Federal Supreme Court [*Bundesgericht*]
Tribunal federal
Tribunale federale
Tribunal federal

[STAMP]

Case No. R11301CH00

30 October 2017

PA/RA CHI OST ERF JED

4A_208/2017

Judgment of 20 October 2017
First Civil Law Chamber

Composition of the Court	Federal Judge Kiss, president, Federal Judges Klett, Hohl, Niquille, May Canellas, Court Reporter Leemann
Parties to the Proceedings	**1. Eli Lilly and Company,** Lilly Corporate Center, Indianapolis - Indiana 46285, United States of America, **2. Eli Lilly (Suisse) SA,** Chemin des Coquelicots 16, 1214 Vernier, both represented by Attorneys at Law Dr. Christian Hilti and Dr. Demian Stauber, Attorneys at Law, Fraumünsterstrasse 9, Postfach 2441, 8022 Zürich, Appellants, **versus** **Actavis Switzerland AG,** Wehntalerstrasse 190, 8105 Regensdorf, represented by Attorney at Law Andrea Mondini, Falkenstrasse 27, 8024 Zürich, Respondent.
Subject Matter	Patent infringement. Appeal against the judgment of 9 March 2017 by the Federal Patent Court (O2015_004).

Facts of the Case:

A.

Eli Lilly and Company, Indianapolis, United States (Patent Proprietor, Defendant 1, Appellant 1) is the proprietor of European Patent EP 1 313 508 (B1), which was filed on 15 June 2001 (with earlier US priority) and granted on 18 April 2007, the subject matter of which is described as "Combination containing an antifolate and methylmalonic acid lowering agent" — "*Zusammensetzung, welche ein Antifolate und ein methylmalonsäuresenkendes Mittel enthält", "Composition comprenant un antifolate et un agent réducteur d'acide methylmalonique.*" The patent relates to the treatment of cancer. Antifolates (which include pemetrexed) are folic acid analogs that intervene in DNA synthesis by inhibiting enzymes, thus preventing cell division and cell growth of cancer cells. Antifolates have the dangerous disadvantage of toxic effects, however, and therefore in effect poison patients. The patent is based upon the discovery that these disadvantages can be reduced by means that lower methylmalonic acid, e.g. vitamin B12, without negatively affecting the antifolate's efficacy.

Eli Lilly (Suisse) SA, Vernier (Licensee, Defendant 2, Appellant 2) is the licensee to the patent of its American parent company, and sells under the brand name "Alimta" a drug with the active substance pemetrexed disodium for treating certain forms of cancer in Switzerland.

Actavis Switzerland AG, Regensdorf (Plaintiff, Respondent) is a vendor of generic drugs. When the suit was filed, it intended to bring onto the market (and did so while the proceedings were pending) a medicament containing pemetrexed dipotassium, pemetrexed ditromethamine, or pemetrexed diacid.

B.

B.a With the submission of 24 February 2015, the Plaintiff called on the Federal Patent Court with an action for a negative declaratory judgment and presented the following requests for relief (as corrected in the reply):

"(1) It shall be declared that the Plaintiff does not infringe any claim of the Swiss part of European Patent EP 1 313 508 B1 by making, using, importing, exporting, transiting, storing, offering and/or selling or otherwise distributing, as well as possessing for any of said purposes, a medicament containing, as the sole antifolate active ingredient

(a) pemetrexed dipotassium or

(b) pemetrexed ditromethamine or

(c) pemetrexed diacid,

but no pemetrexed disodium, in Switzerland for use in combination therapy for treating non-small cell lung cancer and malign pleuramesotheliome in humans, wherein said medicament is to be administered in combination with vitamin B12 and folic acid

(2) In the alternative, prayer for relief according to section 1, wherein the corresponding medicament does not include any excipients which contain sodium ions and the medicament is directed for administration in a diluent that does not contain sodium ions

(3) [Costs]."

B.b Following two exchanges of written submissions, the Federal Patent Court notified the parties on 19 April 2016 that Dr. rer. nat., Dipl. Chem. Roland Dux would author the technical judge's expert opinion.

On 19 April 2016, the Defendants submitted as a new fact the authorization of the Plaintiff's pemetrexed product "Amtiris" by Swissmedic.

With the petition for a preliminary injunction of 1 June 2016, Defendant 1 requested that the Plaintiff be prohibited from selling the medicament "Amtiris" in Switzerland. This petition was dismissed with the judgment of 6 December 2016.

B.c With the judgment of 9 March 2017, the Federal Patent Court ruled as *follows:*

"In granting the alternative request it is found that Plaintiff is not infringing the Swiss part of European Patent EP 1 313 508 61 B1 in that it manufactures, uses, imports, exports, passes through, stores, offers and/or sells or otherwise distributes a drug for use in combination therapy for the treatment of non-small-cell lung cancer and malignant pleura-mesothelioma in humans, and possess it for the said purposes that contains as an antifolate active ingredient exclusively

(a) pemetrexed dipotassium or

(b) pemetrexed ditromethamine or

(c) pemetrexed diacid,

but no pemetrexed disodium, whereby the drug concerned is administered in combination with Vitamin B12 and folic acid, and whereby the drug concerned exhibits no adjuvants that contain sodium ions and the drug is intended for administration in a solution that contains no sodium ions.

In its further scope the action is dismissed"

The Court concluded that the Patent Proprietor had limited the claimed patent in the granting procedure to pemetrexed disodium, and therefore contradicted its

prior conduct when it now wished to once again extend precisely this feature under the doctrine of equivalence (E. 4.5.3). Moreover, the Court also rejected an equivalent infringement ("Nachahmung") because the equivalence criterion of parity/equal value was not satisfied (E. 4.6.3).The Court denied the Defendant's procedural request to expand the panel of judges from three to five (E. 2.3).

C.

C.a With the appeal in civil matters, the Defendants submitted the requests for relief that (1) the judgment of 9 March 2017 of the Federal Patent Court be set aside and the Appellant's complaint be dismissed, (2) in the alternative, that the case be remanded to the lower court with the order to reach a new decision in line with the findings of the Federal Supreme Court and based upon the grounds for appeal under substantive law and procedural law presented below. The Appellants object that the lower court violated Article 2 of the Swiss Civil Code (ZGB) as well as Article 69 EPC including the protocol on the interpretation and Article 66 (a) of the Patent Act (PatG) by assuming that the limitation made in the patent granting procedure was also binding for assessing the scope of protection; and it committed an error of law when assessing the criterion of parity/equal value. Alternatively, in the event that their objections are not approved, the Appellants are arguing that the lower court made arbitrary factual assumptions and infringed their right to evidence by assuming that medical personnel would not prepare a medicament in a solution other than in accordance with instructions; moreover, the court violated Article 21 (2) of the Patent Court Act (PatGG) by refusing to expand the panel to five members. They point out that there are two questions of fundamental importance.

In the response, Respondent requests dismissal of the appeal and confirmation of the disputed judgment.

C.b The Appellants submitted to the record a judgment of 18 May 2017 of the Higher Regional Court of Munich, in which this court addressed in detail both the judgment of 14 June 2016 of the German Federal Court of Justice (GRUR 9/2016 p. 921 et seq.) and the disputed judgment by the Federal Patent Court. In addition, they submitted the judgment of 12 July 2017 of the Supreme Court of the United Kingdom, which was enacted between the parties or companies affiliated with them.

