Machine Translation

Düsseldorf District Court, 4a O 83/22

Date:	January 26, 2023
Court:	Düsseldorf District Court
Panel:	4a. Civil Chamber
Type of decision:	Judgment
File number:	4a O 83/22
ECLI:	ECLI:DE:LGD:2023:0126.4A.O83.22.00

Tenor:

I.

The injunction defendant is ordered,

1.

upon avoidance of a fine of up to EUR 250,000.00 for each case of infringement - or, in the alternative, of imprisonment for up to six months, or, in the case of repeated infringements, up to a total of two years, with the imprisonment to be carried out on the legal representative – to cease and desist from distributing, medicinal products containing

S1P receptor modulator for use in the treatment of relapsing-remitting multiple sclerosis in a daily dose of 0.5 mg p.o. [per os],

wherein the S1P receptor modulator is 2 amino-2-[2-(4-octylphenyl) ethyl]propane-1,3-diol in free form or in the form of a pharmaceutically acceptable salt; and

desist from offering, placing onto the market or using in the Federal Republic of Germany or to either import or possess for the aforementioned purposes

2.

in the territory of the Federal Republic of Germany to surrender to a bailiff the products in its direct or indirect possession or ownership in accordance with Clause I.1. for the purpose of safekeeping, which

shall continue until the existence of a claim for destruction between the parties has been finally decided or an amicable settlement has been reached.

II.

The costs of the proceedings are ordered to be borne 15% by the injunction plaintiff and 85% by the injunction defendant.

III.

The enforcement of the preliminary injunction with regard to item I. is made dependent on the provision of security in the amount of EUR 3,000,000.00. As regards the costs, the judgment is provisionally enforceable without the provision of security.

Facts of the Case 1

The injunction plaintiff sues the injunction defendant for use of the subject-matter of the European Patent EP A (patent specification Annex FBD 8, 8a; hereinafter: injunction patent) by way of preliminary legal protection for injunction and restitution to secure the claim for destruction due to the distribution of the generic drug "B" (embodiment under attack). 2

The injunction plaintiff is the parent company of the C Group, which includes the injunction plaintiff's wholly owned subsidiary, C X. C X is responsible in Germany within the C Group for the distribution of the drug "D" with the active ingredient 2-amino-2-[2-(4-octylphenyl)ethyl]propane-1,3-diol, which is also known as "E" or under the international non-proprietary name "B". The drug is used to treat certain groups of patients with relapsing-remitting multiple sclerosis (RRMS). Until the expiry of March 22, 2022, regulatory marketing protection existed for the drug "D" according to Article 14 (11) of Regulation (EC) 726/2004, Section 24b (1) Sentence 2 AMG. 3

The injunction plaintiff is the registered owner of the injunction patent (see register extract of the DPMA, Annex FBD 1), which was filed on June 25, 2007, claiming the priority of the British patent application GB F of June 27, 2006. It was a divisional application of the European patent application EP G, originally published as WO H. 4

The Examining Division of the EPO initially refused to grant a patent based on the application on November 19, 2020, due to lack of novelty. The injunction plaintiff filed an appeal against this decision on December 22, 2020. The EPO Board of Appeal overturned the Examining Division's decision on February 8, 2022. The third-party objections filed in the appeal proceedings were rejected as being out of time. The Board of Appeal remitted the case to the Examining Division with the order to grant a patent on the basis of a claim with predetermined wording and a description to be adapted thereto (cf. for the preliminary view of the Technical Board of Appeal dated October 8, 2021, together with German translation, Annexes FBD 11 and FBD 11a; 5

minutes of the appeal hearing of February 8, 2022, together with German translation, Annexes FBD 12 and FBD 12a; written reasons of the decision together with German translation, Annexes FBD 13 and FBD 13a). The communication under Rule 71(3) EPC Implementing Regulations was issued on August 18, 2022. The injunction plaintiff filed the claims translated into the official languages under August 19, 2022 and paid the grant fee. The injunction patent was finally granted on October 12, 2022, and the mention of its grant was published in the Official Journal of the EPO on the same day (see Annex FBD 1). Oppositions against the injunction patent are pending before the European Patent Office from various competitors - including a company belonging to the group of companies of the injunction defendant in this case - which have not yet been decided. The injunction patent is in force.

The injunction patent relates to an S1P receptor modulator for use in the treatment of remitting multiple sclerosis (MS). The sole claim 1 of the injunction patent reads as follows in the original English version: 6

"*A S1P receptor modulator for use in the treatment of relapsing-remitting multiple sclerosis, at a daily dosage of 0.5 mg p.o., wherein said S1P receptor modulator is 2-amino-2-[2-(4-octylphenyl) ethyl]propane-1,3-diol in free form or 45 in a pharmaceutically acceptable salt form.*" 7

and in the registered German translation: 8

„*S1P-Rezeptormodulator zur Verwendung bei der Behandlung von schubförmig-remittierender Multipler Sklerose in einer Tagesdosis von 0,5 mg p.o., wobei der S1P-Rezeptormodulator 2-Amino-2-[2-(4-octylphenyl)ethyl]propan-1,3-diol in freier Form oder in Form eines pharmazeutisch unbedenklichen Salzes ist.*“ 9

The injunction defendant is a pharmaceutical company belonging to 'I' which, among other things, sells generic drugs on the German market. On June 25, 2020, 'J', which also belongs to this group of companies and is headquartered in 'X', received a marketing authorization under pharmaceutical law for the embodiment under attack "B" in a dosage of 0.5 mg, whereby the authorization refers to the use of the "D" generic in adults and children and adolescents (from an age of ten years and over 40 kg body weight) with relapsing-remitting multiple sclerosis (cf. Annexes FBD 4 and Set of Annexes FBD 5). In view of the marketing authorization, the injunction plaintiff explained its view of the property right situation to 'J' in a letter dated January 11, 2022 (Annex FBD 7/7a) and referred to the Board of Appeal's decision of February 8, 2022 in a letter dated February 11, 2022 (Set of Annexes FBD 7/7a). After the EPO had issued the grant decision on September 15, 2022, and it was clear that the injunction patent would enter into force on October 12, 2022, the injunction plaintiff contacted 'J' once again to inform it of this new development with regard to the injunction patent. All these letters remained unanswered by 'J'. 10

Since October 1, 2022, the embodiment under attack is listed in the Lauer-Taxe (Annex FBD 6). The selling price for the embodiment under attack stated there corresponds to the price for the drug "D" of the injunction plaintiff. The injunction defendant has not yet concluded any discount agreements for the embodiment under attack. The injunction defendant plans the first delivery of the embodiment under attack on the German market for February 2023. The embodiment under attack realizes all features of the sole claim of the injunction patent. 11

The injunction plaintiff is of the opinion that it is entitled to an injunction. It is entitled to the asserted claims for injunctive relief and for restitution to secure the claim for destruction. In particular, the injunction defendant is still offering the embodiment under attack through its listing in the Lauer-Taxe even after the injunction patent has been granted, so that there is a risk of repetition. 12

Furthermore, there was also a reason for the injunction, since the issuance of the preliminary injunction was urgent due to the grant of the injunction patent. 13

The legal validity of the injunction patent was sufficiently secured. In the present case, the grant procedure is equivalent to an adversarial decision on the legal validity, since the injunction patent was granted only after comprehensive examination by the EPO in proceedings over two instances, in which several generic entrepreneurs were involved with a large number of objections to patentability. The final decision of the Technical Board of Appeal of February 8, 2022 - the highest instance in the grant proceedings and at the same time the body that would have to rule on an opposition in the final instance - shows that there are no reasonable doubts about the sufficiently secure legal validity of the injunction patent. Moreover, the submission of the injunction defendant regarding the legal existence could not shake the indicative effect of the decision to grant. 14

Finally, in view of the irreparable, imminent damage due to the price erosion and the conclusion of open-house contracts, the balance of interests must also be in favor of the injunction plaintiff, especially since the injunction defendant did not enter into any economic risks of its own due to the fact that it did not incur any research and development costs. By concluding open-house and discount agreements with the statutory health insurers, it was initially able to partially mitigate a massive loss of sales caused by the 4G Rule. However, it was only able to maintain its market share because it had accepted massive discounts on the list price averaging more than 80% under these agreements, which would have a significant impact on sales of "D". Its damage would increase with each additional day that the embodiment under attack remained in circulation. Based on the current figures for the current year 2022 (months of October, November and December), it expects a further loss of sales of EUR 41 million in addition to the loss of sales of around EUR 67.3 million that had already occurred before the injunction patent was granted. In addition, without the immediate prohibition of sales, it would be threatened with an additional drop in prices due to the recent initiation of fixed-price proceedings before the Federal Joint Committee. In this respect, there is a threat of the formation of a reference price group for B drugs and thus a fixed selling price, which would in all probability be significantly below its current list price. In addition, due to growing uncertainty among the statutory health insurers in view of the continued generic market presence, it is to be feared that in the future no more discount or open-house contracts at all will be concluded for B and existing contracts with it will be unilaterally terminated. 15

The injunction plaintiff originally filed an additional request for information but withdrew it during the hearing. 16

The injunction plaintiff now requests, 17

as found. 18

19

The injunction defendant requests

to dismiss the request for a preliminary injunction, 20

alternatively, 21

to make the enforcement of the preliminary injunction dependent on the provision of a security of not less than EUR 3,000,000.00. 22

The injunction defendant is of the opinion that there is no reason for injunction. The legal validity of the injunction patent is not sufficiently secured. The EPO overlooked essential facts and did not consider essential objections. The injunction patent was not sufficiently disclosed, not new, not based on an inventive step and also inadmissibly extended. Therefore, it will not be maintained in opposition proceedings. Furthermore, other foreign courts had already determined that it lacked legal validity. 23

The remaining weighing of interests was also to the disadvantage of the injunction plaintiff. The injunction plaintiff had never been interested in prompt patent protection because it had deliberately allowed time to pass. The behavior of the injunction plaintiff with regard to its application strategy had served to unsettle the market, so that it was reasonable for it to wait for the outcome of the opposition proceedings. The alleged damage to the injunction plaintiff can be estimated and no price drop that could not be predicted would be prevented. This had already occurred and the injunction plaintiff had minimized the loss of its market shares by concluding open-house and discount agreements. At the time of publication of the patent grant, the list price could no longer be realized. The fixed price procedure that had begun also did not cause irreversible damage. Furthermore, the interest of the general public in keeping drugs - which help people with RRMS - on the market at affordable prices would have to prevail. 24

The parallel proceedings 4a O 79/22 to 4a O 82/22 as well as 4a O 84/22 to 4a O 86/22 against other injunction defendants, which have the same injunction patent as their subject matter, have been submitted to the Board, have been heard and were subject of oral proceedings. The injunction defendant has adopted the arguments of the injunction defendants of the parallel cases with respect to the reason for injunction and the weighing of interests. 25

The court ex officio permitted the parties and the procedural representatives to be at another location during the oral proceedings and to perform procedural acts there via the Virtual Meeting Room (VMR) provided by the judiciary of the State of North Rhine-Westphalia. The parties to the proceedings have made use of this. 26

For further details of the facts and contentious issues, reference is made to the pleadings of the parties together with the annexes and to the minutes of the oral proceedings of January 5, 2023. 27

Reasons for decision 28

The admissible request for a preliminary injunction is well-founded. 29

The injunction plaintiff has made a prima facie case of a claim for injunction and a reason for injunction, Sections 935 et seq. of the German Code of Civil Procedure (ZPO) in conjunction with Art. 64 EPC, Sections 139 (1), 140a (1), 4 Patent Act (PatG). 30

A.

The injunction plaintiff has a claim for injunction against the injunction defendant because the embodiment under attack infringes the injunction patent and the injunction defendant offers it and threatens to distribute it.

I.

The injunction patent (hereinafter, paragraphs without citation are taken from the injunction patent) relates to a sphingosine-1-phosphate("S1P") receptor modulator for use in the treatment of relapsing-remitting multiple sclerosis.

S1P is a natural serum lipid. In its introductory description, the injunction patent describes that there are currently eight known S1P receptors, S1P1 to S1P8, (para. [0002]). S1P receptor modulators are compounds that act as agonists at one or more sphingosine-1-phosphate receptors, for example, S1P1 to S1P8, (para. [0003]). In addition to their S1P-binding properties, they also accelerate lymphocyte homing. For example, they can induce lymphopenia as a result of redistribution of lymphocytes from the bloodstream to secondary lymphoid tissue without inducing general immunosuppression (para. [0005]). Prior art S1P receptor agonists or modulators are known to have immunosuppressive properties or antiangiogenic properties in the treatment of tumors (para [0009]).

Multiple sclerosis (MS) is an immune-mediated disease of the central nervous system with chronic inflammatory demyelination leading to progressive deterioration of motor and sensory functions and permanent disability. The injunction patent criticizes that multiple sclerosis therapy is only partially effective and in most cases provides only a brief delay in disease progression despite anti-inflammatory and immunosuppressive treatment (para. [0010]).

Thus, underlying the injunction patent is the task (the technical problem) of providing effective means for inhibiting or treating demyelinating diseases, for example, multiple sclerosis or Guillain-Barré syndrome, including reducing, mitigating, stabilizing, or alleviating symptoms affecting the organism (para. [0010]).

Therefore, to solve this technical problem, the injunction patent proposes in its only claim S1P receptor modulators for the treatment of multiple sclerosis with the following features:

- 1. S1P receptor modulator

1.1 for use in the treatment of relapsing-remitting multiple sclerosis.

1.2 in a daily dose of 0.5 mg p.o..

2. The S1P receptor modulator is 2-amino-2-[2-(4-octylphenyl) ethyl]propane-1,3-diol in free form or in the form of a pharmaceutically acceptable salt.

