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Datasheet for the decision of 7 July 2009

Case Number: T 1483/07 - 3.3.08

Application Number: 93921300.5

Publication Number: 0667959

IPC: G01N 33/53

Language of the proceedings: EN

Title of invention:
Methods for identifying inhibitors of the production of beta-amyloid peptide

Patentees:
ELAN PHARMACEUTICALS, INC., et al

Opponents:
BOEHRINGER INGELHEIM Pharma GmbH & Co KG
GLAXO GROUP LIMITED
Merck & Co., Inc.

Headword:
Beta-amyloid peptide/ELAN

Relevant legal provisions:
RPBA Art. 13(1)

Relevant legal provisions (EPC 1973):
-

Keyword:
"Admissibility of the sole request (no)"

Decisions cited:
T 1847/06

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 1483/07 **-** 3.3.08

D E C I S I O N
of the Technical Board of Appeal 3.3.08
of 7 July 2009

Appellants I:
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Decision under appeal:
Interlocutory decision of the Opposition Division of the European Patent Office posted 10 July 2007 concerning maintenance of European patent No. 0667959 in amended form.

Composition of the Board:

Chairman: L. Galligani
Members: T. J. H. Mennessier
T. Karamanli

Summary of Facts and Submissions

I. The patent proprietors (appellants I), opponent O1 (appellant II) and opponent O2 (appellant III) each lodged an appeal against the decision of the opposition division dated 10 July 2007 whereby European patent No. 0 667 959 with the title "*Methods for identifying inhibitors of the production of beta-amyloid peptide*", which had been granted on application No. 93 921 300.5, published as the International application WO 94/10569, was maintained in amended form on the basis of the auxiliary request (claims 1 to 5) filed at the oral proceedings held on 14 March 2007 before the opposition division. The main request (claims 1 to 11), also filed at the oral proceedings, was refused for non-compliance with Article 123(2) EPC.

II. Together with their statement of grounds of 16 November 2007 appellants I filed a main request and an auxiliary request which were identical to the main and auxiliary requests considered by the opposition division in its decision. Appellant II, on 14 November 2007, and appellant III, on 6 November 2007, also filed their statements of grounds in which the request accepted by the opposition division was objected to.

III. Claim 1 of the main request of 16 November 2007 read as:

"1. An in vitro method for identifying β-amyloid peptide (βAP) production inhibitors said method comprising culturing mammalian cells in a culture medium under conditions which result in production of a soluble βAP peptide which can be detected in the culture medium, wherein the cultured mammalian cells

are from a cell line comprising DNA encoding an amyloid precursor protein (APP) variant which provides overproduction of βAP in the cultured mammalian cells; exposing the cultured cells to a test compound; and determining whether the test compound affects the amount of soluble intact βAP present in the culture medium, wherein said DNA encodes an APP variant comprising asparagine and leucine as the residues immediately amino-terminal to the βAP cleavage site."

IV. Appellants I replied on 7 April 2008 to the statements of grounds of appellants II and III.

V. Each of appellants II and III filed a reply, on 14 and 4 April 2008 respectively, to the appellants I' statement of grounds in which they confirmed their objections against the auxiliary request and objected to the main request.

VI. Opponent O3 (respondent) which did not appeal filed submissions on 7 April 2008 in which the main request was objected to.

VII. On 2 March 2009, the board issued a summons to oral proceedings together with a communication under Article 15(1) of the Rules of Procedure of the Boards of Appeal (RPBA) giving an outline of the issues to be discussed at the upcoming oral proceedings.

VIII. On 28 April 2009, for the reason that a written decision in connection with European patent No. 0 730 643 (appeal case T 1847/06) had still to be issued and the reasons therein were important for the

present case, appellants I requested that the oral proceedings be postponed.

IX. A copy of the decision - T 1847/06 of 16 December 2008 - was dispatched on 4 June 2009. The oral proceedings scheduled to take place on 7 July 2009 were not postponed.

X. In reply to the board's communication, appellants I filed on 8 June 2009 additional submissions which were accompanied by five auxiliary requests to replace the only auxiliary request then on file.