On 21 September 2017, the Respondent also submitted to the Federal Supreme Court a judgment of 12 September 2017 of the Tribunale Ordinario di Milano.

The parties have submitted their replies and rejoinders.

Findings:

1.
The complaint is directed against a final judgment (Art. 90 of the Swiss Federal Supreme Court Act (BGG)) of the Federal Patent Court (Article 75 (1) BGG), a value in dispute is not required (Article 74 (2) (b) BGG), the Appellants' did not entirely succeed with their petitions (Article, 76 BGG), and the deadline for appeal was met (Article 100 in connection with Article 46 BGG). The appeal is to be addressed subject to sufficient substantiation (Article 42 (2) and Article 106 (2) BGG).

2.
The Appellants object that the lower court's decision with a three-judge panel is a procedural error; given the fundamental significance of the case, the panel should have consisted of five judges, and thus Article 21 (2) of the Federal Act of 20 March 2009 concerning the Federal Patent Court (Patent Court Act, PatGG; SR 173.41) was violated. They are requesting that the disputed decision therefore be set aside and the case be remanded to the lower court for readjudication with five judges.

2.1 Pursuant to Article 21 (1) PatGG, the court generally makes its decisions with a three-judge panel. Pursuant to Article 21 (2) PatGG, the Court decides in a five-judge panel on order by the presiding judge, wherein at least one person must have technical training and one person must have legal training, if this is necessary in the interest of the further development of law or the uniform application of law. The lower court refused the expansion of the panel to five judges based upon the finding that the assessment of equivalence had been

established for years and the inclusion of events from the granting procedure also did not appear to require the further development of law, even if it was handled differently in different countries.

2.2 The formation of the panel with three or five judges is — as the Applicants themselves acknowledge — at the discretion of the Federal Patent Court. It appears doubtful whether the parties have any claim to a panel of a certain size and thus that a judgment issued in a normal panel with three judges would have to be set aside if the appellate body were to conclude that this involved interests of the further development of law or uniform application of law (cf. Article 20 BGG and Article121 (a) BGG judgment 4F_20/2013 of 11 February 2014 E. 4; also judgment 9C_585/2014 of 8 September 2015). In any case, the lower court did not commit an error of law in the exercise of its discretion when it concluded in the present case that generally established or acknowledged principles were to be applied to the specific case. This is because firstly, it correctly assumed that the principles for the assessment of equivalence could now be considered established. Secondly, the principle of good faith or the prohibition on abuse of law, particularly in the form of contradictory conduct, applies throughout the entire legal system and is not to be considered as subject to technical conditions — even in the area of patent law — such that the Patent Court as a specialized court would appear particularly qualified to assess this question. On the contrary, as the appellate court, the Federal Supreme Court can freely examine this question without the need for special technical knowledge.

2.3 The objection to the effect that the formation of the panel is an error of law is without merit, should it be considered admissible.

3.

The Plaintiff requests the finding that it is not infringing the patent with its product, which contains, instead of pemetrexed disodium, the active substances pemetrexed dipotassium or pemetrexed ditromethamine or pemetrexed diacid, wherein it more precisely defines in the alternative petition that its product does not contain any pemetrexed disodium, and that sodium ions, with which pemetrexed disodium could be formed, are not present either as an adjuvant in the medicament or in a solution intended for administration. According to the finding of the lower court, the parties agree that only the implementation of the feature “pemetrexed disodium” is in dispute.

3.1 Independent claim 1 of EP 1 313 508 B1 reads as follows:

"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."

"Verwendung von Pemetrexeddinatrium zur Herstellung eines Arzneimittels zur Verwendung in einer Kombinationstherapie zur Hemmung eines Tumorwachstums bei Säugern, worin das Arzneimittel in Kombination mit Vitamin B12 oder einem pharmazeutischen Derivat hiervon verabreicht werden soll, wobei das pharmazeutische Derivat von Vitamin B 12 Hydroxocobalamin, Cyano-10-chlorcobalamin, Aquocobalaminperchlorat, Aquo-10-chlorcobalaminperchlorat, Azidocobalamin, Chlorcobalamin oder Cobalamin ist."

Claim 12 of the patent reads as follows:

"A product containing pemetrexed disodium, 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, and, optionally, a folic binding protein binding agent selected from the group consisting of folic acid, (6R)-5-methyl-5,6,7,8-tetrahydrofolic acid and (6R)-5-formyl-5,6,7,8-tetrahydrofolic acid, or a physiologically available salt or ester thereof, as a combined preparation for the simultaneous, separate or sequential use in inhibiting tumor growth."

"Produkt, das Pemetrexeddinatrium, Vitamin B12 oder ein pharmazeutisches Derivat hiervon enthält, wobei das pharmazeutische Derivat von Vitamin B12 Hydroxocobalamin, Cyano-10-chlorcobalamin, Aquocobalaminperchlorat, Aquo-10-chlorcobalaminperchlorat, Azidocobalamin, Chlorcobalamin oder Cobalamin ist, und das optional ein Folsäurebindeproteinbindemittel enthält, das aus der Gruppe ausgewählt ist, die besteht aus Folsäure, (6R)-5-Methyl-5, 6, 7, 8-tetrahydrofolsäure und (6R)-5-Formyl-5, 6, 7, 8-tetrahydrofolsäure oder einem physiologisch verfügbaren Salz oder Ester hiervon, als ein Kombinationspräparat zur simultanen, separaten oder sequenziellen Verwendung bei der Hemmung eines Tumorwachstums."

3.2 The lower court found that a literal infringement ("Nachmachung") of the patent in suit can be ruled out (only) if pemetrexed disodium is contained neither in the medicament itself nor can it be formed by sodium ions that are present as an adjuvant or in the solution for administration of the medicament. It therefore made its assessment of whether an equivalent infringement ("Nachahmung") exists based upon the Plaintiff's correspondingly specified alternative petition. The Appellants do not question that a product with the features pursuant to the Plaintiff's alternative petition makes no literal use of their patent.

3.3 The Appellants maintain, however, that regardless of any instructions in the package insert, etc., medical personnel will administer the Plaintiff's product in a saline solution, since it was accustomed to this dosage form from the originator product. They state that they had thereby asserted a participation by the Plaintiff in the literal use of their patent by the buyers. They object that the lower court's dismissal in its finding of their petition for obtaining an expert opinion, stating that it was well known that for liability reasons alone, medical personnel comply with the instructions on the way of administering a medicament, is a denial of the Appellants' right to evidence and an arbitrary assumption of facts.

3.3.1 Pursuant to Article 66 (d) of the Federal Act of 25 June 1954 on Patents for Invention (Patent Act, PatG; SR 232.14), persons may be held liable under civil and criminal law if they abet, participate in, or aid or facilitate patent infringing acts. Typical examples of such participation are offering or placing on the market devices for use in a patented method, wherein for goods or devices not generally commercially available, participation within the meaning of Article 66 (d) PatG is to be affirmed only under two conditions. Firstly, the concept of accessoriness [*Akzessorietät*] of participation implies that the buyer must use or intend to use the device or goods in a manner that infringes the patent, and secondly, the vendor or supplier is subject to penalty under civil law only if it knows or must know that the means it is offering or supplying are suitable and intended for utilization of the protected invention by the recipient of the offer or delivery (BGE 129 Ill 588 E. 4.1 p. 592 with references).

