BESCHWERDEKAMMERN DES EUROPÄISCHEN PATENTAMTS

BOARDS OF APPEAL OF THE EUROPEAN PATENT OFFICE

CHAMBRES DE RECOURS DE L'OFFICE EUROPEEN DES BREVETS

Internal distribution code:
(A) [ ] Publication in OJ
(B) [ ] To Chairmen and Members
(C) [ ] To Chairmen
(D) [X] No distribution

Datasheet for the decision of 6 February 2009

Case Number: T 0174/07 - 3.3.08

Application Number: 00948918.8

Publication Number: 1200559

IPC: C12N 5/06

Language of the proceedings: EN

Title of invention:
Muscel cells and their use in cardiac repair

Applicant:
GENVEC, INC.

Opponent:
-

Headword:
Cardiac repair/GENVEC

Relevant legal provisions:
EPC Art. 123(2), 54

Relevant legal provisions (EPC 1973):
-

Keyword:
"Main request: added-matter (no)"
"Main request: novelty (No)"

Decisions cited:
T 0290/86, T 0893/90, T 1319/04

Catchword:
-

Europäisches Patentamt | European Patent Office | Office européen des brevets

Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0174/07 - 3.3.08

D E C I S I O N
of the Technical Board of Appeal 3.3.08
of 6 February 2009

Appellant: GENVEC, INC.
65 West Watkins Mill Road
Gaithersburg
MD 20878 (US)

Representative: Care, Alison
Kilburn & Strode
20 Red Lion Street
London EC1R 4PJ (GB)

Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 15 September 2006 refusing European application No. 00948918.8 pursuant to Article 97(1) EPC 1973.**

Composition of the Board:

Chairman: L. Galligani
Members: F. Davison-Brunel
C. Heath

Summary of Facts and Submissions

I. European patent application No. 00 948 918.8 with the title "Muscle cells and their use in cardiac repair" filed as a International application PCT/US 00/20129 was published under No. WO 01/07568. It was refused by the examining division in a decision dated 15 September 2006.

II. The decision of the examining division was taken on the basis of a main request and seven auxiliary requests which were all found to lack of novelty.

Claim 1 of said main request read as follows:

"1. A transplantable composition comprising isolated adult skeletal myoblast cells and isolated fibroblast cells, wherein the composition comprises from 20 to 70% skeletal myoblast cells." (see decision of the examining division, section X)

The examining division observed, in particular, that document (4) on file (infra) described a composition of skeletal myoblast and fibroblast cells which were **adult** cells since the donor was identified as the subject of myocardial treatment. The proportion of skeletal myoblast cells in the composition fell within the now claimed range as essentially **the same method of preparation** had been used. As this composition had the same characteristics as those of the now claimed composition, it was detrimental to novelty. The same novelty objection was found to be applicable to the transplantable composition of the auxiliary requests.

III. The appellant (applicant) lodged an appeal against this decision and filed a statement setting out the grounds of appeal. This statement was accompanied by a claim request replacing all previous requests on file.

IV. The examining division did not rectify its decision and the case was remitted to the board of appeal (cf. Article 109(2) EPC).

V. On 21 September 2007, the board sent a communication pursuant to Article 110(2) EPC 1973 to indicate its preliminary, non-binding opinion.

VI. On 27 March 2008, the appellant submitted arguments as well as a new set of use claims replacing the product claims on file.

VII. Further exchanges by phone took place between the board and the appellant and an amended set of claims was filed on 7 November 2008. Summons to oral proceedings pursuant to Article 15(1) RPBA were issued on 3 December 2008. An answer to the summons was received on 4 February 2009.

VIII. Oral proceedings took place on 6 February 2009. At oral proceedings, the appellant filed a new claim request comprising claims 1 to 24 in replacement of the earlier request.

Claim 1 read as follows:

"1. Use of a transplantable composition comprising isolated adult skeletal myoblast cells and isolated fibroblast cells in the manufacture of a medicament for

the treatment of damaged cardiac tissue, wherein; an isolated population of skeletal myoblasts is cultured in vitro until the composition comprises from 20% to 70% skeletal myoblast cells; and, wherein the transplanted skeletal myoblasts are left to engraft and exhibit skeletal myosin heavy chain positive staining from three weeks post-transplantation."

Dependent claims 2 to 24 related to further features of the claimed use.

IX. The following document is mentioned in the present application:

(4): WO 98/27995 published on 2 July 1998.

X. The appellant's arguments in writing and during oral proceedings insofar as relevant to the present decision may be summarized as follows:

Article 123(2) EPC

A basis for the subject-matter of claim 1 could be found in the application as filed, in Example 6 when read in light of Examples 4 and 5. In Example 6, compositions of skeletal myoblasts and fibroblasts were transplanted into the myocardium of male Lewis rats previously subjected to myocardial infarction. The long term maintenance of the skeletal cell fate was confirmed by staining with anti-skeletal myosin heavy chain antibody beginning at three weeks post implantation. The feature that the population of skeletal myoblasts was cultured in vitro until the composition comprised from 20% to 70% skeletal myoblast

cells was disclosed on page 10, lines 17 to 20 and the feature that the myoblasts were left to engraft was directly derivable from the way the examples had been carried out. The requirements of Article 123(2) EPC were fulfilled.

