DES EUROPÄISCHEN **PATENTAMTS**

GROßE BESCHWERDEKAMMER ENLARGED BOARD OF APPEAL OF THE EUROPEAN PATENT OFFICE

GRANDE CHAMBRE DE RECOURS DE L'OFFICE EUROPÉEN DES BREVETS

Internal distribution code:

- (A) [] Publication in OJ
- (B) [] To Chairmen and Members
- (C) [] To Chairmen
- (D) [X] No distribution

Datasheet for the decision of 24 November 2023

Case Number: R 0007/21

T 2842/18 - 3.3.04 Appeal Number:

06837634.2 Application Number:

Publication Number: 1951304

IPC: A61K39/395, A61P19/02,

A61K31/00, C07K16/28

Language of the proceedings: ΕN

Title of invention:

METHOD FOR TREATING JOINT DAMAGE

Patent Proprietors:

F. Hoffmann-La Roche AG Biogen Idec Inc. Genentech, Inc.

Opponents:

Richter Gedeon Nyrt.

Boehringer Ingelheim Pharma GmbH & Co. KG/
Boehringer Ingelheim International GmbH

Merck Serono S.A.

European Oppositions Limited

Taylor Wessing LLP

Hexal AG

Celltrion, Inc.

Mundipharma GmbH

Mundipharma Pharmaceutical s.r.l

Headword:

Petition for review

Relevant legal provisions:

EPC Art. 56, 83, 112a(2)(c), 113, 113(1), 123(2), 134(1) EPC R. 106, 109(2)(b)

Keyword:

Petition for review - clearly unallowable Fundamental violation of Article 113(1) EPC (no)

Decisions cited:

R 0010/09, R 0013/10, R 0004/11, R 0009/11, R 0010/11, R 0006/17, R 0007/17, R 0003/18, R 0010/18, R 0006/20



Große Beschwerdekammer Enlarged Board of Appeal Grande Chambre de recours

Boards of Appeal of the European Patent Office Richard-Reitzner-Allee 8 85540 Haar GERMANY

Tel. +49 (0)89 2399-0 Fax +49 (0)89 2399-4465

Case Number: R 0007/21

D E C I S I O N of the Enlarged Board of Appeal of 24 November 2023

Petitioners:

(Patent Proprietors)

F. Hoffmann-La Roche AG Grenzacherstrasse 124

4002 Basel (CH)

Biogen Idec Inc. 14 Cambridge Center Cambridge, MA 02142 (US)

Genentech, Inc.

1 DNA Way

South San Francisco, CA 94080-4990 (US)

Representative: Mewburn Ellis LLP

Aurora Building Counterslip

Bristol BS1 6BX (GB)

Other party: Richter Gedeon Nyrt.

(Opponent 1) Gyömröi út 19-21 1103 Budapest (HU)

Representative: Neuefeind, Regina

Maiwald GmbH Elisenhof Elisenstraße 3 80335 München (DE)

Other parties: Boehringer Ingelheim Pharma GmbH & Co. KG/

Boehringer Ingelheim International GmbH

(Opponents 2)

Binger Straße 173

55216 Ingelheim am Rhein (DE)

Representative: D Young & Co LLP

120 Holborn

London EC1N 2DY (GB)

Other party: Merck Serono S.A.

(Opponent 3) Zone Industrielle de l'Ouriettaz

1170 Aubonne (CH)

Representative: Merck Serono S.A.

