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**Datasheet for the decision
of 28 January 2022**

Case Number: R 0002/20

Appeal Number: T 0629/16 - 3.2.02

Application Number: 09783840.3

Publication Number: 2346552

IPC: A61M5/315, A61M5/24

Language of the proceedings: EN

Title of invention:

DRUG DELIVERY DEVICE AND METHOD OF MANUFACTURING A DRUG
DELIVERY DEVICE

Patent Proprietor:

Sanofi-Aventis Deutschland GmbH

Opponents:

Bock Wolfgang
Mylan SAS

Headword:

Petition rejected as unallowable

Relevant legal provisions:

EPC Art. 112a(2)(c), 113(1)
EPC R. 106, 108(1)

Keyword:

Petition for review - unallowable - fundamental violation of the right to be heard (no)

Decisions cited:

R 0002/14, R 0008/15

Catchword:



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Case Number: R 0002/20

D E C I S I O N
of the Enlarged Board of Appeal
of 28 January 2022

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Decision under review:

**Decision of the Technical Board of Appeal 3.2.02
of the European Patent Office of
15 October 2019.**

Composition of the Board:

Chairman	I. Beckedorf
Members:	T. Bokor
	M. Müller
	J. Geschwind
	D. Rogers

Summary of Facts and Submissions

- I. The petition for review of the intervener in case T 0629/16 is directed against the decision of the Technical Board of Appeal 3.2.02 (hereinafter "Board") dated 15 October 2019 setting aside the contested decision of the Opposition Division and maintaining European patent No. 2346552 in an amended form, essentially on the basis of the claims held allowable by the Opposition Division.
- II. With its duly filed and reasoned petition the petitioner contends that a fundamental violation of Article 113(1) EPC occurred in the appeal proceedings (Article 112a(2)(c) EPC).

Overview of the appeal proceedings leading to the petition

- III. In the proceedings before the Opposition Division the patent was upheld with amended claims. The proprietor and opponent appealed. The intervener joined the proceedings during the appeal stage, its intervention was filed on 11 October 2018. At that time the appellant proprietor sought to defend the patent as granted as its main request and additionally with a number of auxiliary requests, also including the claims as upheld by the Opposition Division. The Board's decision refers to the upheld claims as auxiliary request 2.
- IV. The intervention was based on various grounds, among others, novelty and inventive step, and presented various lines of attack starting from a number of documents, among others from D1 (DE102005032705). D1 was a basis of both novelty and inventive step attacks,

against the granted claims and also against auxiliary request 2.

- V. Before the oral proceedings the Board issued a communication, in which substantive points were summarised, but without any detailed analysis of the parties' arguments. The Board's only substantive assessment was a statement that auxiliary request 2 appeared inventive.
- VI. Oral proceedings before the Board were held on 15 October 2019. At the end of the oral proceedings the patent proprietor only maintained auxiliary request 2. The contested decision of the Board was announced at the end. The minutes do not contain the details of the discussed issues.

Overview of the proceedings before the Enlarged Board

- VII. With the petition the petitioner submitted that it had made an inventive step attack starting from a specific embodiment (Figs 1 to 3) of D1, and this attack was not properly dealt with in the decision (this point is dealt with in more detail below). This constituted a violation of the petitioner's right to be heard.
- VIII. The Enlarged Board of Appeal as composed under Rule 109(2)(a) EPC issued a communication under Articles 13 and 14(2) RPEBA dated 24 June 2020, and summoned the petitioner to oral proceedings. The communication indicated that the petition appeared unallowable. The petitioner submitted observations in response to said communication.
- IX. The oral proceedings were held on 30 November 2020 at the end of which the Enlarged Board decided to submit

the petition to the Enlarged Board of Appeal as composed under Rule 109(2)(b) EPC for decision.

- X. All parties to the appeal proceedings were invited to file submissions and did so, whereby the patent proprietor argued that the petition should be rejected and the opponent expressed its agreement with the petitioner, but did not file detailed arguments. The petitioner reacted to the submissions of the patent proprietor with further arguments.

- XI. The Enlarged Board issued a second communication under Articles 13 and 14(2) RPEBA dated 15 November 2021, and summoned the parties to a second oral proceedings.

