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Datasheet for the decision of 12 September 2025

Case Number: R 0006/25

Appeal Number: T 0295/22 - 3.3.07

Application Number: 15177140.9

Publication Number: 2962690

IPC: A61K31/4035, C07D209/48, A61P35/00, C07C317/28

Language of the proceedings: EN

Title of invention:

(+)-2-[1-(3-ETHOXY-4-METHOXYPHENYL)-2-METHYLSULFONYLETHYL]-4-ACETYLAMINOISOINDOLINE-1,3-DIONE: METHODS OF USING AND COMPOSITIONS THEREOF

Patent Proprietor:

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Sanovel Ilaç Sanayi Ve Ticaret Anonim Sirketi
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Química Sintética, S.A.
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Galenicum Health S.L.U.

Headword:
Petition for review

Relevant legal provisions:
EPC Art. 112a(2)(c), 113
EPC R. 106, 109(2)(a)

Keyword:
Petition for review - clearly inadmissible or unallowable - fundamental violation of Art. 113 EPC (no)

Decisions cited:
T 0002/83, T 0249/88, T 0149/93, T 1053/93, T 0318/02, T 1877/08, T 2168/11, T 0867/13, T 3103/19, R 0016/13

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 0006/25

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of 12 September 2025

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Representative:	Galenicum Health S.L.U. CL Sant Gabriel n°50 08950 Esplugues de Llobregat (ES)
Decision under review:	**Decision of the Technical Board of Appeal 3.3.07 of the European Patent Office of 20 November 2024.**

Composition of the Board:

Chairman	C. Josefsson
Members:	D. Rogers
	M. Pregetter

Summary of Facts and Submissions

Background

I. The petition for review concerns decision T 0295/22 of Technical Board of Appeal 3.3.07 ("the Board"). The Board revoked the patent with its decision dated 20 November 2024 ("the Decision"). The Petitioner is the proprietor of the patent in suit and was one of the appellants before the Board.

II. Two documents, D1 and D76, are of importance in this case. D1 was considered to be the closest prior art as regards inventive step in both the opposition and appeal proceedings.

III. D76 is a review document with the title "Recent Advances in PDE4 Inhibitors as Immunoregulators and Anti-Inflammatory Drugs". The Petitioner itself filed D76 with its reply to the grounds of opposition. It has a publication date of June 2002, which is shortly after the earliest priority date of the patent of 20 March 2002.

IV. D76 makes reference to 375 documents, the latest of which, [222], was published in January 2002, that is before the earliest priority date of the patent. D76 makes reference to a drug, CDC-801 (see page 1264 of D76, reference [273], which is a reference to an IDdb Meeting Report, 2001). This drug became important in the discussion of inventive step at the oral proceedings before the Board.

Submissions

V. The Petitioner filed a petition for review alleging a violation of the right to be heard (Article 112a(2)(c) EPC and Article 113 EPC).

VI. The Petitioner's objection concerns the discussion of inventive step.

VII. The Petitioner notes that the opponents argued upon the basis of document D76 that, "…The skilled person would anyway have been motivated to administer apremilast orally..", (first full paragraph on page 12 of the Decision). However, the Petitioner further notes that the Board decided upon the basis that D76 provided a reasonable expectation of success: "the Board considers the prior art provided the skilled person with a reasonable expectation that the oral administration of stereomerically pure apremilast would provide for the safe and well-tolerated effective treatment for PDE4 mediated diseases.", (see last paragraph of para 4.5.1 of the Decision).

VIII. The Petitioner claims that its right to be heard was violated as although it had an opportunity to comment on the "motivation" argument of the opponents, it was not given an opportunity to comment on the "reasonable expectation of success" argument upon which the Board based its decision (see Petition para 30, last sentence).

IX. The Petitioner also complains that it was not given the opportunity to argue on the prior art status of the disclosures in document D76 (see Petition page 3/8 para 18 to 24). The Petitioner would have wished to have the chance to argue that the disclosures of D76 relied upon by

the opponents and the Board did not represent the state of the art as at the priority date.