Intellectual Property
Terre Bonne Business Park

Building Z0

Route de Crassier 1 1262 Eysins (CH)

Other party: Hexal AG

(Opponent 6) Industriestrasse 25 83607 Holzkirchen (DE)

Representative: Breuer, Markus

Sendlinger Straße 29 80331 München (DE)

Other party: Celltrion, Inc. 23 Academy-ro

Yeonsu-gu

Incheon 406-840 (KR)

Representative: Hoffmann Eitle

Patent- und Rechtsanwälte PartmbB

Arabellastraße 30 81925 München (DE)

Other party: Mundipharma GmbH
(Opponent 8) Mundipharma Strasse 2
65549 Limburg (DE)

Other party: Mundipharma Pharmaceutical s.r.l

Via Serbelloni, n. 4

(Opponent 9) Via Serber Milan (IT)

Decision under review: Decision of the Technical Board of Appeal 3.3.04

of the European Patent Office of

1 October 2020.

Composition of the Board:

> P. Acton B. Müller E. Viegas

- 1 - R 0007/21

Summary of Facts and Submissions

- I. The petition for review ("Petition") concerns appeal proceedings T 2842/18 of the Board of Appeal 3.3.04 ("the Board"). The appeal was lodged by the Petitioner against the decision of the opposition division to revoke the patent. The decision of the Board, taken on 1 October 2020 and issued in writing on 19 March 2021, shall be referred to as the "Decision". The minutes of the oral proceedings held before the Board on 1 October 2020 shall be referred to as the "Minutes".
- II. The Petitioner argues that its right to be heard under Article 113(1) EPC has been violated (ground of petition Article 112a(2)(c) EPC). The Petitioner identifies two major aspects of this violation of the right to be heard, the first one will be referred to as "postponement representative argument", and the second as the "added matter reasoning argument".

Postponement - representative argument

- III. The Petitioner made three requests to postpone the oral proceedings in the appeal case, on 2 June 2020, 23 September 2020 and 28 September 2020. The Board granted the first of these requests and rejected the second and third such requests.
- IV. The background to these requests was the COVID-19 situation of 2020. As regards its second and third postponement requests, the Petitioner argued that its principal representative during the opposition and appeal proceedings, (hereafter "SW"), based in the United Kingdom, had certain personal/national characteristics that made travelling to Munich and

- 2 - R 0007/21

attending an in-person oral proceedings on 1 October 2020 inadvisable for him. Points 3.8 to 3.11 of the Petition address this issue.

- V. Thus, a consequence of the holding of the 1 October 2020 oral proceedings was that the Petitioner needed to replace SW at short notice with another representative.
- VI. The Petitioner sets out what it considers to be violations of Article 113(1) EPC at point 3.3 of its Petition. These points are set out verbatim below:
 - (i) The refusal to recognize that parties at the EPO have a right to free choice of representation;
 - (ii) The determination to hold the oral proceedings regardless of the circumstances, both in general and specifically in relation to the appointed representative chosen by the proprietors;

 - (iv) The improper weight given to the acceleration of the proceedings, unfairly to the benefit of the opponents and detriment of the proprietors who were forced to attend oral proceedings without the appointed representative of their choice;
 - (v) The disregard of the proprietors' right to be heard fully, even with explicit statement that the Board regarded the oral proceedings and hearing of the proprietors

- 3 - R 0007/21

as essentially unnecessary for its decision.

VII. The "Protest Note" was submitted at the oral proceedings before the Board at approximately 13:05 hours, after the Board had announced its negative opinion on claim 1 of the main request and added matter. This note makes the argument that points i, ii, iii and iv in para VI above constitute a violation of the right to be heard. The Protest Note also contains arguments on the free choice of representation being a constitutional right in Germany, and that similar provisions can be considered to apply in EPC member states and that Article 134(1) EPC is to a similar effect.

The Added Matter argument

- VIII. The Petitioner argues that it was taken by surprise by the Board's reasoning on the non-compliance of claim 1 of the main request with Article 123(2) EPC in the Decision.
- IX. From para. 20 of the Board's preliminary opinion, and also from the Minutes, the Petitioner believed that the Board was aiming at illegitimately introducing plausibility considerations into the assessment of disclosure under Article 123(2) EPC. It is now the Petitioner's position (see page 14 of the Petition) that the Board made its decision neither upon the basis of plausibility considerations, nor upon the basis of direct and unambiguous disclosure, but upon the basis of "certainty" as a new standard for direct and unambiguous disclosure under Article 123(2) EPC. Such a "certainty" standard had never been raised in the proceedings.

