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**Datasheet for the decision
of 21 August 2007**

Case Number: W 0022/07 - 3.3.08

Application Number: PCT/US 2006/021413

Publication Number: WO 2007/008309

IPC: C12N 15/010

Language of the proceedings: EN

Title of invention:

"Stem and progenitor cell expansion by EVI, EVI-like genes and SETBP 1"

Applicant:

Children's Hospital Medical Center

Opponent:

-

Headword:

Stem cell expansion/CHILDREN'S HOSPITAL

Relevant legal provisions:

PCT Art. 17(3)(a),
PCT R. 13.1, 13.2, 13.3, 40.1(i)(ii)(iii), 40.2(c)

Keyword:

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Decisions cited:

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Catchword:

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Case Number: W 0022/07 - 3.3.08

International Application No. PCT/US 2006/021413

D E C I S I O N
of the Technical Board of Appeal
of 21 August 2007

Applicant: Children's Hospital Medical Center
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Cincinnati, Ohio 45229-3039 (US)

Representative: Knobbe Martens Olson & Bear LLP
2040 Main Street 14th Floor
Irvine, CA 92614 (US)

Subject of this decision: Protest according to Rule 40.2(c) of the Patent Cooperation Treaty made by the applicants against the invitation (payment of additional fees) of the European Patent Office (International Searching Authority) dated 20 December 2006.

Composition of the Board:

Chairman: L. Galligani
Members: P. Julià
T. Bokor

Summary of Facts and Submissions

- I. International patent application no. PCT/US2006/21413 published as WO 2007/008309 and having the title "Stem and progenitor cell expansion by EVI, EVI-like genes and SETBP1" was filed on 1 June 2006 with 25 claims.
- II. On 20 December 2006, the European Patent Office (EPO), acting in its capacity as International Searching Authority (ISA) under Article 16 PCT and Article 154 EPC, informed the applicant that the international application did not comply with the requirement of unity of invention as set forth in Rules 13.1, 13.2 and 13.3 PCT, and invited the applicant to pay within a time limit of one month 98 additional search fees, pursuant to Article 17(3)(a) and Rule 40.1(i)(ii) PCT. The total amount of additional fees to be paid (1.615,00 EUR x 98 = 158.270 EUR) was also indicated.
- III. In an Annex to the invitation to pay additional fees, the ISA defined the different groups of inventions, the reasons for its finding of a lack of unity of invention regarding these groups, and the results of a partial international search carried out for the invention first mentioned in the claims (Group 1). The inventions to which the application related were defined as follows:

"Invention 1: claims 1-20, 22, 25 (all partially)

Methods of expanding cells by transfecting cells with a vector promoting proliferation, persistence or selective advantage of the cells, wherein the nucleic acid sequence which promotes cell growth

is EVI-1, methods of expanding gene-corrected cells and nucleic acid integration sites comprising a sequence encoding EVI-1.

Invention 2: claims 1-20, 22, 25 (all partially)

Methods of expanding cells by transfecting cells with a vector promoting proliferation, persistence or selective advantage of the cells, wherein the nucleic acid sequence which promotes cell growth is PRDM16, methods of expanding gene-corrected cells and nucleic acid integration sites comprising a sequence encoding PRDM16.

Invention 3: claims 1-20, 22, 25 (all partially)

Methods of expanding cells by transfecting cells with a vector promoting proliferation, persistence or selective advantage of the cells, wherein the nucleic acid sequence which promotes cell growth is SETBP1, methods of expanding gene-corrected cells and nucleic acid integration sites comprising a sequence encoding SETBP1.

Inventions 4-98: claims 1-20, 22, 25 (all partially)

Methods of expanding cells by transfecting cells with a vector promoting proliferation, persistence or selective advantage of the cells, wherein the nucleic acid sequence which promotes cell growth is any nucleic acid sequence different from EVI-1, PRDM16, SETBP1; methods of expanding gene-corrected cells and nucleic acid integration

sites comprising a sequence encoding a nucleic acid different from EVI-1, PRDM16, SETBP1.

Invention 99: claims 21, 23, 24

Methods of identifying a gene that modulates cell proliferation and nucleic acid sequences whose modulation of expression is associated with increased cell proliferation."

