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Datasheet for the decision of 3 March 2015

Case Number: T 1173/11 - 3.3.07

Application Number: 00921783.7

Publication Number: 1178779

IPC: A61K9/22, A61F9/00

Language of the proceedings: EN

Title of invention:
OPHTHALMIC INSERT AND METHOD FOR SUSTAINED RELEASE OF MEDICATION TO THE EYE

Patent Proprietor:
Eyelab Group, LLC

Opponent:
Luckhurst, Anthony Henry William, et al

Headword:

Relevant legal provisions:
EPC Art. 56
RPBA Art. 13(1), 13(3)

Keyword:
Inventive step - main request (no) - auxiliary request (no)
Late-filed request - admitted (no)

Decisions cited:

Catchword:

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Case Number: T 1173/11 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 3 March 2015

Appellant: (Opponent)	Luckhurst, Anthony Henry William, et al 90 Long Acre London WC2E 9RA (GB)
Representative:	Atkinson, Jonathan David Mark HGF Limited Belgrave Hall Belgrave Street Leeds LS2 8DD (GB)
Respondent: (Patent Proprietor)	Eyelab Group, LLC 2350 Washtenaw Avenue Ann Arbor, MI 48104 (US)
Representative:	Grünecker, Kinkeldey, Stockmair & Schwanhäusser Anwaltssozietät Leopoldstrasse 4 80802 München (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 17 March 2011 rejecting the opposition filed against European patent No. 1178779 pursuant to Article 101(2) EPC.**

Composition of the Board:

Chairman	J. Riolo
Members:	A. Usuelli
	D. T. Keeling

Summary of Facts and Submissions

I. The appeal of the opponent (appellant) lies against the decision of the opposition division to reject the opposition against European patent EP 1 178 779.

The patent was granted with 14 claim. Claim 1 read as follows:

"1. An ophthalmic insert for sustained release of medication to an eye, comprising:

a body portion sized to pass through a lacrimal punctum and be positioned within a lacrimal canaliculus of an eyelid;

a collarette connected to the body portion and sized to rest on the exterior of the lacrimal punctum, the collarette having at least one pore provided therein;

a reservoir contained at least partially within the body portion and in fluid communication with the at least one pore; and

a medication stored within the reservoir and released through the at least one pore and onto the eye over time in a controlled manner while the insert is positioned in the eyelid."

II. An opposition was filed against the patent as a whole. It was based on Article 100(a) EPC together with Articles 53(c), 54 and 56 EPC and Article 100(b) EPC. The opponent relied *inter alia* on the following documents:

D5: US 3,949,750

D10: WO 95/28984
D12: US 5,334,137

III. In its decision the opposition division came *inter alia* to the following conclusions:

a) The ophthalmic insert of claim 1 of the opposed patent was novel over the devices disclosed in documents D5 and D10.

b) Document D5 represented the closest prior art for the assessment of inventive step. The main advantage of the ophthalmic insert according to the opposed patent over the device of D5, resided in the avoidance of drug release into the canaliculus. The skilled person confronted with the problem of providing an ophthalmic insert having this property would have found no suggestion towards the device of claim 1. The subject-matter of the opposed patent was therefore not obvious.

c) The requirement of sufficiency of disclosure was met. The ground based on Article 53(c) was not substantiated. Moreover, claims 1 to 14 were product claims, hence they did not fall under the exception of Article 53(c) EPC.

IV. The appellant lodged an appeal against that decision. The statement setting out the grounds of appeal was filed on 27 July 2011. The respondent replied with letter of 13 February 2012.

V. On 28 January 2015 the board issued a communication pursuant to Article 15(1) of the Rules of Procedure of the Boards of Appeal (RPBA). In its preliminary opinion

the board indicated that it was inclined to agree with the conclusions made by the opposition division with regard to the requirements of novelty, sufficiency of disclosure and Article 53(c) (points 4, 5 and 6). Doubts were however expressed by the board in relation to the assessment of inventive step made by the opposition division, in particular with regard to the formulation of the technical problem. It was indicated that this matter would have been discussed at the oral proceedings (point 7.3).

VI. The appellant communicated on 17 October 2014 and on 28 January 2015 his decision not to attend the oral proceedings scheduled for 3 March 2015.

