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**Datasheet for the decision
of 11 December 2009**

Case Number: T 1771/07 - 3.3.08

Application Number: 92914266.9

Publication Number: 0592521

IPC: C12N 5/08

Language of the proceedings: EN

Title of invention:

Marrow-derived human mesenchymal stem cells and monoclonal antibodies specific for said cells

Patentee:

Osiris Therapeutics, Inc.

Opponents:

Cognate Therapeutics Inc.
GENZYME CORPORATION

Headword:

Mesenchymal stem cells/OSIRIS

Relevant legal provisions:

EPC Art. 111(2)

Relevant legal provisions (EPC 1973):

-

Keyword:

"Main request and first auxiliary request - remittal for further prosecution"

Decisions cited:

G 0001/03

Catchword:

-



Case Number: T 1771/07 - 3.3.08

DECISION
of the Technical Board of Appeal 3.3.08
of 11 December 2009

Appellant: Osiris Therapeutics, Inc.
(Patent Proprietor) 2001 Aliceanna Street
Baltimore, MD 21231-2001 (US)

Representative: Schnappauf, Georg
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Respondent I Cognate Therapeutics Inc.
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Representative: Vogelsang-Wenke, Heike
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Respondent II: GENZYME CORPORATION
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Representative: Adams, Harvey Vaughan John
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Decision under appeal: Decision of the Opposition Division of the
European Patent Office posted 8 August 2007
revoking European patent No. 0592521 pursuant
to Article 102(1) EPC 1973.

Composition of the Board:

Chairman: F. Davison-Brunel
Members: P. Julià
C. Heath

Summary of Facts and Submissions

- I. European patent No. 0 592 521 with the title "Marrow-derived human mesenchymal stem cells and monoclonal antibodies specific for said cells", based on the European patent application No. 92 914 266 published as International patent application WO 92/022584, was granted with a set of 12 claims.

Claims 1, 4 and 7 as granted read as follows:

"1. A monoclonal antibody that recognizes a human mesenchymal stem cell which can differentiate into cells of more than one connective tissue type; wherein the antibody is the same antibody as produced from the hybridoma cell line SH2, deposited with the ATCC under accession number HB 10743 or hybridoma cell line SH3, deposited with the ATCC under accession number HB 10744 or hybridoma cell line SH4, deposited with the ATCC under accession number HB 10745."

"4. An isolated homogenous population of human mesenchymal stem cells that can differentiate into cells of more than one connective tissue type having the property of binding at least to one of the monoclonal antibodies according to claim 1."

"7. A method for determining the presence of human mesenchymal stem cells in the cell mixture comprising:
contacting the cell mixture with a monoclonal antibody according to claim 1, that selectively binds human mesenchymal stem cells; and
detecting the presence of said antibody."

Claims 2 and 3 were directed, respectively, to an hybridoma producing a monoclonal antibody according to claim 1 and to a process for recovering human mesenchymal stem cells from a cell population using an antibody of claim 1. Claims 5 and 9 related to further features of the mesenchymal stem cells of claim 4. Claim 6 related to the use of the human mesenchymal stem cells of claim 4 for producing a composition for use in treating connective tissue disorders. Claim 8 was a particular embodiment of claim 7. Claims 10 and 11 were directed, respectively, to a composition and to a therapeutic composition comprising the mesenchymal stem cells of claims 4 or 5. Whereas in claim 10 the composition comprised a culture medium expanding the mesenchymal stem cells, in claim 11 the therapeutic composition comprised a pharmaceutically acceptable carrier and an amount of stem cells effective to produce connective tissue cells. The connective tissue was defined as bone or cartilage in claim 12 dependent on claim 11.

- II. Two oppositions were filed on the grounds of Articles 100(a) to (c) EPC. The opposition division considered the subject-matter of granted claims 4-6 and 9-12 of the main request (claims as granted) to be disclosed in earlier US applications filed by the inventors of the patent-in-suit and thus not entitled to the claimed priority date and, as a consequence thereof, to lack novelty (Article 100(a) EPC, Article 54 EPC). The same deficiencies applied to all auxiliary requests then on file. Accordingly, the patent was revoked.

- III. The patentee (appellant) filed a notice of appeal and, on 17 December 2007, a statement setting out its grounds of appeal. The appellant maintained its main request (claims as granted) and, with the grounds of appeal, filed copies of auxiliary requests I to IV of 25 April 2007 and of auxiliary requests I to IV versions A and B, both versions of 22 May 2007 as auxiliary requests to be considered by the board. The appellant also requested that five questions should be referred to the Enlarged Board of Appeal, should the board follow the interpretation of decision G 1/03 (OJ EPO 2004, 413) adopted by the opposition division in its findings on lack of novelty.
- IV. The opponents 01 and 02 (respondents I and II, respectively) replied to the appellant's grounds of appeal in letters of 7 July 2008 and of 7 May 2008, respectively.
- V. In a letter dated 18 November 2008, the appellant replied to the respondents' comments and filed new auxiliary requests 1 to 7. The appellant maintained its main request (claims as granted) and the precautionary request for referral to the Enlarged Board of Appeal.
- VI. On 18 June 2009, the board summoned the parties to oral proceedings. A communication pursuant to Article 15(1) of the Rules of Procedure of the Boards of Appeal (RPBA) annexed to these summons informed the parties of the board's preliminary, non-binding opinion on the procedural and substantive issues of the present appeal proceedings. The board referred *inter alia* to the term "*homogenous*" in the context of Article 100(c) EPC (Article 123(2)(3) EPC), and to a possible remittal of

the case to the first instance for further prosecution if the appellant requested the maintenance of the patent on the basis of auxiliary requests 6 or 7 then on file.

