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**Datasheet for the decision
of 28 January 2022**

Case Number: T 0704/18 - 3.3.01

Application Number: 02778303.4

Publication Number: 1438392

IPC: A61K35/12, C12N5/077,
C12N5/0775, C12N5/0797

Language of the proceedings: EN

Title of invention:

CELL POPULATIONS WHICH CO-EXPRESS CD49C AND CD90

Patent Proprietor:

Garnet BioTherapeutics, Inc

Opponent:

ABT Holding Company

Headword:

Cell Populations/GARNET BIOTHERAPEUTICS

Relevant legal provisions:

EPC Art. 123 (2)

Keyword:

Added matter (yes)

Decisions cited:

Catchword:



Beschwerdekammern
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Chambres de recours

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Case Number: T 0704/18 - 3.3.01

D E C I S I O N
of Technical Board of Appeal 3.3.01
of 28 January 2022

Appellant: Garnet BioTherapeutics, Inc
(Patent Proprietor) 490 Lapp Road
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Representative: Latscha Schöllhorn Partner AG
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Decision under appeal: Decision of the Opposition Division of the
European Patent Office posted on 9 January 2018
revoking European patent No. 1438392 pursuant to
Article 101(2) and Article 101(3)(b) EPC

Composition of the Board:

Chairman A. Lindner
Members: T. Sommerfeld
M. Blasi

Summary of Facts and Submissions

- I. European patent No. 1 438 392 is based on application 02 778 303.4, which was filed as an international application published as WO 2003/025149 ("application as filed"). The patent is entitled "Cell populations which co-express CD49c and CD90" and was granted with 16 claims.

Claim 1 as granted reads as follows:

"1. A method of making an isolated cell population derived from human bone marrow, wherein between 100% to 90% of the cells of the cell population co-express CD49c and CD90, and wherein the cell population has a doubling time of less than 30 hours, comprising the steps of:

- a) culturing a source of the cell population under a low oxygen condition of less than 15% oxygen to produce an adherent cell population; and,
- b) culturing the adherent cell population at a seeding density of less than 2500 cells/cm²."

- II. An opposition was filed against the granted patent, in which the opponent requested that the patent be revoked in its entirety on the grounds of lack of novelty and inventive step (Articles 54(2) and 56 EPC and Article 100(a) EPC), lack of sufficiency of disclosure (Article 100(b) EPC) and added subject-matter (Article 100(c) EPC); additionally, the validity of the claimed priority was also contested.
- III. During the proceedings before the opposition division, the patent proprietor requested that the opposition be rejected and that the patent be maintained as granted

(main request) or alternatively that the patent be maintained in amended form according to the set of claims of the first auxiliary request, filed on 12 October 2016, or the second auxiliary request, filed on 10 October 2017.

- IV. By letter dated 13 October 2017, the opponent withdrew its opposition.
- V. By its decision posted on 9 January 2018, the opposition division revoked the patent under Article 101(2) and 101(3)(b) EPC.

The opposition division decided that the sets of claims according to the main request (claims as granted) and the first and second auxiliary requests added subject-matter within the meaning of Article 100(c) EPC or contrary to Article 123(2) EPC, respectively.

- VI. The patent proprietor (appellant) lodged an appeal against that decision. With the statement of grounds of appeal, the appellant requested that the patent be maintained in amended form on the basis of the claims according to the first or second auxiliary requests, which had been filed on 12 October 2016 and 10 October 2017, respectively.

Claim 1 of the first auxiliary request differs from claim 1 of the main request (claims as granted) in that the following amendments have been made (additions underlined and deletions struck-through):

"1. A method of making an isolated cell population derived from human bone marrow, wherein between 100% to 90% of the cells of the cell population co-express CD49c and CD90, and wherein the cell population has a

doubling time of less than 30 hours, comprising the steps of:

- a) culturing a source of the cell population at a seeding density of less than 75,000 cells/cm² under a low oxygen condition of less than 15% oxygen to produce an adherent cell population; ~~and,~~
- b) culturing the adherent cell population at a seeding density of less than ~~2500~~ 100 cells/cm² under a low oxygen condition of less than 15% oxygen; and
- c) selecting from the cultured adherent cell population, cells which co-express CD40c and CD90."