Article 54 EPC

The feature in claim 1 that the cells were left to engraft was a feature to be taken into account when assessing novelty as it amounted to a regimen of administration of the claimed composition. It led to the transplanted cells still exhibiting a skeletal cell rather than a cardiac cell phenotype three weeks after transplantation. In contrast the composition disclosed in document (4) was treated with a morphogen after transplantation. The cells thus became cardiac cells - they would not exhibit myosin heavy chain positive staining three weeks after transplantation. This was a distinguishing feature which imparted novelty to the claimed subject-matter.

XI. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of claims 1 to 24 filed during the oral proceedings.

Reasons for the decision

Article 123(2) EPC; added subject-matter
Claim 1

1. The use of a mixed population of skeletal myoblast and fibroblast cells to treat cardiac injuries is disclosed

on page 3, lines 15 to 18 of the application as filed. The feature that the population comprises adult cells, with a proportion of from 20% to 70% of skeletal myoblast cells - as obtained by in vitro culturing - is described on page 9, lines 5 to 10, page 10, lines 9 and 10, 17 to 20. Example 6 shows that working in accordance to the method described in the application entails that the cells be left to engraft and results in them being stainable with myosin heavy chain antibodies as from three weeks post transplantation (page 47, lines 17 to 22). The requirements of Article 123(2) EPC are, thus, fulfilled.

Article 54 EPC

2. Document (4) was cited by the examining division as detrimental to the novelty of the transplantable composition of the claim request then on file. This document is concerned with providing methods and pharmaceuticals for treatment of mammalian subjects afflicted with damages to the myocardial tissues. It is intended that skeletal muscle cells should be implanted in the damaged cardiac tissue and that they be treated with a morphogenic activator, eg. "subsequent to implantation" (see page 5, Summary of the invention to page 6, line 4). This implies that, once transplanted, they will acquire a **cardiac cell phenotype** (see page 6, lines 22 to 26). The cells are isolated from the muscle cells of the subject for myocardial treatment, ie. from adult cells, essentially in the same manner as in the present application (see page 13, point 1 and pages 16 and 17, point 4 of document (4)). It has not been disputed that the cell composition for treating myocardial damages disclosed in document (4) would

contain a proportion of myoblast cells falling within the now claimed range, as well as fibroblasts.

3. In order to assess whether the presently claimed use enjoys novelty over the teachings of document (4), it is necessary first of all to have a clear view of the claimed features which are relevant to this assessment. The claimed features are:

– The transplantable composition to be manufactured as a medicament for treating damaged cardiac tissue comprises adult skeletal myoblast cells in the proportion of from 20% to 70%, as well as adult fibroblasts.

– Once transplanted, the cells are left to engraft and from three weeks post-transplantation they exhibit positive skeletal myosin heavy chain staining, this latter feature meaning that they have retained their **skeletal muscle cells phenotype**.

4. The first feature undoubtedly is a technical feature of the transplantable composition per se which has a bearing in the manufacture of the medicament. As for the second one, it is a feature which is to be observed from three weeks **after** the composition has been transplanted. Otherwise stated, it is not a characteristic of the "use of the composition to produce a medicament" as now claimed but a characteristic of a "method of use of the medicament".

5. The case law establishes that in some cases, the use to be made of a medicament may be regarded as a feature to be taken into consideration when assessing the novelty of a claim to the use of a compound to manufacture a medicament. For example, novelty may be given if a group of patients different from that known in the prior art is being treated (see T 893/90, OJ EPO 1992, 414) or if a different technical effect is expected (see T 290/86, OJ EPO 1992,414). It is still a matter of debate whether a regimen of administration of a medicament may or not constitute a potentially distinguishing criterium (see T 1319/04 of 22 April 2008 referring questions to the Enlarged Board of appeal, referral No. G 2/08).

6. At oral proceedings, the appellant submitted that the feature "the transplanted skeletal myoblasts are left to engraft ..." was a regimen of administration. Since this regimen of administration was different from that disclosed in the prior art which involved the addition of a morphogen (see point 2 supra), it was argued that it imparted novelty to the claimed use.

7. Going along these lines would, of course, require that it be established that a regimen of administration is indeed a feature to be considered when assessing novelty, this being an issue for which a definite answer in the case law is still pending. However, in this specific case, the first step to be taken is to evaluate whether or not the feature "the transplanted skeletal myoblasts are left to engraft" corresponds to a regimen of administration. In the board's judgment, it does not for the following reason: when letting the transplanted skeletal myoblast cells engraft after

transplantation, the appellant did nothing but leave them "to their own fate". Devising a regimen of administration cannot merely consist in the negative teaching that biology should follow its own course undisturbed. It does require some active human intervention.

8. It is, thus, concluded that the second "characterizing" feature in claim 1 is not a regimen of administration and, therefore, that it is not of relevance to novelty and would not be in the event that it became allowed to take regimens of administration into consideration.

9. The features relevant to the assessment of novelty are, as mentioned in point 3, supra that the transplantable composition is intended for the treatment of myocardial damages, that it comprises adult skeletal myoblast cells in the proportion of 20% to 70% as well as adult fibroblasts. These are also the features of the composition described in document (4) (see point 2, supra). For this reason, document (4) is detrimental to the novelty of claim 1. The requirements of Article 54 EPC are not fulfilled.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar The Chairman

A. Wolinski L. Galligani