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Datasheet for the decision of 3 December 2024

Case Number: R 0013/24

Appeal Number: T 0702/22 - 3.3.07

Application Number: 17175864.2

Publication Number: 3246021

IPC: A61K9/20, A61K31/4545, A61P7/02

Language of the proceedings: EN

Title of invention:
APIXABAN FORMULATIONS

Patent Proprietors:
Bristol-Myers Squibb Holdings Ireland Unlimited Company
Pfizer Inc.

Opponents:
SANDOZ AG
Zentiva k.s.
Teva Pharmaceutical Industries Ltd
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Alfred E. Tiefenbacher (GmbH & Co. KG)
Wittkopp, Alexander
Generics (U.K.) Limited
STADA Arzneimittel AG

Headword:
Petition for review

Relevant legal provisions:
EPC Art. 112a(1), 112a(2)(c), 112a(2)(d), 113, 114
EPC R. 104, 106, 107, 109(2)(a)
RPEBA Art. 13, 14(2)

Keyword:
Petition for Review - clearly unallowable
Fundamental violation of Article 113(1) EPC (no)

Decisions cited:
T 1557/07, T 1711/16, T 1868/16, R 0001/08, R 0019/11, R 0015/12, R 0008/13, R 0002/14, R 0016/13, R 0008/17

Catchword:
-

Europäisches Patentamt
European Patent Office
Office européen des brevets

Große Beschwerdekammer

Enlarged Board of Appeal

Grande Chambre de recours

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Case Number: R 0013/24

D E C I S I O N
of the Enlarged Board of Appeal
of 3 December 2024

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Decision under review:	**Decision of the Technical Board of Appeal 3.3.07 of the European Patent Office of 21 December 2023.**

Composition of the Board:

Chairman	I. Beckedorf
Members:	E. Mille
	T. Sommerfeld

Summary of Facts and Submissions

I. The petition for review ("petition") concerns decision T 0702/22 of Technical Board of Appeal 3.3.07 ("board") pronounced at the oral proceedings of 21 December 2023 and dispatched on 13 March 2024. In that decision, the board dismissed the appeal against the opposition division's decision revoking the European patent 3246021 and refused a request for referral to the Enlarged Board of Appeal.

II. With the letter dated 13 May 2024, the appellant, patent proprietor ("petitioner") filed a petition for review of the above board's decision. The petition is based on Article 112a(2)(c) EPC. In the petitioner's opinion, fundamental violations of its right to be heard under Article 113(1) EPC occurred because the board did not take into account in its decision petitioner's key arguments. Since the decision was silent on such key arguments, it would be impossible to determine whether they were considered and fully taken into account when making the decision, as required notably by R 02/14. The petitioner requested that decision T 0702/22 be set aside and the proceedings before the board be reopened.

III. By letter dated 15 July 2024, the petitioner filed a request for accelerating proceedings in view of revocation and infringement proceedings against the UK national part of the considered EP patent pending before the Court of Appeal of England and Wales. By email dated 18 July 2024, the Court of Appeal of England and Wales also requested accelerating proceedings for the same reasons. By letter dated 26 July 2024, opponent 01, Sandoz AG, indicated that it

was also a party in the above proceedings before the Court of Appeal of England and Wales and supported the request for accelerating proceedings of the petitioner. The Enlarged Board considered that these circumstances warranted the acceleration of the proceedings (see e.g. T 1868/16 Reasons 3.3. and 3.4) and hence allowed these requests, and accordingly set an early date for oral proceedings.

IV. The Enlarged Board in its composition pursuant to Rule 109(2)(a) EPC summoned the petitioner to oral proceedings and issued a communication in preparation for the oral proceedings pursuant to Article 13 and Article 14(2) RPEBA.

V. By letter dated 7 October 2024, the petitioner made further submissions in advance of the oral proceedings, essentially reiterating its position.

VI. Oral proceedings before the Enlarged Board took place on 3 December 2024, during which the petitioner presented its point of view and requested that decision T 0702/22 be set aside and the proceedings before the board be reopened. At the end of the oral proceedings, the present decision was announced.

During the oral proceedings before the Enlarged Board, the petitioner summarised its arguments as put forward in the petition and its response to the Enlarged Board's preliminary opinion.