X. The Petitioner makes a further argument (see para 31 of the Petition) that document D76, not being itself a prior art document, the opponents should have challenged the priority date of the patent if they wished to rely on a specific disclosure in D76, namely the reference to CDC-801. They did not do so. The Petitioner is thus surprised at the Decision because:

> "…a document relied upon by the proprietor to advance its own case has been used against it in a way that is different from any argument presented against the proprietor at any stage of the proceedings, leaving no chance for the proprietor to comment", (see Petition para 33).

XI. The Petitioner replied to the Enlarged Board's communication on 22 August 2025 ("the Reply"). The Petitioner submitted that the opponent only argued at the oral proceedings that D76 provided a "motivation" towards the claimed invention (Reply page 1/9 para 3). The disclosure of CDC-801 in D76 was not considered "from a reasonable expectation perspective". The Petitioner argued that "motivation" and "reasonable expectation" are distinct legal concepts. No opponent raised a reasonable expectation of success attack with respect to CDC-801 during the entire opposition and appeal procedure. The Board raised this ex officio and this reasoning only became known to the Petitioner when reading the written decision (see para 14 of the Reply).

XII. At the oral proceedings before the Enlarged Board, the Petitioner argued that the concept of a "reasonable expectation of success" could be considered as a ground of

the Decision. The Petitioner referred to section I.D.7.1 of the Case Law Book of the Boards of Appeal, 11th edition ("CLBA") as support for this point. Hence the Petitioner's right to be heard was violated as the Petitioner had not had an opportunity to address this ground. The Petitioner also referred to R 16/13 for a non-limiting understanding of "ground".

Petitioner's requests

XIII. The Petitioner requests that:

The decision of the Board be set aside and that the proceedings before the Board be reopened; and
the petition fee be reimbursed.

Reasons for the Decision

Prior art status of D76

1. The Enlarged Board will first address the Petitioner's objection that it was not given the opportunity to argue on the prior art status of document D76 (see Petition page 3/8 para 18 to 24). This can be combined with its argument that document D76, not being itself a prior art document, the opponents should have challenged the priority date of the patent if they wished to rely on a specific disclosure in D76, such as the reference to CDC-801. They did not do so. (see para 31 of the Petition). The Petitioner is thus surprised at the Decision because:

"…a document relied upon by the proprietor to advance its own case has been used against it in a way that is different from any argument presented against the proprietor at any stage of the proceedings, leaving no chance for the proprietor to comment", (see Petition para 33).

2. It is uncontested that at the oral proceedings one of the opponents argued that (first full paragraph page 12 of the Decision):

"Even if the experimental results reported in the patent concerning the effects of stereomerically pure apremilast were taken into account and the stereomerically pure apremilast could be considered as particularly safe and tolerable for oral administration, the claimed subject-matter was nevertheless obvious to the skilled person. The skilled person would anyway have been motivated to administer apremilast orally in view of the well known advantageous aspects of oral administration in general, the encouraging therapeutic index versus emesis reported in document D76 for the structurally related compound "CDC-801" and the oral administration prominently described in document D1 itself."

3. Thus an opponent argued that a disclosure in D76 was part of the state of the art and that this disclosure was part of its argument on lack of inventive step.

4. The Petitioner has not argued that it only became aware of this line of argument upon reading the Decision. Indeed, from the Decision it is apparent that the Petitioner became aware of this line of argument during the oral proceedings before the Board. Thus any Rule 106 EPC

objection regarding this issue should have been made in these oral proceedings.

5. Pursuant to Rule 106 EPC, a petition for review is only admissible where the objection against the procedural defect was raised during the appeal proceedings and dismissed by the board, except where this objection could not be raised during the appeal proceedings.

