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Datasheet for the decision of 17 October 2019

Case Number: R 0001/19

Appeal Number: T 2471/16 - 3.3.01

Application Number: 11196067.0

Publication Number: 2455083

IPC: A61K31/573, A61K31/593, A61K9/00, A61K9/06, A61K47/06, A61K47/10, A61P17/06

Language of the proceedings: EN

Title of invention:
Pharmaceutical composition for dermal use comprising calcipotriol and betamethasone for treating psoriasis

Patent Proprietor:
Leo Pharma A/S

Opponents:
Teva Pharmaceutical Industries Ltd.
PENTAFARMA S.A.
Generics [UK] Limited (trading as Mylan)
Sandoz B.V.

Headword:
Fundamental violation of the right to be heard

Relevant legal provisions:
EPC Art. 112a(2)(c), 113(1)

Keyword:
Petition admissible (yes) - obligation to raise objection (no)
Right to be heard - violation (no)
no obligation for a Board to inform a party that it deems a particular argument relevant

Decisions cited:
R 0003/10, R 0016/13, R 0002/14

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 0001/19

D E C I S I O N
of the Enlarged Board of Appeal
of 17 October 2019

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Representative:	Greiner, Elisabeth df-mp Dörries Frank-Molnia & Pohlman Patentanwälte Rechtsanwälte PartG mbB Theatinerstraße 16 80333 München (DE)
Decision under review:	**Decision of the Technical Board of Appeal 3.3.01 of the European Patent Office of 23 May 2018.**

Composition of the Board:

Chairman	C. Josefsson
Members:	W. Van der Eijk
	R. Bekkering

Summary of Facts and Submissions

I. On 30 December 2018 the patent proprietor (hereinafter: the petitioner) filed a petition for review in respect of decision T2471/16 of Technical Board of Appeal 3.3.01 (hereinafter: the board) dated 23 May 2018. In the decision under review the board decided to set the decision under appeal, in which the oppositions against European patent No. 2455083 were rejected, aside and to revoke the patent.

II. The petition for review is based on the ground under Article 112a(2)(c) EPC that a fundamental violation of Article 113(1) EPC occurred. The petitioner takes issue with the way the board has based its written decision on D46. It considers firstly that the Board's reasoning is based on an erroneous interpretation of D46, which the Board never explained or discussed during the proceedings. Secondly, the line of reasoning based on D46 was not substantively raised during the proceedings, in particular not during the oral proceedings. The petitioner thus did not have the opportunity to present its comments on the underlying reasons of the decision and thereby its right to be heard was violated.

III. In a communication of 23 July 2019 the Enlarged Board informed the petitioner of its preliminary opinion on the case, namely that the petition seemed to be admissible, but was likely to be rejected as being clearly unallowable.

IV. In the communication the Enlarged Board summarized the procedural history of the case, in particular with respect to the use of D46, as follows:

"In opposition proceedings the opponents had argued that it was not rendered credible that the claimed invention showed an improvement over the prior art (D21) and, in case it would be found that the improvement was rendered credible by the data presented in the patent and in D11, the improvement was not demonstrated over the full scope of the claim. Both arguments were not found to be convincing by the opposition division.

In appeal, opponent 4 filed inter alia D46 to further substantiate its argument that no improvement over the full scope of the claim had been made credible. The argument made by opponent 4 in its grounds of appeal (see V.5.5) was summarized by the Board (see page 6, second paragraph, of the written decision) as follows: "As corroborated by the experimental data reported in document D46 (table 2), the composition of the vehicle had a marked impact on efficacy, and document D11 only related to one specific two-compound formulation with a particularly favourable vehicle composition."

The admission of D46 into the proceedings was contested by the petitioner, who argued that it could and should have been filed earlier. The petitioner however did not present substantive counter arguments on D46 in its response to the grounds of appeal.

In its submission of 23 April 2018 opponent 4 repeated its argument that the claimed improvement was not supported over the whole range of the claim, and referred again to D46 (see paragraph IV.2.5).

In the communication sent by the Board on 16 May 2018 the issues to be discussed during oral proceedings were summarized. With respect to inventive step the Board inter alia mentioned that the appellants contend that "in any case the available data do not show a significant improvement and do not cover the