- IV. The applicant was also informed that, according to Rule 40.2(c) PCT, the payment of any additional fee could be made under protest, i.e. a reasoned statement to the effect that the international application complied with the requirement of unity of invention or that the amount of the required additional fee was excessive. There was, however, no indication of the amount of the protest fee to be paid.
- V. With letter dated 17 January 2007, the applicant requested the debiting of two additional search fees from its deposit account and that the claims in Groups 2 and 3 be examined. The letter was accompanied by a reasoned statement with the intent of establishing that Groups 1 and 2 shared a single inventive concept and, therefore, constituted a single invention. No arguments were put forward with respect to Group 3. The payment was made under protest according to Rule 40.2(c) PCT.
- VI. On 18 January 2007, the EPO debited two additional search fees and the protest fee from the applicant's deposit account.

VII. On 31 May 2007, the applicant was notified that, with regard to its protest, the ISA had reviewed the justification for the invention to pay additional search fees. In the final paragraphs of the Annex to the notification, it was stated that:

"Wishing not to take a too academic approach, the ISA however agrees on searching invention 2 without payment of an extra search fee. Consequently, one of the two additional search fees paid should be refunded".

In the notification, the applicant was again invited to pay a protest fee in the amount of 1.065,00 EUR (unless such fee had already been paid) for the examination of the protest since the prior review of the justification for the invitation to pay additional fees had resulted in the requirement of payment of additional fees to be upheld because the invitation was justified in part. The applicant was further informed (cf. item 3 of the PCT Form 228) that:

"If the applicant has already paid the protest fee but does not wish to continue with the protest in view of the result of the prior review, he is requested to indicate this within the time limit indicated above. In this case the protest fee will be refunded. If no such indication is received within the time limit it is assumed that the applicant wishes to continue with the protest, which will be referred to the Boards of Appeal. The protest fee will only be refunded if the Board finds that the protest was entirely justified."

VIII. On 15 June 2007, the EPO refunded the applicant one search fee.

IX. With letter dated 28 June 2007, the applicant informed the ISA that:

"Applicants had assumed that the protest fee was withdrawn from our Deposit Account when payment of the additional search fees was made in conjunction with our letter dated 17 January 2007. However, if the protest fee was not previously paid, please debit our Deposit Account No. ... for the amount in connection with the invitation to pay the protest fee."

Reasons for the Decision

1. In the reply to the invitation of the ISA to pay for additional search fees, the applicant requested the additional examination of Groups 2 and 3 and, accordingly, requested the debiting of two additional search fees from its deposit account. The applicant further argued that Groups 1 and 2 shared a single inventive concept and therefore constituted a single invention. No arguments were put forward with respect to Group 3. Accordingly, the payment was made under protest (Rule 40.2(c) PCT) and, although the invitation of the ISA failed to indicate the amount of the protest fee as required by Rule 40.1(iii) PCT (cf. Sections IV and V *supra*), the amount of the protest fee was debited from the applicant's deposit account together with two additional search fees (cf. Section VI *supra*).
2. In the review of applicant's protest, the ISA acknowledged the reasons given by the applicant with respect to Group 2 and agreed to search both Groups 1

- and 2 without payment of an extra search fee (cf. Section VII *supra*). Accordingly, the applicant was refunded one search fee (cf. Section VIII *supra*).
3. Since no arguments were put forward by the applicant with respect to Group 3, applicant's protest could have been understood as being limited to the payment of an extra search fee for Group 2. In that case and, in so far as the applicant's protest concerned in substance Groups 1 and 2 and this was accepted by the ISA, there would have been no need to refer the case to the board nor to pay a protest fee.
 4. However, the applicant did not indicate - within the time limit indicated by the ISA, namely one month - its willingness not to continue the protest in view of the result of the review (cf. Section VII *supra*). On the contrary, in its letter dated 28 June 2007, the debit of the protest fee from applicant's Deposit Account was explicitly requested in case that it had not already been paid (cf. Section IX *supra*).
 5. This request can only be interpreted as showing applicant's disagreement with the findings of the review of the ISA and, since Groups 1 and 2 were accepted to be searched without the payment of an additional search fee, it can only be caused by the decision to maintain the request for payment of one additional search fee for Group 3 in this review.
 6. It is noted, however, that neither in the applicant's reply to the first invitation of the ISA to pay additional fees (cf. Section V *supra*) nor in its reply to the notification of the review of the ISA (cf.

Section IX *supra*) did the applicant provide any "reasoned statement" - within the meaning of Rule 40.2(c) PCT - to the effect that Group 3 complies with the requirement of unity with Groups 1 and 2.

7. Since the applicant failed to provide a "reasoned statement", the protest does not comply with the provisions of Rule 40.2(c) PCT and it is therefore refused.

Order

For these reasons it is decided that:

1. The protest is refused.

The Registrar:

The Chairman:

G. Rauh

L. Galligani