

Internal distribution code:

- (A) [] Publication in OJ
(B) [] To Chairmen and Members
(C) [X] To Chairmen

D E C I S I O N
of 8 December 1994

Case Number: T 0067/94 - 3.3.4

Application Number: 90300521.3

Publication Number: 0379367

IPC: A61K7/48

Language of the proceedings: EN

Title of invention:

Method for the treatment or prevention of intrinsically aged skin with retinoids

Applicant:

ORTHO PHARMACEUTICAL CORPORATION

Opponent:

-

Headword:

-

Relevant legal provisions:

EPC Art. 54

Keyword:

"Novelty - (yes) - after amendment"

Decisions cited:

T 0619/88, G 0002/88, G 0005/83

Catchword:

-



Case Number: T 0067/94 - 3.3.4

D E C I S I O N
of the Technical Board of Appeal 3.3.4
of 8 December 1994

Appellant: ORTHO PHARMACEUTICAL CORPORATION
U.S. Route 202
P.O. Box 300
Raritan
New Jersey 08869-0602 (US)

Representative: Fisher, Adrian John
CARPMAELS & RANSFORD
43 Bloomsbury Square
London WC1A 2RA (GB)

Decision under appeal: Decision of the Examining Division of the European
Patent Office dated 30 August 1993 refusing
European patent application No. 90 300 521.3
pursuant to Article 97(1) EPC.

Composition of the Board:

Chairwoman: U. M. Kinkeldey
Members: R. E. Gramaglia
S. C. Perryman

Summary of Facts and Submissions

- I. By a decision of the Examining Division dated 30 August 1993, the Appellant's European patent application No. 90 300 521.3, publication No. 0 379 367, filed 18 January 1990 was refused on grounds of lack of novelty (Article 54 EPC). The decision of refusal was taken on the basis of Claims 1 to 8. Claim 1 and independent Claim 7 read as follows:

"1. A method for the cosmetic treatment or prevention of intrinsically aged skin which comprises the topical administration of an effective amount of a retinoid in a pharmaceutically acceptable carrier."

"7. The use of a retinoid in the manufacture of a medicament for the therapeutic treatment or prevention of intrinsically aged skin, said method comprising administering said retinoid topically in a pharmaceutically acceptable carrier."

- II. The Examining Division rejected Claims 1 to 4 and 6 to 8 for lack of novelty in view of

(1) EP-A-0 229 561 and (4) WO-A-86/06 275.

Document (1) disclosed retinoids entrapped in liposomes for the treatment of both actinic and chronologically (intrinsic) aging of the skin, while document (4) related to retinol topical compositions for reducing fine lines and wrinkles, the presence of fine wrinkling being, according to the patent application in suit (see page 1, line 25), a clinical sign of chronologically aged skin.

III. The Appellant (Applicant) lodged an appeal, received on 2 November 1993, against that decision and paid the fee on the same date. A Statement of Grounds of Appeal was filed on 7 January 1994. The Appellant substantially confirmed the previous line of argument. While he did not dispute that some passages of documents (1) and (4) mentioned the treatment of chronologically aged skin, the Appellant pointed out that the investigations disclosed in the cited prior art on the effect of retinoids upon the skin did not discriminate between photoaging and intrinsic aging. Therefore, the passages of documents (1) to (4) dealing with the treatment of chronologically aged skin were not buttressed by experimental data so as to render them believable by the skilled person. Documents (1) and (4) lacked experimental evidence rendering plausible a beneficial effect of retinoids upon intrinsic skin aging. The teachings of these documents would thus not convey any prospect of success to the skilled person considering the question of retinoids in the treatment of chronologically aged skin. In other words, the prior art document did not make available to the public the present application's teaching that retinoids alleviate intrinsic aging symptoms. In contrast to the cited prior art, the present application provided considerable experimental support for the benefits to be derived from using retinoids in the treatment of intrinsically aged skin. In particular, Example 2 of the application described a one year investigation of the effect of retinoic acid on the skin of the upper lateral thigh of women aged 78-85, a site where photoaging would make a negligible contribution. Decision T 81/87 (OJ EPO 1990, 250) was cited in support of the principle that a prior art disclosure must be sufficiently detailed to be plausible, i.e., enabling.