entire scope claimed" (see paragraph 4.4). No mention was made of D46, only that its admission into the proceedings might have to be discussed.
The petitioner made further observations in its submission of 16 May 2018, but did not comment on D46 or the arguments based thereupon.
According to the minutes of the oral proceedings held on 23 May 2018, the issue of inventive step was discussed under the following aspects: whether starting from D21 there was a technical effect at all and, if so, whether it was achieved over the entire scope claimed. In the context of this debate opponent 4 requested a decision on the admission of D46, which it considered highly relevant for the assessment of inventive step. Parties were heard on this question. The Board then decided to admit D46.
The minutes further state (page 3, paragraph 5): "After resumption of the proceedings, the parties were given further opportunity to discuss inventive step and the content of document D46."
After this discussion the Board deliberated and subsequently informed the parties of its view that the subject-matter of claim 1 did not involve an inventive step.
In the Facts and Submissions part of the written decision (see p.10) the comments from the petitioner with respect to D46 are summarized. These comments must have been made during the oral proceedings, as no written submission from the petitioner on this issue could be found in the file.
It follows from the above that:
-D46 and its relevance for the inventive step discussion was raised by opponent 4 in its grounds of appeal and in its further submission
-the petitioner did not react in writing on the substance but only on the question of its admissibility

-admission of D46 was discussed during oral proceedings
-after admission of D46 its content was discussed in relation to the inventive step question
-during that discussion the petitioner must have made comments about D46."

V. The Enlarged Board concluded that arguments on the basis of D46 had been advanced in appeal by opponent 4 and the petitioner had the opportunity to react to them both in writing and orally, and made use of it at least during the oral proceedings. The Enlarged Board therefore saw provisionally no violation of the right to be heard.

VI. The petitioner reacted with a submission of 23 September 2019, together with 3 sworn statements, relating to the nature and scope of the discussion on inventive step and in particular on D46, during the oral proceedings.

VII. The petitioner did not challenge the above summary but stressed the following issues. Firstly, the scope of the discussion about D46 during the oral proceedings before the board was very narrow and did not relate to the aspect of D46 which formed the basis of the board's reasoned decision. Secondly, the reasoning of the board was based on a unilateral interpretation of D46 for which there was no evidence and which was not raised by any party to the proceedings, neither in writing nor during oral proceedings. The petitioner thus had no opportunity to comment on this interpretation and thereby its right to be heard was violated.
Thirdly, although the petitioner accepted that in general a board is not obliged to give the reasons for its decision before it takes a final decision, it was obliged to bring an ex officio argument or line of

reasoning to the attention of the parties, so that they could comment on it. Failing to do so was in breach of Article 113 (1) EPC.

VIII. Oral proceedings before the Enlarged Board were held on 17 October 2019, during which the petitioner further developed its arguments and explained in more detail which parts of the reasoning of the board were never raised, never discussed and were therefore surprising.

IX. At the end of the oral proceedings the decision was announced.

X. The petitioner requested:
- to set the decision under review aside
- to re-open the proceedings before the Board of Appeal;
- to order reimbursement of the petition fee.

Reasons for the Decision

1. Admissibility.

The petition is timely filed and sufficiently reasoned. The petitioner is also adversely affected by the decision under review. The ground invoked by the petitioner corresponds to a ground mentioned in Article 112a EPC. As regards the obligation to raise an objection during the appeal proceedings in relation to the procedural defect (Rule 106 EPC), the Enlarged Board is satisfied that it could not be raised, as the alleged procedural defect only became apparent in the written reasoned decision. The petition is therefore admissible.

2. Allowability.

2.1 As correctly stated by the petitioner the right to be heard implies that a decision may only be based on grounds or evidence on which the parties concerned had an opportunity to present their comments. A party may not be taken by surprise by the reasons of a decision, referring to unknown grounds or evidence. "Grounds" is to be understood as meaning the essential legal and factual reasoning on which a decision is based. This requirement is fulfilled when the reasons in the written decision correspond to the facts of the case and the arguments put forward by any of the parties to the proceedings, so that they were aware of them and could have commented upon them.

2.1.1 The petitioner firstly alleges that the reasoning of the board contained elements that were unknown to it, and on which it was therefore not heard. The Enlarged Board therefore firstly has to establish whether this allegation is correct.

2.1.2 The petitioner has pointed to a passage from the decision under review, which it alleges contains arguments that were not raised by the opponents, in particular opponent 4, and were never raised by the board. This passage is on p. 23-24 of the decision and reads as follows: "Skin delivery may certainly be regarded as a factor which has an impact on therapeutic efficacy; after all that is why skin permeation data were determined in D46. For that reason, the board agrees with the appellants' argument that it has not been rendered credible by the meta-analysis of document D11 that any non-aqueous composition covered by the scope of claim 1 (…) would provide improved therapeutic

benefit over the alternating combination regimen disclosed in document D21".
The petitioner distinguished in this passage 2 distinct arguments:
A. skin delivery may be regarded as a factor which has an impact on efficacy
B. skin permeation data were therefore (that is: to show the impact on efficacy) determined in D46.