VII. The petitioner's case can be summarised as follows:

Section 3.1 of the petition and corresponding response to the Enlarged Board's communication

The petitioner puts forward that the board did not consider a key argument of the proprietor, according to which D5 provides experimental evidence showing that the solid amorphous dispersion of apixaban provides a more rapid dissolution rate than the crystalline form. Instead the board solely considered that the appellant argued that D5 only provided a mere general disclosure of this amorphous form, which would have led the board to wrongfully conclude that D5 does not teach away from the claimed subject matter.

In its response to the Enlarged Board's communication, the petitioner more precisely states that he argued in its submissions and during oral proceedings in appeal that D5 would guide the skilled person seeking enhanced apixaban dissolution toward a solid amorphous dispersion of apixaban [and not to a crystalline form of this substance as in ex. 7] as it is experimentally proven in D5.

The petitioner further adds in this response that an explicit reference to the argument that "experimental evidence" show that amorphous forms of apixaban have a better solubility than crystalline forms (so that the skilled person would not consider such crystalline form) would have been essential in the decision under review, in order to establish that the board had duly considered the argument, which is not to be confused with the argument that the core teaching of D5 is that the skilled person would disregard IR (immediate

release) forms of apixaban (as in ex. 7) but concentrate on SR (sustained release) forms.

Section 3.2.1 of the petition and corresponding response to the Enlarged Board's communication

The petitioner claims that the board did not consider the proprietors' key argument according to which limiting the formulation of the objective technical problem to providing an "optimized tablet for IR of apixaban" would introduce an element of hindsight: since such an optimization only concerned IR tablets of ex. 7 of D5 whereas this document also (and mostly) covers SR tablets or any other formulation, starting from this example, the skilled person reading the technical problem considered by the board would disregard possible modifications of the tablet of this example towards such SR tablets or any other formulation.

The petitioner further alleges that in the appeal proceedings, the proprietor argued that the case law considered by the board (T 1711/16) did not support the board's approach.

In its response to the Enlarged Board's communication, the petitioner more precisely states that he argued in its submissions and during the oral proceedings in appeal that D5 in its entirety teaches away from IR formulations and rather teaches SR formulations. Accordingly, ex. 7 of D5 which deals with IR formulations is only a comparative example so that the skilled person would not start from this example for improving it but from the general teachings of D5 (SR formulations) and would then not arrive at the claimed invention.

The petitioner moreover holds the view in that response that, according to the case-law,starting inventive step assessment from a comparative example such as example 7 of D5 represents a very specific situation which is applicable when the problem resides in the provision of an mere alternative and not in an improvement. If the problem is regarded as an improvement, then starting inventive step assessment from a comparative example would lead the skilled person to disregard the improvement taught by the closest prior art itself taken as a whole over this comparative example and in the case at hand to wrongfully neglect SR tablets of apixaban. The case law, including T 1711/16, did not support that, in case of an improvement over a comparative example, the problem could be formulated in a manner that suggested ignoring what was taught as the improvement over the comparative example in the prior art itself.

Section 3.2.2 of the petition and corresponding response to the Enlarged Board's communication

The petitioner considers that it is unclear in the decision under review how far the board took into account its key arguments supporting its request to refer a question to the Enlarged Board of Appeal, these arguments being in substance that the teaching of D5 in its entirety, and not the specific disclosure of example 7 of D5, should be taken into account to solve the considered technical problem before turning to another piece of prior art, i.e. D8.

In its response to the Enlarged Board's communication, the petitioner adds that since the decision under review neglected his argument based on "experimental

evidence" in D5, it would be impossible to understand how the board arrived at the conclusion that *"Document D5 does thereby not generally teach away from crystalline apixaban"*.

Section 3.2.3 of the petition and corresponding response to the Enlarged Board's communication

The petitioner argues that its key argument according to which the dose of apixaban could not be neglected when determining inventive step, since the dissolution rate limited exposure of an API (active pharmaceutical ingredient) also depends on the dose of this API in the formulation, has not been taken into consideration by the board in the decision under review. A skilled person entrusted with the task to prepare a formulation containing 5 mg apixaban would not expect any dissolution rate limited absorption and would because of the low dose of apixaban.

