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Datasheet for the decision of 10 April 2015

Case Number: T 0336/10 - 3.3.04

Application Number: 02758181.8

Publication Number: 1420815

IPC: A61K39/00, A61K39/385, C07K14/47, A61P25/28

Language of the proceedings: EN

Title of invention:
Beta-amyloid-analogue - T-cell epitope vaccine

Patent Proprietor:
H. Lundbeck A/S

Opponent:
Elan Pharma International Limited (opposition withdrawn)

Headword:
Beta-amyloid-analogue/LUNDBECK

Relevant legal provisions:
EPC Art. 84, 123(2), 123(3)

Keyword:
Main request:
added subject-matter (no)
extension beyond the content of the application as filed (no)
clarity (yes)

Decisions cited:
G 0002/88, T 0197/88

Catchword:

Europäisches Patentamt
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Case Number: T 0336/10 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 10 April 2015

Appellant: (Patent Proprietor)	H. Lundbeck A/S Ottiliavej 9 2500 Valby (DK)
Representative:	Hoffmann Eitle Patent- und Rechtsanwälte PartmbB Arabellastraße 30 81925 München (DE)

Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted on 15 December 2009 revoking European patent No. 1420815 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairwoman G. Alt
Members: A. Chakravarty
M.-B. Tardo-Dino

Summary of Facts and Submissions

I. An appeal was filed by the patent proprietor (appellant) against the decision of the opposition division to revoke European patent No. 1 420 815. The patent is entitled "Beta-amyloid-analogue - T-cell Epitope Vaccine".

II. The patent was granted with thirty-seven claims.

Claim 1 as granted read:

"1. Use of an immunogen, which

a) is a polyamino acid **which incorporates into the same molecule** a substantial fraction of B-cell epitopes of APP and/or Aβ so that the polyamino acid reacts to the same extent as does APP or Aβ with a polyclonal serum raised against APP or Aβ, and at least one foreign T-helper epitope (T_H epitope), and which contains the at least one foreign T_H epitope and a disrupted APP or Aβ sequence so that the polyamino acid does not include any subsequence of SEQ ID NO: 2 that binds productively to MHC class II molecules initiating a T-cell response; or

b) is a conjugate comprising a polyhydroxypolymer backbone to which is separately coupled a polyamino acid as defined in a); or

c) is a conjugate comprising a polyhydroxypolymer backbone to which is separately coupled 1) the at least one foreign TM epitope and 2) a disrupted sequence of APP or Aβ as defined in a); or

d) is a nucleic acid that encodes the polyamlno acid as defined in a); or

e) is a non-pathogenic microorganism or virus which is carrying a nucleic acid fragment which encodes and expresses the polyamino acid as defined in a),

in the preparation of a pharmaceutical preparation containing the immunogen for the treatment, prevention or amelioration in an animal of Alzheimer's disease or other diseases characterized by amyloid deposition".

Claim 24 as granted read:

"24. A polyamino acid or conjugate which is derived from an animal APP or Aβ wherein is introduced a modification which has as a result that immunization of the animal with the polyamino acid or conjugate induces production of antibodies against the animal's autologous APP or Aβ, and wherein the polyamino acid or conjugate is as defined in any one of claims 1-16".

Notes: i) Emphasis added by the board. ii) APP is amyloid precursor protein; Aβ is amyloid beta protein.

III. The opposition division dealt with a main and two auxiliary requests. It took the view that claim 1 as granted comprised subject-matter which extended beyond the content of the application as originally filed (Article 123(2) EPC). Claim 1 of auxiliary request 1 was found to have been amended in such a way as to extend the protection conferred by the patent (Article 123(3) EPC) and to lack clarity (Article 84 EPC). Claim 1 of auxiliary request 2 was held to both comprise subject-matter which extended beyond the

content of the application as filed (Article 123(2) EPC) and lack clarity (Article 84 EPC).

IV. With the statement of grounds of appeal, the appellant submitted a set of claims as a main request and three further sets of claims as auxiliary requests 1 to 3.