II. 44

The embodiment under attack makes use of all features of the claim of the injunction patent. In this respect, there is no dispute between the parties. 45

III. 46

In this respect, the following tenor legal consequences result. 47

1. 48

The injunction defendant has offered the embodiment under attack nationally even after the injunction patent was granted. This is not contradicted by the fact that the injunction defendant has not yet sold the embodiment under attack on the German market and that the first delivery is not planned until February 2023. For already the - in this case - listing of a patented drug in the Lauer-Taxe during the term of the patent in question constitutes an offering within the meaning of Section 9 Patent Act (PatG) (Court of Appeal (OLG) Düsseldorf, decision of September 21, 2017 - I-2 W 4/17, BeckRS 2017, 142776 Rn. 11 – *Medikamentenrückruf*, with further references). Due to the announced start of sales in the Federal Republic of Germany in February 2023, there is also a first risk of putting the infringing embodiment on the market within the meaning of Section 9 Sentence 2 No. 1 Patent Act. 49

By offering and threatening to sell the embodiment under attack, the injunction defendant is making use of the teaching of the injunction patent contrary to Section 9 Sentence 2 No. 1 Patent Act. The injunction plaintiff is therefore entitled to the asserted claims for injunctive relief under Art. 64 EPC in conjunction with Section 139 (1) Patent Act. In particular, the injunction defendant has not eliminated the risk of repetition indicated by the infringing act by issuing a declaration to cease and desist and a declaration to undertake to comply with a penalty. 50

2. 51

The tenor of the release for safekeeping serves to secure the claim for destruction to which the injunction plaintiff is entitled against the injunction defendant under Art. 64 EPC in conjunction with Section 140a (1) Patent Act, to which the injunction plaintiff is also entitled. 52

The claim to surrender for the purpose of destruction is not called into question by the fact that the injunction defendant does not plan to sell the embodiment under attack until February 2023. Its statement in this regard that a market entry has not yet taken place because of supply bottlenecks does not contradict an existing domestic possession of infringing objects. 53

B. 54

The injunction plaintiff has also substantiated the reason for injunction required for the issuance of a preliminary injunction. 55

Pursuant to Sections 935 and 940 of the German Code of Civil Procedure (ZPO), the issuance of a preliminary injunction requires that the realization of a party's right is frustrated or significantly impeded or that it appears necessary to avert significant disadvantages to the right. The decisive factor for the existence of such a reason for injunction is whether the claimant cannot reasonably be expected to conduct proceedings on the merits of the case and to wait for 56

the issuance of an enforcement order in these proceedings. (Court of Appeal (OLG) Düsseldorf, GRUR-RR 2017, 477 para. 13 - *Vakuumgestütztes Behandlungssystem*; Court of Appeal (OLG) Mannheim, InstGE 11, 143 - *VA-LCD-Fernseher*). In addition to the urgency of the matter, this generally requires a weighing of the interests of the claimant worthy of protection and the interests of the respondent worthy of protection (Court of Appeal (OLG) Düsseldorf, InstGE 9, 140 para. 24 - *Olanzapin*; Court of Appeal (OLG) Düsseldorf, GRUR-RR 2017, 477 para. 1 - *Vakuumgestütztes Behandlungssystem*; District Court (LG) Düsseldorf, judgment of September 21, 2022 - 4b O 23/22; Schulte/Voß, Patent Act ,11th ed.: Section 139 para. 439; Cepl/Voß, German Code of Civil Procedure (ZPO), 2nd ed, Section 940 para. 64; Benkard/Grabinski/Zülch, Patent Act ,11th ed.: Section 139 para. 153a).

In the overall assessment required in the context of the examination of the reason for injunction, all aspects of the individual case must be taken into account, with particular attention being paid to the legal validity of the protective right to injunctive relief and to the threat of damage on the part of the patent owner. However, the extent of the damage on the part of the infringer in the event that the preliminary injunction has to be revoked must also be taken into account. The fact that a preliminary injunction must be revoked, in particular, if the injunction proves not to be legally valid, illustrates the relevance of the secured legal situation. The injunction defendant has a legitimate interest in not having to refrain from actions based on a protective right that later proves to be not legally valid. This applies all the more, the greater the threatened damage due to the enforced omission. If, on the other hand, the legal validity of the protective right to injunctive relief is sufficiently secured, the patent owner's interest in refraining from the patent infringement prevails, unless exceptional individual circumstances exceptionally cause the balance of interests to be in favor of the infringer. 57

I. 58

The legal validity of the injunction patent for the issuance of a preliminary injunction is sufficiently secured in the present case. 59

1. 60

A sufficiently secure legal validity can be assumed in particular if the injunction patent has been maintained in opposition or nullity proceedings in the first instance (compare Court of Appeal (OLG) Düsseldorf, InstGE 9, 140 para. 28 - *Olanzapin*; Court of Appeal (OLG) Düsseldorf, InstGE 10, 114 para. 18 - *Harnkatheterset*) or a preliminary decision has been issued by the EPO or Federal Patent Court (BPatG) which makes such maintenance sufficiently certain (Court of Appeal (OLG) Düsseldorf, GRUR-RR 2021, 249 - *Cinacalcet II*). However, even before the *Phoenix Contact/Harting* decision of the ECJ (GRUR 2022, 811), case law assumed that the legal validity was sufficiently secure for the issuance of a preliminary injunction even without a first instance decision in the legal validity proceedings in special factual constellations - for example, if the objections raised in the opposition or nullity proceedings prove to be groundless upon summary examination (Court of Appeal (OLG) Düsseldorf InstGE 12, 114, para. 18 - *Harnkatheterset*), the grant proceedings were conducted like adversarial proceedings due to objections by third parties, or the secured legal validity can be seen, for example, from the fact that well-known competitors have taken licenses to the right of disposal or that they have not initiated proceedings to establish the legal validity, although this would be expected in the event of doubts about the legal validity (cf. OLG Düsseldorf, InstGE 12, 114, 121 - *Harnkatheterset*; Court of Appeal (OLG) Düsseldorf, judgment of January 11, 2018 - I-15 U 66/17 = GRUR-RS 2018, 1291 para. 45; Kühnen, Handbook of Patent Infringement (Hdb. der Patentverletzung), 15th ed. 2023, Chapter G para. 60 et seq.). Furthermore, after an 61

overall assessment, a preliminary injunction may also be issued if the legal validity of the injunction patent is not secured in one of the aforementioned ways, if exceptional circumstances exist. Such circumstances may arise if the market situation or the disadvantages threatening from the infringement of the property right make it unreasonable for the patent owner to wait or to initiate proceedings on the merits. Such a case can be considered in particular in the case of infringement acts by generic companies (Court of Appeal (OLG) Düsseldorf, GRUR-RR 2021, 249, 252 para. 22 - *Cinacalcet II*). If such circumstances exist, a preliminary injunction may be issued if, from the point of view of the infringement court, the better arguments speak in favor of patentability or - with regard to the distribution of evidence applicable in the proceedings on the existence of rights - the question of patentability remains at least unresolved, so that the infringement court, if it had to rule on the merits, would have to affirm the legal validity (Court of Appeal (OLG) Düsseldorf, judgment of January 11, 2018 - I-15 U 66/17 = GRUR-RS 2018, 1291 para. 57; Court of Appeal (OLG) Düsseldorf, GRUR-RR 2021, 249, 252 para. 22 - *Cinacalcet II*). Ultimately, the relevant circumstances of the individual case must be considered in each case and always included in an overall weighing.

The above standards are not contradicted by the judgment of the ECJ "*Phoenix/Harting"* (judgment of April 28, 2022 - C-44/21, GRUR 2022, 811). In particular, it cannot be inferred from the decision that the mere fact that a patent has been granted would necessarily mean that action based on it would be permissible by way of interim relief, irrespective of the circumstances of the individual case. Insofar as the ECJ pointed out in para. 41 of the above-mentioned decision that a presumption of validity applies to European patents applied for from the time of publication of their grant and that they thus enjoy the full protection guaranteed, inter alia, by Directive 2004/48, it does not follow from this that this presumption could not be shaken in individual cases if the national court has reasonable doubts about the legal validity of the granted patent. 62

In addition, the decision concerns a national case law according to which the patent in question can only enjoy provisional legal protection if it has survived first instance proceedings to establish its legal validity (ECJ, loc. cit., para. 33). According to the ECJ, such a case law is contrary to the possibility provided for in Art. 9(1)(a) of Directive 2004/48 to put an immediate end to the infringement of an intellectual property right by means of the provisional measures provided for in national law. In this case, the national judge would be precluded from ordering, in accordance with this provision, a provisional measure to put an immediate end to the infringement of the patent at issue, which he considers to be valid and infringed (ECJ, loc. cit., paras. 34, 40). 63

However, the case law of the Düsseldorf courts described above deviates from the case law that was the subject of the ECJ decision cited above to the extent that the conduct of first-instance substantive proceedings is not presumed to be mandatory. Rather, there may be circumstances - such as the special cases mentioned - which justify the issuance of a preliminary injunction based on a patent which has not yet survived first-instance legal validity proceedings. 64

2. 65

Based on this, the injunction plaintiff need not await a decision in the opposition proceedings, but the Board must form its own opinion on the legal validity. 66

a. 67

First of all, however, the fact that the grant decision was not made until the appeal proceedings and that, despite the basic "ex parte" procedure, third parties were able to file objections to the patentability of the invention in accordance with Article 115 Sentence 2 EPC, does not in itself constitute, viewed in isolation, a special circumstance which argues for an increased reliability of the grant act and thus for a sufficiently secure body of law. 68

The reason why case law treats the decision to grant a patent in a procedure in which competitors have submitted their own objections as equivalent to a decision in an adversarial procedure is that these objections have already been comprehensively taken into account at the time of granting the patent, i.e. that these have been substantively examined. 69

It is true that several of the injunction plaintiff's competitors, who are to be taken seriously in terms of their potential for attack, had filed their own objections in the grant proceedings. However, not all objections were examined by the Examining Division or the Technical Board of Appeal in the appeal proceedings and taken into account to such an extent that the grant proceedings in this individual case would be equivalent to adversarial opposition proceedings. 70

The fundamental requirement of a litigation regarding the legal validity is not an end in itself. In view of the fact that attacks on the legal validity are typically undertaken by competitors of the owner of a property right on the relevant market who have an overview of the relevant prior art on the basis of their own business and filing activities and, in addition, possess and use sufficient search possibilities, the requirement of an adversarial decision ensures that the opposition or nullity decision favorable to the patent owner is on a secure basis because it takes into account all opposition or nullity grounds under consideration and is issued against the background of the entire relevant prior art. The aim is therefore to compensate for the search and examination deficit that exists in a merely one-sided (e.g. grant) procedure, which can manifest itself in the fact that certain relevant objections are inadvertently not taken into account in the procedure or that certain objections are not assessed or are not assessed from all possible angles. The involvement of third parties in the preparation and assessment of the facts of the decision increases the reliability of the decision reached (Court of Appeal (OLG) Düsseldorf, judgment of February 19, 2016 - I-2 U 54/15, BeckRS 2016, 6344 para. 17). 71

Insofar as objections are raised in the present proceedings which were not at all the subject of third-party objections in the grant proceedings, this circumstance indicates that they do not in any case constitute "more dangerous" attacks on the existence of rights than those already introduced in the grant proceedings. This may be assumed in the present case at any rate, because the injunction defendant accuses the injunction plaintiff in another context of "dragging out" the grant proceedings and otherwise a first-instance decision would already be available in the opposition proceedings. In view of the planning to swiftly follow up with opposition proceedings, it can therefore be assumed that there has already been an in-depth knowledge and treatment of the prior art for highly relevant and promising oppositions. 72

The same may be indicative for third party objections which were not considered and which were filed only after the decision by the Technical Board of Appeal and the remittal of the case to the Examining Division, without any comprehensible reason for the delay being apparent. 73

However, there are also objections in the present proceedings which - be it by the injunction defendant itself or by the injunction defendants in the parallel proceedings 4a O 79/22 to 4a O 82/22 and 4a O 84/22 to 4a O 86/22, the arguments of which the injunction defendant has adopted as its own - were submitted by third parties to substantiate the alleged lack of legal validity of the injunction patent still in the appeal proceedings, but were not taken into account. With regard to these objections, the reliability of the granting act is not in dispute, since here, unlike in the aforementioned constellations (no submission; submission after decision of the Board of Appeal), the procedural conduct of the third parties does not already speak against their relevance, but they were simply not substantively examined. 74

This is because, for formal reasons, the Board of Appeal did not take into account those submissions that were not filed until after the filing of the statement of grounds of appeal on November 18, 2019, which also include, for example, the presentation made by the injunction plaintiff in 2005 (= D 47 = TPO-D1 in the Board of Appeal's decision of February 8, 2022; Annex FBD 15). In this respect, the Board of Appeal stated on page 7 under Item 3.4 (Annex FBD 13/13a) in its decision of February 8, 2022, as follows: 75

„*In view of the foregoing, the board considers that the third-party observations received on 27 April 2021, 2 November 2021, 17 November 2021, 9 December 2021, 23 December 2021 and 18 January 2022 could and should have been filed during the examination proceedings. As a consequence, the board decided not to take these observations into account*.“, 76

in translation 77

„*In Anbetracht dessen ist die Kammer der Ansicht, dass die am 27. April 2021, 2. November 2021, 17. November 2021, 9. Dezember 2021, 23. Dezember 2021 und 18. Januar 2022 eingegangenen Einwendungen Dritter während des Prüfungsverfahrens hätten eingereicht werden können und müssen. Infolgedessen beschloss die Kammer, diese Stellungnahmen nicht zu berücksichtigen.*“ 78

Contrary to the opinion of the injunction plaintiff, it is precisely not clear from the reasoning of the Board of Appeal that the Board dealt with the content of the submissions. Even insofar as it is argued with regard to the provision on lateness under Article 114(2) EPC, which may be invoked, that the relevant panel must, within the scope of its discretionary decision and against the background of the principle of official investigation under Article 114(1) EPC, at least prima facie examine facts or evidence submitted late as to their relevance for the patentability of the subject-matter of the injunction patent before rejecting them as late (cf. BeckOK *PatR/Böhm*, 26th ed. July 15, 2022, para. 29 with further references) and - according to the case law of the Boards of Appeal cited by the injunction plaintiff - should or must take into account documents which prima facie have a "high relevance", it can rather be concluded from the brief reasoning of the Technical Board of Appeal that such an examination did not take place. 79

