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**Datasheet for the decision
of 12 November 2015**

Case Number: T 2477/12 - 3.3.08

Application Number: 10150052.8

Publication Number: 2186823

IPC: C07K14/51

Language of the proceedings: EN

Title of invention:
Gene therapy for renal failure

Applicant:
Merial, Inc.

Headword:
Gene therapy, BMP-7/MERIAL

Relevant legal provisions:
EPC Art. 76(1)

Keyword:
Main request and Auxiliary request - Article 76(1) EPC (no)

Decisions cited:
G 0003/89, G 0001/12, T 0006/84, T 0689/90, T 0196/92,
T 0558/03, T 0908/05, T 1497/06, T 1387/08, T 0664/11,
J 0005/81

Catchword:



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Boards of Appeal
Chambres de recours**

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Case Number: T 2477/12 - 3.3.08

D E C I S I O N
of Technical Board of Appeal 3.3.08
of 12 November 2015

Appellant: Merial, Inc.
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Decision under appeal: **Decision of the Examining Division of the European Patent Office posted on 4 July 2012 refusing European patent application No. 10150052.8 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman M. Wieser
Members: B. Stolz
D. Rogers

Summary of Facts and Submissions

- I. The appeal lies against the decision of the examining division posted on 4 July 2012, whereby European patent application No. 10150052.8 was refused because it did not comply with the requirements laid down in Articles 76(1) and 83 EPC.
- II. This patent application is a divisional application of European patent application No. 06827775.5 (hereinafter referred to as "the parent application").
- III. With its grounds of appeal, the appellant (applicant) submitted an auxiliary request.
- IV. The appellant was summoned to oral proceedings. A communication pursuant to Article 15(1) of the Rules of Procedure of the Boards of Appeal (RPBA) annexed to the summons, set out the preliminary non-binding opinion of the board on some of the issues of the appeal proceedings.
- V. The appellant responded to this communication and submitted further arguments.
- VI. Oral proceedings were held on 12 November 2015.
- VII. Claim 1 of the main request according to appellant's letter of 25 October 2012, originally filed under cover of a letter dated 9 November 2010, reads as follows:

"1. A recombinant plasmid vector comprising a nucleic acid sequence encoding a BMP-7 polypeptide operatively linked to a promoter, wherein the BMP-7 polypeptide is selected from the group consisting of a pre-pro BMP-7 polypeptide, a pro-

BMP-7 polypeptide, and a mature BMP-7 polypeptide; or wherein the BMP-7 polypeptide has an amino acid sequence selected from the group consisting of SEQ ID NO: 3 and fragments, variants, derivatives and homologs thereof that have BMP-7 activity and wherein, the nucleic acid sequence encoding the BMP-7 polypeptide is selected from the group consisting of SEQ ID NO: 1 , SEQ ID NO: 2, and fragments, variants, derivatives and homologs thereof that encode polypeptides having BMP-7 activity."

Claims 2 to 19 refer to specific embodiments of the plasmid vector according to claim 1 and to medical uses thereof.

VIII. Claims 1 and 2 of the auxiliary request read as follows:

- "1. A recombinant plasmid vector comprising a nucleic acid sequence encoding a BMP-7 polypeptide operatively linked to a promoter, wherein the BMP-7 polypeptide is selected from the group consisting of a pre-pro BMP-7 polypeptide, a pro-BMP-7 polypeptide, and a mature BMP-7 polypeptide; or wherein the BMP-7 polypeptide has an amino acid sequence selected from the group consisting of SEQ ID NO: 3 and fragments, variants, derivatives and homologs thereof that have BMP-7 activity.

2. The recombinant plasmid vector according to claim 1, wherein the nucleic acid sequence encoding the BMP-7 polypeptide is selected from the group consisting of SEQ ID NO: 1, SEQ ID NO: 2, and fragments, variants, derivatives and homologs

thereof that encode polypeptides having BMP-7 activity."

Claims 3 to 20 refer to specific embodiments of the plasmid vector according to claim 1 and to medical uses thereof.