Claim 1 of the second auxiliary request differs from claim 1 of the first auxiliary request in that the following amendments have been made (additions underlined and deletions struck-through):

"1. A method of making an isolated cell population derived from human bone marrow, wherein between 100% to 90% of the cells of the cell population co-express CD49c and CD90, and wherein the cell population has a doubling time of less than 30 hours, comprising the steps of:

- a) culturing a source of the cell population at a seeding density of less than 75,000 cells/cm² under a low oxygen condition of ~~less than 15%~~ 5% oxygen to produce an adherent cell population;
- b) culturing the adherent cell population at a seeding density of less than 100 cells/cm² under a low oxygen condition of ~~less than 15%~~ 5% oxygen; and
- c) selecting from the cultured adherent cell population, cells which co-express CD40c and CD90."

VII. Summons to oral proceedings before the board were issued in view of a corresponding request by the appellant, with these oral proceedings being scheduled

for 19 August 2021. In a subsequent communication pursuant to Article 15(1) RPBA dated 17 March 2021 the board expressed its preliminary opinion on the issues relating to Article 123(2) EPC, informing the appellant that it was inclined to dismiss the appeal.

VIII. By letter dated 12 August 2021, the appellant withdrew the request for oral proceedings and announced that it would not attend the oral proceedings.

IX. The board then cancelled the oral proceedings.

X. The appellant's submissions may be summarised as follows:

The paragraph bridging pages 11 and 12 provided a basis for the feature "90-100% cells co-expressing CD49c and CD90". On the basis of common general knowledge, the skilled person would have been aware that cell populations to be used for cell therapies were to be as homogeneous as possible, ideally comprising a single phenotypic population. With regard to the feature "doubling time of less than 30 hours", a basis could be found in the passage on page 13, lines 6 to 17, of the application as filed. Moreover, Figure 4, related to Example 4, demonstrated that the doubling time of less than 30 hours was the lowest doubling time in the application and would have been the preferred doubling time of cells (also for reasons of economical production of the cells). This feature was not taken from a list but rather referred to a discrete embodiment, namely narrowing down the doubling times to the lowest doubling time disclosed in the application. Finally, with regard to the feature "oxygen concentration of less than 15% oxygen", a basis could be found on page 20, lines 8 to 10, of the application

as filed, which made it clear that this corresponded to the preferred range.

XI. As set out in its communication under Article 15(1) RPBA, the board understands from the written submissions that the appellant is no longer pursuing the patent as granted (main request in the decision under appeal) and that the appellant's first and second auxiliary requests presented with the statement of grounds of appeal are in fact the main and auxiliary requests in the appeal proceedings. Hence, the appellant requests that the decision under appeal be set aside and that the patent be maintained in amended form on the basis of the set of claims of the main request, filed as the first auxiliary request by letter dated 12 October 2016 or, alternatively, on the basis of the set of claims of the auxiliary request filed as the second auxiliary request by letter dated 10 October 2017.

Reasons for the Decision

1. The appeal is admissible.
 - 1.1 Since the appellant withdrew its request for oral proceedings, the present decision can be issued without oral proceedings taking place.
2. Main request ("First auxiliary request" dated 12 October 2016) - Article 123(2) EPC
 - 2.1 Claim 1 reads as follows:

"1. A method of making an isolated cell population derived from human bone marrow, wherein between 100% to

90% of the cells of the cell population co-express CD49c and CD90, and wherein the cell population has a doubling time of less than 30 hours, comprising the steps of:

- a) culturing a source of the cell population at a seeding density of less than 75,000 cells/cm² under a low oxygen condition of less than 15% oxygen to produce an adherent cell population;
- b) culturing the adherent cell population at a seeding density of less than 100 cells/cm² under a low oxygen condition of less than 15% oxygen; and
- c) selecting from the cultured adherent cell population, cells which co-express CD40c and CD90."