80

A fundamental distinction must be made between this special case constellation and the further question of whether the circumstance that an appellate instance in grant proceedings has already dealt with specific grounds for opposition in detail in terms of content when reviewing the decision of the Examining Division justifies equal treatment of the injunction patent - but only with regard to these specific grounds - with a patent that has undergone adversarial opposition proceedings. The idea behind this is that the patent originates from a superior instance whose findings on the canon of examination already to be determined ex officio and relevant for the assessment of patentability (such as the inadmissible extension in the case of an amended version of the claim) enjoy special trust (see Kühnen, Hdb. der Patentverletzung, 15th ed. 2022, Chapter G, para. 68). According to the Board, this question has to be decided depending on the individual case.

b. 81

In the present case, however, there are exceptional circumstances because the market situation and the disadvantages threatening from the infringement of the property right make it unreasonable for the injunction plaintiff to wait or for the main action to be taken. The injunction defendant is a generic drug company whose infringement activities may further perpetuate the price erosion - which initially had to be accepted due to the lack of a granted injunction patent - and this is also supported by fixed-price proceedings that have already been initiated. The threatened damages on the part of the injunction plaintiff - see B. II. 2. - therefore justify its action in summary proceedings if, in the Board's view, the better arguments speak in favor of patentability or - with regard to the distribution of evidence applicable in the proceedings on the legal validity of the patent - the question of patentability remains at least unresolved, so that the Board, if it had to decide on the merits, would have to affirm the legal validity of the patent. 82

In the present case, an appellate body in the granting proceedings with specific grounds for opposition has already dealt with the decision of the Examining Division in detail in terms of content during the review. Increased confidence appears to be justified in the expert and detailed discussion of the Board of Appeal, since it already represents a qualified quasi-judicial instance, which has many years of experience in the technical field of pharmaceutics and superior expertise compared to the Board with regard to the technical information or general expertise, which the person skilled in the art makes use of in order to assess the therapeutic efficacy of the invention. In view of Sec. 294 (2) of the German Code of Civil Procedure (ZPO), the board is also prevented from obtaining such expertise externally. With regard to a qualified preliminary decision, the Court of Appeal (OLG) Düsseldorf has considered it inadmissible for an infringement court to doubt and deviate from the independent findings of an Opposition Division with technical expertise, unless the injunction defendant refutes as objectively incorrect those bases on which the conclusions of the Opposition Division are based (GRUR-RR 2021, 249 - *Cinacalcet II*). The Board is of the opinion that a comparable standard must also be applied in the present case in order to be able to assume that the granting decision of the Board of Appeal is no longer in dispute for the injunction plaintiff on this point. In the event of such a rebuttal, better arguments should then speak against the legal validity of the injunction patent. 83

84

As already explained, when assessing the legal validity in this individual case, it can be taken into account that prior art that was not already introduced in the context of the third-party objections could tend to be less promising than prior art that was merely not (or no longer) examined in the granting procedure.

c. 85

The Board has come to the conclusion that, in the result, there is an equal amount in dispute for and against the legal validity, so that the question of the existence of a ground for opposition ultimately remains unresolved and, in view of the burden of proof in opposition proceedings, the Board assumes that the injunction patent is legally valid (cf. OLG Düsseldorf, GRUR-RS 2021, 4420 - *Cinacalcet II*). The injunction patent has been granted and the injunction defendants have not been able to credibly demonstrate that the bases on which the Board of Appeal concluded that the injunction patent should have been granted are objectively incorrect. 86

aa. 87

The teaching of the injunction patent is in principle amenable to patent protection. It is not merely a dosage recommendation for which this would not be the case (BGH, GRUR 2007, 404 - *Carvedilol II*). 88

A mere dose recommendation indicates in what quantities the medicine containing the active ingredient should be administered to patients and at what times. The administration of a medicine intended for the treatment of a specific disease as such is a therapeutic procedure for the treatment of the human body. It is not an element of the preparation of a substance for use in the treatment of a disease but follows it. The determination of the appropriate individual therapy plan for a patient, including the prescription and dosage of medicines, is a formative part of the activity of the treating physician and thus a process excluded from patent protection under Art. 53 lit. c EPC (BGH, GRUR 2007, 404 - *Carvedilol II*). 89

However, this is not the case here. The injunction patent is not limited to providing therapists or physicians with instructions for the specific application of B to a patient, such as in particular individual dosage and frequency of administration. Rather, it teaches - according to its claim 1 - the preparation of a substance for the treatment of a specific disease, namely an S1P receptor modulator for use in the treatment of a specific form of multiple sclerosis in a daily dose of 0.5 mg p.o., wherein the S1P receptor modulator 3 is present in free form or in the form of a pharmaceutically acceptable salt. 90

bb. 91

The subject-matter of the invention of the injunction patent is disclosed in the patent specification in a sufficiently detailed manner. 92

(1) 93

According to Art. 83 EPC or Art. 138(1)(b) EPC, an invention must be disclosed in a manner sufficiently clear and complete for it to be carried out by a skilled person. 94

It is necessary, but also sufficient, to demonstrate the practicability of the invention by a skilled person on the basis of the information content of the application in conjunction with the 95

general knowledge of the art, taking into account a depicted embodiment path and the given embodiment examples (Benkard *EPC/Schäfers/Wieser/Kinkeldey*, 3rd ed. 2019, EPC, Art. 83 para. 90; T 16/87 of July 24, 1990, OJ EPO 1992, 212 Egr. 4). It is sufficient if the application comprises a plausible technical concept and there are no reasonable doubts about the practical implementation of this concept (EPO decision of February 3, 2017 - T 0950/13, BeckRS 2017, 138817 para. 40, 46, with further references).

A therapeutic application is sufficiently disclosed if the aforementioned information content makes it technically plausible from the point of view of a skilled person that the claimed active substances can be used for the claimed therapeutic application (cf. EPO decision of September 13, 2007 - T 1599/06, BeckRS 2007 30693375, with further references). It is not mandatory to disclose results of clinical studies or animal experiments in the patent application. However, the mere assertion that a certain compound is suitable for the treatment of a certain disease is not sufficient as a sufficient disclosure of the therapeutic benefit. Rather, it is necessary that the patent application contains at least some relevant information, e.g. experimental tests, showing an effect on a metabolic mechanism involved in the disease in question, which metabolic process may either be known from the prior art or described in the European patent application. An in vitro study may also suffice to show this clinical effect, provided that for the skilled person the observed effect can be clearly and directly attributed to the therapeutic application, or provided that there is a clear and recognized relationship of action between the physiological activities shown and the disease (EPO decision of October 27, 2004 - T 0609/2002, BeckRS 2004 30613066, with further references). Post-publication studies or publications cannot replace information on sufficient disclosure at the filing date; however, they can be used to support the - in this respect already sufficient - information (cf. EPO decision of October 27, 2004 - T 609/2002; BeckRS 2004 30613066 EG 9; BeckRS 2007, 30584291 EG 28-29; EPO decision of June 14, 2007 - T 0433/2005, BeckRS 2007 30584291). 96

After the patent has been granted, the objection of lack of disclosure can only be raised against an application if there are serious doubts substantiated by verifiable facts (EPO, decision of October 3, 1990 - T 19/90 - *Krebsmaus/HARVARD II,* GRUR Int 1990, 978; EPO, decision of October 14, 2004 - T 890/02 - *Chimäres Gen/BAYER*, GRUR Int 2005, 1030). 97

(2) 98

Measured against these principles, sufficient disclosure is to be assumed in the present case. In its decision of February 8, 2022 (Annexes FBD 13/13a), the Technical Board of Appeal of the EPO dealt in detail with the question of sufficient disclosure and came to the conclusion that the information in the application is sufficient to prove the suitability of the claimed dosage regimen of B for the claimed therapeutic application (para. 5.6 et seq.). This result can be transferred to the injunction patent, since the corresponding descriptive parts of the application were freely adopted in the granted injunction patent. 99

According to the assessment of the Technical Board of Appeal (Annexes FBD 13,13a, para. 5 et seq.), the injunction plaintiff - the appellant in the proceedings before the Technical Board of Appeal - can rely on the animal study disclosed in the application, as well as the clinical 100

study on humans with an oral daily dose of 0.5 mg B announced in the application, in order to demonstrate sufficient plausibility of the claimed medical use. The Technical Board of Appeal dealt in particular with the question whether the differences apparent between the animal study (para. [0016]) and the application in humans, in particular with regard to the different dosage, contradict this sufficient plausibility. The Board of Appeal answered this question in the negative with detailed reasons. In doing so, it comprehensibly stated that the EAE model used was a common and well-known animal model for multiple sclerosis in the state of the art and that it was based on Gijbels, et.al. (Ref: 4a O 80/22: Annex 35/D05 = D44). The various phases of EAE development were comparable to those of human MS (Annexes FBD 13, 13a, para. 5.16). Also, the injunction plaintiff had been able to make plausible on the basis of the pharmacokinetic results that an oral daily dose of about 0.042 mg/kg B-hydrochloride in humans leads to the same total body exposure to the drug as a seven times higher oral weekly dose of 0.3 mg/kg B-hydrochloride - the latter corresponded to the dose used in the animal model. The daily dose was 58% lower than the lowest daily dose in previous EAE studies in rats. The comparable dose in humans was 60% lower. Given the proportional reduction, it had been plausible that the claimed dose of 0.5 mg in humans would block RRMS-associated angiogenesis and inhibit relapses to the same extent as higher doses (Annexes 13, 13a, 5.19 et seq.). Given initial plausibility, subsequently published evidence-such as data from Cohen, et. al. in 2010 (D11, Annexes FBD 10, 10a), which showed significantly reduced B relapse data even at a daily dose of 0.5 mg-could also be considered (Annexes 13, 13a, para. 5.28).

The attacks of the injunction defendant against the decision of the Technical Board of Appeal do not refute the bases there as objectively incorrect. Thus, the Board cannot see any error in the fact that it is not relevant for the question of plausibility that B in the form of hydrochloride is used in the animal experiments mentioned in the injunction patent (para. [0015] et seq.). Since some relevant information is sufficient for the sufficient disclosure, showing the plausibility of one embodiment also seems to be enough. 101

Furthermore, the Board sees no evidence in the statements of Sriram et al. (4a O 79/22, Annex WKS 6) that the EAE model proves to be completely unsuitable for testing therapies. Contrary to the view, neither the injunction plaintiff nor the Board of Appeal claims that it is an accurate model and that research results are transferable 1:1 to RRMS patients. The conclusion on the part of Sriram et. al. that EAE is not a suitable means of investigating therapies is not equivalent to the conclusion that the EAE model is unsuitable for showing a therapeutic effect on relapsing phases. The animal model in the injunction patent shows a suitability of the claimed dosage and not a (complete) investigation. Apart from that, the Board of Appeal made its statements in knowledge of the publication by Gijbels et.al (D44), which also expresses criticism and urges a cautious approach to extrapolations from findings in EAE to MS (cf. Ref: 4a O 80/22: Set of Annexes 35/D05 = D44). 102

Insofar as the injunction defendants criticize the conversion of the weekly dose of 0.3 mg used in the animal experiments to a daily dosage of 0.5 mg in humans because it is not known to the skilled person whether rats show the same blood pharmacological reactions to B as humans, 103

this also does not show that the conclusion of the Board of Appeal in this respect is based on objectively incorrect grounds. Thus, it is not clear why falling below an alleged and unknown lower limit of linearity should eliminate the plausibility that linearity can exist. The injunction defendant also does not show that the assumption that only the bioavailability (AUC) is important is objectively incorrect. The fact that the party expert opinion taken into account in the granting proceedings formulates the expectations of the expert appears sufficient for the demonstration of plausibility on this point.

Furthermore, the injunction plaintiff has made a credible case that the technical effect of proportionally reduced doses in EAE rats and RRMS patients are species equivalent. Thus, it has demonstrated with the publication of Chiba et al. (Annexes FBD 21, 21a = D14) - which was known to the Board of Appeals - that the expert was aware of the correlation between doses in rats and human patients. The fact that in Chiba et. al. studies with B (E) with a lowest dose of 1.0 mg/day shows in kidney transplant patients and not in RRMS patients does not harm, since hereby only the expert knowledge is substantiated that there were observations on the therapeutic efficacy of B, from which the expert could recognize a correlation factor. Accordingly, the dose of 1.25 mg is not the lowest known minimum dose of B in human patients. But this prior art does not disprove that the 1.25 mg dose is the lowest minimum dose that was recognized to be beneficial in terms of efficacy for human patients in RRMS. Nor do the other animal studies cited in Chiba argue against the correlation of doses in rats and humans and the correct conversion to that extent. 104

That the Board of Appeal could not have assumed plausibility for a dosage of 0.5 mg in view of the lower daily dose of 0.25 mg in humans (table 3) disclosed in Thomson (D23, Ref. 4a O 79/22, Annex WKS 7; Ref. 4a O 80/22, Annex AG 24), because its assumption of species equivalence was based on the fact that no lower doses of 1.25 mg/day resp. less than 0.1 mg/kg/day would be beneficial in the treatment of RRMS patients and EAE rats, respectively, is not compelling. For it does not follow from Thomson that lower doses reduce relapses in humans in the same manner as the known 1.25 mg/day dose. 105

Insofar as the injunction defendants complain that the expert would not make the conversions of the dosages in this way, they are merely substituting their view for that of the Board of Appeal. The decision is substantiated in detail on this point. As far as can be seen, there is also no contrary party opinion, which is to be introduced in the opposition proceedings, on this question. Therefore, the Board does not consider the underlying calculation of the expert to be objectively incorrect. Furthermore, it should be added that the suitability of the dosage of 0.5 mg B daily for the treatment of RRMS claimed by the injunction patent has been indisputably proven by subsequently published publications, such as the study by Cohen et al. from February 2010 (Annexes FBD 10, 10a = D11), which further supports the decision of the Technical Board of Appeal. 106

Insofar as the injunction defendant sees contradictions between the experiments described in the application and the subsequently published data of the injunction plaintiff in its report of May 12, 2009 (Ref. 4a O 80/22, Annex AG 35/D2), the aforementioned study by Cohen et. al. is not refuted thereby. Finally, it must be taken into account that from the entire application of the 107

injunction patent, ultimately only one main claim was granted, which has the dosage scheme as its subject matter. In this context, the Board of Appeal addressed the issue of executable disclosure at length, so the decision particularly warrants heightened reliance on this issue.