VII. On 13 February 2015 the respondent submitted a new set of claims as auxiliary request I.

Claim 1 of this request differed from claim 1 of the granted patent on the addition of the following feature at the end of the claim:

"; and wherein the insert is formed of a material impermeable to the medication".

VIII. During the oral proceedings held on 3 March 2015 a new set of claim was filed by the respondent as auxiliary request II.

Claim 1 of auxiliary request II differed from claim I of auxiliary request I on the addition of the following feature at the end of the claim:

", and wherein the at least one pore is constructed with a specific geometry appropriate to control the rate of release of the medication onto the eye."

IX. As far as relevant for the present decision, the appellant's arguments can be summarised as follows:

Document D5 represented the closest prior art for the assessment of inventive step because it related to the same type of insert as the patent in suit. The opposition division considered that the technical problem had to be formulated in terms of providing an improved solution to the issues already identified in D5, in particular with regard to the avoidance of drug release down the canaliculus. However, the patent in suit did not contain any comparative data illustrating such improvements. The technical problem was therefore to be formulated as the provision of an alternative ophthalmic insert for the delivery of a medicament to the eye. The distinguishing feature of the claimed device was represented by the internal reservoir. The device of D5 already included a bore as a means for enabling insertion into the eye. It was within the capability of the skilled person to provide an enlarged bore in the insert of D5 to accommodate medicament. An ophthalmic insert having a bore was disclosed also in document D12. The device claimed in the opposed patent was obvious in view of D5 taken alone or in combination with D12.

X. As far as relevant for the present decision, the respondent's arguments can be summarised as follows:

a) Inventive step

The closest prior art was represented by document D5. This document related to a device which could be made of a porous material that could be impregnated with a medicament. It was however clear in particular from

claims 4 and 5 that only the head of the device was impregnated with a medicament. The device claimed in the patent provided various advantages over the device of D5. In particular, the at least one pore in the head in communication with the reservoir allowed a better control of the drug's release. In the device of D5 the control of the drug's release was more difficult due to the high number of pores. Furthermore, the presence of a reservoir made it possible to have more space for storing the medicament, which resulted in a prolongation of the duration of the release. There was a clear separation in the device of the invention between the storing and the releasing regions. This different geometry was to be seen as an advantage over the device of D5. The technical problem was therefore to be seen in the provision of a punctum plug which ensured a better control of the drug release on the eye over a longer period of time. Document D12 was not relevant in that the device disclosed therein did not contain any drug. The device disclosed in D10 had a different application. This document did not provide any teaching with regard to the release of the medicament onto the eye. There were various different embodiments disclosed in D10. Only the devices of figures 5 and 12 had a reservoir in connection with the head portion. There where no hints in the prior art to combine the teaching of D10 relating to the specific embodiments of figures 5 and 12 with the teaching of D5.

The device defined in claim 1 of auxiliary request I was formed of a material impermeable to the medication. Accordingly, the medicament could be released only to the eye. This represented an additional advantage over the device of D5, which had the drawback of releasing part of the medicament into the canaliculus.

b) Admittance of auxiliary request II

This request was based on the introduction of the features of dependent claim 13 as granted in claim 1 as granted. The subject-matter of claim 1 was not complex in that it was based on the combination of granted claims. The features introduced in claim 1 underlined the advantageous properties of the claimed device with regard to the control of the rate of release of the medicament. Auxiliary request II represented therefore an attempt to overcome the issues concerning inventive step.

XI. The appellant requested in the written proceedings that the decision under appeal be set aside and the patent revoked.

XII. The respondent requested that the appeal be dismissed (main request) or, in the alternative, that the patent be maintained on the basis of the claims of auxiliary request I filed by letter of 13 February 2015 or auxiliary request II filed during oral proceedings held on 3 March 2015.

Reasons for the Decision

Main request

1. Inventive step

The invention underlying the patent in suit relates to an ophthalmic insert to be positioned within a lacrimal canaliculus of an eyelid and which releases a medicament onto the eye in a controlled manner.

Closest prior art

1.1 The board agrees with the parties and with the opposition division that document D5 represents the closest prior art.

