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**Datasheet for the decision
of 1 July 2019**

Case Number: T 2239/16 - 3.3.07

Application Number: 03706082.9

Publication Number: 1471876

IPC: A61K7/06

Language of the proceedings: EN

Title of invention:
METHOD OF ENHANCING HAIR GROWTH

Applicant:
ALLERGAN, INC.

Headword:
METHOD OF ENHANCING HAIR GROWTH/ALLERGAN, INC.

Relevant legal provisions:
EPC Art. 56

Keyword:
Inventive step - (no)

Decisions cited:

Catchword:



Beschwerdekammern
Boards of Appeal
Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0
Fax +49 (0)89 2399-4465

Case Number: T 2239/16 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 1 July 2019

Appellant: ALLERGAN, INC.
(Applicant) 2525 Dupont Drive
Irvine, CA 92612 (US)

Representative: Hoffmann Eitle
Patent- und Rechtsanwälte PartmbB
Arabellastraße 30
81925 München (DE)

Decision under appeal: **Decision of the Examining Division of the
European Patent Office posted on 3 March 2016
refusing European patent application No.
03706082.9 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman J. Riolo
Members: D. Boulois
C. Schmidt

Summary of Facts and Submissions

I. The appeal lies from the decision of the examining division to refuse European patent application n° 03 706 082.9. The decision was based on 2 sets of claims filed as main request with letter of 3 September 2012 and as auxiliary request during the oral proceedings before the examining division on 9 February 2016.

Claims 1 and 6 of the auxiliary request read as follows:

"1. Bimatoprost or a pharmaceutically acceptable salt thereof for use in a therapeutic method for stimulating hair growth in a mammalian species comprising the application of said compound to mammalian skin.

6. Non-therapeutic use of bimatoprost or a pharmaceutically acceptable salt thereof for stimulating hair growth by applying said compound to mammalian skin."

II. The documents cited during the examination proceedings included the following:

D2: Stefano Gandolfi et al: "Three-Month Comparison Bimatoprost and Latanoprost in Patients With Glaucoma and Ocular Hypertension", In Therapy, vol. 18, No 3, May/June 2001, pp 110-121

D3: US 6 262 105 B1

D9: WO 01/74315

III. According to the decision under appeal, claim 1 of the main request was not novel over D9.

Claim 1 of the auxiliary request was not inventive over the closest prior art D3 which disclosed the use of compositions comprising inter alia latanoprost, instead of bimatoprost. The subject-matter of claim 1 differed from D3 in that bimatoprost was claimed for use in a method for stimulating hair growth instead of latanoprost. The problem was the provision of a further composition with hair growing effects. D2 disclosed eyelash growth due to bimatoprost, and the claimed solution was not inventive for this reason.

- IV. The applicant (appellant) filed an appeal against the decision of the examining division. With the statement of grounds of appeal, the appellant submitted a main request and an auxiliary request, corresponding to the requests as filed in the examination proceedings.
- V. A communication expressing the board's preliminary opinion of the board was sent to the appellant. The Board stated in particular that the main request was not novel over D9 and D2, and not inventive over D3 combined with D2. The same applied to the auxiliary request.
- VI. With the letter of 31 May 2019 the appellant withdrew its main request and promoted its auxiliary request as the new main request.
- VII. Oral proceedings before the board of appeal took place on 1 July 2019.
- VIII. The appellant's arguments can be summarised as follows:

As regards inventive step, D3 was the closest prior art, and was the only document which was concerned with the provision of compounds for promoting hair growth.

The objective problem was the provision of an alternative composition with hair growing effects. The claimed solution was the use of bimatoprost instead of latanoprost and this solution was not obvious, since both compounds were not interchangeable and document D2, which related to the use of bimatoprost in the treatment of glaucoma was not in the same field and would not have been consulted. The skilled person would indeed not have assumed that all anti-glaucoma medications could promote hair growth. Instead, the skilled person seeking alternative hair growth promoters to latanoprost would have focused the search on compounds which are structurally very similar to latanoprost and for other compounds which selectively interact with the FP receptor.

Hence, the skilled person would not have looked at document D2 because it addresses something completely different, i.e. treatment of glaucoma. The combination of D2 and D3 was completely artificial, and relied on hindsight.

