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Datasheet for the decision of the Enlarged Board of Appeal of 15 May 2017

Case Number: R 0007/15

Appeal Number: T 1651/11 – 3.3.01

Application Number: 03721414.5

Publication Number: 1485087

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

Language of the proceedings: EN

Title of invention:
(+)-2-[1-(3-ETHOXY-4-METHOXYPHENYL)-2-METHYLSULFONYLETHYL]-4-ACETYLAMINOISOINDOLINE-1,3-DIONE FOR USE IN TREATING PSORIASIS BY ORAL ADMINISTRATION

Patent Proprietor:
CELGENE CORPORATION

Opponent:
Ratiopharm GmbH

Headword:
Petition for review admissible but not allowable

Relevant legal provisions:
EPC Art. 112a (2)(c), 113, 123(2), 100 (c)
EPC Rule 106

Keyword:
Violation of the right to be heard, no

Decisions cited:
R 0001/08, R 0007/09, R 0012/09, R 0015/09, R 0018/19, R 0015/10, R 0022/10, R 0006/11, R 0015/10, R 0015/11, R 0015/12, R 0015/13, R 0016/03, J 0003/90

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It can be changed at any time and without notice.

Catchword:
New grounds, no

Case Number: R 0007/15

D E C I S I O N
of the Enlarged Board of Appeal
of 15 May 2017

Petitioner: (Patent Proprietor)
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Decision under review:
Decision of the Technical Board of Appeal 3.3.01 of the European Patent Office of 17 March 2015.

Composition of the Board:

Chairman: W. van der Eijk
Members: C. Vallet
A. Ritzka
I. Beckedorf
D. Rogers

Summary of Facts and Submissions

I. The petition for review, filed on 30 September 2015, is directed against decision T 1651/11 of Board 3.3.01 dated 17 March 2015 by which the appeal filed by the patent proprietor, Celgene Corporation, against the decision of the Opposition Division to revoke European patent 1 485 087 was dismissed.

The Opposition Division had found that the subject-matter of the sole request then on file was not based on an inventive step. The Board considered that the subject-matter of claim 1 of the main request (claim as granted) and of claim 1 of the auxiliary request extended beyond the content of the application as filed (Art. 100(c) EPC).

II. The patent in suit relates to a second medical use of the compound (+)-2-[1-(3-ethoxy-4-methoxyphenyl)-2-methylsulfonylethyl]-4-acetylaminoisoindoline-1, 3-dione or a pharmaceutically acceptable polymorph, salt, solvate or hydrate thereof, for treating psoriasis by oral administration. This compound is known by the International Non-proprietary Name, (INN), “Apremilast”. This name will be used in the following.

III. The Petitioner (patent proprietor) based its petition for review on the ground of a fundamental procedural violation of its right to be heard (Articles 112a(2)(c) and 113 EPC).

The Petitioner requested to

– set aside the decision under review,

– re-open proceedings before the Board of Appeal,

and

– order reimbursement of the fee for the petition for review.

Oral proceedings have also been requested as an auxiliary measure.

IV. The arguments raised by the Petitioner are in essence as follows.

– The Board’s written decision was based on grounds relating to common general knowledge which were never discussed during the course of the opposition proceedings, be it at first or second instance, so that the Petitioner was given no opportunity to present its comments.

– The argument underlying the ground for opposition in respect of Article 100(c) EPC was that claim 1 of the granted patent constituted an inadmissible selection from multiple lists, namely a selection from each one of the following four “categories”:

  – “polymorph, salt, solvate or hydrate” from “prodrug, metabolite, polymorph, salt, solvate, hydrate or clathrate”,
  – treatment” from “treating or preventing”,
  – “psoriasis” from the list of diseases according to claim 20 of the application as originally filed,
  – “oral administration” from the list of modes of administration according to claims 29 and 30.

– The Opposition Division concurred with the patent proprietor in this respect in considering that the patent in suit did not infringe the requirements of Article 123(2) EPC because the only selection made related to the disease. This was thus a permissible selection from one list. The Petitioner argued at the oral proceedings before the Opposition Division that the opponent had conceded that the restriction to oral administration did not constitute a selection from a list (cf. Minutes, section 4).

– The arguments presented during the written phase of the appeal proceedings did not include any new aspects in respect to Article 123(2) EPC.

– No preliminary opinion was issued by the Board.

– During the oral proceedings, the Board did not give any indication that arguments other than those presented by the opponent would need to be taken into account or could be relevant for the decision.

