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D E C I S I O N
of 7 October 2003

Case Number: T 0836/01 - 3.3.4

Application Number: 97119173.9

Publication Number: 0835661

IPC: A61K 38/21

Language of the proceedings: EN

Title of invention:
Human interferon-Beta2A for use as a medicament

Applicant:
YEDA RESEARCH AND DEVELOPMENT CO. LTD.

Opponent:
-

Headword:
Interferon-beta2/YEDA RESEARCH AND DEVELOPMENT CO. LTD.

Relevant legal provisions:
EPC Art. 123(2), 54(2), 52(4), 54(5)

Keyword:
"Second/further medical use format (yes)"
"Added subject-matter (no)"
"Novelty (yes)"
"Remittal"

Decisions cited:
G 0001/83, G 0005/83, T 0019/86, G 0006/83, T 0290/86, T 0892/94, T 0486/01, T 0254/93

Catchword:
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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0836/01 - 3.3.4

D E C I S I O N
of the Technical Board of Appeal 3.3.4
of 7 October 2003

Appellant: YEDA RESEARCH AND DEVELOPMENT CO. LTD.
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Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 29 September 1999 refusing European application No. 97119173.9 pursuant to Article 97(1) EPC.**

Composition of the Board:

Chairman: S. C. Perryman
Members: R. E. Gramaglia
A. L. L. Marie

Summary of Facts and Submissions

I. The appeal lies from the decision of the examining division issued on 29 September 1999 whereby European patent application No. 97 119 173.9, published under the No. 0 835 661, a divisional application of European patent application No. EP-A-0 220 574, was refused pursuant to Article 97(1) EPC. Basis of the rejection were claims 1 and 2 filed on 20 May 1999:

"1. Use of human interferon-$ß_{2A}$ for preparing a medicament for influencing cell growth and differentiation"

2. Use of human interferon-$ß_{2A}$ for preparing a medicament useful during terminal differentiation of cancer cells".

II. The examining division decided that :

- The claims were not entitled to either priority claimed;

- Document (D1), international application WO 88/00206, for which the conditions of Article 158(2) EPC were fulfilled, was entitled to a priority date earlier than the actual filing date of the present application, and was thus prior art pursuant to Articles 54(3) and (4) EPC for all designated contracting states except ES, GR, and LI;

- And thus document (D1) destroyed the novelty of claims 1 and 2 of the application in suit for the contracting states designated in both;

- Prior published Abstract of JP-A-60 169 424 (Patent Abstracts of Japan) (document (D2)) disclosed the use of a BCDF (another accepted designation for IL-6 or IFN-ß$_2$) as a medicament for patients suffering immune incompetence, and destroyed the novelty of claim 1.

III. Accompanying a summons to oral proceedings, there was sent a communication expressing the board's provisional opinion, *inter alia* raising the issue that the uses of the medicament to be prepared according to the then claim 1 or 2 "for influencing cell growth and differentiation" or "during terminal differentiation of cancer cells" would not appear to relate clearly to the therapeutic treatment of any illness. The question thus arose whether the benefit of Article 54(5) EPC applied. Also as the decision of the examining division did not address inventive step, but the examining division had expressed in a communication of 3 February 1999 the opinion that the disclosure of Proc. Natl. Acad. Sci. USA, vol. 82, pages 5490 to 5494 (August 1985) made the subject matter of claims 1 to 4 then before it obvious, the board indicated that the issue of inventive step was not one which the board would be inclined to consider itself.

IV. During the oral proceedings held on 7 October 2003, the appellant submitted new claims 1 and 2, in place of all earlier filed sets of claims, and reading:

"1. Use of human interferon-ß$_2$ for preparing a medicament for influencing tumor cell growth and differentiation"

"2. Use of human interferon-ß$_2$ for preparing a medicament for influencing terminal differentiation of cancer cells".