IX. Requests

The appellant requests that the decision under appeal be set aside and that a patent be granted on the basis of the main request filed with letter dated 31 May 2019.

Reasons for the Decision

Main request - Inventive step

1. The invention relates to a method for stimulating the growth of mammalian hair by the application of a compound according to claim 1.

2. D3 was considered as the closest prior art during the examination proceedings. This document discloses the use of certain prostaglandins, preferably latanoprost, for stimulating hair growth. Said document mentions in columns 6-7 that said property was discovered accidentally during the eye treatment of glaucoma by latanoprost: "In the course of treating patients having glaucoma, treatment may only be appropriate in one eye. Within the course of daily practice it was discovered that a patient who had taken a representative prostaglandin derivative, latanoprost, for 17 weeks has lashes that were longer, thicker and fuller in the treated eye than in the non-treated eye. On examination the difference was found to be very striking. The lashes were about 30% longer and had a more full dense appearance in the treated eye...".

Example 1 of D3 shows in particular the effect of latanoprost on the eyelashes and hair around the eyes after topical instillation in one eye. In the treated eye, lash and lash-like hair growth was observed.

3. In the absence of any evidence that the topical application of bimatoprost shows an improvement in hair growth over a treatment by latanoprost as shown in D3, the problem is seen as the provision of an alternative composition with hair growing effects.

Example 1 of the patent application shows convincingly that a topical application of bimatoprost on one eye shows a growth of the eyelashes and hair around the eyes. In view of this result, it appears that the problem has been credibly solved.

4. The question remaining is whether the skilled person, starting from the disclosure of D3, would arrive at the subject-matter of claims 1 and 6 of the main request in an obvious manner in order to solve the problem posed.

4.1 D2 relates to a comparison of the effects of bimatoprost and latanoprost in patients with glaucoma and ocular hypertension; the study tries in particular to evaluate the effect of bimatoprost, presented as the first synthetic prostamide analogue to be introduced for this treatment (see page 112, "Introduction"). The efficacy of both prostaglandins was evaluated by application of ophthalmic solutions on the eyes and by measuring the intraocular pressure. Moreover the eyelash growth was also graded in the same study (see page 112, "Outcome Measures").

The document concludes that bimatoprost provides a consistent lower intraocular pressure than latanoprost, but that a long-term comparison was needed to further evaluate the relative safety/tolerability of both drugs and to determine whether bimatoprost would continue to show a greater efficacy than latanoprost.

D2 reports also that eyelash growth was reported in 12.6% of bimatoprost patients and 4.4% of latanoprost patients (see page 117, "Safety and Tolerability"). An effect on hair growth linked with the application of bimatoprost is therefore known from D2.

Accordingly, D2 shows that latanoprost and bimatoprost were both known at the priority date of the application for their effect on the eyelash growth and that bimatoprost shows even an improved effect over latanoprost, which would prompt the skilled person to use it for stimulating hair growth in view of D3.

Consequently, the solution appears to be obvious in view of D2.

- 4.2 The argument of the appellant that the solution could not be not obvious in view of D2, since this document belonged to a different technical field, and since latanoprost and bimatoprost are not interchangeable drugs, could not be followed for the following reasons.

It is true that the teaching of D2 concerns first and foremost the treatment of glaucoma, but the teaching of this document is not limited to this point. Indeed, said document directly and unequivocally also mentions the effect of the two drugs on the growth of eyelashes. The adoption in D2 of a measurement of the length of the eyelashes shows even that an effect on hair growth was known for latanoprost and also expected for bimatoprost.

Then, even if the two compounds have different structures, since latanoprost is an ester and bimatoprost is a prostamide, the two compounds remain prostaglandins used in the same treatment categories, in particular the treatment of glaucoma and of intraocular pressure, and are interchangeable for this reason.

Finally, the content of the document D2 alone already contradicts the argument that the two prostaglandins

are not interchangeable, since D2 precisely relates to a comparison between the two drugs.

4.3 Hence, the claimed solution does not appear to be inventive over D3 in combination with D2 for these reasons.

The lack of inventive step applies to both claims 1 and 6 of the main request, since it is not possible to distinguish between the claimed therapeutic and non-therapeutic applications of respectively claim 1 and claim 6.

5. The main request does not meet the requirements of Article 56 EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



K. Götz-Wein

J. Riolo

Decision electronically authenticated