IX. The appellant's arguments can be summarized as follows:

The parent application contained a clear statement that the application claims priority from US provisional application 60/736,452, which was "*herein incorporated by reference*". According to section H-V 2.5 of the guidelines for examination, in force as of June 2012, the incorporation of a feature by reference was subject to the conditions that it did not contravene Article 123(2) EPC and that the document was made available to the EPO and the public at specific dates. In decision T 689/90 of 21 January 1992, four criteria were established for assessing whether an amendment resulting from the incorporation by reference of a feature into the description contravened the requirements of Article 123(2) EPC. All four criteria were met in the present case.

In particular, the claims of the parent application recited specific SEQ ID Nos, which provided a clear indication that said sequences formed part of the disclosed invention. The skilled person would furthermore recognise that the parent application as filed did not comprise a sequence listing, and would therefore be directed to the priority document by the clear statement of incorporation by reference on page 1.

In this respect the present case differed from that underlying T 1497/06 of 16 November 2007, where reference was made to a long list of documents to be incorporated by reference and where the contents of the patent application and the cross referenced priority application differed to a great extent with regard to the level of detail of their disclosure.

In the present case, the parent application clearly identified US 60/736,452 in its first paragraph as being incorporated by reference. This disclosure was made entirely separately from any statement to any other documents being incorporated by reference. Unlike any other document which might be referenced, there was a presumption that the priority application related to the same invention as the parent application. Accordingly, it would have been clear to the skilled person that the sequences referred to in the parent application were those of the priority document.

Moreover, the described lengths of the sequences mentioned in the parent application corresponded exactly to the lengths of the sequences disclosed in the priority document. Also further structural features mentioned in the parent application corresponded exactly to the respective features in the priority document.

The present case also differed from that in decision T 908/05 of 26 February 2008 which was rather concerned with the correction of an error.

The case was more reminiscent of the case in decision T 196/92 of 15 November 1994.

The statement of "incorporation by reference" on page 1 could also be regarded as a filing of the respective sequences by reference to an earlier application. Article 80 EPC together with Rule 40 EPC implemented Article 5 of the Patent Law Treaty (PLT) which entered into force on 28 April 2005, i.e. before the filing date of the parent application. Article 5(7)(a) PLT explicitly permitted the filing by reference to a previously filed application. Thus, while the EPO did not implement the provisions of the PLT until the entry into force of EPC 2000, there existed an established general principle in worldwide patent law that filing by reference to a previously filed application was permitted.

Finally, the incorporation of the sequences into the parent application by reference also met the requirements for the correction of an obvious error.

- X. The appellant requests that the decision under appeal be set aside and the application be remitted to the examining division for further examination, on the basis of either its main request (claims 1 to 19 filed with letter dated 9 November 2010) or its auxiliary request filed with the grounds of appeal.

Should the board decide otherwise, it requests that the following questions of law be referred to the Enlarged Board of Appeal:

"In order to ensure a uniform application of the law and due to its fundamental importance:

- 1) Is it permissible to incorporate all of the subject matter of a priority document into the text of a patent application if the patent application explicitly*

specifies that the priority document is incorporated therein by reference?

2) If the answer to 1) is no, is it possible to incorporate any subject matter relating to a stated invention mentioned in a priority document into the text of a patent application if the patent application explicitly states that the priority document is incorporated therein by reference?

3) If the answer to 1) is no and/or the answer to 2) is no, is it possible to incorporate amino acid sequences and nucleotide sequences that are said to be important for the subject matter of a priority document into the text of a patent application when said sequences are also said to be important for the subject-matter of the patent application if the patent application explicitly states that the priority document is incorporated therein by reference?"

Reasons for the Decision

1. The present patent application is a divisional application of European patent application No. 06827775.5. The description and the claims of the parent application made reference to SEQ ID Nos without however disclosing such sequences.

The main request (the divisional application as filed) contains the complete description, the claims and figures of the parent application and in addition the complete description and the sequence listing of patent application US 736452P, from which priority rights are claimed. The auxiliary request comprises the content of

the parent application as filed and in addition the sequence listing of the priority application.