– The decision under review was based on a reasoning which included assumptions as to the knowledge of the skilled person, assumptions which had never been debated, namely that:

- the skilled person is aware that psoriasis is a chronic disease with recurring disorder of the skin,
- consequently, two forms of pharmaceutical application are conceivable, prevention, on the

one hand, by reducing inflammation markers, and treatment as soon as the disorders appear on the skin, on the other hand,

- topical application is a valid option for treatment, but is not appropriate for prevention because the location of skin symptoms is not predictable,
- the skilled person would therefore associate treatment with dosage forms other than for prevention and accordingly interpret claim 30 as originally filed as referring back only to the alternative of prevention, but not for treatment.

– The Board had construed the description, in particular page 4, lines 16-30, in the light of the above assumptions which led directly to the conclusion that claim 1 of the main request and claim 1 of the auxiliary request went beyond the application as filed.

– This amounted to a substantial procedural violation which had come to light only with the written decision, so that no objection could have been raised during the oral proceedings.

V. By a decision issued on 11 July 2016, the petition for review was submitted to the Enlarged Board of Appeal as composed under Rule 109(2)(b)EPC.

VI. By a letter dated 15 September 2016 the respondent expressed the view that the petition was unfounded and requested that it was rejected. Oral proceedings were also requested as an auxiliary measure.

The main arguments put forward by the respondent are as follows:

– The ground for opposition based on Article 100(c) EPC has been put forward and discussed in writing and orally from the very beginning of the opposition procedure.

– The argument was that neither original claim 20, 29 and 30, nor the description of the patent as originally filed, disclosed clearly and unambiguously the specific combination of features of claim 1 of the main and auxiliary request but resulted from a selection among several lists. More particularly the debate focused on the issue of whether the mode of treatment of psoriasis may differ from the mode of prevention of this disease.

– The Petitioner has been given many opportunities to develop their arguments on this issue as reflected in the written submissions, the minutes of the oral proceedings and the decisions of the first and the second instance.

– Document D7 to which the decision under review refers has been filed by the Petitioner itself, in order to illustrate the common general knowledge of a person skilled in the art.

The reasoning of the decision under review is based on facts and arguments provided by the parties in order to clarify the issue whether the combination of features of claim 1 of the main and of the auxiliary request is directly and

unambiguously derivable from the application as originally filed.

Moreover, part of the argumentation of the Petitioner is directed to the merit of the reasoning of the decision, although the case law is settled in that it is not open to the Enlarged Board of Appeal in proceedings under Article 112a EPC to review the correctness of the Board's application of substantive law (see R 22/10, point 10 of the Reasons, R 1/08, point 2.1 of the Reasons).

Finally, after the announcement of the Board that the requirement under Article 123(2) EPC was not met, the Petitioner was asked whether he wished to file any additional request which he declined, as reported in the minutes.

As a consequence, the petition for review should be rejected.

VII. In their rejoinder dated 26 January 2017 the Petitioner rebutted the arguments of the Respondent and stressed that the decision under review was based on grounds forming together a new line of argumentation and on new evidence, both absent from the oral debate before the Board, yet directly leading to the final decision.

As evidence of the course of the debate before the Board, the Petitioner also filed three declarations in lieu of oath, a document named " Minutes of the appeal hearing by John Podtetenieff", and a screen shot of the Jones Day electronic file system.

VIII. Oral proceedings took place before the Enlarged Board on 15 May 2017.

Reasons for the Decision

1. Admissibility

1.1 The petition for review, which has been filed in accordance with the provisions of Article 112a(4), second sentence, EPC and with all conditions laid down in Article 112a and Rule 107 EPC, is admissible.

1.2 According to the above description of the facts and submissions, no objection could have been raised during the oral proceedings before the Board because the alleged fundamental procedural defect only became apparent with the written decision. Rule 106 EPC has thus been complied with.

2. Allowability

2.1 Under Article 113(1) EPC, “[t]he decisions of the European Patent Office may only be based on grounds or evidence on which the parties concerned have had an opportunity to present their comments”.

It is settled case law that a failure to observe the right to be heard constitutes a substantial procedural violation with the consequence that the decision made under such circumstances is void.

2.2 In the present case the petitioner alleged that the Board based its reasoning on assumptions concerning the skilled person's technical knowledge as regards the topical and oral administration of Apremilast for the prevention and/or treatment of psoriasis. These allegedly erroneous assumptions, which, in the view of the petitioner, constitute new ground and evidence, have led to the finding that claim 1 of the main and claim 1 of the auxiliary request did not fulfil the requirements of Article 123(2) EPC.

2.3 The reasons for the decision under review are mainly based on the relevant part of the claims and the description of the patent as originally filed, in particular on claims 19, 20, 29 and 30 and on page 3, lines 22 to 25, page 4, lines 16 to 30 and on pages 21 to 23, section 4.3.1. It is not disputed that these passages of the application as filed are those cited and commented upon by the parties.