3.3.2 Based upon the statements in the disputed decision, which the Appellants do not criticize as incomplete (cf. Article 105 (2) BGG and BGE 140 III 86 E. 2 p. 90), the requirements for the Plaintiff's participation in a patent infringing act by its buyers is not fulfilled because it is not evident what interest these buyers could have in administering the Plaintiff's products in a saline solution. The assumption that the buyers of the Plaintiff's medicament would administer it in a patent-infringing manner would however require specific indications that this use could be intended. Contrary to the Appellants' view, no such intent is evident from the alleged routine that medical personnel preferred the form of administration that was prescribed for the originator medicament. The Appellants are not claiming that they had argued that the Plaintiff's products were purchased by the recipients with the intent of administering these in a saline solution. Because the Plaintiff's products were therefore not intended by the recipients for literal use of the protected invention of Appellant 1, the conditions for an act of participation are not fulfilled. The lower court did not violate the right to evidence, and consequently could deny, without violating federal law, that the Plaintiff is participating in a literal infringement ("Nachmachung") of Appellant 1's patent by its buyers.

4.

The lower court initially denied an equivalent infringement ("Nachahmung") of Appellant 1's patent by the Plaintiff in its finding that the feature "pemetrexed disodium" claimed in the patent — which the Plaintiff is replacing with "pemetrexed dipotassium" or "pemetrexed ditromethamine" or "pemetrexed diacid" — was included in the claim as a limitation in the granting procedure, and thus, regardless of the grounds for this limitation, the Patent Proprietor could not in good faith claim any protection for equivalents of this feature.

4.1 According to the findings of the lower court concerning the granting procedure, Appellant 1 replaced the originally used expression "antifolates" with "pemetrexed" because the examiner objected in his Communication of 9 March 2004 that the active substance had not been sufficiently disclosed. The examiner then objected on 17 May 2005 that the change signified an impermissible extension within the meaning of Article 123 (2) of the European Patent Convention of 5 October 1973, amended in Munich on 29 November 2000 (EPC 2000; SR 0.232.142.2), since the expression "pemetrexed" cannot be found in the original documents, and this compound is certainly different from the "pemetrexed disodium" mentioned in the original documents. Appellant 1 then limited the claim to the pemetrexed disodium explicitly mentioned in the

original documents. According to the findings in the disputed decision, the extension of precisely this definition within the context of the assessment of equivalence constitutes a breach of good faith. According to the lower court's findings, this involves a case in which Article 2 ZGB applies, and does not involve the interpretation of the claim. It states (E. 4.5.3) that limiting claims in the granting procedure in order to receive the patent smoothly, and then claiming protection after the patent has been granted as if the limitation had not occurred, constitutes a contravention of the party's own prior conduct within the meaning of Article 2 ZGB.

4.2 Pursuant to Article 2 ZGB, every person must act in good faith in the exercise of his or her rights and in the performance of his or her obligations (para. 1). The manifest abuse of a right is not protected by law (para. 2). As a general legal principle, the prohibition on the abuse of law applies throughout the entire legal system, including public law and laws on procedure and enforcement. This is part of Swiss public policy and must be applied *ex officio* by every court (BGE 128 III 201 E. 1c p. 206; 122 11193 E. 2c/ee p. 198). The assertion of a right is abusive if it contradicts prior conduct and thereby disappoints justifiably raised expectations (BGE 140 Ill 481 E. 2.3.2; 138 Ill 401 E. 2.2; 130 III 113 E. 4.2; 129 Ill 493 E. 5.1 p. 597; 125 III 257 E. 2a; cf. also BGE 137 III 208 E. 2.5 p. 211; 135 III 162 E. 3.3.1 p. 169; 133 I 149 E. 3.3 p. 154; each with references). Contradictory conduct may also exist without the disappointment of justified expectations if present conduct is completely incongruous in itself and therefore contradictory (BGE 138 III 401 E. 2.2). Here it must be noted that Article 2 (2) ZGB does not generally override the provisions of civil law for specific types of cases, but rather simply instructs the court to take the special circumstances of the individual case into account. The standard serves as a corrective "stopgap measure" for cases in which formal law would lead to substantive and blatant injustice (BGE 134 III 52 E. 2.1). Abuse of law must be restrictively assumed (BGE 139 III 24 E. 3.3; 135 III 162 E. 3.3.1 p. 169; judgment 5A_745/2016 of 15 May 2017 E. 3.1, planned for publication). There is no principle of restriction to one's own actions [*Gebundenheit an das eigene Handeln*]. On the contrary, a contradiction relative to prior conduct can be considered a breach of good faith only if this has established a trust worthy of protection that is disappointed by the new actions (BGE 125 Ill 257 E. 2a p. 259 with references, cf. also Heinz Hausheer/Regina A. Aebi-Müller, in: Berner Kommentar, 2012, N. 268 et seqq. to Article 2 ZGB).

4.3 Pursuant to Article 51 (2) PatG and Article 69 (1) sentence 1 EPC 2000, respectively, a patent's scope of protection and extent of protection, respectively, is determined according to the patent claims. The technical instructions described in the patent claims are to be interpreted as they are understood by the skilled person (BGE 132 Ill 83 E. 3.4 p. 87 with references; judgments 4A_131/2016 of 3 October 2016 E. 4.2.1, not published in BGE 142 Ill 772; 4A_371/2016 of 14 October 2016 E. 5.3; 4A_541/2013 of 2 June 2014 E. 4.2.1). The wording is the starting point for every interpretation. The description and the drawings are to be used to interpret the patent claims (Article 51 (3) PatG or Article 69 (1) sentence 2 EPC 2000). As the so-called "available prior art," general technical knowledge likewise serves as a means for interpretation (judgment 4A_131/2016 of 3 October 2016 E. 4.2.1, not publ. in BGE 142 Ill 772 with reference to Peter Heinrich, Commentary to the Patent Act/EPC [*Kommentar zu PatG/EPÜ*], 2nd ed. 2010, N. 54 to Article 51 PatG; Fritz Blumer, The Patent's Scope of Protection [*Schutzbereich des Patents*], in: Bertschinger et al. [ed.], Swiss and European Patent Law, Handbooks for Legal Practice [*Schweizerisches und europäisches Patentrecht, Handbücher für die Anwaltspraxis*], Vol. VI, 2002, margin no. 14.41; Thierry Calame, in: by Büren/David [ed.], Patent Law and Know-How [*Patentrecht und Know-how*], SIWR Vol. IV, 2006, p. 413).

By contrast, according to the prevailing view, the historical origin or the patent prosecution history is generally not determinative for the interpretation of the patent claims and thus also not for determining the scope of protection, although the prosecution files are publicly available (cf. Blumer, loc. cit., margin no. 14.101 with reference to Article 90 (3) of the Patent Ordinance (PatV), Article 128 (4) EPC 2000). The doctrine as well as the case law of other EPC 2000 member states overwhelmingly reject to refer to statements made by the patent proprietor in the granting procedure in order to interpret patent claims (cf. Blumer, loc. cit., margin no. 14.101; Uwe Scharen in: Benkard, European Patent Convention [*Europäisches Patentübereikommen*], 2nd ed., Munich 2012, N. 27 et seqq. to Article 69 EPC; each with numerous references). Waivers and limitations that the applicant has undertaken in the granting procedure must be considered afterwards only insofar as they are reflected in the patent claims and, if applicable, in the description (cf. BGE 122 III 81 E. 4a; Dieter Stauder, in: Singer/Stauder, *Europäisches Patentübereinkommen*, 7th ed., Köln 2016, N. 28 to Article 69 EPC). Following this finding, the prosecution files may not constitute *a priori* the basis for a third party's trust worthy of protection.