The Board also does not reach a different conclusion in view of the Expert Judge's Opinion of the Swiss Federal Patent Court of August 15, 2022 (Ref. 4a O 80/22, Annex AG 20), since ultimately only a different legal assessment is made here with regard to the statement content of the animal experiments shown in para. [0015] et seq. and to the requirements placed on the existence of plausibility. It does not follow from this that the Board of Appeal made its decision on objectively incorrect bases. 108

cc. 109

The injunction patent is new. The injunction defendants were not able to credibly demonstrate that the bases on which the Technical Board of Appeal's conclusion on the novelty of the injunction patent was objectively incorrect. 110

According to Art. 54(1) EPC, an invention is considered new if it does not belong to the state of the art. According to Art. 54(2) EPC, prior art also includes that which has become available to the public through use or otherwise. 111

Any use of the technical teaching which makes it objectively accessible to the public in its entirety is sufficient. It is not necessary that the concrete user has also recognized or even understood the teaching on this occasion, as long as only the knowledge required for its realization can reach the public in this way. It is therefore sufficient if a transfer of the knowledge imparted to him to a person skilled in the art can be expected and this enables the recipient to carry out the teaching used. If an obvious prior use is asserted, the exact subject matter of the use and the circumstances under which the use took place, for example the place of use, must be substantiated and, if necessary, proven (Court of Appeal (OLG) Düsseldorf, GRUR-RR 2021, 249 para. 44 - *Cinacalcet II*, with further references). 112

The patentability of substances or mixtures of substances for specific use in methods for surgical or therapeutic treatment of the human or animal body and in diagnostic methods performed on the human or animal body is governed by the purpose-related substance protection according to Art. 53(4), (5) EPC in conjunction with Art. 53(c) EPC. Art. 53 lit. c EPC. Accordingly, known substances or mixtures of substances are considered to be new only if the claimed specific application in one of the aforementioned processes does not belong to the state of the art. Within the scope of the provision, a known compound not previously used for diagnostic or therapeutic purposes is thus deemed to be new with respect to this specific applicability (usability) disclosed for the first time (Benkard, *EPC/Melullis*, 3rd ed. 2019, EPC Art. 54 para. 308, EPO April 16, 1984 - T 43/82; EPO OJ EPO 1986, 295 - *Thenoylperoxid*). Patent protection for a substance for treating a disease can also be considered if the application to which the sought protection relates differs from applications known in the prior art only by a dosage instruction (BGH, GRUR 2014, 461 para. 15 - *Kollagenese I*). 113

The novelty of a (second) medical indication also requires that the use of the drug in the manner of its application or for its medical field of application has not yet been pre-described 114

or pre-used as effective or at least promising (BGH, GRUR 2011, 999 para. 31 - *Entdeckung zur Wirkung ohne neue Lehre zum technischen Handeln*). According to the case law of the Boards of Appeal of the EPO, a document only precludes the novelty of a claim to a second medical use in this respect if it not only discloses the second medical use, but also that it achieves a therapeutic effect or a pharmacological effect which directly and unambiguously underlies the claimed therapeutic use (cf. EPO decision of October 28, 1998 - T 158/1996, BeckRS 1998 30529649; so also decision of the Board of Appeal of the EPO of February 8, 2022, Annexes FBD 13/13a, under clause 6.4.3). The information or announcement alone that the pharmaceutical is undergoing a clinical trial phase for a specific therapeutic application and thus its efficacy is only being tested does not necessarily imply such a therapeutic or pharmacological effect (cf. EPO, loc. cit.; cf. also EPO May 23, 2002 - T 1031/00; Benkard, *EPC/Melullis*, loc. cit., Art. 54 para. 324).

(1) 115

The press release of April 6, 2006 (D10, Annex FBD 14) does not anticipate the subject matter of the injunction patent claim in a manner detrimental to novelty. This is because it does not directly and unambiguously disclose to the skilled person the clinical efficacy of the therapeutic treatment of RRMS using the dosage regimen claimed by the injunction patent. 116

The assessment of whether the subject matter of a patent is affected by a prior publication in a manner detrimental to novelty requires the determination of the overall content of the prior publication. The decisive factor is what technical information is disclosed to the person skilled in the art. The concept of disclosure is not different from the one used in patent law. Therefore, it is not necessary to determine in which form the person skilled in the art can, for example, implement a given general teaching with the aid of his technical knowledge or how he can possibly modify this teaching, but exclusively what can be directly and unambiguously inferred from the writing from the point of view of a person skilled in the art (BGH, GRUR 2014, 758, para. 38 - *Proteintrennung*; BGH, GRUR 2009, 382, para. 25 - *Olanzapin*). 117

C International's press release of April 6, 2006, presented the results of a Phase II study in RRMS patients in which two groups of patients were given daily doses of 1.25 mg and 5 mg E (B), respectively, over an 18-month period, and reported that a clinical effect had been shown for both doses (see heading of Annex FBD 14: "*Phase II data for E shows sustained efficacy and good tolerability* [...]). After 12 months, all patients who had received a 5 mg daily dose were switched to the 1.25 mg daily dose (Annex FBD 14, p. 2, para. 1). 118

Furthermore, the conduct of a Phase III study was announced, which, in addition to an arm with a daily dose of 1.25 mg B and a placebo arm, was also to include an exploratory arm with a dose of 0.5 mg B. According to the press release, *enrollment of* patients for this study has already begun in several European countries (Annex FBD 14 para. 4: "*This study has begun enrolling patients in several European countries*"). 119

Thus, D10 does disclose the S1P receptor modulator E and thus 2-amino-2-[2-(4-octylphenyl) ethyl]propane-1,3-diol in free form or in the form of a pharmaceutically acceptable salt at a daily dose of 0.5 mg p.o. Meanwhile, D10 does not directly and unambiguously disclose the efficacy of therapeutic treatment of RRMS using the claimed dosage regimen. The D10 120

(alone) does not provide the skilled person with any information that would indicate the clinical efficacy of the further - by more than half - reduced dosage of 0.5 mg instead of 1.25 mg. It is true that the press release shows for the skilled person that the lower dosage of 1.25 mg B in contrast to the dosage of 5 mg proved to be more advantageous with regard to the side effects that occurred, so that there was reason to initiate the exploration of an even lower dosage on the basis of this finding. However, statements about the expected outcome of the study regarding the new dosage are missing. In addition, paragraph 5 of the D10 states that "it is hoped" that the benefits shown by the Phase II study will also be confirmed in the Phase III study that has already been initiated. On the one hand, it is not clear from this that the statement should also extend to the efficacy of the dosage of 0.5 mg daily, which was precisely not part of the Phase II study. Secondly, the results of the study, which was only initiated and therefore still lies in the future, were not the subject of the press release. Against this background, it is not immediately and clearly evident to the expert that the efficacy of a dosage of 1.25 mg daily in the treatment of RRMS also implies the clinical efficacy of a dosage of 0.5 mg. 121

In this respect, the Board therefore agrees with the view of the Technical Board of Appeal which, as can be seen from the decision of February 8, 2022 (Annex FBD 13/13a under item 6), came to the conclusion that citation D10 does not anticipate all the features of the injunction patent for the reasons stated above. 122

Contrary to the opinion of the injunction defendant, feature 1.1 concerning the therapeutic effect is not disclosed directly and unambiguously by D10 and the question of teaching away only arises when examining the inventive step. 123

(2) 124

Nor does the presentation of the injunction plaintiff from 2005 (document TPO-D1, submitted as Annex FBD 15), which was rejected by the Technical Board of Appeal as being late, anticipate the subject matter of the injunction patent in a manner detrimental to novelty. For this also does not disclose clinical efficacy of a dose of 0.5 mg B for use in the treatment of RRMS according to feature 1.1 of the injunction patent. 125

The TPO-D1 presentation (as of June 21, 2005) (also) concerns the Phase II study of RRMS patients given daily doses of 1.25 mg and 5 mg E (B), discussed in D10's later press release, and presents the initial results of the study after a six-month period. In terms of content, it does not go beyond the disclosure of D10 in this respect. 126

Notably, also in the TPO-D1, the Phase III study with an arm with 0.5 mg B is merely announced under the item "nächste Schritte" ("Next steps", see slide 25 of Annex FBD 15), as pasted below: 127

X 128

In this respect, slide 26 only indicates that a meeting with the FDA took place in connection with the results of the phase II trial ("*End of phase II FDA meeting*"), in which, in any case, it was 129

apparently addressed to make a 0.5 mg dose or even a lower dose the subject of the phase III study in addition to the 1.25 mg B dose tested for more than six months ("*Concur with lower 0.5 mg dose as additional arm in phase III*", "*Suggested considering even lower doses*"). The fact that there was already FDA approval for the lower dose does not change the fact that no results on the study, which is still in the future, and thus no statements on clinical efficacy are the subject of the presentation. The decision to include an additional arm in Phase III does not automatically imply that therapeutic efficacy of the 0.5 mg dose will be established.

Contrary to the opinion of the injunction defendant, the document rejected in the proceedings for grant as being late is thus not closer to the subject-matter of the invention than D10. For an unambiguous and direct disclosure it is precisely not sufficient to expect success that the dosage is sufficient for an effective treatment. 130

(3) 131

Also the citation "Kappos et al" (document D14, Annex FBD 22, page II/143 et seq.), a paper by L. Kappos, P. Calabresi, R. Hohlfeld, P. O'Connor, C. Polman and S. Aradhye entitled "*Design of a randomised, placebo-controlled study of oral B (E) in relapsing-remitting multiple sclerosis*", which was also not the subject of the proceedings before the Technical Board of Appeal, is not capable of prejudging the subject-matter of the injunction patent in a manner detrimental to novelty. 132

D14 also does not clearly and directly disclose to the skilled person a clinical efficacy of the dosage of 0.5 mg B claimed by the injunction patent, and thus not feature 1.1 of the injunction patent. 133

The essay does not go beyond disclosing the two citations already discussed, D10 and TPO-D1. The essay cites the results of the six-month Phase II study with B without discussing any specific dosage. It then announces that a phase III study has been *initiated* to evaluate the efficacy and safety of B in patients with RRMS ("*A large randomised, double-blind, placebo-controlled phase III study (Protocol 2301) has been initiated to further evaluate efficacy and safety of B in patients with RRMS*"). Under "Methods" of the announced study, among other study criteria, a single daily dose of 1.25 mg B is announced, as well as 0.5 mg B or placebo use for up to 24 months. Furthermore, it is stated that the "recruitment" is to start in January 2006 and that results are expected in 2009, i.e. not yet available. 134

From the expert's point of view, this only announces the Phase III study. A clinical efficacy of the different dosages is thus not disclosed, but is only to be tested. This is confirmed by the conclusion ("Conclusion") to be found at the end of the article (Annex FBD 22, p. II/144) "*This study will help in defining the role of B as a new oral treatment option for RRMS*", in translation: „*Diese Studie wird dabei helfen, die Rolle von B als neue orale Behandlungsoption für RRMS zu definieren*“. 135

(4) 136

Finally, the "Abstact" to the essay "Kovarik et al." (Ref. 4a O 80/22, Set of Annexes AG 35/D16; Annex FBD 26) does not anticipate the injunction patent in a manner detrimental to novelty. 137

The "Abstract" discusses the "*E exposure/efficacy relationship in* a *6-month phase 2 study in patients with relapsing MS*". (translated: *„Verhältnis zwischen Exposition und Wirksamkeit von E in einer 6-monatigen Phase-2-Studie bei Patienten mit schubförmiger MS“*) 138

The conclusion of the "Abstract" states: 139

„*In line with the comparable efficacy achieved at both the 1.25 and 5.0 mg E dose levels (e.g. reduction of annualized relapse rate by 55% and 53% vs placebo, p /0.009 and 0.014, respectively), pharmacokinetic/dynamic modeling showed a flat exposure-relationship, suggesting near-maximal responses were achieved at the two dose levels tested. These data support exploring potentially lower doses of E in future MS studies.“* 140

In German translation: 141

„*Im Einklang mit der vergleichbaren Wirksamkeit, die mit den E-Dosierungen von 1,25 und 5,0 mg erreicht wurde (z. B. Verringerung der annualisierten Schubrate um 55 % und 53 % gegenüber Placebo, p /0,009 bzw. 0,014), zeigte die pharmakokinetische/dynamische Modellierung eine flache Expositionsbeziehung, was darauf hindeutet, dass bei den beiden getesteten Dosierungen nahezu maximale Reaktionen erzielt wurden. Diese Daten sprechen dafür, in künftigen MS-Studien potenziell niedrigere Dosierungen von E zu untersuchen*.“ 142

Thus, the study reveals only modeling with K doses of 1.25 and 5.0 mg, which achieved promising results, so the study authors recommend further studies with potentially lower doses of the active ingredient. 143

Thus, the citation does not disclose any of the features of the injunction patent. Neither a daily dose of 0.5 mg p.o. of the S1P receptor modulator nor its efficacy for the treatment of relapsing-remitting multiple sclerosis is shown. 144