2.4 The first part of the reasoning (point 2.2.1) is dedicated to the analysis of the features of the above cited claims from which it is concluded that none of them disclosed directly the use of Apremilast for the oral treatment of psoriasis. The Board then considered the common general knowledge in order to be able to assess whether or not the person skilled in the art would have directly and unambiguously derived from the application as originally filed the combination of features of claim 1 of the opposed patent.

2.5 In this respect the Board quoted a passage from document D7, which was already cited in the decision of the opposition division. The Petitioner did not

question that this document was one of the documents that were in the proceedings.

Said quotation read as follows:

"Psoriasis is [a] ... chronic inflammatory skin disorder of unknown cause. The disorder is a chronic recurring condition which varies in severity from minor localized patches to complete body coverage. Plaque psoriasis is the most common type of psoriasis ... which appears as patches of raised, reddish skin covered by silvery-white scales. These patches, or plaques, frequently form on the elbows, knees, lower back, and scalp" (see page 2, the section "About Psoriasis").

Based on the above-cited claims and the teaching of D7, the board came to the conclusion that oral treatment of psoriasis by means of Apremilast was not clearly and unambiguously disclosed in the original claims.

2.6 In a second part of its reasoning (point 2.2.2) the Board analysed the above-cited passages of the description. The Board especially underlined that *"...Neither section 4.3.1 nor examples 8 or 10 mention whether these (oral- added by the Enlarged Board) dosage forms were to be used for the prevention or the treatment of a disease, nor do these parts of the description refer to any specific type of disease,"*. Turning to page 3, lines 22-25 the Board noted that it referred to *"the treatment of diseases and not to their prevention"* and that *"the following parts of the description up to page 4, line 15 were silent on psoriasis, let alone the oral administration of a drug"*.

In respect of page 4, line 16-30, the Board concluded that this passage of the description does not only refer to the sole treatment of psoriasis but also to the treatment or the prevention of numerous diseases including psoriasis. The Board concluded that "*the treatment of psoriasis by oral application was also not disclosed in combination in the parts of the description relied on by the appellant.*".

In point 2.2.3 the Board arrived at the overall conclusion that the subject-matter of claim 1 as granted extended beyond the content of the application as filed.

2.7 The Enlarged Board is not able to recognise that in the first part of its reasoning the Board had made "assumptions as to the knowledge of the skilled person".

2.7.1 The first two statements relied on by the Petitioner belong, as indicated by the Board in the reasons, to the "superficial knowledge of the skilled person" and therefore cannot seriously be called into question. As regards the third statement, namely that topical application "is not appropriate" for prevention, it has to be noted that the Board did not make use of such wording but rather indicated that a topical application "*does not necessarily make sense when trying to prevent..*", by which the Board only expressed a possible doubt or questioning on the part of the skilled person. The fourth alleged assumption is in fact the conclusion drawn by the Board, namely that the skilled person **could** read claim 20 as referring to oral prevention rather than treatment of psoriasis.

2.7.2 The Enlarged Board notes that in following the above cited reasoning the Board adopted the usual way of assessing whether the features of a claim fulfil the requirement under Article 123(2) EPC for a clear and unambiguous disclosure in the application as filed taken as a whole.

The reasoning of the Board expressed in a conditional form, establishes that a doubt existed as to how the skilled person would have understood the above cited paragraph. It is therefore not correct to contend, that the Board has made “assumptions” relating to the knowledge of the skilled person. The Board rather concluded from the information on file that another construction of the claim than the one developed by the Petitioner could have been considered by a skilled reader and therefore drew the conclusion that claim 1 did not pass the disclosure test.

2.7.3 From the above it follows that the Board did not introduce a new ground in their decision in writing. In this respect, the Enlarged Board follows the settled case law which draws a distinction between a ground and an argument (see R 15/12, points 5 to 7 of the Reasons). In the present case the ground of opposition based on the objection of added subject-matter in claim 1 of the opposed patent was whether the patent as filed taken as a whole disclosed in combination the use of Apremilast by oral application for the treatment of psoriasis. The report of the oral proceedings as annexed to the submissions of the petitioner dated 26 January 2017 abundantly shows that this has been extensively debated, and that the chairman guided the discussion so as to emphasise a possible difference between treatment and

prophylaxis. In an attempt to clarify this issue the chairman asked successively four questions to the patent proprietor. Moreover, after the deliberation of the Board, the patent proprietor’s representative asked for the reasons for the provisional opinion that the patent as granted would contravene Art. 100(c) EPC. The chairman responded by explaining that the finding related to the selection of treatment or prevention and thus a selection from two lists. Thereafter, the representative of the patent proprietor took the opportunity to add comments and indicated he was not willing to amend the claim in order to add “prevention” to “treatment”.