Not only are according to the petitioner these arguments incorrect and not backed up by evidence, but they were also not raised by opponent 4 in its grounds of appeal and more importantly not raised during the oral proceedings.

2.1.3 The Enlarged Board disagrees with the petitioner. Argument A corresponds to the argument made in the grounds of appeal of opponent 4, where it reads in paragraph 123 (see page 29) "It can fairly be assumed that these differences in drug delivery will have a significant impact on the efficacy of the respective combination formulations, since the delivery of the drug is a precondition for obtaining a pharmacological effect." The research underlying the results of D46 was described as follows: "In D46, the influence of the vehicle components in topical formulations on the pharmacokinetic behavior of the active components is analyzed. More specifically, the skin permeation parameter is determined for different formulations by measuring the steady state flux as well as the lag time of the active ingredients in an in vitro model using isolated pig skin" (see paragraph 118). It follows that "these differences in drug delivery" were argued to be related to the skin permeation parameters of the different formulations, and thus to skin delivery. From the whole of paragraphs 118-124 of the grounds of

appeal and in particular the cited passages the Enlarged Board thus concludes, that argument A of the board corresponds to the argument made in the grounds of appeal of opponent 4.

2.1.4 As regards argument B, the Enlarged Board does not see it as a distinct and additional argument, but as an indication by the board, that it had understood that the data in D46 were introduced by opponent 4 to make the point reflected in argument A. The Enlarged Board is unable to follow the assertion made by the petitioner during the oral proceedings that argument B was causal for the decision, on the ground that it was a precondition for argument A. Argument A is presented in the reasoned decision as the principal argument and not as a consequence of argument B.

2.1.5 The Enlarged Board is therefore not convinced that the reasoned decision is based on ex officio arguments that were unknown to the parties. The objection raised by the petitioner based on that assumption can therefore not be successful. For this reason the two decisions from the Enlarged Board, R2/14 and R16/13, cited by the petitioner in support of its case that the board should have brought its ex officio argument to the attention of the petitioner, are not pertinent. These decisions do not deal with the situation that a decisive argument used by a board corresponds to an argument made by one of the parties.

2.2 A second objection presented by the petitioner, is that the fundamental argument based on D46 was not mentioned by the board at all, was not discussed during the oral proceedings and that the petitioner therefore could not know that it was decisive for the board. As a result

there was no reason for the petitioner to address it during the oral proceedings.

2.2.1 In discussing this objection the Enlarged Board wishes to make a distinction between the written phase of the proceedings and the oral phase; see also the summary of the procedural history in the Facts and Submissions part.

2.2.2 As regards the written phase, the petitioner explained during oral proceedings before the Enlarged Board that it had decided not to address the substance of the attack based on D46, because it believed D46 would not be admitted into the proceedings. The communication from the board also did not give an indication that D46 was considered to be admissible and relevant.

2.2.3 As regards the oral phase the petitioner explained with reference to the sworn statements, that D46 was only discussed at a late stage of the oral proceedings and that opponent 4 did not raise the decisive point but only addressed a particular example from D46. The petitioner explained that opponent 4 apparently had confused 2 examples in D46 and that its argument was therefore invalid. There was no reason for the petitioner to address other aspects of D46, as they were not mentioned by the board or one of the opponents. The board should however have indicated to the petitioner that beyond this particular aspect it considered D46 relevant for other reasons.

2.2.4 The Enlarged Board comments this objection as follows. As regards the written phase, as explained above in paragraphs 2.1.3-2.1.5, the D46 argument finally used by the board was made in the grounds of appeal and addressed an issue already discussed in the opposition

proceedings. The decision by the petitioner not to rebut the substance of the D46 argument because it assumed D46 would not be admitted, carried the risk that the assumption might be proven wrong and it would have missed an opportunity to present its case. The consequence thereof must be borne by the petitioner and cannot be transferred to the board.

2.2.5 It is true that the board did not address the substance of D46 in its communication, but it did indicate that the admissibility of D46 would need to be discussed during the oral proceedings. That cannot be understood as a confirmation of the assumption of the petitioner that it would not be admitted.

2.2.6 As regards the oral phase, it is also true that D46 was discussed at a later stage. That does not however in itself show that it was only peripheral to the case made by the opponents. It seems to the Enlarged Board, that it was not illogical to discuss D46 only after it had been discussed whether the claimed invention showed an improvement over the prior art at all, as D46 addressed the question whether, if there was an improvement, it was made credible over the whole scope claimed. Anyway, it appears to the Enlarged Board that after opponent 4 had requested to discuss the admission of D46 – which it considered to be highly relevant for inventive step, see the minutes of the oral proceedings – and the decision by the board to admit it, it should have become clear to the petitioner that D46 might be important. The petitioner however decided to only react to the oral submission by opponent 4, which it thought was based on a confusion of examples, and not to address the general arguments presented in the grounds of appeal.