- 4 - R 0007/21

- X. Since "certainty", as the standard to be applied when assessing compliance with Article 123(2) EPC, had not been raised during the proceedings, this reasoning only became apparent once the Decision was issued (see para 4.2.3 of the Petition). Thus, the Petitioner was not able to raise objections under Rule 106 EPC.
- XI. At para 4.1.2 of its Petition, the Petitioner argues that it could be considered to have made a de facto Rule 106 EPC objection. It referred to page 5, third paragraph of the Minutes, where it replied to the Chair's question as to whether its right to be heard had been respected with the following comment:

"The appellants replied that this depended on whether or not they could convince the board that the requirements of Article 123(2) EPC were fulfilled. If not, they indeed considered their right to be heard as being violated."

- XII. From the Board's preliminary opinion of 27 May 2020, the Petitioner considered that the Board was going to introduce plausibility considerations into the Article 123(2) EPC assessments. The Petitioner disagreed that plausibility considerations had any role to play in such an assessment, and prepared and presented its case accordingly.
- XIII. During the oral proceedings, the Chair stated that (see page 4, fourth paragraph of the Minutes) "... the board had not included considerations of plausibility in the assessment of the requirement of Article 123(2) EPC. The question to be addressed, according to the board, was whether or not there was a direct and unambiguous

- 5 - R 0007/21

disclosure for the claimed effect in the application as filed".

- XIV. The Petitioner states that the above statement convinced it that the long established and consistent case law for (literal) disclosure, (see page 14 of the Petition), under Article 123(2) EPC would be applied by the Board and that the Board would not apply any form of plausibility requirement.
- XV. It was only once the Petitioner received the written decision that it realised that the Board had based its consideration of Article 123(2) EPC neither upon plausibility, nor upon direct and unambiguous disclosure. This is clear from para. 45 of the Decision (see points 4.1.1 and 4.2.3 of the Petition). From this part of the Decision the Petitioner argues that the Board assessed the requirements of Article 123(2) EPC, in the context of second medical use claims, not upon the established standard of literal disclosure of the words basis, but upon the basis of a new standard of its own invention. This new standard was that, even if the claim wording had a literal basis in the application, the application as filed had to provide a disclosure that proved to the skilled person with absolute certainty that the claimed therapeutic effect was definitely achieved. The parties were not heard on this line of reasoning, hence there was a violation of the Petitioner's right to be heard.
- XVI. Oral proceedings before the Enlarged Board in a three member composition took place on 28 March 2023. At the end of these oral proceedings the Enlarged Board ordered that the Petition be submitted to the Enlarged Board as composed under Rule 109(2)(b) EPC, (a five member composition), for decision. The parties were

- 6 - R 0007/21

summoned to oral proceedings before the Enlarged Board in its five member composition. The oral proceedings took place on 24 November 2023.

XVII. In preparation for the oral proceedings on 24 November 2023, the following substantive submissions were filed by the parties:

Opponent-Respondent VII filed a letter dated 14 June 2023.

Opponent-Respondent VI filed a letter dated 23 June 2023.

The Petitioner filed a letter dated 4 August 2023. Opponent-Respondent VI filed a further letter dated 6 September 2023.

Opponent-Respondent VII filed a further letter dated 10 October 2023.

The Petitioner filed a further letter dated 10 November 2023.

- XVIII. The parties provided extensive arguments, in some cases supplemented by further evidence, relating to the issues of this case. In particular, the Respondents argue that the Petitioner did not raise its

 Rule 106 EPC objection regarding its postponement representative argument as early as it should have. The Petitioner reiterated its position as set out in the Petition and its letter of 14 March 2022.
- XIX. The parties all made lengthy submissions on the issue of whether the Petitioner was taken by surprise by the Board's reasoning on the compliance of claim 1 of the main request with Article 123(2) EPC. The Petitioner reiterated its position as set out in the Petition and its letter of 14 March 2022.