- XII. The second oral proceedings were held on 28 January 2022 at which the petitioner requested that the decision of the Technical Board of Appeal be set aside; and that the proceedings before the Technical Board of Appeal be re-opened.
The patent proprietor requested that the petition for review be rejected.
The opponent stated that it fully agreed with the submissions of the petitioner, but did not submit formal requests.

- XIII. The Enlarged Board issued the decision at the end of the second oral proceedings.

Reasons for the Decision

Admissibility

1. The petition is admissible under Rules 106 and 108(1) EPC. The Enlarged Board accepts that the allegedly missing reasons in the final decision could not be objected to during the proceedings. The petition is reasoned, it was timely filed and the corresponding fees were paid.

General observations

2. The Enlarged Board agrees with the petitioner that in principle, it is a corollary of the right to be heard in the sense of Article 113(1) EPC that under certain circumstances the absence of reasons in a decision may constitute a violation of this right. Reference is made to R 2/14 of 22 April 2016, No. 6 of the Reasons: "*This requirement [of Article 113(1) EPC] includes the party's right to have the relevant submissions and arguments considered and fully taken into account in the written decision in a manner that enables it to understand, on an objective basis, the reasons for the decision*", and to the further decisions cited therein.
3. However, merely formally addressing a substantive objection, e.g. generally treating inventive step, but ignoring a core argument of the party may also be deemed as a violation of the right to be heard within the meaning of Article 113(1) EPC. Where inventive step is the decisive issue, the choice of a particular prior art as a starting point, the problem to be solved by a particular feature of the prior art and the obviousness of replacing this feature and similar well-known

aspects of the inventive step examination may well constitute such core arguments which cannot be ignored by a Board of Appeal.

Petitioner's inventive step attack

4. D1 was one of the cited documents. Both the patent and D1 are concerned with a special spring for a drug delivery device, and the spring has the same purpose in both. The patent claims define the spring to be a spring washer. What constitutes a spring washer and whether the various pieces of prior art disclose or hint at a spring washer falling under the claims were central points of contention between the parties. The claims as upheld by the Opposition Division added the limitation of (multiple) fixing elements, for the purpose of fixing the spring washer to a sleeve member of the drug delivery device. Certain further features of the fixing elements were also claimed. The features of the fixing elements and their obviousness was another contentious issue between the parties. The other features of the claim are not relevant for the petition.

5. D1 shows two specific embodiments which are described in detail: a single turn coil spring in Figs. 1 to 3, and a bellow spring in Fig. 4. There is also a further, not shown hypothetical embodiment: D1 mentions that the spring can be a cup spring (Tellerfeder) in paragraph [0011]. This "Tellerfeder" embodiment is not elaborated in D1, beyond a statement that the generally claimed spring can be a cup spring. Otherwise D1 leaves it open if and how a cup spring would be applicable to the two specific embodiments of Figs. 1-3 and Fig. 4.

6. The petitioner made an inventive step attack as argued in the petition, i.e. based on the Figs. 1-3 embodiment of D1. The petitioner also emphasised that its attack was substantially different from the inventive step attacks of the opponent, who based its primary arguments on the "Tellerfeder" embodiment of D1. These two lines of attack are also reflected in the Board's decision, pages 5 and 6, where the inventive step arguments of the opponent and the intervener are summarised by the Board. The Board records the argument (without specifically attributing it to either the opponent or the intervener) that the coil spring 10 of D1 is similar to helically wound flat band springs known from D18, and that the single fixing element of the Figs. 1-3 embodiment (upper positioning device 13) had all features of the claimed fixing element, and that providing a plurality of such fixing elements could not establish an inventive step.
7. The decision under review dealt with inventive step in points 6.1-5 of the Reasons. It is undisputed that the "Tellerfeder" embodiment was treated by the Reasons 6.1-3, while the Figs. 1-3 embodiment was discussed in Reasons 6.4.
8. The petitioner argues that the Board had an obligation to demonstrably examine inventive step specifically in the context of the argued starting points, i.e. also when starting from the Figs. 1-3 embodiment of D1 (points 4.14 and 4.15 of the petition), but failed to do so.
9. As the Enlarged Board understands it, the petitioner brings four more or less distinct lines of argument in support of its objection that the inventive step attack

on the basis of the Figs. 1-3 embodiment as closest prior art was ignored:

(1) The reasons in point 6.4 of the decision under review only address novelty, but not inventive step (petition, points 4.10 and 4.11).