In its response to the Enlarge Board's communication, the petitioner adds that he argued in its submissions and during the oral proceedings in appeal that since in an amount of up to 5 mg, apixaban is a BCS class III drug and that for such drugs, absorption and bioavailability are governed not by the dissolution rate but the permeability, the skilled person would not have enhanced this dissolution rate for improving bioavailability and by doing so reach the claimed invention.

The petitioner moreover alleges that since the board’s initial consideration in the assessment of non-obviousness is based on the API alone, absent of any indication of a dose, potential dissolution issues

remain entirely speculative and thus, can only be based on hindsight.

Section 3.2.4 of the petition and corresponding response to the Enlarged Board's communication

The petitioner argues that the decision under review disregarded the proprietor's key arguments and evidence related to the BCS and the absence of an assumption (supported by documents D104, D110, D139 and A48 relied upon by the proprietor during the appeal proceedings) that for a BCS class III drug it was expected that a dissolution rate of at least 85 % within 15/30 minutes represents a known advantageous goal (so called BCS class III reservation). In other words, the petitioner claims that its argument according to which there is no assumption in the literature that dissolution rate of BCS class III drugs should be increased up to at least 85 within 15/30 minutes was not taken into consideration in the said decision.

In its response to the Enlarged Board's communication, the petitioner adds that the board in the decision under review neglected the appellant's argument in response to the preliminary opinion of the board dated 30 June 2023. In this opinion, the board stated that *"the declarations in documents D104, D110, D139, D133 and D148 do not seem to take due account of the above reservation".* In his response of 20 November 2023 to this opinion, the appellant argued that the board's preliminary opinion had failed to address the appellant's explanations, particularly in relying in this response on document D110 according to which the above reservation would in fact not be relevant in the case at hand (because the requirement of rapid dissolution is relevant only for obtaining a biowaiver

but not in the development of a drug to put on the market). Since in the decision under review, the board maintained its view as expressed in its preliminary opinion, the petitioner considers that his argument in response was not taken into consideration by the board.

Reasons for the Decision

Admissibility of the petition

1. The requirements under Article 112a(1) and (4) EPC in conjunction with Rule 107 EPC have been met. Similarly, the requirements of Rule 106 EPC are deemed to have been fulfilled because the Enlarged Board understands from the petitioner's submissions that it only became apparent after the oral proceedings before the board and upon reading the written reasoned decision that the petitioner's key arguments had allegedly been disregarded.

2. Accordingly, the petition appears not to be clearly inadmissible.

Allowability of the petition

3. Pursuant to Article 113(1) EPC, decisions of the European Patent Office, including the boards of appeal, may only be based on grounds or evidence on which the parties concerned have had an opportunity to present their comments. This implies that a party must not be taken by surprise by the reasons for the decision, referring to unknown grounds or evidence. "Grounds or evidence" under Article 113(1) EPC ("Gründe" in the

German text and "motifs" in the French text) is to be understood as the essential legal and factual reasoning on which a decision is based (see also R 8/17, Reasons 15; R 16/13, Reasons 3.3). A party has to have an opportunity to comment on the decisive aspects of the case.

4. On the other hand, the deciding board must be able to draw its own conclusions from the discussion of the grounds put forward (see also R 8/17, Reasons 16; R 16/13, Reasons 3.3 with further references). Thus, the right to be heard does not go so far as to impose an obligation on a board to disclose in advance to the parties how and why, on the basis of the decisive issues under discussion, or at least those foreseeable as the core of the discussion, it will come to its conclusion. This is part of the reasoning given in the written decision (see also R 8/17, Reasons 16; R 8/13 of 15 September 2015, Reasons 2; R 15/12, Reasons 5; R 1/08, Reasons 3.1).

5. The duty of the Enlarged Board is not to re-access technical discussions which took place during the appeal proceedings but to determine whether the reasoning of the board in the decision under review contains gaps which would render unclear whether or not major arguments of the appellant were taken into account.

6. In the case in hand, the Enlarged Board cannot establish that such gaps would be present in the reasoning of the board in its decision which would suggest that a fundamental violation of the petitioner's right to be heard occurred.

