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**Datasheet for the decision
of 18 January 2008**

Case Number: T 0641/04 - 3.3.02

Application Number: 98955026.4

Publication Number: 1027048

IPC: A61K 31/415

Language of the proceedings: EN

Title of invention:

Selective cyclooxygenase-2 inhibitors against premature labor

Applicant:

G.D. Searle LLC

Opponent:

-

Headword:

Cyclooxygenase-2 inhibitors/G.D. SEARLE LLC

Relevant legal provisions:

EPC Art. 56

Relevant legal provisions (EPC 1973):

-

Keyword:

"Novelty - No: claimed second medical indication anticipated"

Decisions cited:

-

Catchword:

-



Case Number: T 0641/04 - 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 18 January 2008

Appellant: G.D. Searle LLC
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Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 30 December 2003
refusing European application No. 98955026.4
pursuant to Article 97(1) EPC.

Composition of the Board:

Chairman: U. Oswald
Members: J. Riolo
P. Mühlens

Summary of Facts and Submissions

I. European patent application No. 98 955 026 was refused by a decision of the Examining Division pronounced on 12 December 2003 because neither the main nor the auxiliary request fulfilled the requirements of the EPC.

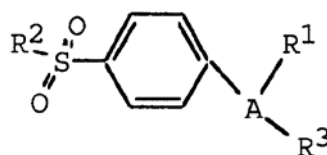
II. The following document was cited *inter alia* during the proceedings before the Examining Division and the Board of Appeal:

(6) WO-A-9731631

III. According to the Examining Division's decision, the main request, filed with the appellant's letter dated 27 January 2003, was anticipated by document (6), which disclosed the use of a compound according to claim 1 for the treatment of pre-term labour, while simultaneously avoiding the side effect of obstructing the ductus arteriosus (Article 54 EPC), while the auxiliary request, which related to obvious structural alternatives to the compounds disclosed in (6), was not inventive vis-à-vis this document (Article 56 EPC).

Claim 1 of the main request filed with letter of 27 January 2003 reads as follows:

1. Use of a compound of Formula I:



I

wherein A is a 5- or 6-member ring substituent selected from partially unsaturated or unsaturated

heterocyclo and carbocyclic rings;

wherein R¹ is at least one substituent selected from heterocyclo, cycloalkyl, cycloalkenyl and aryl, wherein R¹- is optionally substituted at a substitutable position with one or more radicals selected from alkyl, haloalkyl, cyano, carboxyl, alkoxy-carbonyl, hydroxyl, hydroxyalkyl, haloalkoxy, amino, alkylamino, arylamino, nitro, alkoxyalkyl, alkylsulfinyl, halo, alkoxy and alkylthio;

wherein R₂ is selected from alkyl, and amino; and wherein R₃ is a radical selected from halo, alkyl, alkenyl, alkynyl, oxo, cyano, carboxyl, cyanoalkyl, heterocyclooxy, alkyloxy, alkylthio, alkylcarbonyl, cycloalkyl, aryl, haloalkyl, heterocyclo, cycloalkenyl, aralkyl, heterocycloalkyl, acyl, alkylthioalkyl, hydroxyalkyl, alkoxy-carbonyl, arylcarbonyl, aralkylcarbonyl, aralkenyl, alkoxyalkyl, arylthioalkyl, aryloxyalkyl, aralkylthioalkyl, aralkoxyalkyl, alkoxyaralkoxyalkyl, alkoxy-carbonylalkyl, aminocarbonyl, aminocarbonylalkyl, alkylaminocarbonyl, N-arylaminocarbonyl, N-alkyl-N-arylaminocarbonyl, alkylaminocarbonylalkyl, carboxyalkyl, alkylamino, N-aryl-amino, N-aralkylamino, N-alkyl-N-aralkylamino, N-alkyl-N-aryl-amino, aminoalkyl, alkylaminoalkyl, N-aryl-aminoalkyl, N-aralkyl-aminoalkyl, N-alkyl-N-aralkyl-aminoalkyl, N-alkyl-N-aryl-aminoalkyl, aryloxy, aralkoxy, arylthio, aralkylthio, alkylsulfinyl, alkylsulfonyl, aminosulfonyl, alkylaminosulfonyl, N-arylaminosulfonyl, arylsulfonyl, N-alkyl-N-arylaminosulfonyl;

or a pharmaceutically-acceptable salt thereof or derivative thereof **for preparing a medicament for maintaining circulation through fetal ductus arteriosus**

during treatment of preterm labor in a subject in need of such treatment. (Emphasis added).