1.2 D5 relates to a plug useful to close the upper as well as the lower punctual opening of the eye (column 1, line 60 to 68). It is composed of three portions namely (1) a projecting tip, (2) a middle body of smaller diameter and (3) a larger smooth head (column 2, lines 1 to 6). The size and shape of the plug are designed to allow the insertion of parts (1) and (2) into the lacrimal canaliculus while the head portion (3) rests on the exterior of the lacrimal punctum thereby preventing the plug from passing down into the canaliculus (column 4, line 68 to column 5 line 7; figures 3 and 3A). By comparing the plug of D5 with the ophthalmic insert defined in claim 1 of the patent in suit it can be concluded that parts (1) and (2) of the device of D5 taken together correspond to the body portion of the insert of the patent in suit while the head (3) of the plug of D5 corresponds to the collarette of the insert of claim 1.

According to a specific embodiment the plug of document D5 may be made of a medication-impregnable porous material such as hydroxyethylmethacrylate (HEMA) (column 5, lines 7 to 14). Preferably only part of the plug, in particular the head is impregnated with a medicament (claims 4 and 9). The porous structure of the plug of D5 has the function of storing the medication and dispensing it to the surface of the eye by the leaching action of the lacrimal fluids (column 5, lines 12 to 14 and claim 5).

The ophthalmic insert defined in claim 1 of the patent differs from the plug of D5 in that the medication is stored in a reservoir which is in a fluid communication which at least one pore of the collarette from which the medication is released.

Technical problem

1.3 In its decision the opposition division considered that the main advantage of the ophthalmic insert according to the patent in suit over the device of D5, resided in the avoidance of drug release into the canaliculus and consequently in the prevention of the systemic absorption in favour of the topical (i.e. ocular) absorption. This conclusion was apparently based on the observation that since the plug of D5 was made of a medicament-impregnable porous material, at least part of the medicament would have been released unavoidably into the interior of the canaliculus thereby lowering the amount of drug available for topical absorption.

The board observes in this respect that no experiments have been carried out in order to compare the properties of the claimed device and the device of D5. In particular, there is no evidence on file showing an improvement of the insert of the patent in suit in relation to the topical delivery of the medication. This fact was pointed out by the board in its communication of 28 January 2015 (point 7.3).

Also the observation that the plug of D5 must release part of the medication into the canaliculus in view of its porous structure is an assumption which is not supported by any evidence. As already remarked by the board in its communication of 28 January 2015, the

device of D5 is conceived to release the medication topically, i.e. to the eye and not to the canaliculus (see column 1, lines 56 to 66 and claim 9). Furthermore, it is explained in D5 that the release of the medication is caused by the leaching action of the lacrimal fluid (column 5, lines 8 to 14 and claim 5). By this mechanism, the medication's release can occur only in the direction of the eye.

The board cannot establish whether the opposition division was correct in its assumption that the device of D5 would release part of the medication into the canaliculus instead of dispensing it to the eye. However, having regard to the fact that this assumption goes against the teaching of D5 it cannot be accepted as true in the absence of any evidence.

From the above it is concluded that the technical effect of improving the topical delivery of the medication cannot be taken into account for the formulation of the technical problem.

1.4 The respondent submitted that the ophthalmic insert of the patent in suit presented various other advantages over the device disclosed in D5. In particular, he argued that the presence of a pore in the collarette in communication with the reservoir allowed a good control of the drug's release while in the device of D5 this was more difficult due to the high number of pores. Further advantages were represented by the presence of a reservoir which provided more space for storing the medicament and the different geometry of the device with a clear separation between the storing and the releasing regions.

1.5 However, none of these purported improvements over the device of D5 has been shown to exist by means of experiments or any other evidence. Furthermore, some of the advantages claimed for the device of the patent appear to be inferred from the presence of structural features of the device which are not implied by the wording of claim 1. For instance, claim 1 does not require the reservoir to have a minimum volume. Hence, the observation that more medication can be stored in the device of the patent in suit cannot apply to the whole range of devices covered by claim 1. Also the alleged better control of the medication's release (see 2.4 above) does not take into account of the fact that claim 1 does not impose any restriction as to the number of pores in the collarette.

1.6 In the light of the considerations made in points 1.3 to 1.5 above, the board concludes that no improvement over the device disclosed in D5 has been shown to exist.

The technical problem is therefore formulated as the provision of an alternative ophthalmic insert to be positioned in the lacrimal canaliculus for releasing a medication to the eye.