(2) A proper inventive step examination by the Board ought to have discussed various points, such as the problem to be solved and the technical effect of the differentiating features, etc. (point 4.12).

(3) During the oral proceedings before the Board the petitioner reacted to the Board's opinion that the helical spring of D1 was not a spring washer, and argued that it would be obvious to replace the helical spring in the Figs. 1-3 embodiment with a helical but otherwise generally flat spring washer as disclosed in D18. This argument of the petitioner was recognisably distinct from the arguments based on the Tellerfeder embodiment, and it is also not addressed in the decision. This line of argument (3) was first submitted to the Enlarged Board with the petitioner's letter of 30 October 2020 (page 1, last paragraph and page 2, third and last paragraphs), and was also confirmed in its letter of 15 February 2021 (page 1, penultimate paragraph). The line of argument (3) was pursued by the petitioner in the course of the first oral proceedings before the Enlarged Board as the main argument of the petition.

(4) The petitioner argued that the Figs. 1-3 embodiment already comprised a fixing arrangement having a fixing element as claimed, but the Board's decision only discussed such a fixing arrangement in combination with the Tellerfeder embodiment (point 4.8 of the petition). The petitioner stated

at the second oral proceedings that the line of argument (4) was the main argument of the petition.

10. The Enlarged Board holds that the facts set out by the petitioner do not demonstrate that the Board ignored any of the petitioner's core arguments, as explained below.
11. As to argument (1): The Enlarged Board does not see that the decision under review treated the Figs. 1-3 embodiment attack as a novelty attack. The argued point 6.4 of the Board's decision is plainly embedded in the overall reasoning addressing inventive step, and it explicitly addresses the Figs. 1-3 embodiment.
12. As to argument (2): The Enlarged Board does not dispute that an examination of inventive step is mostly done by following the problem-solution approach. However, this does not mean that a party has an entitlement to receive a reasoning whose structure is derivable in a formulaic way from the problem-solution approach. The Board was not obliged to go through all steps that are normally taken in this method of examining inventive step. The Enlarged Board points out that a board has no obligation to follow strictly the structure of the arguments as put forward by the parties, or to take up every issue raised. Reference is made to the settled case law that a board is not required to consider each and every argument of the parties (see CLBA Chapter V.B.4.3.10(b), 9th Edition 2019 and the decisions cited).
13. The reasoning given by the Board in point 6.4 of the Reasons is sufficient to deal with those inventive step attacks that were presented by the petitioner in writing on the basis of Figs. 1-3 embodiment. It is an

acceptable way of reasoning for the purposes of the inventive step examination to show that an alleged feature is not disclosed in the closest prior art, and once this difference has been established, there is no need for the Board to develop the reasoning any further, unless the parties did so.

14. The petitioner points to its submissions of 30 April 2019, page 5, and 13 September 2019, page 3, to demonstrate that an inventive step attack was made explicitly on the basis of the Figs. 1-3 embodiment.
15. The Enlarged Board holds that the arguments set out in these two written submissions are properly treated by the decision under review. It is true that the response of the intervener dated 30 April 2019 briefly deals with the possibility that the coil spring 10 of D1 might not be accepted as a spring washer, but does not develop any specific arguments beyond pointing to paragraph 11 of D1, and with it to the Tellerfeder embodiment. In this manner, the Enlarged Board considers that points 6.1-3 of the impugned decision clearly deal with this line of attack.
16. As to the submissions of 13 September 2019, there the petitioner only identifies the plurality of the fixing elements as a difference over D1. Such an argument cannot counter the argument of the missing spring washer. As pointed out above, it is not necessary to consider each and every argument of the parties in detail. The Board did not have to discuss the difference of the fixing elements for the purposes of the Figs. 1-3 embodiment, once the difference of the spring washer feature was established.