4.4 There is no need to establish whether the prosecution files can nevertheless be referred to exceptionally for interpretation because the lower court explicitly did not exclude the feature “pemetrexed disodium” from the assessment of equivalency based upon an interpretation of the patent claims. Nevertheless, the lower court’s derivation in this context, based upon the description (no. 0022), of a limitation of the scope of protection to cover literal infringement (“Nachmachung”) only cannot be accepted. According to the disputed judgment, Appellant 1's patent clearly defines that in this patent, the term “antifolate” or “antifolate drug” is understood to mean pemetrexed disodium. This is because in a first sentence, “antifolate” or “antifolate drug” are described in a general way, and in a second sentence it is explained that the terms “antifolate” or “antifolate drug” as used in this patent refer to the pemetrexed disodium with the brand name “Alimta” as manufactured by Appellant 1. The Appellants correctly point out that the description does not even refer to pemetrexed disodium in general as the antifolate used by Appellant 1, but instead there is a specific declaration that it is using its own brand name product. The lower court itself indicates that the term “pemetrexed disodium” is used to claim the substance, and not specifically Appellant 1’s brand name product when it states in another context that the use of the substance “pemetrexed disodium” — not merely the brand name product “Alimta” — would lead to a literal infringement (“Nachmachung”) or literal use of the patent. The description does not show that Appellant 1 would have waived protection against equivalent infringement (“Nachahmung”) with respect to the feature “pemetrexed disodium.” However, this is not to be further addressed here, since the lower court clarifies that it is excluding the feature “pemetrexed disodium” from the assessment of equivalence, not based upon the interpretation of the patent, but instead based upon the finding that the Patent Proprietor was bound by good faith to the limitations that it undertook in the granting procedure.

4.5 The fact that limitations are undertaken for an original feature and subsequently protection against equivalent infringement (“Nachahmung”) is claimed (based upon the limited patent claim) cannot be the sole grounds for establishing contradictory conduct by the Patent Proprietor. The limitation of a feature does not automatically and regardless of the grounds for such limitation constitute a declaration of waiver on protection against equivalent infringement (“Nachahmung”). The limitation of a patent claim in the granting procedure results in a limitation of the scope of protection even without a waiver of protection against equivalent infringement (“Nachahmung”): if the features that qualify as equivalents were to be claimed, then one would have to evaluate with regard to these — additional — features as well whether an asserted infringing form uses equivalents for these.

In this context, the Appellants correctly refer to the restrictive practice for extension pursuant to Article 123 (2) EPC 2000 in the granting procedure. According to this, to comply with the prohibition on extension, an amendment may be made only within the scope of what the skilled person can *directly and unambiguously* derive from the original documents, which specifically does not include equivalents. The lower court's view to the effect that the limitation of a feature in the granting procedure leads to a waiver of protection against equivalent infringement ("Nachahmung") with respect to this feature, regardless of the grounds for the limitation, contradicts Article 66 (a) PatG, under which equivalent infringement ("Nachahmung") is also considered as use.

Apart from this, it would also not be evident how the prosecution files could establish a third parties' trust worthy of protection pursuant to Article 2 ZGB to the effect that the patent proprietor will later make use of the granted patent protection only in a specific manner, should these documents— contrary to the aforementioned prevailing view — be substantial.

4.6 After the disputed decision in the granting procedure, Appellant 1 limited the controversial feature in order to respond to the objections and thus a refusal of the patent by the examiner. There are no special circumstances here that would require the corrective "stopgap measure" of Article 2 ZGB in order to prevent substantive and blatant injustice; the fact that Appellant 1 would have had other options available if need be (such as the intermediate generalization mentioned by the lower court) does nothing to change this. Appellant 1 is not to be charged with any violation of the prohibition on abuse of law by invoking - in spite of the limitation to "pemetrexed disodium" - protection against equivalent infringement ("Nachahmung") through equivalents with respect to this feature.

5.

In an alternative finding, the lower court denied patent infringement through equivalents (E. 4.6). The Appellants object that the lower court thereby violated Article 69 EPC 2000 and Article 66 (a) PatG, respectively. They refer to, among others, the judgment of 14 June 2016 of the German Federal Court of Justice (BGH) (X ZR 29/15 publ. in: GRUR 9/2016 p. 921 et seqq.) issued in a parallel litigation between the same parties or their affiliates, and submit as evidence a judgment of 18 May 2017 of the Higher Regional Court of Munich (6 U 3039/16). In addition, they have submitted to the record the judgment of 12 July 2017 of the Supreme Court of the United Kingdom ([2017] UKSC 48) — which must likewise be considered *ex officio*.

5.1 A party infringes a patent if it uses the patented invention unlawfully, wherein equivalent infringement ("Nachahmung") is also considered as use (Article 66 (a) PatG). A party commits an equivalent infringement ("Nachahmung") within the meaning of Article 66 (a) second half-sentence PatG if it implements the result in accordance with the patent in a divergent or modified form while having knowledge of the patented teaching (BGE 142 Ill 772 E. 6.2 p. 776 with references). Pursuant to Article 2 of the Protocol on the Interpretation of Article 69 of the European Patent Convention of 29 November 2000 (SR 0.232.142.25; hereinafter: Interpretative Protocol), elements that are equivalents of the elements specified in the patent claims must be properly taken into account when determining the European patent's scope of protection.

The assessment whether the patented teaching is used with equivalent means is routinely based upon three questions. Firstly, the modified feature must objectively achieve the same function for the implementation of the technical teaching as the feature claimed in the patent ("same effect"); secondly, the modified feature must be made obvious to the skilled person by the patented teaching ("findability"), and as third criterion, parity is required in the sense that the skilled person considers the modified embodiment as a solution of equal value (BGE 142 III 772 E. 6.2 with references). Here it must always be considered that pursuant to Article 1 of the Interpretative Protocol, the European patent's scope of protection should be understood not only as that defined by the strict, literal meaning of the wording used in the claims. Nor should it be taken to mean that the claims serve only as a guideline and that the actual protection conferred may extend to what, from a consideration of the description and drawings by a person skilled in the art, the patent proprietor has contemplated. On the contrary, it is to be interpreted as defining a position between these extremes which combines a fair protection for the patent proprietor with a reasonable degree of legal certainty for third parties.

5.2 In the present case, it is undisputed that the Plaintiff is infringing the Appellant 1's patent by equivalents when the formulas "pemetrexed dipotassium" or "pemetrexed ditromethamine" or "pemetrexed diacid," which it uses instead of the claimed antifolate "pemetrexed disodium," implement the

patented teaching in an equivalent form. The lower court (E. 4.6.1) affirmed the first question of ‘same effect’ for the active substance “pemetrexed diacid” based upon the finding that the Plaintiff’s product with “pemetrexed diacid” or the corresponding tromethamine salt was approved by Swissmedic as a known active substance. It likewise affirmed the second question in the finding (E. 4.6.2) that in accordance with common general knowledge, it was clear for the skilled person or the specialist team — which it defines as an oncologist and a chemist or at least an experienced pharmacologist — that protons, potassium, and tromethamine were cations commonly used in pharmaceutical compounds; since pemetrexed works with anions, it would have been clear to the skilled person that the same effect was to be expected with the Plaintiff’s products. By contrast, the lower court (E. 4.6.3) essentially denied parity/equal value in its finding that Appellant 1 willingly limited itself to the disodium form and the patent in suit contained no references to other suitable forms of pemetrexed.