(5) 145

To the extent that the novelty of the injunction patent was denied in part by foreign courts, the Board is not convinced. In this respect, the Tribunal Judiciaire de Paris in its decision of June 3, 2022 (Annex AG 15/15a in 4a O 80/22 and 81/22, there page 19) as well as the Stockholm District Court - Patent and Market Court in its decision shown in Annex AG 47a in 4a O 80/22 and 81/22 assume, that for the skilled person it was already apparent from the announcement of the Phase III study with the dosage of 0.5 mg B daily claimed by the injunction patent that the therapeutic effect was no longer merely hypothetical and that the results achieved in Phase II represented a reasonable hope of success (Annex AG 13a in 4a O 80/22 and 81/22, there page 19), respectively that, from the point of view of the skilled person, the description of an agreement with the FDA in the C presentation (document TPO-D1) to include the 0.5 mg dose in the Phase III trial proved the therapeutic effect (see decision of the Stockholm District Court, Annex AG 47a in 4a O 80/22 and 81/22). As already stated, the information or announcement alone that the dosage is undergoing a clinical trial phase for a specific therapeutic application and thus its efficacy is first being tested is not necessarily sufficient for the direct and unambiguous disclosure of a therapeutic or pharmacological effect. From the C-presentation (document TPO-D1) and the meeting with the FDA mentioned there, nothing else results from the point of view of the Board - as stated. 146

dd. 147

Furthermore, it cannot be established that the bases on which the conclusion of the Technical Board of Appeal on the inventive step of the injunction patent is based would be objectively incorrect. 148

According to Art. 56 EPC, an invention is deemed to involve an inventive step if it is not obvious to a skilled person from the prior art. It must therefore be asked whether a skilled person having average knowledge and skills, as typically entrusted with development tasks in the technical field of the invention in companies operating in this field on the priority date and who is assumed to have had the entire prior art publicly available on the priority date at his disposal for his development work, would have been able to find the subject-matter of the invention without having to perform a task exceeding the average knowledge and skills including any routine tests (Court of Appeal (OLG) Braunschweig, GRUR-RR 2012, 97, 98). The effort required to find or refer to the prior art is irrelevant (OLG Braunschweig, GRUR-RR 2012, 97, 98). 149

Therefore, in order to consider the adoption of a solution deviating from the paths taken so far not only as possible, but as suggested to the skilled person - apart from those cases in which it is obvious to the skilled person in the art what has to be done - additional impulses, suggestions, hints or other reasons beyond the recognizability of the technical problem are usually required for seeking the solution of the technical problem on the path of the invention (Federal Supreme Court (BGH), GRUR 2009, 746, 748 - *Betrieb einer Sicherheitseinrichtung*; BGH, GRUR 2012, 378, 379 - *Installiereinrichtung II*). 150

When examining whether a specific application of a medicament is based on inventive step, also courses of action are to be taken into account which were suggested to the skilled person because they were part of the standard medical repertoire on the priority date (Federal Supreme Court (*BGH) GRUR 2014, 464 - Kollagenese II*). 151

Whether it is obvious for the skilled person to follow a solution path may also depend on the associated expectation of success. The requirements for a reasonable expectation of success cannot be formulated in a generally applicable manner, but must be determined in each individual case, taking into account the field of expertise at issue, the size of the incentive for the person skilled in the art, the effort required to take and pursue a particular approach and the alternatives that may be considered, as well as their respective advantages and disadvantages (Federal Supreme Court (BGH), GRUR 2019, 1032 - *Fulvestrant;* BGH, GRUR 2016, 1027 - *Zöliakiediagnoseverfahren*; GRUR 2012, 803 - *Calcipotriol-Monohydrat*; GRUR 2010, 123 - *Escitalopram*). 152

Insofar as a patent is concerned with a specific composition of an active ingredient, the following applies: If, on the priority date, there is an announcement by a pharmaceutical company that it will conduct a clinical trial on a particular active ingredient or dosage, this indicates that there is a concrete plan to introduce a commercially viable product which, among other things, has a useful degree of efficacy. The skilled person would not dismiss such an announcement as mere speculation, but would rather consider it as a promising approach (cf. EPO, decision of March 13, 2017 - T 0725/11 - *Combination Antiviral Therapy/GILEAD*). 153

According to these standards, the board is not able to recognize, also with regard to the inventive step, that the board of appeal started from objectively incorrect bases, the correction 154

of which should have led it to the conclusion that there was no inventive step. Insofar as the respondent raises various arguments against the inventive step and also raises new objections that have not yet been addressed in the grant proceedings, it ultimately substitutes its view for that of the Board of Appeal. These arguments, on the other hand, do not lead to a finding of lack of patentability by the board, which is not technically competent. For, from its point of view, there are still sufficient reasonable arguments in favor of the inventive step, so that the at most unresolved patentability would lead to the board affirming the validity if it had to decide on it itself.

(1) 155

According to the practice of the European Patent Office, the assessment of inventive step is to be based on the state of knowledge known at the priority date which comes closest to the technical teaching and technical progress provided by the injunction patent (cf. Court of Appeal (OLG) Düsseldorf, GRUR-RR 2021, 249 para. 54). According to the explanations of the Technical Board of Appeal, this is D10 (cf. Annex FBD 13/13a No. 7.1), whereby the following explanations can be used accordingly for the case that, deviating from this, TPO-D1 (= D 47) or Kappos et. al (D14) would be used as the closest prior art. 156

As stated in the context of novelty over D10, the difference in the disclosure of D10 and the injunction patent claim is only that D10 does not directly and unambiguously disclose to the skilled person a clinical effect or the therapeutic effect of the claimed dosage regimen of 0.5 mg B daily for the treatment of RRMS. 157

Therefore, based on the results of the Phase II study and the announced Phase III study, the technical problem to be solved for the expert is to provide a further agent for the effective treatment of RRMS (cf. Annex FBD 13/13a, clause 7.5). By effective treatment, the skilled person will understand the reduction/interruption of relapses. 158

(a) 159

On the basis of the disclosed study results of D10, there was in principle sufficient prospect of success for the expert to consider and clinically test a dosage of 0.5 mg B as a solution to the technical problem. 160

The fact that the active ingredient B had been successfully clinically tested in humans in the dosage of 1.25 mg and 5 mg as shown in D10, in conjunction with the announcement of a further study arm with a lower dosage - considered in isolation - provided a strong incentive for the skilled person to find out in further clinical studies which lower dosage still exhibited the efficacy and tolerability reported in D10, and thus to find a favorable relationship between the administered amount of B and its effect as an S1P receptor modulator, taking undesirable side effects into account. Explicitly, the skilled person was led to a reduced dosage of 0.5 mg B, starting from D10. 161

In this respect, the fact that it was announced in the D10 that an oral dose of 0.5 mg B to patients with RRMS would be included as an additional arm in the phase III clinical trial basically raised a reasonable expectation of success in the treatment of RRMS in the view 162

of the expert. This is because clinical trials are regularly based on data obtained through preclinical in vitro testing and animal experimentation, and must be officially approved taking into account ethical considerations. The person skilled in the art will therefore expect that any experimental arm of a study in humans will be effective in treating the disease, insofar as the person skilled in the art, by considering the documents in the prior art, does not come to the reasonable expectation that the experimental arm will fail, or insofar as the prior art does not teach away from this solution (cf. EPO, decision of September 13, 2017 - T 239/16, BeckRS 2017, 146633 para. 90; cf. EPO, decision of October 4, 2016 - T 2506/12, BeckRS 2016, 121266 para. 84; cf. EPO, decision of April 22, 2021 - T 0096/20, GRUR-RS 2021, 16767 para. 29; cf. EPO, decision of April 13, 2021 - T 1123/16, GRUR-RS 2021, 54217 para. 58 and, as a matter of fact, also Technical Board of Appeal Annex FBD 13/13a under clause 7.9).

Neither the information further obtained from D10, which has already been the subject of consideration by the Technical Board of Appeal, nor the pre-published documents TPO-D1 and D14 explicitly teach away from a clinical efficacy of a dose of 0.5 mg B in the treatment of RRMS. 163

There is no indication from the D10 itself that the use of a 0.5 mg dosage would not be promising for the effective treatment of RRMS or was included solely to demonstrate the efficacy of the 1.25 mg B dose. The skilled person was aware, based on the D10 disclosure at the priority date, that both a once-daily dose of 1.25 mg and a 5 mg B were effective in RRMS patients (D10, p. 1 et seq., see also slides 17 to 19 of TPO-D1). This is because it was at this dose that relapse rates were reduced during the 18-month Phase II study presented in D10, with the 1.25 mg dose reported as the lowest effective dose. Furthermore, D10 showed that administration of the higher 5 mg dose was associated with more adverse events than the lower 1.25 mg dose (see also slides 20 to 23 of TPO-D1, among others). 164

For the expert, therefore, at any rate on the basis of D10, there was nothing to prevent an even lower dosage of 0.5 mg, as announced as a further experimental arm, from being considered for an equally effective treatment of RRMS. 165

Also from the presentation of the TPO-D1 and from the essay of the D14 there were no indications for the expert to deviate from a reasonable expectation of the efficacy of a 0.5 mg dose. In particular, according to slide 26 of TPO-D1, there were no objections from the FDA at a meeting with the FDA in connection with the results of the Phase II study, in which it was agreed to make a 0.5 mg dose or even a lower dose the subject of the Phase III study in addition to the 1.25 mg B dose tested over six months. 166

(b) 167

However, it must be examined whether the further state of the art dissuaded the skilled person from a corresponding expectation of success with regard to the lower dose or nullified such an expectation. 168

The Technical Board of Appeal affirmed this (cf. decision Annex FBD 13/13a, 169 para. 7.10). In support of this, it stated that it was clear to the expert from document D28 "Webb et al." (Annex FBD 16) that a threshold value of at least 70% lymphocyte reduction must be achieved for successful therapeutic treatment of RRMS. Based on the disclosures of 169

documents D26 "Park et al." (Annex FBD 17) and D27 "Kahan et al." (Annex FBD 18) in combination with document D23 "Thomson" (Annex AG 24/24a in 4a O 80/22), the skilled person would conclude that a dose of 0.5 mg B does not achieve this threshold of lymphocyte reduction in clinical trials.

First of all, it should be noted that in view of the fact that the Technical Board of Appeal also focused on whether, from the point of view of a person skilled in the art and based on the prior art, there is a "teaching away" from the dosage scheme claimed by the patent for invalidity and affirmed this with regard to the documents examined, the Board sees no reason here to address whether the citations examined are sufficient to (also) show a "technical prejudice" within the meaning of the EPO case law (cf. e.g. EPO decision of February 3, 2005 - T 1212/01, BeckRS 2005 30686899, beck-online; EPO decision of July 21, 2010 - T 1989/08, BeckRS 2010, 146803 para. 49). 170

As a result, the board does not see any far-reaching arguments that refute the basis of the board of appeal's technical opinion and argue that the board of appeal assumed, on the basis of objectively incorrect assumptions, that the rest of the prior art taught the skilled person away from the expectation of success. Rather, the Board is also of the opinion that the prior art taught away from the dosage claimed in the patent-in-suit, and that the skilled person did not assume that the dosage would be successful in the treatment of RRMS, despite the announcement of the phase III trial with the reduced dosage of 0.5 mg B. In this respect, it is also not decisive whether the person skilled in the art had the additional understanding that the additional arm was included in the phase III study merely to prove the efficacy or safety of the tested drug with the higher dosage. 171

(aa) 172

The Technical Board of Appeal is of the opinion that the expert deduces from document D28 "Webb et al." (Annex FBD 16, there on page 118, last paragraph) that a threshold value for the reduction of lymphocytes of at least 70% is required for a therapeutic treatment of RRMS. That this - to the contrary - would not be the case is not evident. 173

On p. 118, last paragraph of D28, it is stated in this respect: 174

"*In dose response experiments. we found that a threshold of about 70% depletion of peripheral lymphocytes was required to see any efficacy, and thereafter, the close response relationship between clinical benefit and lympho-poenia was very steep."* 175

translated: 176

„*In Dosis-Wirkungs-Experimenten stellten wir fest, dass ein Schwellenwert einer etwa 70-prozentigen Reduktion der peripheren Lymphozyten erforderlich war, um irgendeine Wirksamkeit zu erzielen, und dass danach die Dosis-Wirkungs-Beziehung zwischen klinischem Nutzen und Lymphopenie sehr steil war.*“ 177

It is not evident that the expert would recognize contradictions in D28 and therefore - contrary to the opinion of the Technical Board of Appeal - would not attach any importance to it. That on p. 119, 1st paragraph of D28 the correlation between clinical benefit and lymphopenia is 178

described as "imperfect", does not necessarily contradict the disclosed threshold, since this statement, according to the explanations on p. 118, last paragraph, seems to refer essentially ("in particular") to the initiation and termination of dose administration ("*In spite of these obervations, we did observe disconnection between lymphopoenia and clinical scores. This was particularly seen at the initiation and termination of dosing*", translated as "*Despite these observations, we observed a disconnection between lymphopenia and clinical scores. This was particularly the case at the initiation and termination of treatment.*"). Moreover, it is not decisive which - possibly deviating - information the skilled person can take from Figures 5 and 6 of D28, which merely reproduce data of initial experiments ("initial experiments", cf. D28, p. 114). For what matters is the conclusion of the paper, which, in the absence of other indications, is based on the results of all experiments performed. That this would be incorrect or contradictory is not evident.