6. Meeting the requirements under Rule 106 EPC is a precondition for access to the petition for review.

7. In the present case, the minutes of the oral proceedings do not mention any objection under Rule 106 EPC having been raised by the Petitioner during the oral proceedings. No request for correction of those minutes was filed by the Petitioner challenging an absence of objections under Rule 106 EPC in the course of those oral proceedings.

8. Accordingly, the Petition is clearly inadmissible under Rule 109(2)(a) EPC in so far as the Petitioner’s objection that it was not given the opportunity to argue on the prior art status of document D76 is concerned.

Inventive Step Reasoning in the Decision

9. The Petitioner claims that its right to be heard has been violated as it was not able to make submissions on whether a specific disclosure in D76 created “a reasonable expectation” that orally administered apremilast would be successful as a drug.

10. Section I.D.7.1 of the CLBA is entitled "Reasonable expectation of success". The Petitioner referred to this

section of the CLBA during its submissions at the oral proceedings before the Enlarged Board. The first paragraph of this section states:

> "In accordance with the case law of the boards of appeal, a course of action can be considered obvious within the meaning of Art. 56 EPC if the skilled person would have carried it out in expectation of some improvement or advantage (T 2/83, OJ 1984, 265). In other words, obviousness is not only at hand when the results are clearly predictable but also when there is a reasonable expectation of success (T 149/93)... In order to render a solution obvious it is sufficient to establish that the skilled person would have followed the teaching of the prior art with a reasonable expectation of success (T 249/88, T 1053/93, T 318/02, T 1877/08, T 2168/11, T 867/13, T 3103/19)..."

11. The Enlarged Board agrees with the statements in the CLBA set out above: "reasonable expectation of success" forms part of the concept of obviousness when the issue of inventive step is considered.

12. At the oral proceedings before the Board a discussion took place on whether the subject matter of claim 1 of main request A involved an inventive step when starting from D1 as closest prior art. This discussion also included a discussion of, amongst other documents, the disclosures of document D76 (see minutes of oral proceedings before the Board and para VIII of the Decision).

13. The minutes show that the Chairman announced the Board's opinion that claim 1 of main request A did not involve an inventive step. The discussion then continued with a consideration of main request B.

14. As is clear from the CLBA, "reasonable expectation of success" is part of any discussion of inventive step.

15. Whether the parties use these actual words in their submissions, or consider them implicitly, is a matter of choice for the party.

16. Given that the minutes do not give a verbatim record of the submissions, the Enlarged Board is not in a position to say which of the alternatives set out in para 15 above was the case.

17. The Petitioner made no objections or further comments at the point in the oral proceedings before the Board where the Board stated its opinion that claim 1 of main request A did not involve an inventive step. The Petitioner moved directly on to its submissions regarding main request B. From this the Enlarged Board concludes that the Petitioner had had the opportunity to make all the submissions it wished to regarding whether claim 1 of main request A involved an inventive step.

18. Given the above course of conduct by the Petitioner at the oral proceedings before the Board, it is not open to it to subsequently claim that it was given no opportunity to address "reasonable expectation of success" when this forms an inherent part of the discussion of inventive step, a discussion which clearly took place. The issue of whether "reasonable expectation of success" is a "ground" of the Decision, or not, does not affect this finding.

19. In the light of the above, the Enlarged Board considers that the Petitioner’s arguments on inventive step were duly considered by the Board. This can be derived from the Decision. Therefore the petition for review is clearly

unallowable under Rule 109(2)(a) EPC as far as it concerns the reasoning on inventive step.

20. The Enlarged Board thus considers that no fundamental violation of Article 113 EPC within the meaning of Article 112a(2)(c) EPC occurred in respect of the Petitioner's arguments on inventive step, so that the Petition (including the request for reimbursement of the fee for petition for review) is clearly not allowable to the extent that it is not inadmissible.

Order

For these reasons it is decided that:

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

The Registrar: The Chairman:

M. Schalow C. Josefsson

Decision electronically authenticated