IV. In a communication accompanying the summons to oral proceedings issued on 5 August 1994, the Board expressed the preliminary view that the decision of the First Instance was well founded. In the Board's view, there appeared two questions of fact to be answered, namely:

- (i) Was the use in the prior art documents disclosed in a manner sufficiently clear for it to be carried out by a person skilled in the art?
- (ii) Would the use proposed in the prior art documents be taken to be meant as a serious suggestion?

Since, in the Board's opinion, the answer to both questions appeared to be yes, documents (1) and (4) could not be disregarded when assessing novelty. The Board also drew the Appellant's attention to Example 15 of document (4) describing an investigation on the effect of retinol applied to the upper inner arm's skin of 10-women. Since a woman's upper inner arm was as little exposed to the sun as her upper lateral thigh (see end of Section III above), said test seemed to contradict the Appellant's thesis that the investigation disclosed by the cited prior art did not discriminate between photoaging and intrinsic aging.

V. During oral proceedings held on 8 December 1994, the Appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the newly submitted main request. Claim 1 and independent Claim 7 of the main request were as follows:

"1. The use of a retinoid in a cosmetic treatment of intrinsically aged skin by topical application, for increasing the production of lymphocytes and fibroblasts in the dermis."

"7. The use of a retinoid in the manufacture of a medicament for increasing the production of lymphocytes and fibroblasts in the dermis of intrinsically aged skin, said medicament being for topical application to the skin."

Reasons for the Decision

1. The appeal is admissible.

Main Request

Compliance with Article 123(2) EPC

2. Being based on original Claims 1 and 9 and on page 12, line 30 of the original description, Claims 1 and 7 of the main request do not go beyond the original disclosure of the application. Likewise, the reformulation by the Appellant of the original method Claims 1 to 6 as use claims does not infringe the requirement of Article 123(2) EPC, because the use claims are concerned with the same use of the retinoids as the one already defined in the method claim: there is in fact no change of claim category, see e.g., decision T 619/88 of 1 March 1990 (not published in the OJ EPO).

Novelty

3. Neither document (1) nor document (4) states that topically applied retinoids exert on the dermis of intrinsically aged skin the effect of increasing lymphocytes and fibroblasts. Yet achieving this effect is a technical feature of cosmetic use Claim 1 (following the reasoning of the decision of the Enlarged Board of Appeal in decision G 2/88 (OJ EPO 1990, 93))

and of the further medical use Claim 7, which is in the format approved in decision G 5/83 (OJ EPO 1985, 64). Accordingly Claims 1 and 7 of the main request must be considered as novel.

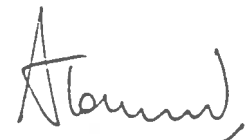
4. The appeal was against the rejection for lack of novelty over documents (1) and (4). The Board holds that the claims of the main request now put forward satisfy the requirements of Article 123(2) EPC and are novel over documents (1) and (4), but the Board has not considered the question of inventive step. In order not to deprive the Appellant of the two instance procedure instituted under the European Patent Convention for the consideration of objections to the grant of a patent, the Board considers it appropriate to exercise its powers under Article 111(1) EPC, by remitting the case to the first instance for further prosecution.

Order

For these reasons it is decided that:

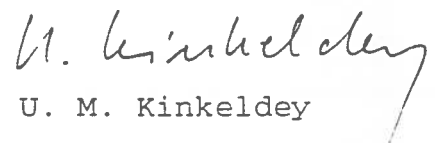
1. The decision under appeal is set aside.
2. The case is remitted to the first instance for further prosecution on the basis of the claims filed as main request during the oral proceedings.

The Registrar:



A. Townend

The Chairwoman:



U. M. Kinkeldey