The fact that the explanations in D28 refer to experiments on mice also does not indicate that the expert would not have taken into account the threshold value disclosed therein. It is not apparent that EAE models, contrary to the submission of the plaintiff in the injunction (and contrary to the statements in document D23 "Thomson", cf. Annex AG 24/24a in Ref. 4a O 80/22), would necessarily be ruled out as a recognized animal model for research into human MS in the prior art. Even if the expert in charge should consist of a team of a clinician and a pharmacologist, the board cannot exclude that he additionally pays attention to the results of the preclinical studies despite the existence of clinical studies at the priority date. Thus, it seems quite understandable that the person skilled in the art would in any case take into account the animal studies dealing with exactly the same clinical picture as that of the invention. 179

The statements in the paper by "Park et al." (D26, Annex FBD 17) do not contradict the threshold disclosed in D28. At the time of the article, the dose of 1.25 mg B had already shown positive results in the phase II study and was therefore familiar to the expert. It is true that Figure 7A in the paper by "Park et al." (D26, Annex FBD 17) appears to show a lymphocyte reduction of slightly less than 70% for this 1.25 mg B dose. However, unlike the doses of 0.25 mg, 0.5 mg, 1.0 mg, and 2.5 mg, this dose was not studied in the underlying experiment, so that the graph shown could not provide a reliable indication of the dose-response relationship of the 1.25 mg. Furthermore, the study by "Kahan et al." (D27, Annex FBD 18) already showed that a dose of 1.0 mg B already reaches the threshold value of 70 % (cf. D27 Figure 1). 180

Furthermore, the excerpt from chapter 16.4 of the textbook Multiple Sclerosis (Schmidt/Hoffmann (Eds.), Urban & Fischer, Munich 2006, Annex AR 15 in Case No. 4a O 85/22) does not contradict the assumed threshold value. It is already not evident that the expert would pay closer attention to the explanations. Because the excerpt does not treat the active substance B, which is already well-known in the state of the art, but the active substance Azathioprin, which exhibits another mode of action than B. The injunction plaintiff has also shown that the efficacy of azathioprine in the treatment of MS has been challenged in practice (see review paper by Farrell et al. from 2005 in the journal Expert Opinion on Emerging Drugs, submitted as Annex FBD 27). It is therefore not apparent why the expert should have had any reason to apply the comments on the active substance azathioprine to the effect of B in the effective treatment of RRMS. 181

Nor are any other reasons apparent for the person skilled in the art not to refer to document D28 as prior art. The fact that document D28 is not mentioned in the summary paper of "Thomson" (document D23) does not necessarily indicate that document 28 was not relevant. Also, as far as the D28 mentions a relative threshold value for a clinical efficacy and not an absolute value of lymphocyte counts, this seems understandable due to the fact that the absolute number of lymphocytes in the bloodstream can vary greatly from patient to patient. 182

(bb) 183

Furthermore, the Board is not able to establish that the view of the Technical Board of Appeal that the prior art further shows that the indicated dose of 0.5 mg B will not reach the threshold value of 70% (cf. decision Annex FBD 13/13a No. 5.4 (c) with reference to documents D27, Figure 1, and D26, Figure 7A) is based on objectively incorrect grounds. 184

(i) 185

The paper "Kahan et al." (document D27, Annex FBD 18) examines, among other things, the influence of different doses of B on lymphocyte reduction in stable kidney transplanted patients. The expert took from figure 1 of the paper of D27, which is shown below - color-coded by the injunction plaintiff - for illustration: 186

X 187

that a lymphocyte reduction equal to the 70% threshold required by D28 "Webb et al." (green dashed line) was achieved with doses of 1.0 mg (open diamonds, highlighted in green), 2.5 mg (asterisks) and 5.0 mg (closed triangles), but not with the much lower dose of 0.5 mg B claimed by the injunction patent. Rather, the figure showed that the lymphocyte reduction correlated with the increase in dosage. 188

(ii) 189

From the paper "Park et al." (Document D26, Annex FBD 17), there from Figure 7A superimposed below, showing the correlation between administered dose B (x-axis) and percent lymphocyte reduction in blood (y-axis), 190

X 191

also showed that a dose of 0.5 mg B clearly does not reach the threshold value of 70% lymphocyte reduction and that higher doses tend to lead to a more effective percent reduction of lymphocytes (see also D26, p. 683 "*E produced a dose-dependent increase in mean percent reduction of peripheral lymphocyte counts.*"). 192

Figure 6 of D26 does not contradict this finding. This is because the latter does not deal with the percentage reduction of lymphocytes (relative threshold value), but with the development of the absolute lymphocyte concentration. For the same reason figures 5a and 5b do not have 193

the same significance. The lymphocyte count differentiates in the population, it can range from about 1000 to 3000 in an adult human (see table Column Lymphocytes, last value in Annex AR 16 in Ref. 4a O 85/22). Due to the fluctuations, this value is not as meaningful as the relative decrease in the number of lymphocytes.

(iii) 194

Finally, it was apparent to the skilled person from the review article on B "Thomson" (document D23, Annex AG 24/24a in 4a O 80/22; Annex WKS 7 in Ref. 4a O 79/22) that the pharmacokinetic and pharmacodynamic results after administration of one or more doses of B in transplant patients - as evident from D26 and D27 - can be extrapolated, i.e. transferred, to patients with MS (cf. thus also decision of the Technical Board of Appeal Annex FBD 13/13a No. 5.4 (d)). Thus, on page 162, in the right column, in the second complete paragraph, it is stated as follows: 195

"*Pharmacokinetic and pharmacodynamic outcomes following single- or multiple-dose administration of E have been determined in both healthy subjects and transplant patients (Table 3). These data are included here as these outcomes are not affected by disease status and may be extrapolated to include those patients with multiple sclerosis.*", 196

translated: 197

„*Die pharmakokinetischen und pharmakodynamischen Ergebnisse nach der Verabreichung einer oder mehrerer Dosen E wurden sowohl bei gesunden Probanden als auch bei Transplantationspatienten ermittelt (Tabelle 3). Diese Daten werden hier aufgenommen, da diese Ergebnisse nicht durch den Krankheitsstatus beeinflusst werden und auf die Patienten mit Multipler Sklerose extrapoliert werden können.*“ 198

It is not evident that the skilled person would have inferred from the further content of the article that dosages lower than 1.25 mg also ensure effective treatment of RRMS. Insofar as it is further stated in D23 that studies on healthy subjects and kidney transplant patients have shown that even lower dosages than the dose of 1.25 mg B, which is known in the prior art to be effective, have led to a measurable reduction in the number of lymphocytes, the various individual oral dosages of 1 mg and 0.25 mg - 3.5 mg have not already led to a (relative) 70% reduction in lymphocytes, but only to 38% and 44% respectively. Insofar as the injunction defendant means that from these figures of the Thomson publication the required threshold value of a reduction of 70% of the peripheral lymphocytes for the effectiveness of the dosage is just not confirmed, since no clear dose-effect relationship can be determined, the board is not able to recognize that this statement of the Thomson publication is to be taken compellingly. On the contrary, it is stated in the same sentence that higher doses also led to greater degradation. Moreover, it is a question of single doses and not of a long-term, daily administration to be applied for the treatment of RRMS. Apart from that, the Board of Appeal, knowing D23, considered the threshold of 70% as decisive. 199

(cc) 200

201

As a result, despite the announcement of a phase III study with a dose of 0.5 mg B, the board cannot come to the conclusion, taking into account the aforementioned prior art, that, contrary to the present expert opinion, there was sufficient reason for the skilled person to seriously consider this dosage as an effective treatment for RRMS. In particular, the Board is unable to conclude that the skilled person would have attached greater importance to the announcement of the phase III trial than to the disclosures in the prior art which taught against reducing the dosage.

In conclusion, this is also contradicted by the fact that the aforementioned prior art studies showed a tendency that higher doses of B were associated with a higher or better decrease in the lymphocyte count (even if this tendency was not yet described as "clear" in D23, cf. D23, p. 163 below: "*Although the higher doses of E produced a more rapid and sustained lymphocyte sequestration, the actual degree of this property was similar across the range of doses used in the study and no clear dose-response relationship was detected*."). Thus, there was no evidence for the expert on the effectiveness of a further reduction of the dose of 1.25 mg. 202

Another argument against a reduction of the dose to 0.5 mg is that it was evident to the skilled person from the prior art that an increased dose B leads to a reduction of the scatter of *the* lymphocyte reduction measured in the patients (so-called "inter- and intra-patient variability") (cf. Annex D26, p. 692 "*Inter- and intra-individual variability of percent reduction of lyphocyte counts decreases with increasing E doses, perhaps due to achievment of maximal pharmacodynamic effect*"). Insofar as the respondent states that the scatter at best shows that an equilibrium ("steady state") must first be reached and does not allow any conclusion to be drawn as to the effectiveness of the 0.5 mg dose, the Board does not see in this any argument that would have compelled the expert to select the demanding dose. 203

(2) 204

Also the citation Tedesco-Silva et. al (Annex TW 18, Ref. 4a O 84/22) is not able to confirm the expectation of success of the 205 skilled person in the result just as little as the prior art already discussed. Here, too, the number of absolute lymphocytes and their changes were examined, i.e. the mechanism of B relevant to the present invention. The results are shown in Figure 2. Even though the number of patients in the study is higher than in other studies discussed above, the conclusion based on the absolute lymphocyte count does not seem robust enough to allow the skilled person to consider the dose of 0.5 mg as promising, despite the results of the EAE study in Webb et al. In addition, Figure 2 does not show a uniform zero line, so that the expert cannot draw any reliable conclusion from it for the comparability of the reduction at the different doses. 205

In view of the fact that this citation was not submitted in the grant proceedings as a third party objection - as the Board understands the submission of the respondent - this may be an indication that it in any case does not represent a prior art that is closer than the one already introduced. 206

(3) 207

Insofar as the injunction defendant also wishes to cite Abstract #612, by Kovarik. et al. (Annex TW 13, Ref. 4a O 84/22) as a new citation, the injunction plaintiff has objected that this 208

contribution corresponds to the Tedesco-Silva citation, which is the more complete analysis. This is supported by the personal identity with the second author and the later publication with a higher number of patients. In this respect, reference is to be made to the above statements. The denial with ignorance of the respondent is in this context unhelpful, since the content of a published conference paper is not the subject of one's own perception, but can be researched by the party and is therefore verifiable.

(4) 209

Also based on the citation "Kovarik et al." (Annex AG 35/ D16, Ref. 4a O 80/22; Annex FBD 26), an abstract published in 2005 in the journal "Multiple Sclerosis" under the title "*E exposure/efficacy relationship in a 6-month phase 2 study in patients with relapsing MS*", which was not explicitly examined by the Technical Board of Appeal in the appeal proceedings, the subject-matter of the patent in suit is not suggested to the skilled person. 210

In this respect, the disclosure content of D16 already does not go beyond D10 or TPO-D1. Also, the D16 reports the results of the C study on the relationship between exposure and efficacy of E (B) in the international, multicenter, double-blind, 6-month study conducted in 281 patients with relapsing-remitting MS. The D16 discloses that E (according to the first 6-month results) at the doses used of 1.25 mg/day (n=94) and 5.0 mg/day (n=94) significantly reduced both MRI and clinical MS activity compared with placebo (n=93). 211

As far as it is stated under the point "Conclusion" that the pharmacokinetic/dynamic modeling shows a flat exposure ratio, which indicates that a nearly maximal response was achieved at the two tested doses and that these data support *exploring* potentially lower doses of E in future MS studies (D16, penultimate sentence: "*These data support exploring polentially lower doses of E in future MS studies.*"), in the expert's view, this information or conclusion is already apparent from D10 and also from TPO-D1 due to the announcement of the phase III trial with a reduced dose study arm (see above). 212

Even if the skilled person, on the basis of D16, thus in principle arrives at the expectation of success that lower dosages should also be clinically tested for their efficacy in the treatment of RRMS, there is on the one hand no suggestion that the dosage of 0.5 mg B (feature 1.2) according to the patent should be selected, and on the other hand this expectation of success is - as stated above - shaken by the teaching away in the prior art. In this respect, reference is made to the above statements. Moreover, it is also not evident why the skilled person should test the dose of 0.5 mg B, which is not sufficiently effective according to the information in the prior art, on the basis of D16 and not, for example, the dose of 1.0 mg B, which is more promising according to D27. 213

(2) 214

Even taking into account the decisions of foreign courts, the board does not come to the conclusion that the inventive step must necessarily be denied. Rather, the question of patentability remains unresolved in any case, even taking the decisions into account. 215

The decisions of foreign courts denying inventive step do not base their view on arguments that go beyond those put forward by the injunction defendant. Thus, both the Commercial Court of Barcelona (decision of October 10, 2022, Annexes AG 36/36a in 4a O 80/22 and 81/22), the Tribunal Judiciaire de Paris (decisions of May 16, 2022, Annexes AG 13/13a and AG 19/19a), a Swiss specialist judge's opinion by specialist judge X of August 15, 2022 (Annex AG 20 in 4a O 80/22 and 81/22), the Stockholm District Court (Annex AG 47a in 4a O 80/22 and 81/22), and the Finnish Market Court (decision of December 23, 2022, Annex AG 53/53a in 4a O 80/22 and 81/22) concluded that, contrary to the view of the Technical Board of Appeal, the announcement of a Phase III study with the dosage claimed by the patent in suit in D10 or TPO-D1 suggests its clinical efficacy from the point of view of the skilled person and that a teaching away from this dosage was not sufficiently evident from the prior art. The decisions predominantly apply a stricter standard to the prevalence or weight of views teaching away from the claimed dosage in the prior art. Furthermore, the announcement of the Phase III study is given greater importance in comparison (see, for example, Barcelona Commercial Court, decision of October 10, 2022, Annexes AG 36/36a in 4a O 80/22 and 81/22, there p. 13, para. 36; Tribunal Judiciaire de Paris, decision of May 19, 2022, Annexes AG 19/19a; decisions of the Stockholm District Court, Annex AG 47a in 4a O 80/22 and 81/22). To the extent that the foreign courts, with more (e.g., Specialist Judge X's Opinion of August 15, 2022, Annex AG 20 at 4a O 80/22 and 81/22) or less in-depth reasoning (e.g., Finnish Market Court, decision of December 23, 2022, Annex AG 53/53a in 4a O 80/22 and 81/22) conclude that the documents, which according to the injunction plaintiff teach the skilled person away from the claimed dosage, do not clearly indicate from the perspective of the skilled person that a dosage of 0.5 mg B daily does not ensure an effective treatment of RRMS, it is in each case merely a matter of a legal opinion differing from that of the Technical Board of Appeal on the inventive step of the injunction patent. In this respect, it is of course conceivable and also realistic that the legal status of a patent is ultimately judged differently in different jurisdictions. This primarily concerns the dispute about the inventive step, which does not raise a mathematically exact question, but rather a question that is weighed up in an evaluative manner, which can be answered in one direction or the other in individual cases with just as good reasons. 216

Against this background, the other foreign decisions are not able to present any far-reaching arguments that would lead the Board to deviate from the technical opinion of the Technical Board of Appeal. 217

ee. 218

The Board is also unable to identify any inadmissible extension. 219

(1) 220

Art. 123(2) EPC prohibits amendments to the application and patent which have the consequence that their subject-matter "goes beyond the content of the application as originally filed". Decisive is the content of the application as it appears on the accorded filing date (EPO GrBK decision of November 19, 1992 - G 0011/1991, BeckRS 1992 30480722 - *Glu-Gln*). The content of the application in this sense is everything which the person skilled in the art can directly and unambiguously take from the entire application documents (description, claims and drawings, excluding the abstract and priority documents), taking 221

into account his general technical knowledge. Not only any correction, but above all any amendment of the parts of a European patent application or a European patent relating to the disclosure (the description, the claims and the drawings) may only be made within the scope of what the person skilled in the art can directly and unambiguously infer from the entirety of these documents in their originally filed version, taking into account the general knowledge of the art - objectively and with reference to the filing date (EPO decision of November 19, 1992 - G 0003/1989, BeckRS 1992 30479462; EPO GrBK decision of November 19, 1992 - G 0011/1991, BeckRS 1992 30480722 - *Glu-Gln*; EPO, GRUR Int 1985, 44 - *Bleilegierungen/SHELL*; see also EPO, decision of July 22, 2009 - T 0465/07; BGH, GRUR 2010, 910 - *Fälschungssicheres Dokument*).