5.3 To support its petition for confirmation, the Appellant, as the victorious party in the lower court proceeding, must be heard with objections against reasoning of the disputed judgment in which its standpoint is rejected. In the response, it disputes the assertion that the medicament it offers implements the feature “pemetrexed disodium” with the same effect. Specifically, it criticizes the lower court’s statement that the “pemetrexed diacid” it actually sells under the brand name “Amtiris” was approved as a generic drug. It states that on the contrary, this was approved as a hybrid drug in the sense that although a complete clinical trial program was no longer required, nevertheless more studies had to be performed than in the case of a generic drug.

5.3.1 According to the Respondent's submission, in addition to its actual pharmacological effect, a medicament must be sufficiently stable for storage (e.g. it must not decompose due to the effects of light or temperature), it must also have sufficient solubility if it is to be administered as an intravenous solution, it must be suitable for reliable and cost-effective production (without interfering impurities), and must not have any unacceptable side effects. The Plaintiff had to formulate its active substance pemetrexed diacid in a tromethamine buffer because it was practically insoluble in water; the studies to determine stability also took several months. Finally, pemetrexed disodium and pemetrexed diacid/tromethamine did not act identically in the body. The two products had a similar behavior, but by no means identical. For example, pemetrexed disodium entered into the cell interior in somewhat larger quantities, and was therefore more extensively available for the tumor-inhibiting effect. The lower court did indeed accurately recognize that the matter depended upon the properties essential to the invention, which in this case is the suitability of both substances for therapy for inhibiting tumor growth in mammals. Nevertheless, it wrongfully failed to consider that the quantity of the antifolate available in the cell was different, and that the Plaintiff's product had to be stored under refrigeration and was recommended only for storage for 18 months, whereas such restrictions were not known for the pemetrexed disodium of Appellant 1. The Plaintiff's product contained the adjuvant tromethamine, which was incompatible with cisplatin, a standard drug for the treatment of lung cancer, which is of primary interest here, a fact that could restrict cancer treatment with its product.

5.3.2 In the reply, the Appellants support their standpoint that the tumor-inhibiting active substance was the free pemetrexed alone, wherein the existence of the pemetrexed anion was the prerequisite for both transport into the cell and transformation into the polyglutamated form. The free pemetrexed — and not one of its salt forms — was the active substance in both the Appellants' product and the Respondent's product. The differences reviewed by the Respondent would relate to the physical properties such as stability, different properties of the alternative saltformer tromethamine used in the Respondent's product, or alleged differences in certain tests. Because the specific form decomposed due to dissolution of the respective products in the infusion solution intended for administration and no longer existed, it was obvious that this form could not be relevant for the efficacy of the treatment; the Respondent itself then also confirmed in another context that the ions disassociated in an aqueous solution, the active pemetrexed was released, and the salt form no longer existed in the intravenous solution. The Appellants refer

to the assessment report of the European Medicines Agency dated 19 November 2015 regarding Pemetrexed Actavis (EMA Report or EPAR), where it is stated (on p. 26) that the pemetrexed 25 mg/mL concentrate for dissolution in the infusion solution contained the same active substance as the reference product “Alimta,” but conjugated to a different salt (tromethamine instead of sodium) or in the original “Pemetrexed 25mg/mL concentrate for solution for infusion contains the same active substance as the reference product Alimta, but conjugated to a different salt (tromethamine salt instead of sodium salt)”. They cite EPAR (p. 27), according to which additional clinical studies were not required due to the interchangeability of the salt forms.

5.3.3 A feature has the same effect in principle when the technical problem underlying the invention is thereby solved with the same effect, which cannot be assessed as a whole either through a mere individual comparison or by assessing the performance result (cf. Scharen, loc. cit., N. 58 to Article 69 EPC; Blumer, loc. cit., margin no. 14.87). On the contrary, the modified embodiment must achieve all of those effects that in the understanding of the skilled person can be achieved with the individual technical features of the patent claim *per se* and in their interaction (Peter Meier-Beck, Purposive Construction or Equivalence? GRUR Int. 10/2005 p. 800). In the present case, the problem underlying the invention can be formulated with the German courts concerned with the parallel litigation such that the toxic effects disadvantageous for the patients that are caused by the administration of pemetrexed disodium as an antifolate or through the antifolate being used should be reduced without adversely affecting therapeutic efficacy (BGH judgment X ZR 29/15 of 14 June 2016, loc. cit., p. 921 margin no. 10, 17). Accordingly, the features claimed for the solution of the problem in the use patent can be broken down as follows (loc. cit., p. 922 margin no. 19):

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

2. The medicament is intended for use in a combination therapy for inhibiting 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."

5.3.4 According to feature 1, the tumor-inhibiting active substance in the medicament is pemetrexed (anion). This is clearly evident from the authorization of the Plaintiff's preparation, upon which the lower court relies. The Respondent's assertion in the rejoinder that the term "active substance" in the EMA Report is used in a "vague" manner cannot cast doubt on the report's statement that the active substance for tumor inhibition is pemetrexed, which is indeed initially conjugated to a different salt ("but conjugated to a different salt"), but which dissociates in the infusion solution so that pemetrexed (anion) is intravenously administered to the patients. The differences enumerated by the Respondent essentially relate to the starting materials for production of the tumor-inhibiting medicament with the active substance pemetrexed. The diacid appended to the active substance in the Respondent's product fulfills the same function as the disodium designated in the patent. According to the Respondent's own presentation, it is intended for storage, and is so soluble that the tumor-inhibiting pemetrexed can be administered in an infusion solution. The differences enumerated by the Respondent — less active substance per cell, inferior shelf life, different solubility, and possible intolerance — cannot cast doubt on the same effect of the appended diacid with the claimed disodium for the combined medicament according to the invention. They relate to the manufacture of the medicament intended for tumor inhibition, for which product protection for a specific purpose is claimed in Appellant 1's patent (cf. BGH judgment of 14 June 2016, loc. cit., p. 923 margin no. 30)

5.3.5 Based upon the documents for authorization of the Respondent's product, the lower court concluded, without violating federal law, that the technical problem underlying the invention is solved with the same effect if the pemetrexed diacid actually used by the Respondent is utilized as starting material for production of the tumor-inhibiting medicament instead of "pemetrexed disodium,". This is because the active, tumor-inhibiting substance

whose efficacy through the methylmalonic acid-lowering means is not to be questioned according to the instructions in the patent, is pemetrexed, whereas it is irrelevant for the solution of the problem underlying the patent, which counterion is used since such has no influence on tumor inhibition or on the side effects caused by pemetrexed, or on the effects of the claimed methylmalonic acid lowering means (cf. Higher Regional Court of Munich in the judgment of 18 May 2017, E. II.B. 3b/cc S. 42). The response also does not indicate to which extent it may be material for the Plaintiff's product having the same effect for the solution claimed in the patent that, according to the Respondent's assertion, somewhat less active substance can be transported into the cell with the medicament manufactured on the basis of pemetrexed diacid, and that an intolerance with cisplatin — put in perspective in the rejoinder — needs to be considered. In its judgment of 12 July 2017 (margin no. 60, 68 as the first "Improver" question), the UK Supreme Court also affirmed that the modification essentially achieves the same result as the invention in essentially the same manner.