V. Claim 1 of the main request reads:

"1. Use of an immunogen, which

(a) is a polyamino acid which preserves the overall tertiary structure of APP or Aβ so that the polyamino acid reacts to the same extent as does APP or Aβ with a polyclonal serum raised against APP or Aβ, and **which incorporates into the same molecule** at least one foreign T-helper epitope (T_H epitope), and which contains the at least one foreign T_H epitope and a disrupted APP or Aβ sequence so that the polyamino acid does not include any subsequence of SEQ ID NO: 2 that binds productively to MHC class II molecules initiating a T-cell response; or

(b) is a conjugate comprising a polyhydroxypolymer backbone to which is separately coupled a polyamino acid as defined in a); or

(c) is a conjugate comprising a polyhydroxypolymer backbone to which is separately coupled 1) the at least one foreign T_H epitope and 2) a disrupted sequence of APP or Aβ as defined in a); or

(d) is a nucleic acid that encodes the polyamino acid as defined in a); or

(e) is a non-pathogenic microorganism or virus which is carrying a nucleic acid fragment which encodes and expresses the polyamino acid as defined in a), in the preparation of a pharmaceutical preparation containing the immunogen for the treatment, prevention or amelioration in an animal of Alzheimer's disease or other diseases characterized by amyloid deposition". Emphasis added by the board.

VI. The board issued a summons to oral proceedings accompanied by a communication setting out its preliminary appreciation of the substantive and legal matters concerning the appeal, *i.a.* informing the parties that, should the board find that any claim request met the requirements of both Article 123(3) and Article 84 EPC, it envisaged remitting the case to the department of first instance for further prosecution.

VII. With a letter dated 5 January 2015, the opponent (respondent) withdrew the opposition.

VIII. The board cancelled the scheduled oral proceedings and stated its intention to continue the procedure in writing.

IX. The appellant requested that the decision under appeal revoking the patent be set aside and that the patent be maintained based on the main request or on one of the three auxiliary requests, all submitted with statement of grounds of appeal.

Reasons for the Decision

1. The appeal is admissible.

Main request

Claim 1

Article 123(2) EPC (Added subject-matter)

2. Claim 1 differs from claim 1 of auxiliary request 1 considered in the decision under appeal in the reintroduction of the phrase "which incorporates in the same molecule" which was present in claim 1 as granted. It is now inserted before the definition of the T-helper epitope(s), see highlighted passages of the claims in Sections II and V above.

3. In the board's view, the reintroduction of the phrase at issue at its present position does not alter the meaning and thus the subject-matter of claim 1 compared to claim 1 of the previous auxiliary request 1. In fact the amendment was grammatically necessary to take account of the change, already present in auxiliary request 1 considered in the decision under appeal, in the previous section of the claim where the phrase "preserves the overall tertiary structure of APP or Aβ" replaced "which incorporates into the same molecule a substantial fraction of B-cell epitopes". This amendment was done to address an objection under Article 123(2) EPC made in the decision under appeal (point 2.1 of that decision).

4. Added subject-matter was not an issue in the decision under appeal in relation to auxiliary request 1 and

considering that the meaning of both claims is the same, the board has no reason to take a different view. Moreover, the respondent in the reply to the statement of grounds did not raise an objection in this regard.

5. Claim 1 meets the requirements of Article 123(2) EPC.

Article 123(3) EPC (Extent of protection)

6. The opposition division considered that claim 1 of auxiliary request 1 had been amended in such a way as to extend the protection beyond that of the claims as granted. The reason given for this was that a polyamino acid which "*preserves the overall tertiary structure of APP or Aβ so that the polyamino acid reacts to the same extent as does APP or Aβ with a polyclonal serum raised against APP or Aβ*" (claim 1 of the main request - see section V above) was not regarded as identical to a polyamino acid that "*incorporates [...] a substantial fraction of the B cell epitopes of APP or Aβ" since a "fraction*" (claim as granted - see section II above) could not be regarded as including all of the B cell epitopes of APP or Aβ, whereas a polyamino acid "*which preserves the overall tertiary structure of APP or Aβ*" may include 100% of the B cell epitopes.

7. Article 123(3) EPC provides that "*The claims of the European patent may not be amended ... in such a way as to extend the protection conferred*". The Enlarged Board of Appeal (EBA) decided that it is the totality of the claims before amendment in comparison with the totality of the claims after the proposed amendment that has to be considered (G 02/88 of 11 December 1989, Reasons 3.2) when determining whether an amendment extends the protection conferred by a patent.

