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**Datasheet for the decision
of 28 May 2009**

Case Number: T 0522/04 - 3.3.08

Application Number: 93921175.1

Publication Number: 0658194

IPC: C12N 5/06

Language of the proceedings: EN

Title of invention:

Mammalian multipotent neural stem cells

Applicant:

CALIFORNIA INSTITUTE OF TECHNOLOGY

Headword:

Stem cells/CALIFORNIA

Relevant legal provisions:

EPC Art. 53(a), 123(2)

EPC R. 28(c)

Relevant legal provisions (EPC 1973):

-

Keyword:

"Main request: forbidden patenting (yes)"

"First auxiliary request: added matter (yes)"

"Second auxiliary request: added matter (yes)"

Decisions cited:

G 0002/06, T 1374/04

Catchword:

Destruction of human embryos (see Reasons, Items 4 to 7)



Case Number: T 0522/04 - 3.3.08

D E C I S I O N
of the Technical Board of Appeal 3.3.08
of 28 May 2009

Appellant:

CALIFORNIA INSTITUTE OF TECHNOLOGY
1201 East California Boulevard
Pasadena
California 91125 (US)

Representative:

Crump, Julian Richard John
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Decision under appeal:

Decision of the Examining Division of the
European Patent Office posted 17 October 2003
refusing European application No. 93921175.1
pursuant to Article 97(1) EPC 1973.

Composition of the Board:

Chairman: L. Galligani
Members: T. J. H. Mennessier
C. Rennie-Smith

Summary of Facts and Submissions

- I. The applicant (appellant) lodged an appeal against the decision of the examining division dated 17 October 2003, whereby the European patent application No. 93 921 175.1 with publication number 0 658 194 was refused. The application, entitled "*Mammalian multipotent neural stem cells*", originated from an International application published as WO 94/02593.
- II. Basis for the refusal were a main request (request A) and two auxiliary requests (requests B and C, respectively) then on file.
- III. Both requests A and B were considered not only to lack novelty vis-à-vis document D2 (L.-C. Lo et al., *Developmental Biology*, Vol. 145, 1991, pages 139 to 153) but also to contravene the provisions of Rule 23d(c) EPC 1973 (now Rule 28(c) EPC 2000) which under Article 53(a) EPC prohibited the patentability of inventions based on the use of human embryos for industrial or commercial purposes. Request C was considered to be new (Article 54 EPC) but was refused for non-compliance with the requirements of Article 53(a) EPC in combination with Rule 23d(c) EPC 1973 (now Rule 28(c) EPC 2000).
- IV. The statement setting out the grounds of appeal was filed on 25 February 2004. It was accompanied by three claim requests to replace the requests on file, namely a main request which corresponded to previous request C as well as a first and a second auxiliary request. A request for oral proceedings was made in the event that

the board would have formed a provisional view to refuse the main request.

V. Claim 1 of the main request read:

"1. A method of proliferating *in vitro* a clonal population of mammalian neural crest stem cells, wherein the cells are cultured *in vitro* in a feeder cell-independent culture medium on a substrate, wherein the culture medium does not contain fetal calf serum to produce a population of neural crest- stem cells and differentiated progeny thereof, wherein the neural crest- stem cells are characterised by being capable of self-renewal in the culture medium and capable of differentiation to progeny cells that are peripheral nervous system neuronal or glial cells, wherein said neural crest- stem cells express low-affinity nerve growth factor receptor (LNGFR) and nestin, but do not express glial fibrillary acidic protein (GFAP), and wherein progeny cells that are peripheral nervous system neuronal cells do not express LNGFR or nestin but do express neurofilament and progeny cells that are peripheral nervous system glial cells express LNGFR, nestin and GFAP."

Claim 1 of the first auxiliary request differed from claim 1 of the main request, in that the phrase "*wherein the cells are not derived from an embryo*" had been added in the preamble just after the words "*mammalian neural crest stem cells*".

Claim 1 of the second auxiliary request differed from claim 1 of the main request, in that the phrase "*capable of being derived from adult tissue*" had been

added in the preamble just after the words "*mammalian neural crest stem cells*".

- VI. The examining division did not rectify its decision and referred the appeal to the Board of Appeal (Article 109 EPC).
- VII. In a communication dated 23 October 2006, the board informed the appellant that it regarded it as appropriate to delay any further action until the referral G 2/06 (Stem cells) was dealt with by the Enlarged Board of Appeal. The appellant did not react thereto. Consequently, the appeal proceedings were stayed.
- VIII. In a communication attached to the summons to oral proceedings dated 30 January 2009, the board informed the appellant that, as the Enlarged Board of Appeal had now decided on that referral (see decision G 2/06 of 25 November 2008, to be published in the OJ EPO), the appeal proceedings were resumed.
- IX. In that communication, the board expressed the preliminary view that the method of claim 1 of the main request would have to be found not patentable under Article 53(a) EPC in combination with Rule 28(c) EPC 2000 (formerly Rule 23d(c) EPC 1973) and that the method of claim 1 of each of the two auxiliary requests would have to be found not patentable under Article 123(2) EPC. Doubts were also expressed regarding compliance of claim 1 of the main request with Article 123(2) EPC.