5.3.6 The Respondent's objection that the lower court affirmed the same effect in violation of federal law is without merit.

5.4 The lower court affirmed the findability of the modified form for the skilled person, which the Respondent likewise criticizes in the response as a violation of federal law.

5.4.1 According to the case law of not only the Federal Supreme Court but also the German Federal Court of Justice, and in accordance with the precedents in Great Britain, the modified feature must be made obvious to the skilled person by the patented teaching ("findability"; BGE 142 III 772 E. E. 6.2.1 p. 777 with references, cf. the judgment of the UK Supreme Court of 12 July 2017, margin no. 62 et seqq.). The skilled person in the area in question must be motivated by the patented invention to make the change based upon his general knowledge; findability is ruled out if the modification for its part is based upon an inventive step (cf. BGE 125 III 29 E. 3b p. 32 with references). In the present case, the lower court — essentially in agreement with the foreign judgments in the parallel proceedings — describes the skilled person as a specialist team consisting of an oncologist and a chemist or an experienced pharmacologist. According to the findings of the lower court, the skilled person on the priority date was in general aware of tromethamine or protons as pharmaceutically acceptable and commonly used cations for active substances.

According to the findings in the disputed decision, it was clear for the skilled person that pemetrexed diacid must be at least partially deprotonated in the case of a physiological pH. Thus it would have been clear for the skilled person that the same effect (caused in each case by the anions) is to be expected with pemetrexed diacid as that achieved with pemetrexed disodium. The lower court countered the Respondent's objection that it was not known which ions would be suitable, by stating that this could be clarified with reasonable experimental effort. This assessment was shared by the Higher Regional Court of Munich in is judgment of 18 May 2017 (E. II.B. 3c p. 44 et seqq., p. 48 et seq.) (cf. also the judgment of the UK Supreme Court of 12 July 2017, margin no. 69).

5.4.2 The Respondent's primary objection to findability is that the same effect would have had to be initially determined experimentally, and the need to perform experiments argued *prima facie* against obvious findability. It does though note that the performance of experiments within the context of the second question of equivalence may be acceptable in cases involving merely the confirmation of a reasonable expectation of success. Nevertheless, it maintains the view that because the result of the experiments was not foreseeable and the stability test required for authorization would have taken a year, the same effect of the alternative forms was not findable. Specifically, it objects to the lower court's view that the experiments would have been regarded as reasonable for the skilled person; this because the decisive factor was not whether the skilled person could have performed the experiments, but instead whether he would have done so with the expectation of an improvement or an advantage. It also criticizes the modification of the second "Improver" question by the UK Supreme Court.

5.4.3 The lower court found that, based upon the determinative common general knowledge, the same effect is to be expected with pemetrexed diacid as with the pemetrexed disodium designated in the patent. Accordingly, contrary to the Respondent's assertion in this regard, the same effect was to be expected by the skilled person. The Respondent itself acknowledges that the performance of experiments within the context of the second question of equivalence is acceptable for the confirmation of a reasonable expectation of success. The Respondent does not argue, however, that, contrary to the finding of the lower court, the experiments for eliminating unsuitable pemetrexed counterions that do not fulfill the justified expectations would not have involved routine activities. The fact that the expectation held by the skilled person for the same effect of individual salts conjugated with the active substance pemetrexed

could be disappointed in experiments does not change the fact that the success expected based upon technical expertise for the diacid used by the Respondent was achieved and experimentally confirmed. The same effect was findable because the skilled person recognized based on his general knowledge, that the pemetrexed claimed in the patent can be conjugated with other salts commonly used for this purpose, rather than with the specified disodium — particularly with the diacid/tromethamine used by the Respondent — with the same effect. Findability is not changed by the fact that the skilled person had to perform routine experiments to verify his expectation for the actually used salts, and in the process his expectations could have been disappointed.

5.4.4 The lower court did not violate federal law when it affirmed findability for the skilled person.

5.5 The lower court denied patent infringement through equivalents, based upon the reasoning that the formulation used by the Respondent for producing the pemetrexed medicament was not of equal value.

5.5.1 The Federal Supreme Court recently took up the third question of equivalence in confirmation of the practice of the Federal Patent Court, which for its part builds upon the practice of the UK and German courts. Accordingly, the matter to be assessed is whether the technically competent third party, in an objective reading of the patent specification, will conclude that the patent proprietor formulated the claim — for whatever reason — so narrowly that it did not claim protection for a findable embodiment with same effect (BGE 142 III 772 E. 6.2.3, cf. BGH judgment of 14 June 2016, loc. cit., p. 924 margin no. 51: “[...] 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 [..].”).

The lower court denied (E. 4.6.3 p. 28) parity/equal value of the embodiments pemetrexed dipotassium, pemetrexed ditromethamine, and pemetrexed diacid used by the Respondent on the grounds that in the granting procedure, the applicant waived with the limitation an equivalence protection for the feature “pemetrexed disodium”; moreover, according to the findings of the lower court, even apart from the granting procedure, the Patent Proprietor knowingly limited itself to pemetrexed disodium even though other salt forms were known, e.g. from the substance patent EP 0 432 477 (correctly: EP 0 432 677). Accordingly,

there are no references in the patent in suit to other suitable forms of pemetrexed, whereas with regard to folate and vitamin B12, derivatives were described and claimed. When reading the wording of the claim in light of the description, the skilled person would, according to the disputed judgment, ascribe importance to the fact that there was no reference to other suitable forms in the case of pemetrexed disodium. For this reason, the skilled person would not consider the free acid or another alternative formulation as a substitute of equal value for disodium.

5.5.2 The Appellants object that the lower court wrongfully denied parity/equal value. They argue that the skilled person would not ascribe any importance to the form of the active substance pemetrexed because the description of their patent did not contain any kind of statement concerning the importance of the pemetrexed form. In case the form had been deliberately selected, the description would have disclosed its importance. As it said nothing in this regard and also nothing regarding the method of production, no reason could be inferred from the description as to why the claim feature pemetrexed disodium had been selected. Thus, contrary to the lower court's view, one could not assume that an average skilled person would have considered other common forms such as dipotassium, ditromethamine, or diacid as being ruled out based upon the claim feature in light of the description. As the form of pemetrexed had no influence on the tumor-inhibiting effect of the combination therapy with vitamin B-12 or derivatives thereof, it was also not evident why the skilled person should give importance to the specific form, even more since the claim was formulated as a "Swiss type claim" and the Appellants brand name product was specifically named as the starting material for the tumor-inhibiting medicament.

By contrast, in the response the Respondent emphasizes the fact that the antifolate was limited to pemetrexed disodium in the claims, whereas for the methylmalonic acid lowering means not only vitamin B12, but also derivatives, were cited as well as a selection of folic acid binding protein binding agents was mentioned. The Respondent considers the reference to the wording of the claim as being confirmed, according to which the patent's scope of protection was deliberately limited to pemetrexed disodium as the sole antifolate active substance, because the description does not contain any reference to the fact that the invention claimed in the patent in suit could also be realized with antifolates other than pemetrexed disodium.