2.2 In the appealed decision, the opposition division noted that, while claim 1 as granted was derived from claims 48 and 51 as filed, the following features were not found in said claims:

- i) cell population derived from human bone marrow;
- ii) 90-100% cells co-expressing CD49c and CD90;
- iii) doubling time of less than 30 hours;
- iv) oxygen concentration of less than 15% oxygen.

The opposition division then came to the conclusion that feature i) found a basis on page 15, lines 21 to 23, but that no basis could be found in the application as filed for the other features listed above, namely features (ii), (iii) and (iv), let alone for their combination, which involved multiple selections from different lists. The same applied to claim 1 of the auxiliary request 1, which contained the same disputed features.

2.3 The board agrees that at least the following selections do indeed have to be made in order to arrive at the

claimed specific combination of features (ii), (iii) and (iv):

feature (ii): selection of "90-100%" from "about 100% to about 70" and "about 100% to about 90%" (paragraph bridging pages 11 and 12);

feature (iii): selection of "doubling time of less than 30 hours" from "less than between about 144 hours to about 48 hours", "less than about 144 hours", "less than about 72 hours", "less than about 65 hours", "less than about 48 hours", "less than about 35 hours", or "less than about 30 hours" (page 13, lines 6 to 17);

feature (iv): selection of "oxygen concentration less than 15% oxygen" from "less than about 21 mole percent (volume)", "less than about 23% by weight", "less than about 15% by volume (mole percent) oxygen", "less than about 10% by volume", and "less than about 5% by volume oxygen" (page 20, lines 6 to 12).

2.4 While the board agrees with the appellant's arguments that the first selection (feature (ii)) only requires a choice from a list of two alternatives and that this choice, which also appears in the examples, can be considered to be the preferred embodiment, the same cannot be concluded for the other features.

The passage indicated above for feature (iii) gives a list of seven alternatives and it is not apparent that the one in the claim should be the preferred one. Moreover, this passage even goes on to explain (see page 13, lines 14 to 17) that "The doubling time of the cells of the invention can be varied depending on, for example, the density of the cells in culture (e.g., 100 cells/cm²) and/or the concentration of oxygen

employed to culture the cells (e.g., a low oxygen concentration such as about 5% oxygen)"; it thus appears that it may not be possible to combine each of the indicated doubling times with all the possible cell densities and oxygen concentrations.

The same applies to feature (iv), which involves a selection of one alternative from five alternatives, two of them (not the one in the claim) even being indicated as the most preferred: "more preferably an oxygen concentration less than about 10% by volume, and most preferably an oxygen concentration is less than about 5% by volume oxygen" (see page 20, lines 10 and 11).

- 2.5 Hence the board considers that, while all the features appear to be conceptually disclosed in the application as filed, their combination involves multiple selections from different lists without there being a pointer to the specifically claimed combination.
- 2.6 Claim 1 of the main request thus relates to subject-matter extending beyond the application as filed within the meaning of Article 123(2) EPC.
3. Auxiliary request ("Second auxiliary request" dated 10 October 2017) - Article 123(2) EPC
- 3.1 In the appealed decision, the opposition division came to the conclusion that at least the deficiencies arising from the combination of features (ii) and (iii) were still present in claim 1.
- 3.2 Features (ii) and (iii) of claim 1 are in fact each identical to features (ii) and (iii) of claim 1 of the main request, whereas feature (iv) has been amended to

refer to "5% oxygen" (instead of 15%). While feature (iv) has been restricted to the most preferred alternative from the five possible alternatives listed for the oxygen concentration, the board still fails to find a specific pointer to this particular combination of features in the application as filed.

- 3.3 The board thus comes to the conclusion that claim 1 of the auxiliary request also relates to added subject-matter and is thus not allowable under Article 123(2) EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



M. Schalow

A. Lindner

Decision electronically authenticated