XI. Appellant II and the respondent also filed additional submissions on 8 and 5 June 2009 respectively.

XII. Oral proceedings took place on 7 July 2009. It was first debated whether the main request of 16 November 2007 (see Section III *supra*) complied with the requirements of Article 123(2) EPC. After deliberation, the board announced that it had come to a negative conclusion and indicated that the presence of added matter was associated with an inappropriate definition of the APP variant as referred to at the end of claim 1, with respect *inter alia* to the mutations and the precise isoform(s) involved. In view of this finding, appellants I withdrew their main request and filed a new one. The debate then focused on the issue of whether the new main request should be admitted into the appeal's proceedings in view of Article 13 RPBA. The admissibility having eventually been denied by the board, appellants I declared that, assuming that the other parties might be interested in having a decision on the added matter issue in relation to the withdrawn

main request of 16 November 2007, they were prepared to request that their previous main request be reinstated and that their main request filed at the oral proceedings before the board be regarded as their auxiliary request. Appellants II and III as well as the respondent having expressed that they were opposed to the reinstatement of the previous main request, appellants I withdrew the five auxiliary requests then on file and maintained as their sole request the request filed as main request at the oral proceedings.

XIII. The single request consisted of 11 claims, of which claim 1 read as follows:

"1. An in vitro method for identifying β-amyloid peptide (βAP) production inhibitors said method comprising culturing mammalian cells in a culture medium under conditions which result in production of a soluble βAP peptide which can be detected in the culture medium, wherein the cultured mammalian cells are from a cell line comprising DNA encoding an amyloid precursor protein (APP) variant which provides overproduction of βAP in the cultured mammalian cells; exposing the cultured cells to a test compound; and determining whether the test compound affects the amount of soluble intact βAP present in the culture medium, wherein said DNA encodes an APP variant **having a double mutation such that** asparagine and leucine **are** the residues **at positions 595 and 596, respectively, with reference to the 695 isoform, directly** amino-terminal to the βAP cleavage site."

(emphasis added by the board to show the differences with claim 1 of the former main request of 16 November 2007)

XIV. The following document is referred to in the present decision:

(D8) M. Mulan et al., Nature Genetics, Vol. 1, August 1992, pages 345 to 347

XV. The submissions made by appellants I with respect to the admissibility of the request filed at the oral proceedings may be summarised as follows:

The request was filed as a direct reaction to an objection raised under Article 123(2) EPC in particular by appellant II for the first time at the oral proceedings. Appellants II and III had argued at the oral proceedings that as derivable from Figure 3 on page 346 of document D8 not only one but two (and possibly three) βAP cleavage sites might be identified in the APP molecule. The amendments contained in claim 1, which reflected the precise wording found at the bottom of page 16 of the application as filed, should be regarded as a *bona fide* attempt to overcome that particular objection.

Moreover, account being taken of the opinion expressed by the board in its communication of 2 March 2009, appellants I had prepared themselves to deal with the issue of added matter in relation to the presence in the APP variant of the Swedish mutation and further mutations rather than in relation with the location of the Swedish mutation with reference to the βAP cleavage

site. Thus, appellants I had been taken by surprise and their request at this late stage of proceedings had to be admitted.

XVI. The submissions made by appellants II and III as well as the respondent with respect to the admissibility of the request filed at the oral proceedings may be summarised as follows:

Claim 1 of the auxiliary request which was accepted by the opposition division corresponded exactly to claim 1 of the main request of 16 November 2007. Claim 1 had been objected to at the onset of the appeal proceedings *inter alia* for reasons of added matter. It was submitted that page 16 of the application as filed did not provide a general teaching of a variant comprising asparagine and leucine as the residues immediately amino terminal to the βAP cleavage site as defined at the end of the claim (see appellant II's statement of grounds of appeal). Due to said definition, not the APP found in a Swedish FAD family but any APP containing the double mutation lysine->asparagine/methionine->leucine (see appellant III's statement of grounds of appeal) was referred to in the claim.

The argument with regard to Figure 3 of document D8 was in relation to a document which had been on file from the beginning of the opposition proceedings and did also not change the line of argumentation.

Thus, appellants I could not have been taken by surprise at the oral proceedings. The request filed at the oral proceedings could and should have been filed earlier.

