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Datasheet for the decision of 10 June 2022

Case Number: T 1652/18 - 3.2.08

Application Number: 12180924.8

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IPC: A61F9/007

Language of the proceedings: EN

Title of invention:
Glaucoma treatment device

Patent Proprietor:
Alcon Inc.

Opponent:
Glaukos Corporation

Headword:

Relevant legal provisions:
EPC Art. 76(1), 100(c)

Keyword:
Divisional application - subject-matter extends beyond content of earlier application (yes)

Decisions cited:

Catchword:

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Beschwerdekammern

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Chambres de recours

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Case Number: T 1652/18 - 3.2.08

D E C I S I O N
of Technical Board of Appeal 3.2.08
of 10 June 2022

Appellant: (Patent Proprietor)	Alcon Inc. Rue Louis-d'Affry 6 1701 Fribourg (CH)
Representative:	Mathys & Squire The Shard 32 London Bridge Street London SE1 9SG (GB)
Appellant: (Opponent)	Glaukos Corporation 26061 Merit Circle Suite 101 Laguna Hills, CA 92653 (US)
Representative:	Hoffmann Eitle Patent- und Rechtsanwälte PartmbB Arabellastraße 30 81925 München (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 26 April 2018 concerning maintenance of the European Patent No. 2526910 in amended form.**

Composition of the Board:

Chairman	M. Foulger
Members:	A. Björklund
	E. Mille

Summary of Facts and Submissions

I. Appeals were filed by the patent proprietor (appellant I) and opponent (appellant II) against the interlocutory decision of the opposition division which found that, on the basis of auxiliary request 6 (then on file), the patent in suit met the requirements of the EPC.

In particular, the opposition division considered that the subject-matter of the claims of this request did not extend beyond the content of the earlier application as filed.

II. Oral proceedings were held before the Board on 10 June 2022.

III. Appellant I (patent proprietor) requested that the decision under appeal be set aside and that the patent be maintained as granted (main request) or alternatively on the basis of the set of claims of any of auxiliary requests 1, 2A to 10A, 2B to 10B filed with the statement setting out the grounds of appeal dated 5 September 2018 or of any of auxiliary requests C to E, 2C to 10C, 2D to 10D, 2E to 10E filed with letter of 29 January 2019.

Appellant II (opponent) requested that the decision under appeal be set aside and the patent be revoked, that auxiliary requests C to E, 2C to 10C, 2D to 10D, 2E to 10E not be admitted into the appeal proceedings.

The parties requests regarding the admittance of documents or objections are not relevant to the decision.

IV. Independent claim 1 of the main request (patent as granted) reads:

A An ocular implant system for reducing intraocular pressure in an eye, comprising:

B an ocular implant (105) comprising a proximal implant end (110), a distal implant end (120), and an internal lumen (305) having a proximal lumen end, a distal lumen end, the ocular implant (105) having a circular cross-sectional shape,

C wherein the ocular implant (105) is adapted for deployment in the eye such that the distal lumen end is in fluid communication with the suprachoroidal space and the proximal lumen end is in fluid communication with the anterior chamber when the ocular implant (105) is in a deployed location such that the internal lumen provides a fluid passageway for draining aqueous humor from the anterior chamber towards the suprachoroidal space;

D a delivery instrument (510) comprising a hand-held component (515) operatively coupled to an elongated applier (525),

E wherein the elongated applier (525) is adapted for deployment of the ocular implant (105) into the deployed location in the eye by inserting the ocular implant (105)_[sic] through the anterior chamber of the eye, and through a dissected tissue plane between the ciliary body and the sclera at a location proximate the scleral spur into the deployed location,

characterized in that:

F the ocular implant is characterized for deployment through a self-sealing corneal incision,

G and the elongated applier (525) having a diameter and cross-sectional shape configured to be inserted through the internal lumen (305) of the ocular implant (105) such that the elongated applier is removably coupled to the ocular implant (105),

H and such that a distal end of the applier (525) extends beyond the distal implant end

I and the elongated applier (525) is adapted for insertion of the ocular implant (105) through the self-sealing corneal incision into the anterior chamber of the eye."

