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Datasheet for the decision of 24 June 2009

Case Number: T 1885/07 - 3.3.08

Application Number: 95914666.3

Publication Number: 0753053

IPC: C12N 7/01

Language of the proceedings: EN

Title of invention:
Alphavirus cDNA vectors

Patentee:
BIOPTION AB

Opponent:
Novartis Vaccines and Diagnostics, Inc.

Headword:
Alphavirus vectors/BIOPTION

Relevant legal provisions:
EPC Art. 123(2)

Relevant legal provisions (EPC 1973):
-

Keyword:
"Main and auxiliary requests: added matter (yes)"

Decisions cited:
-

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 1885/07 - 3.3.08

D E C I S I O N
of the Technical Board of Appeal 3.3.08
of 24 June 2009

Appellant: (Patent Proprietor)	BIOPTION AB Herrgårdsvägen 9 S-135 53 Tyresö (SE)
Representative:	Onn, Thorsten Zacco Sweden AB P.O. Box 23101 S-104 35 Stockholm (SE)
Respondent: (Opponent)	Novartis Vaccines and Diagnostics, Inc. 4560 Horton Street Emeryville, CA 94608-2917 (US)
Representative:	Hallybone, Huw George Carpmaels & Ransford 43-45 Bloomsbury Square London WC1A 2RA (GB)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted 10 August 2007 revoking European patent No. 0753053 pursuant to Article 102(1) EPC 1973.**

Composition of the Board:

Chairman: L. Galligani
Members: F. Davison-Brunel
C. Rennie-Smith

Summary of Facts and Submissions

I. European patent No. 0 753 053 with the title "Alphavirus cDNA vectors" was granted with a set of 34 claims based on European patent application No. 95 914 666.3.

Originally filed claims 1, 14 and 20 read as follows:

"1. A cDNA molecule complementary to at least part of an alphavirus RNA genome, which cDNA molecule comprises the complement of the complete alphavirus RNA genome regions, which are essential for replication of the said alphavirus RNA, and further comprises an exogenous cDNA sequence capable of expressing its function in an animal or human host cell, said exogenous cDNA sequence being inserted into a region of the cDNA molecule, which is non-essential to replication thereof, and said cDNA molecule being placed under transcriptional control of a promoter sequence functional in said animal or human cell.

14. A method for achieving expression of the cDNA of any preceding claim in cultured animal or human cells or in an animal or human individual, said method comprising contacting the cultured cells with the cDNA or introducing the cDNA into said individual, in a way that causes the cDNA to be taken up into the interior of the cultured cells or of cells of said individual and to express its function in said cells.

20. The method of any of claims 14-17, wherein the cDNA, or the cultured cells comprising the cDNA is (are) introduced into an animal to produce a product by

expression of said cDNA, which product can be recovered from the animal and which product has no effect, which is beneficial to the individual animal, wherein it is produced."

II. An opposition was filed under Article 100 (a) and (c) EPC. In the course of the opposition proceedings, the patentee filed a new main request and five auxiliary requests. The first auxiliary request was withdrawn at oral proceedings. All other requests were rejected by the opposition division for failing to fulfil the requirements of, in particular, Article 123(2) EPC.

III. The appellant (patentee) filed a notice of appeal and submitted on 19 December 2007 a statement of grounds of appeal together with a new main request and a new auxiliary request in replacement of the requests on file.

IV. Claims 1, 12 and 15 of the **main request** read as follows:

"1. A cDNA molecule complementary to at least part of an alphavirus RNA genome, which cDNA molecule comprises the complement of the complete alphavirus RNA genome regions, which are essential for replication of the said alphavirus RNA, and further comprises an exogenous cDNA sequence capable of expressing its function in an animal or human host cell, said exogenous cDNA sequence being inserted into a region of the cDNA molecule, which is non-essential to replication thereof, and said cDNA molecule, that is complementary to at least part of an alphavirus genome, being placed under transcriptional control of a promoter sequence functional in said animal or human cell and wherein

said cDNA molecule that is complementary to at least part of an alphavirus genome comprises the complement to a self-cleaving ribozyme sequence at the 3' end of said alphavirus genomic sequence and positioned in such a way that the ribozyme sequence when self-cleaved generates the proper alphavirus 3' end.

12. A method for achieving expression of the cDNA of any preceding claim in cultured animal or human cells, said method comprising contacting the cultured cells with the cDNA in a way that causes the cDNA to be taken up into the interior of the cultured cells and to express its function in said cells.

15. The method of any of claims 12-14, wherein the cDNA is introduced into the cultured cells by transformation, such as transfection or infection, in vitro and wherein further the cultured cells comprising the cDNA are introduced into an animal exclusive of humans to produce a product by expression of said cDNA, which product in a further step is recovered from the animal."