- X. With a letter dated 4 March 2009, the appellant informed the board that it withdrew its request for oral proceedings.
- XI. Oral proceedings took place on 28 May 2009 in the absence of the appellant.
- XII. The only submissions made by the appellant in this case are those in the statement of grounds, no reply in substance having been made to the board's preliminary view in its communications (see VII and IX above). The submissions in writing, insofar as they are relevant to the decision, may be summarised as follows:

Main request

Requirements of Article 53(a) EPC in combination with Rule 23d(c) EPC 1973

The method of claim 1 did not fall under the prohibition of Rule 23d(c) EPC 1973 which related to biotechnical inventions that concerned uses of human embryos for industrial or commercial purposes. There was no step or feature in the claim reciting use of an embryo or even removal of cells from an embryo. The claim was not directed to cells from an embryo nor even to a method of proliferating cells taken from an embryo as such. Steps outside the claimed process were not part of the invention. Furthermore, the cells specified as subject of the claimed method could be obtained not only from embryos, but also from the adult peripheral nervous system and central nervous system. There was no inevitable use of a human embryo.

First and second auxiliary requests

Requirements of Article 123(2) EPC

Basis for the terms "*not derived from an embryo*" and "*capable of being derived from adult tissue*" used in claim 1 of the first auxiliary request and in claim 1 of the second auxiliary request, respectively, was apparent throughout the application as filed.

- XIII. In the statement of grounds of appeal, the appellant requested that the decision under appeal be set aside and a patent be granted on the basis of the main request or of one of the two auxiliary requests, all filed together with the statement of grounds of appeal. It further requested that, should any new or as yet unexamined issue arise in the course of the appeal proceedings, consideration be given to remittal to the first instance for further prosecution. In view of the fact that the case law could develop, it further requested an opportunity if need be to provide further arguments and/or amended claim requests prior to a decision to take into account any such development.

Reasons for the Decision

Procedural issues

1. A central issue in this case was the question whether the claimed subject-matter concerned *inter alia* the use of human embryos for industrial or commercial purposes and thus offended against Article 53(a) EPC in conjunction with Rule 23d(c) EPC 1973 (now Rule 28(c)

EPC 2000) (see the reasons for refusal in the decision under appeal). As questions in this respect were pending before the Enlarged Board of Appeal (cf. interlocutory decision T 1374/04 of 7 April 2006 and referral G 2/06), the board stayed the present appeal proceedings in compliance with the appellant's request to give it the opportunity to take into account developments in the case law. However, the appellant made no submissions dealing with subsequent developments.

2. After the issuance of decision G 2/06 (see *supra*), a communication was sent to the appellant with an invitation to oral proceedings which had been requested in case the board was minded not to accept the main request. In that communication the pending objections under Article 53(a)/Rule 28(c) EPC 2000 against the main request were outlined together with objections under Article 123(2) EPC against all requests.
3. The appellant has decided not to reply to those objections and did not attend the oral proceedings on 28 May 2009. The present decision is therefore taken on the basis of the written submissions by the appellant and the communications of the board (see Article 12(1) RPBA).

Main request

*Requirements of Article 53(a) EPC in combination with
Rule 28(c) EPC (formerly Rule 23d(c) EPC 1973)*

4. Decision G 2/06 (see *supra*) has ruled that Rule 28(c) EPC forbids the patenting of claims directed to products which at the filing date could be prepared exclusively by a method which necessarily involved the destruction of **human** embryos. Therefore, it follows that methods involving such destruction are also to be regarded as not patentable.

5. Claim 1 is directed to a method of proliferating *in vitro* a clonal population of **neural crest stem cells** of mammalian origin. This clearly includes cells of **human** origin. The statement made by the appellant at the top of page 3 in its statement of grounds that "*the cells specified as subject of the claimed method can be obtained not only from embryos, but also from the adult peripheral nervous system and central nervous system*" is not supported by the application as filed (see the published version WO 94/02593). Indeed, the passage on page 26, lines 4 to 6 of that version reads "*In order to isolate the subject **neural crest stem cells**, it is necessary to separate the stem cell from other cells in the embryo*". In the following lines 8 to 10 on page 26, it is explained that, in a first step, the region containing the caudal-most 10 somites are **dissected from early embryos**. Further steps of the isolation process are described at lines 11 to 31 on page 26. The process as a whole is detailed in Example 1 (see pages 36 to 37).

6. In its statement of grounds, the appellant did not point to any precise passage of the application as filed in support of its mere contention (see top of page 3 of the statement of grounds) that at the filing date neural crest stem cells could be obtained also from the adult peripheral nervous system and central nervous system.

7. Since in the application as filed the only teaching of how to prepare human neural crest stem cell cultures is the use (involving their destruction) of human embryos, the conclusion is reached that at the filing date **human** neural crest stem cells could be prepared exclusively by a method which necessarily involved the destruction of human embryos with the inescapable result that the invention of claim 1 falls under the prohibition of Article 53(a) EPC taken in combination with Rule 28(c) EPC (cf. also G 2/06 (see *supra*), in particular point 29 of the reasons).

First and second auxiliary requests

Requirements of Article 123(2) EPC

8. Each of the two auxiliary requests differs from the main request in that the mammalian neural crest stem cells as referred to in claim 1 have been limited to cells which are "*not derived from an embryo*" (see the first auxiliary request) and cells which are capable of being "*derived from adult tissue*" (see the second auxiliary request).

9. These two features cannot be seen as a disclaimer introduced in order to avoid a non-patentability issue

as they are not limited to human. They are features which intend to provide a technical teaching.

10. In line with the comments made at point 3 (see *supra*), the further mere contention that basis for the terms "not derived from an embryo" and "derived from adult tissue" as used in claim 1 of the auxiliary requests is apparent throughout the application as filed (see the third paragraph of the first page of the statement of grounds) has no support in the application as filed, wherein no technical disclosure other than isolation from embryos is found.

11. Thus, the introduction of those features in the claims has resulted in the application being amended in such a way that it contains subject-matter which extends beyond the content of the application as filed. Therefore, neither of the first and second auxiliary requests complies with Article 123(2) EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:

A. Wolinski

L. Galligani