V. The appellant submitted in writing and at the oral proceedings the following arguments:

Therapeutic use (Articles 52(4) and 54(5) EPC)

- The term "tumor" in claim 1 ("cancer" in claim 2), preceding the word "cells", implied that interferon-ß$_2$ had to find use as an anti-tumor/anti-cancer therapeutic agent. These claims thus related to interferon-ß$_2$ for use in the therapeutic treatment of an illness, for which the benefit of Article 54(5) EPC applied.

Fair basis (Article 123(2) EPC)

- The wordings "for influencing tumor cell growth and differentiation" (claim 1) and "for influencing terminal differentiation of cancer cells" (claim 2) found a basis on page 3, lines 29 to 32 of the application as filed.

- The appellant explained that whereas the application as filed referred to interferon–ß$_{2A}$ and interferon–ß$_{2B}$the latter had turned out to be an artefact, whereas interferon–ß$_{2A}$ was the same as what was already known in the art as interferon–ß$_2$

Accordingly it was proposed to refer in the claims only to interferon-ß$_2$, delete all the references in the description to interferon—ß$_{2B}$ and change the references to interferon—ß$_{2A}$ to references to interferon—ß$_2$ in accordance with the standard nomenclature in this field. No new subject matter was introduced thereby.

Novelty

- It was true that document (D1) disclosed therapeutic compositions comprising IL-6 (another name for interferon-ß$_2$) useful for the treatment of cancer (see page 3, end of the third full paragraph and claim 10 of document (D1)), however, this treatment relied on the IL-6's capacity of stimulating the patient's immune system.

- Document (D2) was not concerned with cancer treatment.

- Therefore, claims 1 and 2 were novel vis-à-vis documents (D1) and (D2).

VI. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of claims 1 and 2 submitted during the oral proceedings.

Reasons for the Decision

1. The appeal is admissible.

Therapeutic use (Articles 52(4) and 54(5) EPC)

2. Although claims 1 and 2 at issue (see section IV supra) do not explicitly recite any medical treatment, it can nevertheless be derived from the term "tumor" in claim 1 ("cancer" in claim 2), preceding the word "cells", that interferon-$ß_2$ must find use as an anti-tumor/anti-cancer therapeutic agent. Both claims thus relate to (and are in the format of) a second/further medical use of interferon-$ß_2$ in the therapeutic treatment of a disease, for which the benefits of Article 54(5) EPC apply (see decisions G 1/83, OJ EPO 1985, 60; G 5/83, OJ EPO 1985, 64 and G 6/83, OJ EPO 1985, 65).

Fair basis (Article 123(2) EPC)

3. The term "interferon-$ß_2$" in the claims is justified by the appellant intention to delete all the references in the description to interferon-$ß_{2B}$ which turned out to be an artefact, and changing the references to interferon- $ß_{2A}$ to references to interferon- $ß_2$ in accordance with the standard nomenclature in this field. No new subject matter is introduced thereby, so this deletion and change of nomenclature is in conformity with Article 123(2) EPC.

The wording "for influencing tumor cell growth and differentiation" in claim 1 has a basis on page 3, line 31 of the application as filed when read in the context of cancer cells (see line 32). It should be noted that no distinction is made in the application as filed between tumor and cancer (compare page 1, line 20: "antitumor" with page 3, line 32: "cancer"). Finally, the wording "for influencing terminal

differentiation of cancer cells" in present claim 2 finds a basis in the passage "especially during terminal differentiation of cancer cells" on page 3, line 32 of the application as filed.

4. In view of the foregoing, the board is satisfied that the subject-matter of claims 1 and 2 fulfils the requirements of Article 123(2) EPC.

Novelty (Article 54(2) EPC)

5. Unlike document (D2) which is not concerned with any cancer treatment, document (D1) is relevant to the novelty of present claims 1 and 2, directed to interferon-$ß_2$ for treating cancer (see section 2 supra), as it discloses therapeutic compositions comprising IL-6 (another name for interferon-$ß_2$) useful for the treatment of cancer (see page 3, end of the third full paragraph and claim 10 of document (D1)).