Claim 1 of the **auxiliary request** read as follows:

"1. A cDNA molecule complementary to at least part of an alphavirus RNA genome, which cDNA molecule comprises the complement of the complete alphavirus RNA genome regions, which are essential for replication of the said alphavirus RNA, and further comprises an exogenous cDNA sequence capable of expressing its function in an animal or human host cell, said exogenous cDNA sequence being inserted into a region of the cDNA molecule, which is non-essential to replication thereof, and said

cDNA molecule, that is complementary to at least part of an alphavirus genome, being placed under transcriptional control of a promoter sequence functional in said animal or human cell and wherein said cDNA molecule that is complementary to at least part of an alphavirus genome comprises 3' end sequences required for replication of said alphavirus RNA, a eukaryotic transcription stop signal and the complement of a self-cleaving ribozyme sequence inserted before the transcription stop signal in such a way that the ribosome sequence when self-cleaved generated a proper alphavirus 3' end."

The wording of claims 12 and 15 of this request is identical to that of claims 12 and 15 of the main request.

V. On 7 May 2008, the respondent (opponent) submitted observations on the appellant's statement of grounds of appeal.

VI. On 19 November 2008, the board sent a communication pursuant to Article 15(1) of the Rules of Procedure of the Boards of Appeal (RPBA) indicating its preliminary, non-binding opinion, in particular that claim 15 of each of the main and first auxiliary requests may not fulfil the requirements of Article 123(2) EPC (point 5 of the communication).

VII. On 7 May 2009, the appellant informed the board that it would not attend oral proceedings.

VIII. On 4 June 2009, the appellant further informed the board that it withdrew its request for oral proceedings.

IX. Oral proceedings were cancelled on 9 June 2009.

X. The appellant's submissions in writing insofar as relevant to the present decision may be summarized as follows:

Article 123(2) EPC; added subject-matter
Main and first auxiliary requests; claim 15

The subject-matter of claim 15 found a basis in the application as filed, in claim 20 and on page 10, lines 18 to 23. Since claim 15 required that the expressed product be recovered from the animal, it was evident that said product could not have any effect which would be beneficial to the animal. Therefore, omitting this last feature from the claim did not enlarge its scope ie. did not add subject-matter.

XI. The respondent's submissions in writing insofar as relevant to the present decision may be summarized as follows:

Article 123(2) EPC; added subject-matter
Main and first auxiliary requests; claim 15

There were no statements of invention in the application as filed corresponding to claim 15 and the closest statements contained the specific limitation that the product "has no effect, which is beneficial to the individual animal, wherein it is produced" (page 10, lines 20 to 23 of the application as filed, claim 20). In contrast to this disclosure, claim 15 did not exclude a therapeutic effect of the product for the

animal. Accordingly, subject-matter was added and the claim contravened Article 123(2) EPC.

XII. The appellant requested that the decision of the opposition division be set aside and that the patent be maintained on the basis of the main request or of the auxiliary request filed on 19 December 2007.

The respondent requested that the appeal be dismissed.

Reasons for the decision

Article 123(2) EPC, added subject-matter
Main and auxiliary requests; claim 15

1. The appellant argued that the application as filed provided a basis for the subject-matter of claim 15 (main and auxiliary requests, section III, supra) in originally filed claim 20 (section I, supra) and on page 10, lines 18 to 23. This passage reads as follows:

"The present invention is also related to a method, wherein the present cDNA, or the cultured cells comprising this cDNA, is (are) introduced into an animal to produce a product by expression of said cDNA, which product can be recovered from the animal and which product has no effect, which is beneficial to the individual animal, wherein it is produced."

2. When comparing claim 15 with originally filed claim 20 or with the passage on page 10, lines 18 to 23 of the application as filed, it becomes readily apparent that the expressed product was originally intended to have

no beneficial effect for the animal which produced it. This limiting property of the expressed product is missing in claim 15.

3. The board was not able to find any other parts of the application as filed which could be regarded as disclosing the now claimed subject-matter. The appellant's argument that it was unambiguous although implicit that the expressed product could not be beneficial to the animal since it was recovered from it, is not convincing. Indeed, product recovery does not necessarily imply that the product could not be beneficial to the animal prior to recovery nor, of course, that the animal be sacrificed.

4. For these reasons, the board is convinced that the scope of claim 15 is wider than that afforded by the original disclosure which did not extend to **any** possible product being expressed. Therefore, claim 15 must be regarded as an impermissible generalisation which adds subject-matter.

5. As claim 15 is present in the main request and in the auxiliary request, both of them are rejected for failing to comply with the requirements of Article 123(2) EPC.

Order:

For these reasons, it is decided that:

The appeal is dismissed.

The Registrar The Chairman

A. Wolinski L. Galligani