Section 3.1 of the petition and corresponding response to the Enlarged Board's communication

7. The decision under review (section 5.3.3) reads that "The patent proprietors argued, that the core teaching of document D5 was concerned with the development of sustained release formulations of a solubility improved amorphous form of apixaban. In their view the skilled person would therefore not have modified the IR tablet [of example 7 of D5] to provide an optimized IR tablet, let alone an optimized tablet with crystalline apixaban, because this would go against the teaching of document D5 when considered in its entirety" (emphasis added).

8. The Enlarged Board thus holds the view that the board did not consider that the petitioner only referred to a mere general disclosure of the considered amorphous form by D5. On the contrary, the board considered the petitioner's argument that this was the core teaching of this document and that therefore it would teach away from the claimed subject matter.

9. The above underlined passage shows that the board took not only due consideration of the argument regarding the core teaching of D5 but also of the argument based on the "experimental" evidence" which concerns the better dissolution rate of amorphous over crystalline forms of apixaban. In addition, section 5.3.3 of the decision under review explicitly states that D5 "also mentions other solubility-improved forms of apixaban to be suitable, including crystalline highly soluble forms". This also shows that the board took due consideration of the "experimental evidence" argument of the appellant.

10. It thus appears that the board referred in the decision under review to both arguments put forward by the petitioner. Even though no explicit reference was made to "experimental evidence", on which one of these arguments was based, but instead on the argument itself (crystalline forms of apixaban have poorer solubility than amorphous forms), the board did take up this argument and reacted to it (highly soluble crystalline forms are mentioned in D5).

11. That the decision under review did not explicitly refer to “experimental evidence” is not decisive since due consideration appears to have been given by the board to what was regarded as the core teaching of document D5 by the proprietor and to examples (notably providing such experimental evidence) of this core teaching. Besides, the petitioner does not specify why such an explicit reference to “experimental evidence” would have been essential for having its argument regarded as duly considered.

12. In this regard, it is to be underlined that according to the case law (see T 1557/07, Reasons 2.6), not explicitly addressing specific points which, in the deciding organ’s view, did not have to be addressed in order to arrive at an understandable decision did not mean that such points are ignored. This applies to the case at hand in which, despite the fact that the board did not explicitly refer to “experimental evidence” in D5, it properly took into account in its decision what was for the proprietor regarded as the core of this document and the examples it comprises.

13. Therefore the Enlarged board concludes that the reviewed decision did duly take into account the argument raised by the proprietor during the appeal

proceedings.

Section 3.2.1 of the petition and corresponding response to the Enlarged Board's communication

14. The decision under review (section 5.2) explicitly states that the board rejected the suggestion by the patent proprietor that the formulation of the objective technical problem by the board would include an impermissible pointer to the solution by anticipating that the improved tablet is a tablet for the immediate release of apixaban. It also explains why it disagrees with the petitioner, namely that such a pointer would not be present because example 7 of D5 already discloses a tablet for such immediate release.

15. The Enlarged Board therefore holds the view that the decision under review rightfully took into account the key argument the petitioner refers to (problem formulated with hindsight or with pointers to the solution), but simply did not follow this argument for the reasons set out in the decision (see e.g. section 5.2 page 26 2nd paragraph to page 27 1st paragraph).

16. Regarding the petitioner's allegation that its argument that the case-law considered by the board (T 1711/16) would not support the board's approach was not taken into account by the board, the petitioner failed to refer to any passage of its submissions or declarations during the oral proceedings which would be reflected in the minutes in which such argument would appear. If this argument were regarded by the petitioner as fundamental, he could have requested a correction of the minutes. The considered argument is therefore not to be taken into account by the Enlarged Board in the absence of evidence that it was actually put forward

during the appeal proceedings.

17. Concerning the petitioner's point of view according to which the board would have disregarded the argument that starting from a comparative example (such as example 7 of D5) would mean that the problem to be solved must reside in the provision of a mere alternative, the board indeed considered this argument but rejected it, as indicated above under Reasons 19 and 20, section 5.2 of the decision under review (p. 26 2nd para. to p. 27 1st para).