If a patent claims a therapeutic effect as a technical feature, for the assessment of the requirements of Article 123(2) EPC it must be examined whether the application as filed contains a disclosure from which it can be directly and unambiguously inferred that the therapeutic effect will be achieved if the treatment is carried out as claimed. Where a patent application announces a clinical trial whose aim is to investigate the clinical benefit of a particular treatment, statements about the aim and purpose of the trial cannot be understood by the skilled person as a clear and unambiguous disclosure that the intended effect will actually be achieved. Rather, such an announcement would be understood by the person skilled in the art to mean that there are uncertainties as to whether or not the effects to be tested are achievable and that these uncertainties necessitate the study. (EPO, decision of October 1, 2020 - T 2842/18, para. 39, 48 - *Rituximab*). 222

(2) 223

Even though the inadmissible extension was not dealt with in the Board of Appeal's decision, it already addressed the objection in its communication of October 8, 2021 (Annex FBD 11, item IV. (a)) and denied the inadmissible extension. It can be concluded from this that the Board of Appeal considered this objection to be unproblematic in the context of the decision and therefore did not deal with it further, but not that it was overlooked and/or not examined. In view of the fact that, in the context of the grant, the examination of the inadmissible extension in particular constitutes one of the core points to be taken into account ex officio, the decision rendered at second instance can also be given increased reliance on this point. 224

Furthermore, it is not evident that the Technical Board of Appeal's denial of the inadmissible extension would be based on objectively incorrect grounds. 225

(a) 226

Thus, contrary to the opinion of the injunction defendant, an inadmissible extension does not result from the fact that only the administration of a 0.5 mg dose in the form of a hydrochloride salt, but not in free form or in the form of other pharmaceutically acceptable salts - as is the case with the injunction patent - would be disclosed in the application. The application for the patent of disposition (EP 2 959 894 A1; hereinafter: A1 writing) discloses in paragraph [0016] a preferred compound of the formula I described above, namely 2-amino-2-tetradecyl-1,3-propanediol. As a particularly preferred S1 P receptor agonist of formula I, E, i.e., 2-amino-2-[2-(4-octylphenyl) ethyl]propane-1,3-diol in free form or in a pharmaceutically acceptable salt 227

form, e.g. the hydrochloride salt ("*A preferred compound of formula I is 2-amino-2-tetradecyl-1,3-propanediol. A particularly preferred S1 P receptor agonist of formula I is E, i.e. 2-amino-2-[2-(4-octylphenyl) ethyl]propane-1,3-diol in free form or in a pharmaceutically acceptable salt form [...], e.g. the hydrochloride salt, [...]*"). The skilled person understands the publication at this point to the effect that a hydrochloride salt is merely an example of a pharmaceutically acceptable salt in which the E - in addition to being presented in free form - can be contained. 227

Regarding clinical utility, the application states in paragraph [0033] as follows: 228

"*C. Clinical Trial* 229

Investigation of clinical benefit of a S1P receptor agonist, e.g. a compound of formula I, e.g. Compound A. 20 patients with relapsing-remitting MS receive said compound at a daily dosage of 0.5, 1.25 or 2.5 mg p.o. The general clinical state of the patient is investigated weekly by physical and laboratory examination. Disease state and changes in disease progression are assessed every 2 months by radiological examination (MRI) and physical examination. Initially patients receive treatment for 2 to 6 months. Thereafter, they remain on treatment for as long as their disease does not progress and the drug is satisfactorily tolerated." 230

In German translation: 231

"*C. Klinische Studie* 232

Untersuchung des klinischen Nutzens eines S1P-Rezeptor-Agonisten, z. B. einer Verbindung der Formel I, z. B. Verbindung A. 20 Patienten mit schubförmiger MS erhalten die genannte Verbindung in einer täglichen Dosis von 0,5, 1,25 oder 2,5 mg p.o. Der allgemeine klinische Zustand des Patienten wird wöchentlich durch körperliche Untersuchung und Laboruntersuchung untersucht. Der Krankheitszustand und die Veränderungen des Krankheitsverlaufs werden alle 2 Monate durch eine radiologische Untersuchung (MRT) und eine körperliche Untersuchung beurteilt. Zu Beginn werden die Patienten 2 bis 6 Monate lang behandelt. Danach werden sie so lange behandelt, wie ihre Krankheit nicht fortschreitet und das Medikament zufriedenstellend vertragen wird.“ 233

In the context of the above-quoted disclosure content paragraph [0016] of the A1 document, the skilled person will not understand this clinical study presentation to disclose solely the administration of a 0.5 mg dose of B in the form of a hydrochloride salt. The passage cited above speaks of the study of the clinical utility of an S1P receptor agonist, such as a compound according to Formula I. The passage is not limited, either literally or functionally, to the use of a hydrochloride salt. Rather, based on the discussion in paragraph [0016], the person skilled in the art will assume that the clinical study can refer without limitation to all possible dosage forms of the S1 P receptor agonist, including the free form or the form of a pharmaceutically acceptable salt, of which hydrochloride salt is merely an example. In the context of the clinical study presentation, it is also clear that the dosage of the active ingredient does not change depending on the dosage form. For paragraph [0033] of the A1 document clearly discloses that the 20 study participants receive the S1P receptor agonist, i.e., the said compound according to, e.g., formula I - according to p. 9, i.e., 2-amino-2-tetradecyl-1,3-propanediol - at a daily dose of 0.5, 1.25 *or 2.5* mg *p.*o. ("*20 patients [...] receive said compound at a daily dosage of 0.5, 1.25 or 2.5 mg p.o*."). The specialist 234

understands this as the administration of the stated amounts of active ingredient and not related to the dosage form - free form or pharmaceutically acceptable salt.

(b) 235

Furthermore, the therapeutic benefit of the 0.5 mg dose B for the treatment of relapsing-remitting multiple sclerosis in humans is also clearly and directly disclosed in the application. The person skilled in the art can infer - also by applying its general knowledge of the art - an unambiguous and direct disclosure of the aforementioned clinical benefit from the application. 236

The person skilled in the art will understand the above-mentioned passage in connection with paragraph [0030] to mean that, although it is a future study, it is not only intended to investigate the effectiveness of the therapeutic treatment, but also to demonstrate it ("*preventing or treating [...], may be demonstrated [...] as well as in clinic [test methods]*, *for example in accordance with the methods described hereinafter*"). In this respect, the result is not left open for the person skilled in the art, but a way is shown to prove the effectiveness of the invention. In this respect, patients remain in treatment as long as the disease does not progress. This is sufficient as a disclosure of the use in the treatment of relapsing RRMS and does not appear as a mere announcement. 237

2. 238

From the decisions of foreign courts on the legal validity of the injunction patent cited by both parties, the Board is in any case unable to derive any conviction that the legal validity of the injunction patent is not sufficiently secured for the question of the ground for injunction in this case. In this respect, reference is made to the above statements on the individual objections. 239

Thus, in a decision dated October 25, 2022, the Tribunale de Milano ruled in favor of a legal existence of the injunction patent (Annex FBD 29 and Annex FBD 29a). 240

The following courts have ruled against a secured body of law: 241

- Court of Commerce of Barcelona, decision of October 10, 2022, Annexes AG 36/36a in 4a O 80/22 and 81/22; 242

- Gerechtshof den Haag, first instance decision of June 21, 2022, Annexes AG 17/17a in 4a O 80/22 and 81/22; appeal decision of October 18, 2022, Annexes AG 37/37a in 4a O 80/22 and 81/22; 243

- Tribunal Judiciaire de Paris, decisions dated June 3, 2022, Annexes AG 15/15a, May 19, 2022, Annexes AG 13/13a, and May 19, 2022, Annexes AG 19/19a in 4a O 80/22 and 81/22; 244

- Swiss Specialist Judge X's Opinion of August 15, 2022, Annex AG 20 in 4a O 80/22 and 81/22; 245

- three decisions of the Stockholm District Court (“Stockholm District Court - Patent and Market Court”), Annex AG 47a in 4a O 80/22 and 81/22; 246

247

- Finnish Market Court, decision of December 23, 2022, Annex AG 53/53a in 4a O 80/22 and 81/22.

Insofar as it is argued that the existence of a well-founded maintenance decision on a foreign parallel protection right from a renowned jurisdiction, which also deals with the citations relevant in the injunction proceedings, can lead to the assessment that an adversarial decision is not required for a sufficiently secured legal existence (compare Kühnen, Hdb. der Patentverletzung, 15th ed., Chapter G, para. 62), the Board has already derived this assessment from the existence of exceptional circumstances. The (divergent) decisions of the foreign courts are therefore at most relevant in the context of the examination whether better arguments speak for or against the validity (see above; compare BGH GRUR 2010, 950 - *Walzenformgebungsmaschine*), whereby the board, in view of the above, comes to the conclusion that the patentability is at most unclear, with the consequence that in the case of its own decision, it would have to affirm the validity. 248

II. 249

Furthermore, the injunction defendant has not shown or substantiated any individual circumstances that could either call into question the high damages on the part of the injunction plaintiff and/or justify a special interest of the injunction defendant that would predominantly speak against a decision in expedited legal protection. The overall circumstances of the individual case therefore allow the weighing of interests to be in favor of the injunction plaintiff. 250

1. 251

First of all, the interest of the injunction plaintiff as owner of the injunction patent in a decision in the summary proceedings is not contradicted by the statements of the Board of Appeal in its judgment of September 2, 2022 (Ref. 4a O 44/22), according to which the general interest in the fundamental sale of generics and the supplementation of health care in addition to the original product of the injunction plaintiff, as well as in a price regulation resulting therefrom, is not to be assessed per se as lower than the interest of the injunction plaintiff in continuing to offer the original exclusively on the market. This is because the facts underlying the decision were different. In the case cited above, the distribution of the generics complained of by the injunction plaintiff here - unlike here - did not yet conflict with a granted patent. The interest of the injunction plaintiff as the patent holder in having the distribution of a patent-infringing generic product prohibited is already to be rated higher than its interest in exclusively offering an original product on the market that is not (yet) protected by a patent, due to the legal assessment of awarding a monopoly position as a reward for technical innovation investments and guaranteeing its enforcement through the injunctive relief. 252

2. 253

The injunction plaintiff has plausibly shown that it is threatened with irreversible price erosion and thus damage as a result of the offer and further distribution of "D" generics, which include the challenged embodiment. 254

a. 255

256

The injunction plaintiff has substantiated the occurrence and imminent occurrence of significant sales losses after the injunction patent was granted.

aa. 257

By submitting the affidavit of L for the entire MS portfolio, including "D", Ms. M, (Annex FBD 3), the injunction plaintiff has made it credible that, in the event of unhindered distribution of "D" generics, sales losses of EUR 41 million are to be expected for the months of October, November and December of 2022. The injunction plaintiff has currently concluded open-house or discount agreements with effect for 93% of SHI-insured persons in Germany in order to minimize losses in its market shares following the entry of its generic competitors. In this respect, the conclusion of the agreements is intended to nullify the "4G rule" from Section 12 (1) of the Framework Agreement on the Supply of Medicines pursuant to Section 129 (2) of the German Social Code, Book V, according to which the patent-protected original drug of the injunction plaintiff may only be dispensed by pharmacies in the presence of at least four less expensive competing products if the prescribing physician expressly excludes substitution by placing the "aut-idem" cross. 258

Ms. M further affirmed in lieu of an oath that discounts of 80% on the list price for "D" had thus been accepted, in particular in the context of the open-house contracts concluded. These were made up of a "basic discount" and a "price protection discount". The percentage of the basic discount in the respective open-house contract is fixed, while the price protection discount is completely variable and is based on the current sales prices of the three most favorable pharmaceutical companies on the market. If there are no other competitors on the market, the price protection discount does not apply. 259

Even if the sales losses associated with the open-house or discount agreements are not relevant here - since the sale of the challenged embodiment was lawful until then - the existence of generic competitors on the market also leads to sales losses for the injunction plaintiff after the patent has been granted. This is because the price protection discount remains in place. 260

In addition, Ms. M affirmed under oath that in the event of a further reduction of the dispensing prices by the generic suppliers in the market, for which a trend is apparent, the price protection discounts of the current open-house contracts would also increase and discount demands of the health insurance companies under the individual discount agreements are to be expected. The fact that there is a threat of a further reduction in dispensing prices even after the injunction patent has been granted has also been further substantiated by the injunction plaintiff by submitting excerpts from the Lauer-Taxe as of October 1, 2022, October 15, 2022, and November 1, 2022 (Annex FBD 31). Finally, it cannot be dismissed that unhindered further distribution of the challenged embodiment would provide an incentive for the market entry of further generic companies, which in turn would lead to further price reductions. 261

bb. 262

The injunction defendant was not able to shake the plausibility of the losses in sales that had occurred and were still threatening. 263

264

Even assuming that the B-market as a whole is actually declining, there is still a risk of irreparable price erosion. The fact that the sales forecasts of the injunction plaintiff may be more optimistic than the market situation indicates is harmless in this respect, since considerable sales losses were nevertheless made credible.