17. As to argument (3): The petitioner submitted that the obvious replacement of the coil spring with a flat helical spring became its core argument during the oral proceedings before the Board. The patent proprietor acknowledged that such an argument was brought, but argued that this was merely a side argument of the petitioner, without any great emphasis. Instead, the discussion concentrated on the features of the fixing means and the fixing elements, and whether they would have been obvious.

18. In this respect, the Enlarged Board finds the submissions of the patent proprietor more convincing. The decision certainly discusses in great detail the inventive merit of the multiple fixing elements (Reasons 6.2-3). Even the petitioner states that the Board accurately summarised its arguments with respect to the fixation elements on pages 5-6 of the decision (letter of 23 February 2021, page 2, penultimate paragraph). There, the Board indeed discusses the arguments relating to the fixation means in the context of the Figs. 1-3 embodiment, but without mentioning the petitioner's specific argument that the coil spring 10 of D1 could be replaced by a spring washer, if the Board would not accept the coil spring 10 to be a spring washer.

19. However, the petition does not mention that the intervener made an obviousness argument during the discussion in the oral proceedings in which it was suggested to replace the coil spring with a flat helical spring. It only states that the Board ought to have examined inventive step starting from the Figs. 1-3 embodiment. The petition does not state that specifically those arguments, which were only made in the oral proceedings against the Board's own (and

possibly unexpected) objections, are not to be found in the decision. On the contrary, the petition suggests - given its general reference to the petitioner's arguments "*both in writing and at the oral proceedings*" (point 4.7 of the petition) - that the petitioner is complaining about the non-treatment of arguments which had already been extensively discussed in writing, or had been raised by the petitioner itself at the oral proceedings. Such arguments would thus have come from the parties own submissions, and not from statements by the Board, either in the preliminary opinion or in the oral proceedings.

20. The impression that the arguments discussed at the oral proceedings before the Board did not decisively differ from the written arguments is further confirmed by the totality of the petition. For example, in point 4.12 of the petition several aspects of an expected inventive step analysis are mentioned (the problem to be solved, the technical effect of the differentiating features, the obviousness of replacing them etc.), but it is not stated anywhere that these specific aspects were actually argued by the petitioner in the oral proceedings. On this basis, the Enlarged Board must assume that the oral proceedings mostly concentrated on the same arguments that were already presented in writing. The written submissions of the petitioner, in particular the arguments given in the letters of 30 April and 13 September 2019 were properly treated, as explained in points 15 and 16 above.

21. As to argument (4): The Enlarged Board accepts that the decision does not discuss whether the provision of a plurality of fixing means of the type shown for the Figs. 1-3 embodiment would be obvious, while maintaining the other features of the Figs. 1-3

embodiment. The decision only discusses the fixing means in combination with the "Tellerfeder" embodiment. However, at point 4.8 of the petition it is stated that the similarity of the fixing means and the other features of the Figs. 1-3 embodiment was already set out in its letter of 13 September 2019. As explained above in point 13, this line of argument did not have to be treated further by the Board in view of the Reasons 6.4 of the Board's decision.

22. The petitioner argues that during the oral proceedings before the Board the petitioner countered the Board's finding on the absence of a spring washer from the Figs. 1-3 embodiment, and put to the Board that a replacement of the coil spring 9 with a flat helical spring would be an obvious modification of the Figs. 1-3 embodiment. As explained above in points 18 to 20, the Enlarged Board does not see that this argument, if made, would have been a core argument of the petitioner.
23. For these reasons, the Enlarged Board concludes that no further reasons could have been expected in the Board's decision, contrary to the position of the petitioner.
24. But even if the Enlarged Board were to accept, *arguendo*, that an embodiment as explained by the petitioner was also extensively discussed during the oral proceedings, it must be seen that this would have constituted a further (fourth) embodiment, namely a modified version of the Figs. 1-3 embodiment (i.e. where the coil spring 10 is replaced with a flat helical spring, which would then qualify as a spring washer). This being the case, this theoretical fourth embodiment still had to be fitted with multiple fixing elements in order to arrive at the claim in dispute.