Section 3.2.2 of the petition and corresponding response to the Enlarged Board's communication

18. Regarding the argument of the petitioner according to which the teaching of D5 in its entirety, and not the specific disclosure of example 7 of D5, should be taken into account to solve the objective technical problem before turning to another piece of prior art, i.e. D8, the decision under review reads "document D5 describes the solid amorphous dispersion of apixaban as a preferred example of a solidity-improved form of apixaban (…) but also mentions other solubility improved forms of apixaban to be suitable, including crystalline highly soluble forms (…) Document D5 does thereby not generally teach away from crystalline apixaban" (second paragraph of page 35 of the decision). The board thus explained for which reason it did not share the petitioner' view according to which D5 taken in its entirety would teach away from the claimed invention. This also explains why the board combined D5 (starting from the crystalline form of example 7) with D8 which also concerns such crystalline forms.

19. The board explicitly concluded that "[t]he patent proprietor's argument relying on the teaching of document D5 as teaching away from the claimed subject-matter when considered in its entirety is therefore not considered convincing" (decision page 35, third paragraph).

20. Contrary to the petitioner's point of view, it does not therefore appear from the decision under review that its argument was not taken into consideration by the board. The board simply did not consider that the teaching of D5 in its entirety would be against the use of a crystalline form of apixaban and thus that the skilled person would not have combined D8 with D5 and arrived at the claimed invention.

21. Concerning the petitioner's view that, since the decision under review would have neglected his argument based on "experimental evidence" in D5, it would be impossible to understand how the board arrived at the conclusion that *"Document D5 does thereby not generally teach away from crystalline apixaban"*, reference is made to Reasons 23 and 24 above, where it is explained that the said "experimental evidence" argument was indeed considered by the board in its decision and that it is actually possible to understand how the board arrived to its conclusion.

Section 3.2.3 of the petition and corresponding response to the Enlarged Board's communication

22. Regarding the petitioner's view that its key argument, according to which the dose of apixaban could not be neglected when determining inventive step, was not considered by the board in the decision under review, this decision reads (section 5.3.1 second paragraph of

page 28) "apixaban may qualify at a dose of 5 mg as such a BCS [biopharmaceutical classification system] class III drug". Hence the considered dose was indeed taken into consideration by the board.

23. The Enlarged Board also notices that the board actually acknowledged the proprietor's argument according to which "the skilled person would therefore not have expected that the dissolution rate of apixaban, as a BCS class III drug, would have affected its absorption [due to the low dose] and would thus not have considered measures aimed at increasing apixaban's dissolution rate in order to optimize the IR tablet of document D5" (Reasons 5.3.1, page 28, 2nd paragraph).

24. In fact, the board explained in paragraphs 2 and seq. on page 32 of the decision under review why, despite this argument, it considered that "in addressing the problem of providing an optimized tablet for immediate release of apixaban starting from example 7 of document D5 the skilled person would take up measures to secure the rapid apixaban dissolution".

25. As far as the petitioner's allegation that, since the board's initial consideration in the assessment of non-obviousness is based on the API alone, absent of any indication of a dose, potential dissolution issues remain entirely speculative and thus, can only be based on hindsight, it is considered that the fact that the decision under review did not explicitly refer to the dosage and the above petitioner's argument in its initial considerations in the two first para. of section 5.3.1 of the decision under review is not a deficiency in the reasoning but a mere matter of style or at most of reasoning organisation. Indeed, what is essential is that this argument was as a matter of fact

taken into consideration in the inventive step reasoning of the board. The board actually explained why the person skilled in the art would not be discouraged from seeking for measures to secure a rapid apixaban dissolution, contrary to the proprietor's point of view and therefore properly took into consideration the considered argument.

26. Moreover, in addition to acknowledging the appellant's argument, in section 5.3.1 of the decision under review (p. 28 paras. 2 and 3), the board explains that if for low dosage apixaban [as 5 mg] the skilled person would in principle not be motivated to address its dissolution characteristics because it would normally not affect its absorption which will be affected by the permeability of the API, this is not necessarily so since there is a reservation in the literature according to which this permeability governs absorption only if the dosage form dissolves rapidly, i.e. 85% of the drug dissolves within 30 minutes. This is why the board stated in p. 32 para. 2 of the decision that the skilled person would take this reservation into account and thus take measures to secure such a rapid dissolution of apixaban of at least 85% within 15/30 min for optimizing the IR tablet of example 7 of D5.