- 7 - R 0007/21

Board regarded the oral proceedings and hearing of the proprietors as essentially unnecessary for its decision

XX. This is point v. of the Petitioner's list of violations of its right to be heard, see page 6 of the Petition. The Petitioner withdrew its objection under this head during the oral proceedings before the Enlarged Board on 24 November 2023.

One-day rather than two-day oral proceedings

XXI. The Board originally summoned the parties to a two-day oral proceeding with its summons of 18 September 2019. This was subsequently changed by the Board to a one-day oral proceedings. The Petitioner withdrew its objection under this head during the oral proceedings before the Enlarged Board on 24 November 2023.

XXII. The Petitioner requests that:

- (i) The decision under review is set aside and that the proceedings are re-opened; and
- (ii) The members of the Board who participated in the Decision set aside shall be replaced, such that the board of appeal to consider the case on re-opening of appeal proceedings is composed of different members than the composition in the impugned Decision; and
- (iii) The fee for the Petition for Review is reimbursed.

- 8 - R 0007/21

Reasons for the Decision

Review of the Board's discretionary decision to not postpone the oral proceedings

- 1. The Enlarged Board has no competence under
 Article 112a EPC to examine the merits of the decision
 and to go into the substance of a case (R 13/10 para 4,
 R 7/17 para 7 and 8), not even indirectly (R 3/18 para
 2.4, pages 13 14). The Enlarged Board not being
 competent to decide on the merits of a case necessarily
 implies that the Enlarged Board, as a rule, has no
 power to control the normal exercise a board makes of
 its discretion (R 10/09 para 2.2, see also R 6/17 para
 3.5). In this case, the Board exercised its
 discretionary power under Article 15(2) RPBA as regards
 its decision not to further postpone the oral
 proceedings.
- 2. The exercise of discretion is only subject to review if arbitrary or manifestly illegal, ("... illégalité manifestes ...", see R 10/11 para 5.2), thereby involving a fundamental violation of the right to be heard (R 9/11).
- 3. The Petitioner cannot claim that the right to be heard has been infringed in respect of its request that the oral proceedings before the Board be postponed. Whether to postpone the 1 October 2020 oral proceedings was the subject of submissions by the Petitioner and a communication of the Board dated 30 September 2020 setting out the reasons for the Board's rejection of this request. Indeed, the Decision sets out in full detail the various submissions of the parties and the communications of the board on this point, see para XIV to XX, XXIII to XXXV, XLI of the Decision. The Decision

- 9 - R 0007/21

substantively considers those submissions in para 5 to 30. Thus, there has been no violation of the Petitioner's right to be heard in this respect.

4. The Enlarged Board thus finds this ground of petition unallowable.

Added matter reasoning argument

- 5. The Board's reasoning on added matter is set out at paras. 31 to 57 of the Decision. The wording of claim 1 of the main request was amended to include the therapeutic effect of "preventing or slowing down the progression in structural joint damage and erosion caused by rheumatoid arthritis" (hereafter "the First Feature"). The issue before the Board was whether there was a disclosure in the application as filed from which it was directly and unambiguously derivable that this was the effect achieved when the treatment was carried out as claimed see para. 39 of the Decision.
- 6. The above objection against the First Feature under Article 123(2) EPC was made by opponent 6, (respondent VI on appeal) on page 14 of its submissions of 8 June 2018 before the opposition division, (where it was directed against auxiliary request 5 filed on 27 April 2018), and on page 7 of its submissions of 19 August 2019 before the Board, (where it was directed against the main request, which had been auxiliary request 14 filed at the oral proceedings before the opposition division). The opposition division found the then auxiliary request 5 not to comply with Article 123(2) EPC for reasons other than those advanced by opponent 6 and found that auxiliary request 14 complied with the requirements of Article 123(2) EPC.