7.1 Claim 24 as granted was directed to the immunogen as a product *per se* and conferred the broadest protection. The immunogen was defined by reference to claims 1 to 16 and so the question of whether or not the protection conferred by the claims of the current main request is broader than that conferred by the claims as granted can be answered by comparing the extent of protection of claim 1 as granted with claim 1 of the main request. The determination of whether the immunogen referred to in claim 1 as granted also included a polyamino acid "*which preserves the overall tertiary structure of APP or Aβ*" can be done by considering that the claim as granted qualified the original structural indication "*incorporates [...] a substantial fraction of the B cell epitopes of APP or Aβ*" with a functional one, namely that the modification is done "*so that the polyamino acid reacts to the same extent as does APP or Aβ with a polyclonal serum raised against APP or Aβ*". The identical functional limitation is present in claim 1 of the main request. The skilled person comparing the extent of protection conferred by the two claims would realise that in both cases the immunogen is supposed to retain the same antigenicity as the parent molecule as determined by reactivity with a polyclonal serum raised against APP or Aβ. Thus, since both structural indications serve as an explanation of the functional requirement, they are essentially equivalent as neither affects the extent of protection provided. Indeed, the structural indications could even have been deleted without changing the subject-matter of the claim.

8. The requirements of Article 123(3) EPC are fulfilled.

Article 84 EPC (Clarity)

9. It is established case law of the boards of appeal that when interpreting a claim in the context of Article 84 EPC, each claim should be read giving the words the meaning which they normally have to the skilled person in the relevant art (Case Law of the Boards of Appeal of the European Patent Office, 7th edn, II.A. 6.3.3).

10. Applying this to claim 1, the skilled person would realise that the claimed subject-matter is an immunogen being a polyamino acid derived from APP or Aβ with modified T_H epitopes, which modifications are done such as to preserve the overall tertiary structure of APP or Aβ (claim 1 (a)) or related subject-matter (claim 1 (b) to (e)). The structural indication is coupled to a functional one, namely the testable limitation "*that the polyamino acid reacts to the same extent as does APP or Aβ with a polyclonal serum raised against APP or Aβ*". The board therefore cannot agree with the opposition division that "*the term 'preserves the overall tertiary structure' [...] is too complex and vague to be clearly measurable, or generally acceptable for the skilled man*". Instead the skilled person would realise that the polyamino acid of claim 1 should have the same immunogenicity as APP or Aβ while having the native T_H epitopes removed to avoid the danger that once the immune response has been established, in some vaccinated individuals the immune response induced cannot be discontinued simply by discontinuing the immunisation because the induced immune response in such individuals may be driven by a native T_H epitope of the autologous protein (paragraphs [0118] to [0119] of the patent). The indication that the "polyamino acid [...] preserves the overall tertiary structure of APP

or Aβ", is to be seen in this context and also in the context of the fact that the polyamino acid reacts to the same extent as does APP or Aβ with a polyclonal serum raised against APP or Aβ.

11. In view of the above considerations, the board concludes that claim 1 fulfills the clarity requirement of Article 84 EPC.

Remittal

12. With the letter dated 5 January 2015, the opposition was withdrawn. Rule 84(2) EPC, second sentence, provides that the opposition proceedings may be continued by the EPO of its own motion if the opposition is withdrawn.

13. A case is normally remitted to the first instance department, *i.a.* if essential questions regarding the patentability of the claimed subject-matter have not yet been examined and decided by the department of first instance.

14. The opposition division in the decision under appeal only dealt with the question of amendments in relation to Article 100(c) EPC and examined the claims amended during opposition proceedings for compliance with Article 123(3) EPC and Article 84 EPC without touching upon any other substantive requirements of the EPC. In this particular case it appears appropriate to remit the case to the opposition division which, pursuant to Rule 84 EPC, may continue the opposition proceedings according to criteria established in the case law, for instance if the opposition division comes to the conclusion that the opposition proceedings have reached a stage at which they are likely to result in a

limitation or revocation of the European patent without further assistance from the opponent and without the opposition division itself having to undertake extensive investigations (T 197/88 of 2 August 1988, point 3.2 of the reasons).

14.1 Therefore the board exercises its discretion under Article 111(1) EPC to remit the case to the opposition division for further prosecution.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the opposition division for further prosecution on the basis of the main request filed on 14 April 2010.

The Registrar: The Chairwoman:

P. Cremona G. Alt

Decision electronically authenticated