VII. In letters dated 25 June 2009 and 2 September 2009, respondents I and II replied, respectively, to the board's communication. None of these letters contained comments on the procedural and substantive issues of the appeal proceedings but they informed the board of the respondents' intention not to attend the oral proceedings.

VIII. On 2 September 2009, the appellant filed auxiliary requests 1 to 6 to replace previous auxiliary requests on file. The appellant maintained the main request (claims as granted) and the precautionary request for referral to the Enlarged Board of Appeal.

IX. Claim 4 of **auxiliary requests 1 to 4** read as follows:

"4. An isolated homogenous population of human mesenchymal stem cells that can differentiate into cells of more than one connective tissue type wherein 99-100% of the mesenchymal stem cells have the property of binding at least to one of the monoclonal antibodies according to claim 1." (in **auxiliary request 1**).

"4. An isolated homogenous population of human mesenchymal stem cells that can differentiate into cells of more than one connective tissue type having the property of binding at least to the monoclonal antibody produced from the hybridoma cell line SH2,

deposited with the ATCC under accession number HB 10743." (in **auxiliary request 2**).

"4. An isolated homogenous population of human mesenchymal stem cells that can differentiate into cells of more than one connective tissue type having the property of binding at least to one of the monoclonal antibodies according to claim 1, wherein said mesenchymal stem cells have been purified using a monoclonal antibody according to claim 1 as a probe." (in **auxiliary request 3**).

"4. An isolated homogenous population of human mesenchymal stem cells that can differentiate into cells of more than one connective tissue type having the property of binding at least to the monoclonal antibody produced from the hybridoma cell line SH2, deposited with the ATCC under accession number HB 10743, wherein said mesenchymal stem cells have been purified using the monoclonal antibody produced from the hybridoma cell line SH2 as a probe." (in **auxiliary request 4**).

Claims 1 to 3 and 5 to 12 of these auxiliary requests read as in the main request. **Auxiliary request 5** contained granted claims 1-3 and 7-8 (renumbered 4 and 5) and **auxiliary request 6** contained granted claims 1 and 2.

- X. Auxiliary requests 5 and 6 were identical to previous auxiliary requests 6 and 7 for which the board, in its communication pursuant to Article 15(1) RPBA, had indicated its intention to remit to the first instance for further prosecution (cf. point VI *supra*).

- XI. Oral proceedings took place on 11 December 2009 in the absence of both respondents. During these proceedings, the appellant withdrew its main request and auxiliary requests 1 to 4 after a discussion on whether the term "*homogenous*" contained in claim 4 of these requests complied with Article 123(2) EPC and the board had come to the conclusion that this was not the case. Subsequently, the appellant made auxiliary requests 5 and 6 its main request and auxiliary request 1, respectively. The request for referral of questions to the Enlarged Board of Appeal was also withdrawn.
- XII. The appellant (patentee) requested that the decision under appeal be set aside and that the patent be maintained on the basis of the auxiliary requests 5 or 6 as filed with letter of 2 September 2009 (now the Main Request and Auxiliary Request 1) or, in the alternative, to refer the case back to the first instance for discussion of the remaining issues.
- XIII. The respondents (opponents) requested in writing that the appeal be dismissed.

Reasons for the Decision

Main request and auxiliary request 1

1. The main request and auxiliary request 1 - earlier claim requests 6 and 7 - contain subject-matter which has not been considered in the decision under appeal

since the patent in suit was revoked for deficiencies relating to claims which are no more contained in either of these requests. Yet, during opposition proceedings, the present claims had been objected to by both respondents - then opponents - under Article 100(a) and (b) EPC for lack of inventive step and for lack of sufficient disclosure (points 5 and 6 of the statement of grounds of opposition of opponent 01 and points 6 and 7.24 of the statement of grounds of opposition of opponent 02).

2. In its communication pursuant to Article 15(1) RPBA, the board pointed out as regards the then claim requests 6 and 7 that the opposition division had not carried out a complete examination on the requirements of Article 83 EPC and that there had been no discussion on inventive step in the decision under appeal (see point 4.4 of the decision under appeal). The preliminary, non-binding opinion was, thus, expressed that, were these requests to become relevant, the case should be remitted to the first instance for further prosecution (cf. point 28 of the board's communication). None of the respondents provided any argument in this respect (cf. point VII *supra*).
3. In view of the above facts and reasons, the board concludes that it is appropriate and justified to remit the appellant's main request and auxiliary request 1 to the first instance for further prosecution (Article 111(2) EPC).

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is referred back to the first instance for further prosecution.

The Registrar:

The Chairman:

A. Wolinski

F. Davison-Brunel