- 10 - R 0007/21

- 7. In its communication of 27 May 2020, the Board at points 18 to 28 of the communication took up respondent VI's Article 123(2) EPC objection to the First Feature and pointed out in para 21 that the Proprietor had not responded to this objection.
- 8. The Petitioner responded to these objections on 31 July 2020. The Petitioner argued that the Board and respondent VI were trying to introduce plausibility requirements into Article 123(2) EPC, plausibility not being a legal requirement of Article 123(2) EPC, but rather being an issue under Articles 83 and 56 EPC. The Petitioner pointed out that Example 3 of the application as filed contained verbatim the First Feature and that Example 1 of the application proved that this technical effect became available (see pages 5 to 8 of Petitioner's submissions of 31 July 2020).
- 9. At oral proceedings before the Board, whether the First Feature of claim 1 of the main request, (which had been auxiliary request 14 filed at the oral proceedings before the opposition division), complied with the requirements of Article 123(2) EPC was discussed with the parties between 09:35 and 12:10 hours. During this discussion, the issue of whether the Board was applying a plausibility requirement to Article 123(2) EPC was discussed. The Board denied that it was applying any such requirement and that the issue to be addressed was "... whether or not there was a direct and unambiguous disclosure of the claimed effect in the application as filed" (see last sentence, penultimate para, page 4 of the Minutes).
- 10. Claim 1 of the main request claims an effect, "preventing or slowing down the progression in

- 11 - R 0007/21

structural joint damage and erosion caused by rheumatoid arthritis" (that is, the First Feature). These words are found verbatim in Example 3 of the application as filed (see para 43 of the Decision). For the Board, the wording directly before the First Feature in Example 3, "... [i]t is expected that retreatment under the protocol herein (or with a different CD20 antibody) will be effective in ..." meant that the skilled person reading Example 3 would not conclude that the effect of the First Feature was definitely achieved, which is what is being claimed (see paras 43 and 45 of the Decision). Hence, the Board found that claim 1 of the main request did not comply with Article 123(2) EPC.

- 11. For a decision to comply with Article 113 EPC, the Enlarged Board of Appeal has held that the following three requirements need to be fulfilled, (see R 4/11, point 2.5 and Case Law of the Boards of Appeal, 10th edition, section V.B.4.3.8d)):
 - (i) the party concerned had an adequate opportunity to present its point of view to the board before a decision was taken; and
 - (ii) the board considered the arguments presented by the party; and
 - (iii) the decision was based on a line of reasoning that could be said to have been in the proceedings.

In more recent case law (R 10/18, affirmed in R 6/20), requirement iii. was not mentioned.

12. The main objection of the Petitioner appears to be under (iii) above, that the Board decided the

- 12 - R 0007/21

Article 123(2) EPC point upon the basis of "certainty", this having never been discussed in the proceedings.

13. The Petitioner arrived at this position from its analysis of para 45 of the Decision. We quote this para of the Decision in full below:

"The board agrees with the respondents that the statement on page 129, lines 20 to 22 of the application does not amount to an explicit disclosure that retreatment ("under the protocol ...") does achieve the effect of "preventing or slowing down the progression ...", but rather expresses an expectation of what the outcome of the clinical trial might be. It is the board's view that the skilled person would derive from the passage in question that the above-mentioned effect might or might not be achieved. The skilled person would not conclude that the effect was definitely achieved."

14. These considerations led the Board to conclude in para 50 of the Decision:

"Therefore while the wording "preventing or slowing down (...) rheumatoid arthritis" is disclosed in the application, see point 43., the board concludes that the skilled person does not derive from page 129, lines 20 to 22, when read alone or in the context of Example 3 as a whole, a clear and unambiguous disclosure that the therapeutic effect of "preventing or slowing down the progression in structural joint damage and erosion caused by rheumatoid arthritis" is achieved when patients with active RA are retreated under the protocol described."

- 13 - R 0007/21

- 15. It thus appears that the Board based its decision on a line of reasoning that had been in the proceedings and thus complied with the requirements mentioned above (in point 11).
- 16. The Enlarged Board is thus of the view that the Petitioner was able to exercise its right to be heard and that the Decision is not based upon any reasons that the Petitioner had not been afforded an opportunity to comment on. The Petition is thus unallowable on this point as well.

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