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D E C I S I O N
of 6 October 2005

Case Number: T 0739/01 - 3.3.02

Application Number: 92910600.3

Publication Number: 0642336

IPC: A61K 31/00

Language of the proceedings: EN

Title of invention:
Use of NSAID in the treatment of dementia

Patentee:
University of British Columbia

Opponents:
Merck & Co., Inc.
Monsanto Company

Headword:
NSAID for dementia/UNIVERSITY OF BRITISH COLUMBIA

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

Keyword:
"Disclaimer (not accepted): No accidental anticipation"

Decisions cited:
G 0001/03

Catchword:
With respect to the admissibility of disclaimers, it does not matter if the skilled person finds reasons in the relevant prior-art document that make him believe that the particular novelty-destroying embodiment in the context of the citation appears accidental. As long as the document in which this embodiment is set out relates to the same technical field as the alleged invention, the anticipation is related and not remote.

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0739/01 - 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 6 October 2005

Appellant: (Proprietor of the patent)
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Decision under appeal: **Decision of the opposition division of the European Patent Office posted 28 May 2001 revoking European patent No. 0642336 pursuant to Article 102(1) EPC.**

Composition of the Board:

Chairman: U. Oswald
Members: H. Kellner
J. P. Seitz

Summary of Facts and Submissions

I. European patent No. 0 642 336 based on application No. 92 910 600.3 was granted with 7 claims.

Claim 1 as granted read as follows:

"Use of a non-steroidal anti-inflammatory substance which has the ability to inhibit prostaglandin synthesis in the human being in the manufacture of a pharmaceutical formulation for the treatment of dementia in a human being."

II. Opposition was filed against the granted patent under Article 100(a) EPC for lack of novelty and inventive step and under Article 100(b) EPC for insufficiency of disclosure.

The following document was cited *inter alia* during the proceedings before the opposition division and the board of appeal:

(3) EP-A-0 234 733

III. By its decision pronounced on 28 March 2001 and posted on 28 May 2001, the opposition division revoked the patent under Article 102(1) EPC because neither the set of claims of the main request nor the sets of claims of the first, second and third auxiliary requests filed in writing and during oral proceedings met the requirements of the EPC.

The subject-matter of the main request was not new with respect to document (3), where the use of lithium acetylsalicylate for the treatment of Alzheimer's disease was disclosed.

The subject-matter of the first auxiliary request was regarded as not inventive.

With respect to the sets of claims of the second and third auxiliary requests the opposition division noted that they contained disclaimers that did not fulfil the requirements of Article 123(2) EPC.

IV. The appellant (patentee) lodged an appeal against said decision and filed grounds of appeal together with a set of claims as main request that was identical to the first auxiliary request in the proceedings before the opposition division (for the full text of this request see point VI).

V. On 11 April 2005, in an annex to the summons to attend oral proceedings, a communication was sent out, drawing the parties' attention to Enlarged Board of Appeal decisions G 1/03, OJ EPO 2004, 413, and G 2/03, OJ EPO 2004, 448, concerning disclaimers.

VI. With a letter dated 3 October 2005, the appellant introduced a single claim as the new "first" auxiliary request (with no other auxiliary requests following).

The subject-matter of claim 1 of the main request reads as follows:

"Use of a non-steroidal anti-inflammatory substance (NSAIS) which has the ability to inhibit prostaglandin synthesis in the human being, in the manufacture of a pharmaceutical formulation for the treatment of Alzheimer's dementia in a human being,

but excluding a treatment comprising co-administration of the NSAIS with a sex or anabolic hormone,

excluding a treatment comprising administration of lithium acetylsalicylate and

further excluding a treatment comprising co-administration of acetylsalicylic acid with procaine."

The only difference in corresponding claim 1 of the first auxiliary request relative to claim 1 of the main request is the addition of the following wording at its end:

", wherein the substance is salicylic acid, acetylsalicylic acid, diflunisal, choline magnesium trisalicylate, salicylate, benorylate, flufenamic acid, mefenamic acid, meclofenamic acid, niflumic acid, diclofenac, fenclofenac, aclofenac, fentiazac, ibuprofen, flurbiprofen, ketoprofen, naproxen, fenoprofen, fenbufen, suprofen, indoprofen, tiaprofenic acid, benoxaprofen, pirprofen, tolmetin, zomepirac, clopinac, indomethacin, sulindac, phenylbutazone, oxyphenbutazone, azapropazone, feprazone, piroxicam, isoxicam or sudoxicam."

VII. On 6 October 2005, oral proceedings were held before the board in the presence of representatives of the appellant and the representative of respondent (opponent) 01; duly summoned, respondent (opponent) 02 had informed the board in advance that it did not wish to attend the hearings.

VIII. With respect to the admissibility of its requests, the appellant mainly argued that all claims on file had been reworded in order to overcome the objections raised with regard to novelty.