Obviousness

1.7 Claim 1 does not impose any restriction as to the shape, the dimensions or any other property of the reservoir. It is merely a space, such as a cavity, within the body of the ophthalmic insert suitable for storing the medication.

In the ophthalmic insert disclosed in D5 the medication is stored in the pores which can be present in the

whole structure of the device or only in a portion of it. The board considers that a porous structure and a reservoir, in the form for instance of a cavity, would be regarded by a skilled person as suitable alternatives for the purpose of storing a medication. An example of the possibility of using a reservoir to store a medication in an ophthalmic insert is provided for instance by document D10 (see figure 12). Accordingly, the skilled person faced with the problem of providing a mere alternative to the device of D5 would regard it as a straightforward solution to introduce a cavity in this device in order to store the medication.

Claim 1 also requires the reservoir to be in fluid communication with the at least one pore of the collarette. This is however an obvious structural requirement since the function of the ophthalmic insert is to deliver the medication to the eye. Accordingly, the reservoir must be in connection with the pore(s) of the collarette in order to provide an outlet to the medication.

1.8 It follows from the above that the subject-matter of claim 1 does not involve an inventive step.

Auxiliary request I

2. Admittance into the appeal proceedings

Auxiliary request I was filed by the respondent on 13 February 2015 in reaction to the observations made by the board in the communication dated 28 January 2015, in particular with regard to the definition of the technical problem. The board regards

the filing of this request as a genuine attempt to address the issues raised in that communication.

Auxiliary request I is therefore admitted into the appeal proceedings (Article 13(1) RPBA).

3. Inventive step

3.1 Claim 1 of this request differs from claim 1 of the main request in the condition that the insert is formed of a material impermeable to the medication.

3.2 The respondent argued that in view of its impermeable structure the insert defined in claim 1 of this request could not release the medication into the canaliculus. The absence of this drawback represented an advantage over the device of D5.

3.3 However, as already discussed in point 1.3 above, there is no evidence supporting the allegation that the device of D5 suffers from the drawback of releasing part of the medication in the wrong direction, i.e. into the canaliculus. Moreover, this assumption would be against the teaching of D5 (see point 1.3 above).

In the absence of any effect over the device of D5 brought about by the selection of materials impermeable to the medication, the technical problem must be formulated as in point 1.6 above.

3.4 As discussed above, the skilled person starting from the disclosure of D5 would obviously consider the use of a reservoir instead of the medication-impregnable porous structure in order to store the medication. This choice would lead the skilled person to regard as suitable material for the ophthalmic insert not only the medication-impregnable HEMA, which is disclosed in

column 5 (lines 7 to 14) of D5 as preferred material for the porous parts of the device, but also other materials such as polytetrafluoroethylene, silicon, stainless steel and aluminium which are mentioned in column 4, lines 40 to 55. Document D5 indicates therefore that various materials not necessarily permeable to the medication can be used for construction of the ophthalmic insert.

3.5 On that basis the subject-matter of claim 1 of auxiliary request I does not involve an inventive step.

Auxiliary request II

4. Admittance into the appeal proceedings

4.1 Auxiliary request II was submitted during oral proceedings before the board on 3 March 2015.

Claim 1 of this request results from the combination of claims 1 and 13 of auxiliary request I. Claim 13 provides the condition that the at least one pore is constructed with a specific geometry appropriate to control the rate of release of the medication onto the eye.

4.2 Granted claim 1 and claim 1 of auxiliary request I already required the medication to be released onto the eye in a controlled manner. Hence, claim 1 of auxiliary request II does not impose any more specific condition with regard to the medication's release.

As to the feature requiring the pore to have a "specific geometry", this is so generic and vague that it cannot result in any relevant limitation to the subject-matter of claim 1.

It follows from the above that the amendments introduced in claim 1 of auxiliary request II have *prima facie* no impact on the assessment of inventive step.

4.3 Since the outstanding issues under Article 56 EPC are not adequately addressed, the board, having regard to the advanced state of the proceedings and the need for procedural economy, considers it appropriate not to admit auxiliary request II into the appeal proceedings (Article 13(1)(3) RPBA).

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chairman:

S. Fabiani J. Riolo

Decision electronically authenticated