27. Thus, the decision draws a link between a low dosage drug and the considered reservation which will lead the skilled person to secure a rapid dissolution of the drug.

28. This confirms that the low dosage argument of the petitioner appears to have been duly taken into account in the decision under review.

Section 3.2.4 of the petition and corresponding response to the Enlarged Board's communication

29. Concerning the petitioner's view that its argument, according to which there is no assumption in the literature that dissolution rate of BCS class III drugs should be increased up to at least 85 within 15/30 minutes, was not taken into consideration in the decision under review, it is apparent from section 5.3.4 of this decision that this argument was indeed taken into account. In section 5.3.4 of the decision under review the board states that "The patent proprietors' argument relying on the declarations in documents D104, D110, D139 and A148 that the enhanced dissolution of apixaban from a formulation with a 5 mg dose was not expected to have any effect on the bioavailability of the apixaban, because at such dose the apixaban is to be regarded as a BCS class III drug is also not considered convincing. As explained in section 5.3.1 above, the expectations for the bioavailability of a 5 mg dose of apixaban as a BCS class III drug are subject to the reservation that the dissolution rate of the drug is sufficiently rapid. In contrast to the declarations in documents D145 and A151 relied upon by the opponents the declarations in documents D104, D110, D139 and A148 relied upon by the patent proprietors do not seem to take due account of this reservation.".

30. Accordingly, the decision under review did actually consider the proprietor's argument and provided reasons as to why it was not regarded as convincing.

31. Regarding the petitioner's argument that the board in the decision under review neglected the appellant's argument in response to the preliminary opinion of the

board dated 30 June 2023, as pointed out in Reasons 34 above, section 5.3.4 of the decision under review actually responds to the appellant's arguments based on documents D104, D110, D139, D133 and D148 but does not find them convincing. In addition, in section 5.3.1, the decision reads regarding the reservation of rapid dissolution "Such assumptions are not only relevant for granting "biowaivers", which represent permission to proceed with clinical studies for obtaining regulatory approval (...), but also in the original development of an IR tablet of a drug, because solution-like in vivo behaviour corresponds to optimal performance of an immediate release formulation" (p. 32 1st para.).

32. Even if the decision does not explicitly refer to the response of the appellant to the preliminary opinion of the board, it thus addresses the substance of this response properly in contesting the assumption made in this response based on document D110. Consequently, the fact that the conclusion of the board in the decision under review does not depart from the conclusion of its preliminary opinion does not imply that the appellant's arguments in his response to this opinion were neglected.

Conclusion

33. What the petitioner primarily appears to complain about is that the board arrived at conclusions different from the petitioner's ones. The Enlarged Board understands that a party may have a different view to the deciding board on technical or legal considerations and may even be convinced that a decision is wrong from a technical or legal point of view and may, therefore, wish to have the case reviewed. However, the Enlarged Board has no competence to review the case as to its merits,

including whether correct conclusions have been drawn by the board. Under no circumstances may the petition for review be a means to review the application of substantive law, since a review of the correct application of substantive law would amount to the Enlarged Board being a third instance. This has been explicitly excluded by the legislator (see also explanatory remarks 1 to 5 on Article 112a EPC, OJ EPO 2007, Special edition no. 4 and established case law since decision R 1/08). Thus, the Enlarged Board has no competence under Article 112a EPC to examine the merits of a board's decision and go into the substance of a case, not even indirectly (see also Case Law of the Boards of Appeal, 10th edn. 2022, V.B.3.1 and V.B. 3.4.3, and the decisions cited there, e.g. R 19/11, Reasons 2.2).

34. In light of the considerations set out above, the Enlarged Board concludes that the petitioner's arguments were duly considered by the board, as can be derived from the board's written reasoned decision. Therefore, the petition for review is clearly unallowable under Rule 109(2)(a) EPC.

Order

For these reasons it is decided that:

The petition for review is unanimously rejected as clearly unallowable.

The Registrar: The Chairman:

N. Michaleczek I. Beckedorf

Decision electronically authenticated