Nor should it be taken into account to the detriment of the plaintiff that it had increased the sales price of "D" in April 2022 compared to the sales price of its generic competitors and that the sale of its product thus became less likely under the "4G" rule. This is because the mechanism associated with the "4G" rule, which makes it more difficult for the injunction plaintiff as the patent holder to freely set prices due to the existence of cheaper generic products, is the decisive factor here. This mechanism still exists after the patent has been granted. 265

Furthermore, the fact that the sales forecasts for 2022 presented by the injunction plaintiff were adjusted several times during the course of the year to reflect the actual situation does not undermine the plausibility of the expected decline in sales. Also a consolidated tendency of the physicians to increasingly put the "aut-idem" cross when prescribing "D" is not sufficiently demonstrated. 266

Furthermore, the SARS-CoV-2 Drug Supply Ordinance, which is initially limited in time until April 7, 2023, does not prevent a price erosion to the detriment of the injunction plaintiff. According to this, unavailable drugs to be dispensed with priority can be substituted with available drugs with the same active ingredient - partially bypassing the "4G rule" and independent of existing discount agreements. However, it is not evident that the generic competitor products in dispute here will not be available in the foreseeable future. This has also not been made credible. In particular, it is not sufficient to show that one of the competing products is in stock in fewer pharmacies than the original product. Moreover, the fact that a drug is not "in stock" does not necessarily mean that it would not be available, for example, that it can be ordered for collection on the same working day, as is customary in pharmacies. 267

b. 268

By submitting the affidavit of Annex FBD 3, the injunction plaintiff has further made it credible that - as is regularly the case with infringement acts by generic drug companies - the formation of a reference price group for B by way of the reference price group formation procedure before the Federal Joint Committee, which has already begun, is imminent and thus a further price erosion. 269

In this respect, Ms. M explained in her affidavit (Annex FBD 3) that it was to be feared that the fixed amount, which is the maximum amount paid by the statutory health insurance funds for the drug, would be considerably lower than the current list price for "D". This is because this is measured on the basis of the selling prices of the standard packs available on the market (which are also up to 89% cheaper from the generic suppliers). 270

In this respect, the reference price for the drugs in a reference price group pursuant to Section 35 (5) Sentence 4 SGB V should not exceed the highest sales price of the lower third of the interval between the lowest and the highest price of a standard package. The more generic drugs are on the market whose selling prices are below the list price of the injunction plaintiff's original drug, the more likely it is that a lower reference price will be set. In contrast, it is 271

not evident that the reference price to be set for B will be close to the (higher) selling price of "D", in particular since, according to Section 35 (5) Sentence 2 clause 1 of the German Social Code, Book V, reference prices are to be based on the lowest possible cost of care options.

It is therefore obvious that setting a lower reference price would result in an irreversible price erosion. If the sales price of the injunction plaintiff's original drug is higher than the reference price, patients either have to pay the difference themselves or - as is obvious - they opt for a therapeutically equivalent drug without additional payment. The injunction plaintiff therefore has an urgent interest in prohibiting the sale of "D" generics in order to avoid group formation and thus the setting of a reference price. 272

This is true even if one were to assume that the already initiated procedure for the formation of a reference price in accordance with Section 35 of the German Social Code, Book V can take a period of more than one year, so that the price decline triggered by this would actually only occur later. This is because the fact that the generic drug continues to be on the market after the granting of the injunction patent perpetuates the cause of the price decline. The alleged time delay therefore does not change the fact that the injunction plaintiff, as the manufacturer of the original drug, has a legitimate and vital interest in at least mitigating the causal chain that is likely to lead to a significant price erosion (see Court of Appeal (OLG) Düsseldorf, GRUR-RR 2021, 249 para. 25 - *Cinacalcet II*). The purely theoretical possibility that a fixed levy price can in principle also be adjusted or revoked again, and that immediate enforcement can be suspended in the event of an action relating to the fixing of the fixed amount, does not change this. 273

Finally, it is also not evident that the prohibition of the distribution of the challenged embodiment sought here - in parallel with the action against the other "D" generics offered and distributed - could not prevent the formation of a reference price group disadvantageous to the injunction plaintiff or would otherwise be inappropriate. Even if imported original products and also the "D" products with an active strength of 0.25 mg available on the market were to be used for the formation of a group of medicinal products within the meaning of Section 35 (1) Sentence 1 of the German Social Code, Book V, it is not evident that - if a corresponding reference price group were to be formed - these would also be taken into account within the framework of the calculation of the reference price or that their inclusion would have a significant effect to the detriment of the injunction plaintiff. 274

In view of the credibly asserted impending formation of a reference price group, the fact that the challenged version of the injunction defendant is listed in the Lauer-Taxe at a price which corresponds to the price of the injunction plaintiff's "D" product does not prevent the assumption of a generic case. For, as explained, the mere existence of several generic manufacturers on the market means that it is to be expected that a fixed amount group will be formed and a fixed amount will be set far below the sales price of "D" or the challenged embodiment (see Court of Appeal (OLG) Düsseldorf, GRUR-RR 2021, 249 - *Cinacalcet II*, para. 26). As the injunction defendant itself submits, the formation of a reference price group is precisely not dependent on the market shares of the respective drug, so that a reference price group can be threatened regardless of the fact that the injunction defendant does not yet sell the challenged embodiment on the German market and is listed in the Lauer-Taxe with the same price as the drug of the injunction plaintiff. 275

c. 276

The injunction plaintiff has further made it credible by submitting the affidavit of Annex FBD 3 that individual statutory health insurers are already considering completely refraining from concluding discount or open-house contracts for B in the event of a continuation of the distribution of B generics even after the granting of the injunction patent in order to avoid their own risks, furthermore that there is a risk that discount contracts already concluded, which only provide for an ordinary notice period of four to six weeks, will be terminated. 277

d. 278

Finally, the fact that C X, and not the injunction plaintiff, markets the original product in Germany does not prevent the injunction plaintiff from suffering damage of its own. This is because C X is its wholly owned subsidiary. In this respect, it participates in a loss of sales of C X. Against this background, it is not sufficient to simply deny the occurrence of damage to the injunction plaintiff or to deny it with ignorance. 279

3. 280

Finally, the injunction defendant as patent infringer is also not particularly in need of protection in the present dispute. 281

It remains the case that it can benefit from the high research and development expenditure of the group of companies of the injunction plaintiff, which has sufficiently medically tested the original preparation and established it on the market. The fact that the market entry of the challenged embodiment of the injunction defendant took place at a time when regulatory marketing protection of the original preparation did not (any longer) exist and no patent protection (yet) existed, and that this could therefore also lawfully already establish itself on the market as a generic product, does not change this. In particular, at the time of the listing of its generic product in the Lauer-Taxe, it already had knowledge of the circumstances of the individual case, namely of the gap in protection created for the injunction plaintiff after the expiry of the regulatory marketing protection. It also knew that the patent in suit would be granted on the basis of the EPO Technical Board of Appeal's decision of February 8, 2022, and that the challenged embodiment would likely fall within its scope of protection. Even if this does not constitute anti-competitive conduct, against this background it has deliberately taken the risk that it may only be able to offer the contested embodiment on the market for a shorter period of time, so that it may not be able to recoup its investment. Therefore, it cannot cite this in its favor. 282

Insofar as the injunction defendant denies on page 5 of its response to the application (p. 128 court file) that it had full knowledge of the facts just mentioned from the pre-litigation correspondence, since all correspondence was conducted with J, this cannot exonerate it. For in this respect, the injunction defendant would have been obliged, in view of the substantiated submission of the injunction plaintiff on the pre-litigation correspondence, in particular on the occasion of the notified grant of the injunction patent, to provide more detailed information on the extent of its knowledge, insofar as this differs from that of the sister company. 283

Moreover, the fact that the injunction prevents the injunction defendant from further establishing the challenged embodiment on the pharmaceutical market is the inevitable consequence of the patent infringement associated with the further distribution of the challenged embodiment, although not yet associated with the first market entry. 284

This is not per se suitable to eliminate the overriding interest of the injunction plaintiff resulting from the patent infringement (see OLG Düsseldorf, judgment of September 26, 2019 - I-2 U 28/19, GRUR-RS 2019, 33227 para. 49, with further references; see also comments above). Without the injunction, the injunction plaintiff is threatened with damage due to the fact that the injunction defendant takes market shares for itself with the challenged embodiment and ultimately consolidates them, which without the competitive situation would in principle at least also benefit the injunction plaintiff. The interests of the injunction defendant can also be effectively countered in a sufficient manner by the - in this case - order of an appropriate security, on the provision of which the execution of the preliminary injunction is dependent (Section 938 of the German Code of Civil Procedure (ZPO)) (see OLG Düsseldorf, loc.cit.). 284

4. 285

Nor does the general interest preclude the issuance of a preliminary injunction. 286

The fact that the treatment of patients suffering from MS with B-preparations would be endangered has already neither been demonstrated nor made credible. Even if the injunction were to make it more difficult for patients to access treatment, these are also typical consequences of a preliminary injunction in the pharmaceutical sector, which cannot outweigh the patent proprietor's interest in issuing the preliminary injunction from the outset (see Court of Appeal (OLG) Düsseldorf, loc. cit., para. 50). The fact that the health care system, in the form of the health insurers of the patients concerned, bears the higher costs of therapy with the original product of the injunction plaintiff also does not constitute an overriding general interest that blocks a title by way of protection of summary proceedings. This is because the basis of this argument is that it is an unjustified action on the part of the injunction plaintiff. However, this is not the case in view of the grant of the injunction patent and the fact that the legal status of the injunction patent is sufficiently secured - in the absence of a ground for opposition according to the above standards. Rather, the injunction plaintiff in the is entitled to prohibit the injunction defendant from further market entry due to its monopoly position. 287

5. 288

Finally, the injunction plaintiff's overriding interest in the issuance of the preliminary injunction cannot be denied on the grounds that the injunction plaintiff abused its rights in the grant proceedings and unfairly delayed a final decision on the grant of the injunction patent. 289

Insofar as the injunction defendant claims that the injunction plaintiff pursues a strategy before the EPO of repeatedly abandoning earlier applications and then proceeding to the next (divisional) application, it is already not apparent how this should affect the present proceedings. It is undisputed that the injunction plaintiff has not abandoned the injunction patent at issue, and it is a regularly granted patent from which the injunction plaintiff can derive corresponding rights. Thus, there is also no evidence that the injunction plaintiff now wants to prevent a substantive decision of the EPO in the first instance opposition proceedings (cf. for the opposition appeal proceedings District Court Munich I, GRUR-RS 2020, 18395). In contrast to the case which the District Court Munich I had to decide, it is not apparent here how the injunction plaintiff in the action for a preliminary injunction should take advantage of the circumstance of a non-execution of a decision of first instance in an unfair manner. Furthermore, in the absence of a corresponding national ruling – which is evidently 290

present in Spanish law - the legal concept used by the Barcelona Commercial Court (see Ref. 4a O 79/22, Annex WKS 9, 9a), which was able to establish a market uncertainty, does not apply here either. 289

Furthermore, the behavior of the injunction plaintiff in the proceedings for granting the injunction patent cannot be objected to in such a way that it can be classified as abuse of rights and would thus be contrary to a legitimate interest of the injunction plaintiff in the issuance of the preliminary injunction. To the extent that the injunction defendant refers to applications for extension of time limits and postponement of deadlines filed by the injunction plaintiff in the proceedings for granting the injunction, it does not substantiate in more detail and does not make a credible case that these applications were filed solely with the intention of abusing the law and did not have any factual background, such as prevention or work overload of the involved clerks on the part of the injunction plaintiff. The same applies to the application of the injunction plaintiff, highlighted by the injunction defendant, concerning the rescheduling of a date on April 20, 2020, with which it requested a date for the proceedings after the summer vacations, i.e. from October 2020. In this respect, too, it has not been shown in detail that this request was based solely on unfair reasons and was not in turn due, for example, to vacation absences - which are quite common during the summer months. It is therefore not apparent that the injunction plaintiff would have intentionally prevented the grant of a patent. Moreover, it is ultimately a purely hypothetical consideration whether a previously granted patent would already have gone through opposition proceedings at the current time and would "certainly" have been revoked. 291

III. 292

Moreover, the urgency in terms of time is also given. The injunction patent was granted on October 12, 2022. The request for the preliminary injunction was received by the court on the same day. 293

C. 294

Within the scope of the discretion opened up by Section 938 (1) of the German Code of Civil Procedure (ZPO), enforcement of the preliminary injunction - insofar as the injunction and restitution are concerned - is made dependent on the provision of security by the injunction plaintiff. Since, due to the limited possibilities of knowledge in summary proceedings, it cannot be ruled out that the preliminary injunction will prove to be unjustified in the proceedings on the merits and that the injunction plaintiff will have to pay damages to the injunction defendant under Section 945 of the German Code of Civil Procedure, the enforcement of an injunction for patent infringement cannot be subject to lower requirements than the enforcement of a first-instance injunction (cf. Kühnen, loc. cit., ch. G para. 118; Court of Appeal (OLG) Düsseldorf, judgment of September 26, 2019 - I-2 U 28/19, GRUR-RS 2019, 33227 para. 56). In determining the amount of the security deposit, the Board is guided by the established amount in dispute of EUR 3 million. 295

D. 296

The decision on costs follows from Sections 92 (1), 269 (3) Sentence 2 of the German Code of Civil Procedure. The decision on the provisional enforceability of the costs decision is made for reasons of clarification and against the background that judgments by which a preliminary injunction is issued are in principle provisionally enforceable per se without the provision of security, without the need for a separate pronouncement (MüKoZPO/Götz, 6th ed. 2020, Section 704 (15) of the German Code of Civil Procedure (ZPO)). 297

Dr. Thom Hammans Hengemühle