IV. The appellant (applicant) lodged an appeal against this decision.

In its grounds of appeal it argued that, as claim 1 of the main request was directed to the use of a compound of formula I for preparing a medicament for maintaining circulation through fetal ductus arteriosus during treatment of preterm labor in a subject in need of such treatment, this contemplated independent treatment of the preterm labor with a secondary agent or other means, e.g. bed rest, and this, despite the fact that the description of the rejected application pointed out that the compounds of formula I as recited in claim 1 might be used to treat and prevent preterm labor.

V. In a communication dated 4 January 2008, the Board expressed the preliminary view that the analysis and conclusions of the Examining Division vis-à-vis document (6) were correct and that the appeal would have to be dismissed.

VI. In a fax dated 17 January 2008, the appellant informed the Board that it would not be represented at the oral proceedings.

VII. Oral proceedings were held on 18 January 2008.

VIII. The appellant had requested in writing that the decision under appeal be set aside and that a patent be granted on the basis of the set of claims filed with letter dated 27 January 2003.

Reasons for the Decision

1. The appeal is admissible.
2. *Main and sole request*
 - 2.1 Claim 1 of this request is directed to the use of a compound of formula I for preparing a medicament for maintaining circulation through fetal ductus arteriosus during treatment of preterm labor in a subject in need of such treatment

Thus, for novelty purposes it has to be established whether or not this therapeutic application has already been disclosed in the available prior art for a compound according to formula I of claim 1 of the refused application.

In that respect, document (6) discloses the use of a compound according to claim 1 of the patent in suit (celecoxib) for preparing a medicament for the treatment of preterm labor which reduces harm to the foetus during such treatment (page 1, lines 4 and 5; page 18, lines 11-12 and 17-18 and page 19, lines 19-21).

Typical foetal side effects are specifically mentioned on page 7, lines 4 to 30, in relation to the prior art compound Indomethacin and concern **constriction of ductus arteriosus** and renal blood flow.

Example 3 of this document shows moreover that ductus circulation in the foetus remains normal when an example compound according to the subject-matter of the invention disclosed in document (6) (ie nimesulide) is administered for preventing preterm labor.

Accordingly, document (6) already discloses that a compound according to claim 1 of the application in suit has the effect of maintaining circulation through fetal ductus arteriosus when administered for preventing preterm labor.

Therefore, in the absence, in the patent application as originally filed, of any data providing additional technical information in relation to the treatment according to the refused application compared with the disclosure in the prior art document (6), it must be concluded that the subject-matter of the patent application is anticipated by the disclosure in that document, ie that document (6) discloses the same "therapeutic application" as the present application.

- 2.2 The Board agrees with the appellant that the wording of the claims encompasses alternatives wherein a compound according to formula I of claim 1 is used for maintaining circulation through the fetal ductus arteriosus while a different means or a different tocolytic agent may be used for the treatment of preterm labor.

The subject-matter of claim 1 does not however exclude the embodiment wherein a compound of formula I is used for both aspects of the treatment as it is the case in document (6) (see 2.1 above). This alternative is

moreover not excluded in the description of the application, as pointed out by the appellant itself in its grounds of appeal dated 29 April 2004 (page 2, last sentence).

In any case, as it appears from the above (point 2.1, paragraph 5), the effect of maintaining circulation through the fetal ductus arteriosus *per se* is already disclosed in document (6), so that this application cannot be regarded as novel anymore.

In view of the foregoing, the Board considers that the subject-matter of claim 1 does not fulfil the requirements of novelty of Article 54 EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar

The Chairman

A. Townend

U. Oswald