2. For the assessment of the requirements of Article 76(1) EPC, it is the appellant's position that the description and the sequence listing contained in the priority document implicitly belonged to the disclosure of the parent application as filed because on page 1, lines 8 and 9, the parent application contains the following statement:

"This application claims priority to US provisional application 60/736,452, filed November 14, 2005, herein incorporated by reference".

3. The parent application discloses recombinant expression vectors, pharmaceutical compositions comprising such vectors and methods for prevention and/or treatment of acute and/or chronic renal failure. The vectors encode a polypeptide belonging to the OP-1/BMP-7 family of proteins. In a preferred embodiment, the vector encodes a canine pre-proBMP-7, a canine proBMP-7 or a canine mature BMP-7 polypeptide (page 7, line 16).

In relation to nucleic acid sequences encoding canine BMP-7, the following is stated on page 9:

"Also included as part of the present application is a sequence listing in which: SEQ ID NO: 1 is the nucleotide sequence of the pre-proBMP7 polypeptide, SEQ ID NO: 2 is the codon-optimized nucleotide sequence of the pre-proBMP7 polypeptide, SEQ ID NO: 3 is the amino acid sequence of the pre-proBMP7 polypeptide".

The parent application as filed does, however, not disclose any amino acid or nucleic acid sequences encoding canine BMP-7.

4. In view of the degenerate nature of the genetic code, a mere verbal reference to a nucleic acid sequence encoding canine pre-proBMP-7 cannot be regarded as an implicit disclosure of a particular nucleic acid sequence encoding said gene. As far as protein sequences are concerned, a mere verbal reference to an amino acid sequence of canine pre-proBMP-7 does not necessarily disclose a particular amino acid sequence, as more than one such sequence may be known.
5. The appellant argued that the incorporation of the priority document by reference in effect amounted to the filing of the parent application by reference to an earlier application as foreseen by Rule 4.18 of the PCT regulations, in the version in force from 1 April 2007, and Rule 40 EPC.
6. The PCT regulations in force at the filing date of the parent application, 14 November 2006, did not provide for the filing of sequence listings by reference to an earlier application.
7. Rule 40(1)(c) EPC 2000 defines that *"the filing date of a European patent application shall be the date on which the documents filed by the applicant contain: ... a description or reference to a previously filed application."* However, as set out in decision J 3/06 (OJ 3/2009, 170), Article 80 EPC and Rule 40 as amended in EPC 2000 are not in the catalogue of provisions stated to be applicable also to pending procedures (point 3, paragraphs 4 to 6). Rule 40 EPC 2000 can therefore not help the appellant's case.

8. The appellant argued that Rule 40(1)(c) EPC 2000 implemented Article 5 of the Patent Law Treaty which entered into force on 28 April 2005, i.e. before the present priority date. Therefore, at the date of filing of the present application, there was an established general principle in world-wide patent law for allowing the contents of the priority application to be incorporated into the current patent application.
9. The board has to take its decisions by applying the law as laid down in the PCT and the EPC in force at the relevant time. The appellant's argument referring to a vague "established general principle" which apparently takes precedence over such statutory provisions cannot therefore be accepted.
10. The appellant further argued that, due to the incorporation of the priority document by reference, the sequences disclosed in the priority application implicitly belonged to the disclosure of the parent application.
11. With regard to the incorporation of technical information by reference, the Enlarged Board of Appeal stated in point 7, second paragraph of decision G 3/89 (OJ 1993, 117):

"Under certain circumstances the content of a document not belonging to the parts of a European patent application relating to the disclosure may be included, by means of reference, partially or wholly in the disclosure. The Enlarged Board, however, sees no reason to specify these circumstances in the present procedure."

12. Although decision G 3/89 does not shed any light on this issue, the definition of these "certain circumstances" has been the subject of several decisions of the Boards of Appeal.