6. Document (D1) and the claimed invention being concerned with the same composition (interferon-$ß_2$) for treating the same disease (cancer/tumor), it has to be decided whether the medical uses now claimed represent further and different therapeutic uses from that disclosed in document (D1).

7. In spite of the above overlap in composition and disease treatment aimed at, the board observes that the claimed invention relies upon a different technical effect from the one disclosed in document (1). Document (1) discloses indeed the use of interferon-$ß_2$ for the purpose of activating mature lymphoid cells exerting cytolytic T cell activity on cancer cells (see

document (D1), page 11, lines 2 to 12) or to stimulate the immune system of patients undergoing (cancer) radio- or chemotherapy (page 9, end of first full-paragraph). Document (D1) thus teaches an **indirect** effect of interferon-ß$_2$ on cancer cells. This is in clear contrast to the technical effect relied upon by the claimed invention, namely the **direct** influence of interferon-ß$_2$ on the tumor cell growth and (terminal) differentiation.

8. It must be pointed out that a hitherto unsuspected property of a known molecule/composition does not necessarily translate into a novel use (be it medical or otherwise) of that molecule/composition, but for an application to be construed as a further use or "further medical use"/"further therapeutic application", this new technical effect would have to lead to a truly new industrial/commercial application (see eg decision G 5/83, point 16) arising from eg the opening a new field of application, the healing of a different pathology/ clinical situation, the creation of a distinct group or sub-group of subjects (either end-users or patients) or the new use must involve new physical means/measures for its practise.

9. For instance, in (non-medical) case T 892/94 (see point 3.5), a claim to the use of an aromatic acid ester of a phenol or of an aromatic alcohol as an inhibitor of esterase producing micro-organisms in a deodorant composition, was considered to be the mere explanation of an effect obtained when using these compounds in a known composition, without ending in a hitherto unknown purpose reflecting said effect. The

same conclusion was reached in (medical) cases T 254/93 (see point 4.8) T 486/01 (see point 12).

However, in case T 19/86 (Pigs II/Duphar), the board considered that the therapeutic application of a known vaccine, which was known for treatment of a particular class of animal (sero-negative pigs), to a new and different class of the same animal (sero-positive pigs), was an acceptable second medical use claim formulation.

10. Turning to the present case, the conclusion cannot be drawn that the technical effect relied upon by the claimed invention, namely the direct influence of interferon-$ß_2$ on the tumor cell growth and (terminal) differentiation is a mere explanation of how interferon-$ß_2$ heals cancer. Rather, this effect identifies a new clinical situation, namely one in which it could be preferable to target the cancer cells themselves, not lymphoid cells or the immune system as in document (D1), in order to heal cancer. But since a new clinical frame is not separable, as an abstract concept, from a patient suffering under it, it must be concluded that this new clinical situation also identifies a new sub-group of subjects being treated.

11. In view of the foregoing, the board is satisfied that the subject-matter of claims 1 and 2 at issue fulfils the requirements of Article 54(2) EPC.

Remittal

12. The present application was rejected for reasons of non-compliance with Article 54(2) EPC only and was

based on claims with a different content to that of the claims presently on file. Consequently, in order not to deprive the appellant of his right to have his invention examined by two instances, and in accordance with the established jurisprudence of the boards of appeal, the board uses its discretion under Article 111(1), second sentence, EPC, and remits the case to the first instance for further prosecution.

13. The description will need amendment to conform to the present claims, by the deletion of all references in the description to interferon–$ß_{2B}$, and the changing of the references to interferon–$ß_{2A}$ to references to interferon-$ß_2$ in accordance with the standard nomenclature in this field.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The matter is remitted to the first instance for further prosecution on the basis of claims 1 and 2 submitted during the oral proceedings on 7 October 2003.

The Registrar: The Chairman:

P. Cremona S. Perryman