The Enlarged Board notes in this context that it is not convinced that opponent 4 limited itself exclusively during oral proceedings to a specific example. The passage at the bottom of page 1 to the top of page 2 of the Sworn Statement of Mr. Cameron Marshall, seems to indicate that although the intervention focused on a particular example, opponent 4 made the broader argument that the ointment vehicle can have an effect on the efficacy of the drug. This passage reads: "O4 used D46 to argue that any improvement seen in D11 could be due to the different ointment vehicle which was used in the combination product, and in particular could be due to the "Arlamol E" solvent. O4 stated that the "TCF" product in D11 was "ointment 7" in D46, and referred to the data in Figures 1A & 1B. It concluded that the "Arlamol E" solvent affects the bioavailability of calcipotriol and betamethasone, and that this effect could explain any improvement seen in D11." The decision by the petitioner to only reply in a narrow way had as a consequence that the petitioner did not rebut the general line of argument based on D46 (argument A) either in writing or during the oral proceedings.

2.2.7 The Enlarged Board concludes from the above that the decisive D46 arguments were in the proceedings but were not discussed during the appeal proceedings, neither in writing or orally, because the petitioner decided not to address them. The question is not however whether they were discussed, but whether there was an opportunity to discuss them. In light of the above, the Enlarged Board is convinced that there have been several opportunities for the petitioner to present its comments and it therefore fails to see a violation of the right to be heard.

2.3 This conclusion could only be different if, as the petitioner argues, there was an obligation for the board to bring the decisive points for the decision to the attention of the parties and make sure they were properly discussed during oral proceedings.

2.3.1 The petitioner relies for this argument on decision R3/10, in particular the following paragraphs (see paragraph 2.11, page 19): "In a case such as the present, in which the ground of opposition, i.e. lack of inventive step, on which the revocation was based, was not discussed at all in the oral proceedings, it is also irrelevant that that issue was discussed in writing between the parties. The purpose of oral proceedings is to allow each party to make an oral presentation of its arguments, to allow the Board to ask each party questions, to allow the parties to respond to such questions and to allow the Board and the parties to discuss issues, including controversial and perhaps crucial issues. The value of oral proceedings is that matters may as a result be clarified and the Board may ultimately be satisfied that a party's position is the right one, although it was not so satisfied by the written submission alone."

2.3.2 The petitioner sees this decision as relevant for the present case because, although inventive step was discussed, the decisive D46 argument was not discussed. The Enlarged Board does not consider R3/10 to be pertinent. The factual constellation underlying R3/10 was that the patent was revoked for lack of inventive step, after a discussion that had only dealt with novelty. There was thus no opportunity for the losing party to present its case on inventive step orally. In the present case inventive step was discussed, the admission of D46 was discussed, and after admission

there was an opportunity to discuss the substance of D46 and its relevance for inventive step.

2.3.3 The petitioner however takes issue with another aspect, namely that the relevance of D46 for the decision had not been made clear and there was thus no reason to address all the arguments based on it, but only those presented orally. The Enlarged Board is of the view that R3/10 cannot be used to argue that a board has an obligation to make sure that during oral proceedings all decisive points are addressed by each party. Assuming the existence of such an obligation would go against a consistent line in the jurisprudence of the Enlarged Board. Reference is made to the jurisprudence summarized in the Case Law of the Boards of Appeal of the European Patent Office (9th edition 2019), Chapter V.B.4.3.5 " No obligation to provide detailed reasons for a decision in advance", 4.3.6 "Board's obligation to remain neutral" (in opposition appeal proceedings, addition by Enlarged Board) and 4.3.7 "Parties' obligation to participate actively in the appeal proceedings", and the decisions cited in these paragraphs. In particular, attention is drawn to the summarizing sentence in 4.3.6. "By giving a party possible reasons to decide against its requests, by prompting a party to make further submissions, by informing a party of a possible different interpretation of a passage in a prior art document or by suggesting a possible wording of a claim a board would assist a party and compromise its neutrality."

3. Conclusion

In summary, the Enlarged Board is not convinced that the board violated the right to be heard of the petitioner. The board based itself on D46 with an

argument that corresponds to an argument made by one of the opponents as early as in the grounds of appeal, the petitioner had several opportunities in the written phase and during the oral proceedings to address that argument but for reasons that are not related to an omission of the board, decided not to do so. For these reasons, the petition must be rejected as being clearly unallowable.

Order

For these reasons it is decided that:

The petition for review is unanimously rejected as being clearly unallowable.

The Registrar: The Chairman:

N. Michaleczek C. Josefsson

Decision electronically authenticated