5.5.3 The Patent Act and EPC 2000 grant protection to the patent proprietor, not only against literal infringement (“Nachmachung”) or the literal use of the patent, but also against equivalent infringement (“Nachahmung”) or equivalents. With the exception of the deliberately selected limitation to be discussed below, the scope of protection is granted beyond the precise literal application of the patent claims, in the knowledge that even with careful and thorough editing, it is impossible to designate all possible embodiments in a technical instruction. The protection should therefore also be granted if the technical instruction instructs the skilled person, beyond the overly narrow literal meaning, how to implement the invention. If the third question of equivalence is therefore to be used to assess whether the technically competent recipient may understand the patent claims such that the exact literal meaning of the patent claim is determinative, this cannot mean that the protection against equivalents under this heading will be denied in every case. This would contradict the Interpretative Protocol as well as the Patent Act (cf. E. 5.1 above). Special reasons are therefore required why the technically competent recipient can and must assume that the patent protection is not being claimed for embodiments that he can find as having the same effect based upon his common general knowledge having regard to the invention.

In doing so, the lower court correctly found that the Patent Proprietor must remain committed to a deliberately selected limitation. However, this requires that the limiting wording must be understood to mean that the Patent Proprietor has waived equivalence or equivalent infringement (“Nachahmung”) protection. In this regard, it cannot be accepted that the lower court does not accept the findings of the Federal Court of Justice in the parallel proceedings, on the grounds that these were overly focused on the question of the waiver. As the Patent Proprietor is to be committed to its declaration of intent concerning the scope of protection by the third question of equivalence, (cf. BGE 122 III 81 E. 4a p. 84 et seq. with references), the limitation of the scope of protection to the literal embodiment is justified insofar as the skilled third party may understand the patent specification to mean that the Patent Proprietor has precluded protection for the equivalent embodiment. In doing so, according to Swiss case law, the principle of good faith generally applies to the interpretation of declarations of intent — insofar as the actual subjective intent of the declaring party cannot be ascertained. A party that explicitly or analogously expresses its intent must thereafter commit itself to

that meaning of its conduct, which the recipient of such statement may in good faith attribute to it (cf. instead of many BGE 142 III 375 E. 3.3 p. 377; 140 III 367 E. 3.1; 135 III 410 E. 3.2 p. 413, 562 E. 3.4 p. 565; 133 III 161 E. 2.2.1; 123 III 35 E. 2b; 102 II 143 E. 1b p. 146; each with references). The principle of good faith insofar justifies not only the declaring party's commitment to its declaration of intent, but also guides the interpretation of the declaration: the recipient of the statement can and must understand this declaration as a reasonable and honest person in the recipient's position would understand it.

5.5.4 It cannot be accepted that the lower court derives a waiver on protection against equivalents for this feature based upon the mere limitation of a feature in the granting procedure, without regard to the reason for this limitation. The equivalence protection can only refer to the limited features, not the original features. In the present case, therefore, the question is not whether other antifolates adequately implement the feature "pemetrexed," but whether forms of pemetrexed other than the claimed pemetrexed disodium infringe the patent by equivalents. Therefore, a waiver of specific equivalent embodiments cannot be automatically derived from a mere limitation (cf. Blumer, loc. cit., margin no. 14.102). On the contrary, the reason for this is important.

According to the findings of the lower court, the first limitation (from "antifolate" to "pemetrexed") occurred because the examiner considered the expression "antifolate" to be too indefinite and therefore the medicament manufactured with it was not sufficiently disclosed; the second limitation (from "pemetrexed" to "pemetrexed disodium") was made because pemetrexed appeared in the original documents only with the conjugated salt form disodium, and thus the examiner assumed that the specification of pemetrexed alone was an impermissible extension of the claim. Appellant 1 therefore limited its claim in order to take account of the formal objections in the examination proceeding and, as the lower court notes, to possibly achieve patent protection more quickly than if it had countered the objections. One cannot infer from this, however, that it thereby took account of objections relating to patent protection for the Respondent's embodiment disputed here — e.g. that it restricted the patent claim with respect to the free prior art for the embodiment disputed here — (cf. for limitation to a claim version narrower than would have been necessary based upon the technical content of the invention and relative to the

prior art, BGH judgment of 14 June 2016, loc. cit., p. 924 margin no. 50 et seq.). This is also not a case, for example, in which the description of the patent discloses (at least) two specific embodiments with which the effect according to the patent can be achieved, yet only one of these embodiments was reflected in the patent claim (with respect to the patent proprietor's selection decision, BGH judgment of 14 June 2016, loc. cit., p. 924 margin no. 52 et seqq.).

With the limitation of the disputed feature in the granting procedure (from initially "antifolate" to "pemetrexed" to finally "pemetrexed disodium"), the patent proprietor did not waive equivalence protection for the "pemetrexed disodium" claimed in the patent.

5.5.5 Appellant 1 is the proprietor of the patent for "Combination containing an antifolate and methylmalonic acid lowering agent" — "*Zusammensetzung, welche ein Antifolate und ein methylmalonsäuresenkendes Mittel enthält.*" According to the binding findings of the lower court (on findability, E. 4.6.2.2 p. 26), the skilled person recognizes that the tumor-inhibiting active substance is the antifolate pemetrexed, which is deprotonized in the infusion solution and transported into the cell (as a result of the anions). The patent claims this antifolate (in the starting form as pemetrexed disodium) as a tumor-inhibiting active substance together with a methylmalonic acid lowering means, which is designated in the patent claims as vitamin B12, as well as folate and other described and claimed derivatives. The lower court ascribed no importance to the fact that the claim in the patent is formulated as a "Swiss type claim" (i.e. it describes the manufacture of a medicament and not the substance directly). It inferred the limitation of the claim "pemetrexed disodium" to its literal sense based upon the fact that firstly, the patent makes no reference to other suitable forms of pemetrexed, and secondly, by claiming pemetrexed disodium, the patent is claiming a single, specific substance, whereas in contrast to this, the patent describes and claims for the methylmalonic acid lowering means further derivative forms besides the folate and vitamin B12. This raises the question whether a technically competent third party while perceiving in good faith the patent claims in light of the description will recognize a limitation of the patent claim with respect to the tumor-inhibiting active substance pemetrexed to its disodium form.

5.5.6 Together with the lower court, it is to be assumed that no references to other suitable forms of pemetrexed can be inferred from the patent, either in the claims or in the description. According to the findings of the lower court, the skilled person could discover these based solely upon his available general knowledge. In the description — as in the title of the patent — the discussion generally concerns antifolates. In this respect — as the lower court finds in another context (p. 20, top) — the description states [0022] that the terms "antifolate" or "antifolate drug" refer to a chemical preparation whose properties are defined; it is added that the antifolate for use in this invention ("for use in this invention") is pemetrexed disodium (brand name "Alimta"), as it is manufactured by the Patent Proprietor. One must therefore infer from the description that the active substance is the antifolate with the described (tumor-inhibiting) properties. If it is also declared in the description that the antifolate used for the invention is the pemetrexed disodium manufactured by the Patent Proprietor under the brand name "Alimta," then based upon an objective appraisal, this does not result in a limitation exclusively to this antifolate in the overall context of the description. This, because it is not evident why the properties and the mechanism of action of antifolates should be generally described in the patent if the tumor-inhibiting product claimed by the invention is to be exclusively the brand name product manufactured by the Patent Proprietor. The description does not show that the methylmalonic acid lowering means claimed in the patent would be suitable only for this antifolate manufactured by Appellant 1 for reducing the harmful side effects without impairing the tumor-inhibiting therapeutic effect.

