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D E C I S I O N
of 24 January 2005

Case Number: T 0983/03 - 3.3.2

Application Number: 91108655.1

Publication Number: 0459377

IPC: A61K 31/557

Language of the proceedings: EN

Title of invention:

Use of E1 prostaglandin to cure male erectile impotence

Patentee:

Reale, Alberto

Opponent:

Schwarz Pharma AG
PHARMACIA & UPJOHN S.p.A.

Headword:

Treatment of impotence/REALE ALBERTO

Relevant legal provisions:

EPC Art. 54

Keyword:

"Novelty - no - prior art alcohol solution falls within the scope of claim 1 of the patent in suit"

Decisions cited:

G 0003/97

Catchword:

-



Case Number: T 0983/03 - 3.3.2

D E C I S I O N
of the Technical Board of Appeal 3.3.2
of 24 January 2005

Appellant: Reale, Alberto
(Proprietor of the patent) Viale Beatrice d'Este 30
I-20122 Milano (IT)

Respondent R2: Schwarz Pharma AG
(Opponent 02) Alfred-Nobel-Strasse 10
D-40789 Monheim (DE)

Representative: -

Respondent R3: PHARMACIA & UPJOHN S.p.A.
(Opponent 03) Viale Pasteur, 10
I-20014 Nerviano (MI) (IT)

Representative: Bianchetti, Giuseppe, Prof.
Bianchetti Bracco Minoja S.r.l.
Via Plinio, 63
I-20129 Milano (IT)

Decision under appeal: Decision of the Opposition Division of the
European Patent Office posted 1 August 2003
revoking European patent No. 0459377 pursuant
to Article 102(1) EPC.

Composition of the Board:

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

Summary of Facts and Submissions

- I. European patent No. 0 459 377 based on application No. 91 108 655.1 was granted on the basis of two claims.

Independent claim 1 as granted reads as follows:

1. Use of Prostaglandin E₁ (Alprostadil) in the preparation of pharmaceutical compositions for the treatment of male erectile impotence, characterized in that said compositions consist of low alcohol content alcohol solutions of Alprostadil suitable to be introduced in the *corpora cavernosa* by local injection or by iontophoresis.

- II. Notices of opposition were filed against the granted patent by opponents O1, O2 and O3.

The patent was opposed under Article 100(a) EPC for lack of novelty and lack of inventive step and under Article 100(b) EPC for insufficiency of disclosure.

An objection with respect to Article 100(c) was also raised in the notices of opposition but not further substantiated.

Opponent O1 withdrew its opposition by its letter dated 8 May 2000.

The following document was *inter alia* cited during the proceedings.

(1) Br. J. clin. Pharmac. (1989), 28, 567-571

III. The decision of the Opposition Division, pronounced on 16 July 2003, posted on 1 August 2003, revoked the patent under Article 102(1) EPC.

The Opposition Division took the view that the subject-matter of claim 1 of the patent in suit did not meet the requirements of Article 54 EPC.

In its opinion, document (1) anticipated the subject-matter of claim 1 as it described pharmaceutical compositions consisting of an alcoholic solution (ie a solution of benzethylalcohol) of prostaglandin E1 for the treatment of male erectile impotence by local injection into the corpora cavernosa. It accordingly concluded that all the features of claim 1 of the patent in suit were disclosed in document (1).

As to the objection raised by the patentee with respect to the admissibility of the opposition filed by Opponent O3, the Opposition Division considered that the mere change of name of the company of the Opponent did not render the opposition inadmissible.

It further added that it could not see any attempt by opponent O3 either to circumvent the law by abuse of process contrary to the patentee's statement.

IV. The appellant (patentee) lodged an appeal against the said decision.

V. In its written submissions, the appellant stated merely that document (1) did not disclose the use of a low alcohol content alcohol solution, so that the subject-

matter of claim 1 of the contested patent was novel vis-à-vis said document.

Moreover, it repeated its objection with respect to the admissibility of the opposition filed by opponent 03 for two reasons, namely because in its opinion Pharmacia/Upjohn S.p.A did not exist and because Pharmacia/Upjohn S.p.A and Pharmacia S.p.A were two different companies.

- VI. Respondent R3 (opponent 03) submitted in writing that the reasons explained in the Opposition Division's decision as to lack of novelty of claim 1 of the patent in suit held good.

It argued moreover that the opposition filed by opponent 03, ie Pharmacia/Upjohn S.p.A., was admissible as this company still existed and as it identified a legal person within the meaning of the decision of the Enlarged Board of Appeal G 3/97 (OJ, 1999, 245).

- VII. The appellant requested that the decision under appeal be set aside and that the patent be maintained as granted and the opposition filed by opponent 03 be rejected as inadmissible.

The respondents requested that the appeal be dismissed.

Reasons for the decision

1. The appeal is admissible.

2. *Admissibility of opposition filed by opponent 03*

The appellant contested the admissibility of the opposition filed by opponent 03.

In that respect, the Board observes that the opposition filed by respondent R2 (opponent 2) was not disputed and the Board sees no reason to differ.

Moreover, during the opposition procedure, respondent R2 raised the same novelty objections as the one raised by respondent 3 (see opponent 02's letter dated 4 May 2000, point 2.1).

Having regard to the Board's conclusions under point 3.2 below and to the facts mentioned above, it appears that, under the present circumstances, there is no need to decide on the admissibility of the opposition filed by opponent 03 since its outcome would in any case have no effect on the present decision.

3. *Novelty*

- 3.1 Document (1) discloses the use of prostaglandin E₁ (Alprostadil) in the preparation of a pharmaceutical composition suitable for introducing into the corpora cavernosa by local injection for the treatment of male erectile impotence. The composition is a 0,5 ml saline solution containing 5µg prostaglandin E₁, 0,6% benzethyl-alcohol and 0,01% benzalkonium chloride, 0,01% EDTA, ie a low alcohol content solution of Alprostadil (page 568, right-hand column, last paragraph, to page 569, left-hand column, first paragraph; page 567, summary).

Accordingly, the subject-matter of claim 1 of the contested patent is anticipated by the disclosure in document (1).

- 3.2 The main argument put forward by the appellant during the opposition proceedings in defence of novelty was that the features "low alcohol content alcohol solutions" and "iontophoresis" were not present in document (1).

As to the feature relating to "iontophoresis", the Board notes that this feature is optional, so that it cannot be used to establish novelty.

Concerning the second feature, the Board does not accept the appellant's view that since the words "consisting of" precede this feature it must be concluded that the solution contains exclusively a low alcohol content.

In fact, the Board agrees that words "consisting of" restrict the compositions exclusively to the presence of a solvent, an alcohol and Alprostadil. It however does not restrict the term "solution" to any particular solution.

As no basis, either in the claim itself or in the description, can be found for a narrow definition of this term, it must be considered that the low alcohol content alcoholic solution disclosed in the document falls within claim 1 although it contains other dissolved ingredients.

Under these circumstances, the Board concludes that claim 1 lacks novelty vis-à-vis document 1 contrary to the requirements of Articles 52(1) and 54 EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:

A. Townend

U. Oswald