13. Taking an older case that pre-dates decision G 3/89 as a starting point, the headnote of decision T 6/84 of 21 February 1985 states:

"Structural features of a means for performing a chemical process (here: the catalyst "offretite") which are not mentioned in the application documents themselves but in a document (here: a Canadian Patent specification) to which they refer may be incorporated into a patent claim if they unequivocally form part of the invention for which protection is sought."

14. In decision T 6/84 the board considered it necessary to incorporate a more specific structural definition of the term "offretite" into a claim. It allowed an amendment by insertion of features disclosed in a prior art patent document which was clearly referenced as describing *"the synthetic offretite useful in the present invention and its method of preparation"*. The board held that it was necessary to incorporate all the essential structural features into the claim.

15. In point 2.2 of decision T 689/90, the board stated:

" ... having regard partly to what is set out in the headnote to Decision T 6/84, in the Board's view, when determining whether features which are not mentioned in the description of the invention but only in a cross-referenced document may be incorporated into a claim of a European patent application, it is necessary to

consider whether the description of the invention as filed leaves no doubt to a skilled reader:

(a) that protection is or may be sought for features which are only disclosed in the reference document;

(b) that the features which are only disclosed in the reference document contribute to achieving the technical aim of the invention and are thus comprised in the solution of the technical problem underlying the invention which is the subject of the application;

(c) that the features which are only disclosed in the reference document implicitly clearly belong to the description of the invention contained in the application (Article 78(1)(b) EPC) and thus to the content of the application as filed (Article 123(2) EPC); and

(d) that such features are precisely defined and identifiable within the total technical information within the reference document.

If the above particular conditions are satisfied, in the Board's view it is permissible for the features which are only disclosed in the reference document to be introduced into the claims of the application without contravening Article 123(2) EPC because such features are then properly to be considered as within "the content of the application as filed".

16. In a number of cases the criteria developed in T 689/90 have been taken into account (e.g. T 196/02, T 558/03 of 2 June 2005, T 1497/06, T 1378/08 of 29 April 2011, T 664/11 of 25 February 2015).

17. As concluded in point 11 of decision T 1497/06, the reasons for incorporating a document by reference (why is it taken?) as well as the result thereof (what subject matter is incorporated?) must already be clear from the original application. Without this, a mere incorporation by reference of a whole document is not sufficient as it does not disclose anything about the contents of the referenced document.
18. As a first step (step (a)), it is therefore necessary to examine whether the description of the invention in the parent application as filed leaves no doubt to a skilled reader that protection is sought for nucleic acid sequences only disclosed in the priority document.
19. There is no indication to be found in the parent application as filed that a nucleic acid sequence, only disclosed in the priority document, is an essential feature for carrying out the invention.
20. The appellant argued that, unlike any other document which might be referenced, there was a presumption that the priority application relates to the same invention as the parent application. Therefore, the skilled person would not doubt that the sequences referred to in the parent application were those of the priority document.
21. The board rejects this argument. While, generally speaking, a priority document relates to the same invention as a subsequent patent application, there is no presumption that the disclosure of a patent application is limited to subject matter disclosed in the respective priority document. Frequently, a subsequent filing contains additional or different structural or functional technical information. In the

- case of sequence listings in particular, there is no automatic presumption that the missing sequences of the parent application have to be identical with the sequences disclosed in the priority document.
22. Therefore, criterion (a) as set out in T 689/90 (supra) is not met.
 23. The mere reference to a sequence listing, which obviously itself is missing in the parent application, cannot be regarded as an implicit disclosure of all the particular structural features defined by the sequence listing of the priority document. Therefore, also criterion (c) as set out in T 689/90 (supra) is not met.
 24. As a consequence, the argument that the "incorporation of the priority document by reference" implicitly disclosed the missing sequences must fail.
 25. The appellant also argued that the skilled reader upon noticing that the parent application contains no sequence listing and being guided by the "incorporated by reference" feature would turn to the priority document to retrieve the missing sequences. This seems more to be an argument in support of a request for a correction of an error.
 26. At no point during the prosecution of the parent application was a request for correction of an obvious error according to Rule 139 EPC made.