XVII. Appellants I (patentees) requested that the decision under appeal be set aside and the patent be maintained on the basis of the single request filed during the oral proceedings.

XVIII. Appellants II and III (opponents 01 and 02) requested that the decision under appeal be set aside and the patent be revoked.

XIX. The respondent (opponent 03) requested that the appeal of the patent proprietors be dismissed.

Reasons for the Decision

Admissibility of the request filed at the oral proceedings

1. The sole request presently on file was only submitted by appellants I at a late stage of the proceedings, namely during the hearing before the board. The board decided not to admit this request into the proceedings exercising its discretion conferred on it by Article 13(1) RPBA. The discretion shall be exercised in view of *inter alia* the complexity of the new subject matter submitted, the current state of the proceedings and the need for procedural economy.

2. After an extensive discussion during the hearing on the objections raised under Article 123(2) EPC by appellants II and III as well as by the respondent and the subsequent deliberation, the board announced its conclusion that the main request of 16 November 2007 then on file contravened Article 123(2) EPC. The board

also indicated that the presence of added matter was associated with an inappropriate general definition of the APP variant referred to at the end of claim 1, in particular with respect to the mutations, and the precise isoform(s) involved, support therefor not being found on page 16, last paragraph of the application as filed (see the application WO 94/10569) which used a more specific language.

3. Only after that, appellants I filed the present request with amended claim 1, the phrase "*wherein said DNA encodes an APP variant comprising asparagine and leucine as the residues immediately amino-terminal to the βAP cleavage site*" being amended to read "*wherein said DNA encodes an APP variant* ***having a double mutation such that*** *asparagine and leucine* ***are*** *the residues* ***at positions 595 and 596, respectively, with reference to the 695 isoform, directly*** *amino-terminal to the βAP cleavage site*" (emphasis added by the board).

4. Contrary to the appellants I's submissions, the newly introduced wording of claim 1 is not exactly found on page 16, last paragraph of the application as filed. The amendments in claim 1 raise therefore new issues concerning whether the amendments were directly and unambiguously derivable from the application as filed (compare with the passages on page 3, lines 7 to 9 and page 16, lines 33 to 37 taken together with pages 27, lines 8 to 17 in the experimental part of the description). In particular, neither the specific Swedish double mutation (Lys^{595}->Asn^{595} and Met^{596}->Leu^{596}) nor the isoform(s) involved are referred to in the claim. The wording used does not exclude that Asn and Leu may substitute for residues other than Lys and Met

as is the case for the Swedish mutation. Furthermore, the expression "*with reference to the 695 isoform*" as used in the claim does not mean necessarily that the APP variant is the 695 isoform but rather serves the purpose of specifying the location of the mutations. Thus, the amended wording of claim 1 is not a straightforward matter. In other terms, the amendments would have caused the proceedings to diverge, opening a debate on new and complex issues and further increasing the complexity of the oral proceedings, contrary to the principle of procedural economy.

5. Appellants I have essentially justified the late filing of their request as being a direct response to the objections raised under Article 123(2) EPC based on an analysis of Figure 3 on page 346 of document D8. Moreover, they argued that they had been taken by surprise by the objections regarding the location of the Swedish mutation with reference to the βAP cleavage site which were raised for the first time by appellants II and III during oral proceedings.

6. The definition of the APP variant as referred to in claim 1 has been the landmark of the objections raised under Article 123(2) EPC by appellants II and III as from the onset of the appeal proceedings (see their respective statements of grounds). Also document D8 has been in the opposition proceedings from the beginning. Appellants I could not reasonable exclude that the issue of the definition of the APP variant with respect *inter alia* to the mutations and the precise isoform(s) involved would be discussed at the oral proceedings. Thus, appellants I were objectively not taken by surprise at the oral proceedings.

7. On this basis, the board exercised its discretion under Article 13(1) RPBA in not admitting the appellants I' single request into the proceedings.

8. Appellants I clearly indicated with their single request that maintenance of the patent in a form different from that underlying the impugned decision was sought. Therefore, it is not necessary in the present case to examine whether the patent in suit can be maintained on the basis of the text underlying the impugned decision.

9. Since there is no allowable request of appellants I, the patent must be revoked.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar The Chairman

A. Wolinski L. Galligani