2.7.4 As a consequence, it is to be concluded that **no new ground** has been introduced into the debate by the Board on which the Petitioner did not have the opportunity to comment before the decision was reached. What forms the core of the petition for review are **arguments** made by the Board in respect of how the skilled person would have understood the claim taking into account the content of document D7. However it is settled case law that the Board has no obligation to inform the parties about all the arguments supporting the reasoning of the decision. The requirement of Article 113(1) EPC does not extend that far.

In this respect see for instance R 15/13, Reasons point 15, where it was stated that: “The fact that the Board of Appeal did not agree with the petitioner means neither that the petitioner was not heard nor that the petitioner was entitled to know in advance the Board's reasons... the Board is under no obligation to inform

the parties in advance of its decision what the reasons for that decision will be.”.

See also in this respect decision R 6/11 (Reasons, point 8.3): “The Enlarged Board's jurisprudence clearly demonstrates the principle that parties are not entitled to advance indications of the reason or reasons for a decision before it is taken (see the summary of the case-law in R 12/09 of 15 January 2010, Reasons, point 11 and the several other decisions there referred to; and subsequent decisions R 15/09 of 5 July 2010, Reasons, point 4; R 18/09 of 27 September 2010, Reasons, points 14 to 15 and 18; and R 15/10 of 25 November 2010, reasons, points 7 to 9).”

2.7.5 Lastly and for the sake of completeness it is obvious that no new material has been introduced in the debate as **evidence** since document D7 was part of the file from the start of the opposition proceedings as already noted.

2.8 What is in fact contested is the outcome of the proceedings. However, this belongs to the substance of the decision, which, according to a consistent body of case-law of the Enlarged Board of Appeal, is excluded from the petition for review procedure.

2.9 With the view of supporting its position the Petitioner referred to decisions J 3/90, R 7/09, R 15/11 and R 16/13.

2.9.1 In J 3/90, the Legal Board found that the right to be heard had been infringed in that the appellant had no opportunity to comment on correspondence between the

EPO and the UK postal authorities about a disruption in the postal services, letters of which he did not receive any copies. Such a lack of information cannot be complained of by the Petitioner in the present case.

2.9.2 Decision R 7/09 relates to a case where the petitioner (respondent in the appeal proceedings) alleged that he did not receive the communication containing the statement of grounds of appeal, no evidence to the contrary being available. This decision is not comparable to the present case either.

2.9.3 The present case is also different from the situation underlying decision R 15/11 of 13 May 2013. In that decision, the Enlarged Board recognised a substantial procedural violation, and consequently set the decision under review aside, because the Board reached a final decision based on lack of clarity of a claim although this issue had not been debated or at least no evidence of such a debate was to be found in the file. The violation of the right to be heard was qualified as fundamental because it concerned the ground under Article 84 EPC on which the appeal was eventually dismissed (see point 7 of the Reasons).

2.9.4 At the oral proceedings the Petitioner referred to decision R 16/13 of 8 December 2014 (see point 5.2 of the Reasons). In this decision the Enlarged Board stated that, *“when a board makes observations/draws conclusions which have never been discussed so far during the proceedings it should have brought them to the knowledge of the parties in the communication annexed to the summons or at the latest during the oral proceedings. The situation would have been different if*

the board had been legitimately convinced that the patent proprietor and the opponent or their representatives, due to their technical knowledge and their experience relating to comparative examples in patent matters had been able to recognise without any doubt the reasoning of the board and take it into account in their submissions".

This quotation alone taken out of its context could appear perfectly applicable to the present case. However, the factual situation underlying decision R 16/13 is different from the case at hand. In R 16/13 the Board -*ex officio*- put into question the probative value of comparative examples relied upon by the patent proprietor although their conclusiveness for demonstrating a technical effect of the claimed invention had not been disputed by the opponent. On the basis of its finding the Board denied any inventive merit to the patent in suit without having given the patent proprietor an opportunity to comment. According to the Enlarged Board the patent proprietor was deprived of an opportunity to comment upon the conclusion of the Board of which it could not be aware.

The way the Board of Appeal has conducted the present case is in line with the general requirement for respecting the right to be heard as summarised in par. 3.3 of the Reasons of decision R 16/13.

As a consequence, the petition for review must fail and the other requests need not be decided upon.

Order

For these reasons it is decided that:

The petition for review is rejected as being unallowable.

The Registrar: The Chairman:

P. Martorana W. van der Eijk