Moreover, such a request could only have been granted if it were unmistakably clear from the application document itself what the structural features of the missing sequences were. Absent any specific pointer,

and for the same reasons as given in points 4 and 23 above, the skilled person could not derive that the missing BMP-7 sequences were the particular sequences disclosed in the priority document. Any other BMP-7 nucleic acid sequences could equally well have been envisaged.

27. Therefore, this argument also fails.

28. As a consequence, neither the main request nor the auxiliary request comply with the requirements of Article 76(1) EPC.

Referral of certain questions of law

29. Under Article 112(1) EPC, in order to ensure uniform application of the law, or if a point of law of fundamental importance arises, a board shall refer any question to the Enlarged Board of Appeal if it considers that a decision is required for the above purposes.

30. The appellant argued that the board's decision with regard to Article 76(1) EPC was in contradiction with the existing case law, in particular decisions T 6/84 and T 196/92. Therefore certain questions of law (see para. X above) should be referred to the Enlarged Board of Appeal.

31. In decision T 689/90, the board analysed the circumstances under which an amendment had been allowed in decision T 6/84 and concluded that the principles set out in the headnote of said decision could not be properly applied to the facts of the case in front of it (point 2.1, last paragraph). Taking into account what was stated in decision T 6/84, the board, in

- decision T 689/90, developed the four criteria, recited in point 15 above, for the assessment of the allowability of an amendment resulting from the incorporation by reference of a feature which was not originally disclosed (cf. point 2.2 of the Reasons of decision T 689/90).
32. Also in decision T 196/92 the amendment in question was found to meet these requirements (cf. the last sentence of point 2.4 of the Reasons, where the board in relation to the criteria developed in decision T 689/90 stated: *"Also these requirements are fulfilled in the present case because it is clear from the application as filed"*).
33. In the present case, the board likewise applied the criteria developed in decision T 689/90 in order to decide whether the main request and the auxiliary request meet the requirements of Article 76(1) EPC. Turning on the specific facts of the case, it came to the conclusion that the requirements of said Article are not met.
34. The four respective criteria were also taken into consideration in the decisions mentioned in point 16 above.
35. The application of the same legal principles and criteria may lead to different results in different cases. This is a consequence of the specific facts of each individual case and not, however, an indication of a contradictory interpretation or an inconsistent application of the law.

36. The interpretation of the law in the present appeal is therefore consistent with the interpretation in the cited decisions.
37. The appellant has also argued that its questions concern a point of law of fundamental importance. The board does not question this assertion. As set out in decision G 1/12 (Reasons, point 10) of 30 April 2014, a point of law is to be regarded as of fundamental importance *"if its impact extends beyond the specific case at hand. Such importance is established if it could be relevant to a large number of similar cases"*. Notwithstanding that it is impossible to ascertain the number of cases in which the question "incorporation by reference" was, is or might become relevant, it is apparent that the impact of this point of law is not isolated to the present case but is clearly relevant to a number of similar cases.
38. However, the case law of the boards of appeal consistently provides that when deciding whether to refer such questions a board should consider whether the board itself can answer the questions by reference to the EPC in such a way as to leave the board in no doubt as to the correctness of its answer. If this is the case, then the board should not refer the questions (decision J 5/81, OJ EPO 1982, 153). This approach was confirmed in decision G 1/12 (Reasons, point 10) in which the Enlarged Board held that the ground *"point of law of fundamental importance"* for referring a question requires that a board considers that the question cannot be answered directly and unambiguously by reference to the EPC.
39. In the present case, the questions can be answered directly and unambiguously by reference to the EPC in

such a way as to leave the board in no doubt as to the correctness of its answer.

40. The board, therefore, holds that the referral of the appellant's questions to the Enlarged Board of Appeal is not necessary.

Order

For these reasons it is decided that:

1. The request for referral of questions to the Enlarged Board of Appeal is refused.
2. The appeal is dismissed.

The Registrar:

The Chairman:



A. Wolinski

M. Wieser

Decision electronically authenticated