, essentially, a particular property of the substance is protected which is also inherent to the drug manufactured.

85 A different assessment would not be conceivable even if Swiss type claims, in accordance with their wording, were understood as claims that are aimed at protecting a manufacturing process. Starting from such an understanding, a drug which is

manufactured in accordance with the protected process would have to be deemed a direct product of such process which, pursuant to sec. 9 no. 3 *PatG*, may be offered, placed on the market and used for the protected purpose only by the patent proprietor. This would ultimately also lead to substance protection restricted to the purpose of use.

86 b) The appellate court's decision contradicts these principles.

87 The appellate court left it open whether the medicinal product which the Defendant intends to distribute should be dissolved in a saline solution before being administered and whether, in the process, a mixture of pemetrexed ions and at least twice as many sodium ions is generated. It considered the Plaintiff's submissions made in this respect to be irrelevant for the reason alone that, in the appellate court's view, the patent claim is aimed at the use of the disodium salt for manufacturing a medicinal product.

88 In this respect, the appellate court failed to take into account that such a claim version, too, grants restricted substance protection. An infringement of the patent in suit cannot be dismissed due to this claim version alone. In actual fact, if a mixture of pemetrexed ions and at least twice as many sodium ions must be deemed pemetrexed disodium within the meaning of claim 1, and such a mixture is manufactured prior to the administration in accordance with the intended purpose of the medicinal product which the Defendant wishes to distribute, an indirect patent infringement must be regarded as having been committed in accordance with the decision of the Court of Appeals for England and Wales (Floyd Li, [2015] EWCA Civ 555, margin no. 74–92), which was issued after the judgment under appeal.

89 IV. The matter is not ready for a final decision.

90 The appellate court expressly left it open whether the use of pemetrexed dipotassium must be deemed a means with the same effect and whether it was discoverable as such by the person skilled in the art. The assessment of these two questions – the second of which was answered in the negative by the British courts (Arnold J, [2014] EWHC 1511, margin nos. 120–128 [not in GRUR Int. 2015, 52]; Floyd LJ, [2015] EWCA Civ 555, margin nos. 62–71) – requires additional factual statements.

91 Moreover, the appellate court will have to clarify the questions regarding indirect patent infringement which it left unanswered, should this aspect still be relevant in the further course of the proceedings despite the declaration submitted in the meantime by the Defendant to the British courts that it intends to distribute the medicinal product for administration in a dextrose solution (cf. Arnold J [2016] EWHC 234).

Meier-Beck Gröning Bacher

Hoffmann Schuster

Prior instances:
District Court of Dusseldorf, decision of 3 April 2014 – 4b O 114/12 –
Dusseldorf Court of Appeals, decision of 5 March 2015 – I-2 U 16/14 –

I, the undersigned translator for the English language authorised by the President of the *Landgericht* [District Court of] Frankfurt for the courts and notaries of the State of Hesse, *Katrin Hollerbach*, hereby certify that the foregoing translation is a complete and true translation of the document in the German language which was presented to me as an electronic copy and which is attached hereto as a copy.

Frankfurt am Main, 15 August 2016

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