The Board's decision gave reasons why it saw multiple fixing elements to be inventive, and it examined those fixing elements that were disclosed in D1, for both the Figs. 1-3 and the Fig. 4 embodiments.

25. The Enlarged Board points to the 2nd paragraph of the Reasons 6.1, where the Board states the following: *"According to paragraph [0011] [of D1], first two sentences, the coil spring 10 in Figure 1 or the coil spring 20 in Figure 4 may be replaced by a spring washer (Tellerfeder). It is implicit that such a spring washer needs to be fixed to the housing, and in fact D1 discloses, in paragraphs [0008] and [0009], positioning devices for the coil spring, in particular in the form of snap-fit securements"*. This demonstrates that the Board did proceed to examine an embodiment - the "Tellerfeder" embodiment - that could be based on the Figs. 1-3 embodiment, already fitted with a spring washer, as an apparently obvious option.
26. In the referred paragraphs [0008] and [0009] of D1 the fixing elements of D1 are quite generally worded (Positioniereinrichtung, Halteeinrichtung). The "Positioniereinrichtung" of paragraph [0008] appears to cover the specific fixing elements of the Fig. 1-3 embodiment, as also demonstrated by claims 6, 7, 14 of D1. The "Halteeinrichtung" of paragraph [0009] appears to be directed at the snap-fit connection ("Rastverbindung") of the Fig. 4 embodiment, see claim 20 of D1. This shows that the Board also examined if the adoption of the fixing means of the two other embodiments of D1 would lead the skilled person to the claim in dispute.
27. It is true that in the Reasons 6.2-3 the Board appears to limit its analysis to the "Tellerfeder" embodiment

as its starting point, but it remains that the Board did consider the fixing elements of both the Figs. 1-3 and the Fig. 4 embodiments. Of these, it appears that the Board held the snap-fit securements of the Fig. 4 embodiment more relevant. Importantly, while the Board found that the multiple fixing elements as claimed were not obvious, this was not based on a finding that the fixing elements of the two other embodiments of D1 may have been incompatible with the "Tellerfeder" embodiment. Thus there is no reason to assume that the Board's findings for the "Tellerfeder" embodiment may not have been applicable to the petitioner's modified embodiment, even if arguably being closer to the Figs. 1-3 embodiment than the "Tellerfeder" embodiment.

28. The Board's conclusion that the snap-fit securements of the Fig. 4 embodiment is a better starting point for the claimed fixing elements may have been erroneous, and the Board may have overlooked that the single fixing element of the Fig. 1-3 embodiment (the upper positioning device 13) may have had more common features with the claimed fixing elements, but this does not change the fact that also the fixing elements of the Figs. 1-3 embodiment were considered by the Board as a possible and even feasible option. The correctness of the Board's decision cannot be reviewed by the Enlarged Board in the petition proceedings. The Enlarged Board also refers to decision R 8/15, which held that for the purpose of compliance with the right to be heard, reasons may be incomplete, but as long as they allow drawing the conclusion that the board, in the course of the appeal proceedings, substantively assessed a certain point being part of the procedure and that it found to be relevant, there will be no violation of Article 113(1) EPC (Catchword No. 2).

29. In this manner the Board's reasoning on the inventive merit of the distinguishing multiple fixing elements (in point 6.2-3 of the Reasons) must be seen to apply to the argued "flat spring" version of the Figs. 1-3 embodiment as well, even if discussed in the context of the "Tellerfeder" embodiment. For these reasons, the Enlarged Board holds that it is possible to objectively understand the reasons why the petitioner's attack with the modified Figs. 1-3 embodiment could not succeed, irrespective of the Board's finding on the petitioner's argument that the spring coil 10 was either a spring washer or that it would be obvious to replace it with a spring washer. This means that the reasoning of the decision is sufficient, and the petitioner's right to be heard with respect to its arguments based on the modified Figs. 1-3 embodiment was also respected by the Board.

Order

For these reasons it is decided that:

The petition for review is rejected as unallowable.

The Registrar:

The Chairman:



N. Michaleczek

I. Beckedorf

Decision electronically authenticated