5.5.7 Together with the lower court, it is to be assumed that only the pemetrexed disodium with the brand name "Alimta" manufactured by the Patent Proprietor is specified in the description as a tumor-inhibiting antifolate, and only pemetrexed disodium is claimed in the patent claims, whereas for the methylmalonic acid lowering means claimed in the patent derivative forms are also specified and described besides folate and vitamin B12. In doing so, it must be assumed, in accordance with the findings in the disputed decision, that the tumor-inhibiting effect of pemetrexed belonged to the prior art and that other salt forms were also known — specifically from patent EP 0 432 677 of Appellant 1. It is not evident from the findings in the disputed judgment that the methylmalonic acid lowering means claimed in the patent were previously known in a similar manner.

The overall possible conclusion that the lower court draws from the comparison of the enumeration of multiple forms for the methylmalonic acid lowering means on the one hand, and the specification of a single substance for the tumor-inhibiting means on the other hand, is not convincing in the present case. This, because the specifically claimed tumor-inhibiting active substance pemetrexed in the disodium conjugated form can easily be understood as the preferred form from the group of antifolates, namely when it is previously known, without having to conclude therefrom that the claimed methylmalonic acid lowering means were only when in combination with capable of reducing the harmful side effects with unchanged healing effect. It cannot be concluded in good faith, based upon the comparison of the specified tumor-inhibiting means in the form of pemetrexed disodium on the one hand, and the enumeration of the methylmalonic acid lowering means on the other hand, that the Patent Proprietor limited protection to the literally claimed pemetrexed disodium. The skilled person, whose understanding of the literal sense is also decisive in the context of the question of same effect (BGE 142 III 772 E. 6.2.3 p. 778) could, in accordance with his or her general knowledge as established by the lower court, find the disputed embodiment with same effect; he would have no reason to assume that the Patent Proprietor had claimed protection only for the literal embodiment.

5.5.8 The conclusion drawn by the German Federal Court of Justice in the parallel proceedings is convincing, namely that the specific designation of the chemical substance — comparable to the specification of numerical figure — is not automatically sufficient to deny parity/equal value (BGH judgment of 14 June 2016, loc. cit., p. 926, margin no. 79-81). As the Higher Regional Court of Munich states in its decision of 18 May 2017 (E. II.B. 3d/cc [2] p. 52), equivalence protection would come into question altogether if the practice regarding same effect — which was developed specifically based upon selection decisions of the patent proprietor — were extended to findable embodiments with the same effect not disclosed in the patent specification. In its judgment of 12 July 2012 (margin no. 70 et seqq.). The Supreme Court of the United Kingdom also modified the third “Improver” question in the finding

that protection against equivalents would be brought into question all together if in each case, after affirmation of a findable embodiment with the same effect, the literal sense of the patent claims were once again declared determinative, with reference to a lack of parity/equal value (margin no. 71). The UK Supreme Court convincingly states for the parallel case being assessed that the description generally mentions the effects of antifolates, and thus there are no evident reasonable grounds to believe that the Patent Proprietor claimed such a narrow protection as that resulting from the literal sense (margin no. 73). On the contrary, the President of the Supreme Court at the time, Lord Neuberger, finds that the reason for the narrow literal sense may be due to the fact that the experiments presented in the description were carried out with this form of pemetrexed (margin no. 74). This is also plausible when taking into account the patent's prosecution history as presented in the disputed decision.

5.5.9 The lower court's denial of parity/equal value cannot be accepted. The appeal has merit.

6.
If the Federal Supreme Court approves the appeal, then it decides on the matter itself or remands it to the lower court for reassessment (Article 107 (2) BGG).

6.1 The lower court approved the Respondent's alternative petition and found that the Respondent is not infringing patent EP 1 313 508 61 B1 (intended: EP 1 313 508 B1) by manufacturing in Switzerland a medicament for use in combination therapy for treatment of non-small cell lung cancer and malignant pleural mesothelioma in humans, etc., which contains as an antifolate active substance exclusively (a) pemetrexed dipotassium or (b) pemetrexed ditromethamine or (c) pemetrexed diacid, yet no pemetrexed disodium, wherein the medicament in question has no adjuvants that contain sodium ions, and the medicament is intended for administration in a solution that contains no sodium ions. The lower court generally assumed that Appellant 1 had waived protection against equivalent infringement ("Nachahmung") for all three forms of pemetrexed, which form the subject matter of the Respondent's request for relief. In its subsidiary arguments, it affirmed the same effect only for the preparation approved by Swissmedic and actually sold by the Plaintiff based on pemetrexed diacid, but explicitly left the matter open (E. 4.6.1) for the forms -dipotassium and -ditromethamine, although the same effect was considered as given in the technical judge's expert opinion, with the reasoning that the authorization was issued for "one of the alternative formulations."

6.2 Even though it is hardly possible to see how the disputed patent infringement could be assessed differently with regard to the forms explicitly left open by the lower court than for the “Amtiris” with the same effect in the form of the pemetrexed diacid (or the tromethamine salt thereof), there are no binding findings of the lower court in this regard. Therefore, in order to ensure the right to be heard, the matter is to be remanded to the lower court in accordance with the Appellants alternative petition. The lower court will have to dismiss the complaint with respect to the Respondent’s preparation of the brand name “Amtiris,” which was approved by Swissmedic, and otherwise, in addition to the findings of fact binding for the Federal Supreme Court (Article 105 BGG), assess the Plaintiff’s request for a declaratory judgment for the two other forms of pemetrexed.

7.

The appeal is to be approved, the disputed judgment of the Federal Patent Court is to be set aside, and the matter is to be remanded to the lower court for reassessment in line with the findings. In accordance with this outcome of the proceedings, the court costs are to be imposed upon the Respondent (Article 66 (1) BGG). The Respondent must reimburse the Appellants — who are represented by joint attorneys — for their costs of litigation for the proceedings before the Federal Supreme Court (Article 68 (2) BGG). A decision on the costs of the lower court proceeding will be have to be made in the new judgment by the Federal Patent Court.

The Federal Supreme Court therefore finds as follows:

1,
The appeal is approved and the judgment of 9 March 2017 of the Federal Patent Court is set aside. The matter shall be remanded to the lower court for reassessment.

2.
The court costs of CHF 15,000.00 shall be imposed upon the Respondent.

3.
The Respondent must reimburse the Appellants for their costs of litigation for the proceeding before the Federal Supreme Court in a total amount of CHF 17,000.00.

4.
The parties and the Federal Patent Court shall be notified of this judgment in writing.

Lausanne, 20 October 2017

On behalf of the First Civil Law Chamber
of the Swiss Federal Supreme Court

President: Court Reporter:

/Signature/ /Signature/

Kiss Leemann

[SEAL]

SWISS FEDERAL SUPREME COURT