The subject-matter of claim 1 of the main request contained the disclaimer concerning lithium acetylsalicylate because document (3) related to the use of this salt for the treatment of Alzheimer's disease.

While claim 1 of (3) was directed to the use of a physiologically acceptable lithium compound for the manufacture of a therapeutic agent for combating presenile or senile dementia, lithium acetylsalicylate was only disclosed accidentally in the list of lithium salts in its claim 4. The person skilled in the art, a scientist or physician working in the field of NSAIS and Alzheimer's disease, would not have recognised that this lithium salt would be active not only because of its lithium content but also because of its non-lithium part, the NSAIS moiety acetylsalicylate. Therefore he would never have taken it into consideration when making the invention in suit.

The additional wording in the claim of the appellant's first auxiliary request, a list of possible compounds to be used, was introduced in order to restrict the requested subject-matter in a way that ensured that it could be accepted as novel over the state of the art.

IX. The respondents' arguments as submitted in writing and during oral proceedings may be summarised as follows:

In their view, the disclaimers added subject-matter that was not disclosed in the application as filed, and claim 1 of each of the requests contravened Article 123(2) EPC.

Document (3) related to the use of substances for the manufacture of therapeutic agents for use in the treatment of Alzheimer's disease, and even the need to reduce prostaglandin synthesis was indicated. In claim 4 of (3), lithium acetylsalicylate was disclosed as one of the substances to be used.

Therefore, one of the embodiments of the patent in suit was not novel with respect to the teaching of document (3), and this anticipation could not be called either unrelated to or remote from the claimed invention.

X. The appellant (patentee) requested that the decision under appeal be set aside and that the patent be maintained on the basis of either his main request filed on 24 September 2001 (corresponding to the first auxiliary request in the proceedings before the opposition division), or his auxiliary request filed on 3 October 2005.

The respondents (opponents) requested (O2 in writing) that the appeal be dismissed.

Reasons for the decision

1. The appeal is admissible.

2. The auxiliary request constitutes a response to the arguments set out during the proceedings. It is to be regarded as an attempt to overcome the problems discussed by narrowing the scope of the subject-matter of the patent in suit, and it was therefore admitted into the proceedings.

3. The patent in suit refers to the use of an NSAIS in the treatment of Alzheimer's dementia.

3.1 As regards its subject-matter as now claimed in amended form, there is a disclaimer with respect to

the use of lithium acetylsalicylate in the manufacture of a pharmaceutical formulation for the treatment of Alzheimer's dementia in a human being.

3.2 This disclaimer finds no basis in the application as filed. It is derived from the disclosure of document (3) (see page 2, lines 1 to 3, together with claims 1 to 4).

Both claim 1 of the main request and the single claim of the first auxiliary request include said disclaimer in addition to the wording of claim 1 of the patent as granted.

3.3 Thus far the appellant did not disagree.

3.4 Since the use of an NSAIS in the manufacture of a pharmaceutical formulation for the treatment of Alzheimer's dementia is claimed, the patent in suit relates to the technical field of medicaments.

3.5 Document (3) however not only relates to the technical field of medicaments as well; it even deals with the treatment of the same illness to be cured as in the patent in suit, Alzheimer's disease.

Therefore, document (3) cannot be regarded as an accidental disclosure, and the addition of the disclaimer contravenes Article 123(2) EPC.

4. In these circumstances, the appellant's arguments cannot succeed:

The appellant submitted that the use of "the acetylsalicylate moiety" in the manufacture of a pharmaceutical formulation for the treatment of Alzheimer's dementia accidentally appeared in the teaching of document (3). Acetylsalicylate was one of the numerous anions that could accompany the lithium cation (see claim 4 of (3)). The teaching of (3) was that the activity against Alzheimer's dementia was based solely on the presence of the lithium ion. Therefore, the skilled person would never have taken "the acectylsalicylate moiety" into consideration when making the invention.

The Enlarged Board of Appeal, however, in its decision G 1/03 defined the requirement for a disclosure to be accidental in a different manner: "An anticipation is accidental if it is so unrelated to and remote from the claimed invention that the person skilled in the art would never have taken it into consideration when making the invention".

In the current case, the prior-art disclosure in question is the use of lithium acetylsalicylate in the manufacture of a pharmaceutical formulation for the treatment of Alzheimer's dementia, set out in document (3). This document represents the anticipation in the current case, and it is neither unrelated to nor remote from the claimed invention, because it belongs to the same technical field, as already established in point 3.5 of this decision.

Under these circumstances, it does not matter if the skilled person finds reasons in the cited prior-art document that make him believe that a particular novelty-destroying embodiment in its context appears accidental. As long as the document in which this embodiment is set out relates to the same technical field as the alleged invention, the anticipation is related and not remote.

5. Accordingly, claim 1 of the main request and the claim of the "first" auxiliary request both contravene Article 123(2) EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

A. Townend U. Oswald