Claim 1 of **auxiliary request C** differs from claim 1 of the main request in that feature E has been amended and the typing error removed. It will be designated feature E1 and reads:

"wherein the elongated applier (525) is adapted for deployment of the ocular implant (105) into the deployed location in the eye by inserting the ocular implant (105) through the anterior chamber of the eye, through the scleral spur and through a dissected tissue plane between the ciliary body and the sclera at a location proximate the scleral spur into the deployed location,"

Claim 1 of **auxiliary request D** differs from claim 1 of the main request in that feature E has been amended and the typing error removed. It will be designated feature E2 and reads:

"wherein the elongated applier (525) is adapted for deployment of the ocular implant (105) into the deployed location in the eye by inserting the ocular implant (105) through the anterior chamber of the eye, and through a dissected tissue plane between the ciliary body and the sclera at a location proximate the scleral spur and through a dissected tissue plane between the choroid and the sclera into the deployed location,"

Claim 1 of **auxiliary request E** differs from claim 1 of the main request in that feature J has been added at the end of the claim. It reads:

",
the delivery instrument including an actuator that removes the implant from the applier"

Claim 1 of **auxiliary request 1** differs from claim 1 of the main request in that feature F has been amended. It will be designated feature F1 and reads:

"the ocular implant is characterized for deployment through a self-sealing corneal incision no greater than 2.85mm,"

Claim 1 of **auxiliary request 2A** differs from claim 1 of the main request in that feature K has been added at the end of the claim. It reads:

"; and
wherein the elongated applier (525) is curved along a portion of its length."

Claim 1 of **auxiliary request 3A** differs from claim 1 of auxiliary request 2A in that feature K has been amended. It will be designated K1 and reads:

"; and
wherein the elongated applier (525) ~~is curved~~ has a pre-shaped curvature along a portion of its length."

Claim 1 of **auxiliary request 4A** differs from claim 1 of auxiliary request 2A in that feature K has been amended. It will be designated K2 and reads:

"; and wherein:
the elongated applier (525) is curved along a portion of its length such that the radius of curvature complements the curved contour of the dissected tissue plane."

Claim 1 of **auxiliary request 5A** differs from claim 1 of auxiliary request 4A in that feature K2 has been amended. It will be designated K3 and reads:

; and wherein:
the distal portion of the elongated applier (525) is curved ~~along a portion of its length~~ such that the radius of curvature complements the curved contour of the dissected tissue plane.

Claim 1 of **auxiliary request 6A** differs from claim 1 of auxiliary request 2A in that feature K has been amended. It will be designated K4 and reads:

"; and
wherein the elongated applier (525) is curved along a portion of its length and wherein the radius of

curvature varies moving along the length of the applier."

Claim 1 of **auxiliary request 7A** differs from claim 1 of auxiliary request 6A in that feature K4 has been amended. It will be designated K5 and reads:

"; and
wherein the elongated applier (525) ~~is curved~~ has a pre-shaped curvature along a portion of its length and wherein the radius of the pre-shaped curvature varies moving along the length of the applier."

Claim 1 of **auxiliary request 8A** differs from claim 1 of the main request in that feature L has been added at the end of the claim. It reads:

"; and
wherein the ocular implant (105) has a curvature that matches a curvature of the eye."

Claim 1 of **auxiliary request 9A** differs from claim 1 of the main request in that feature Fa has been added between features F and G. It reads:

"the ocular implant (105) has a radius of curvature that conforms to the radius of curvature of the suprachoroidal space, "

Claim 1 of **auxiliary request 10A** differs from claim 1 of the main request in that feature M has been added at the end of the claim. It reads:

"; and

wherein the elongated applier (525) has a blunt distal tip for performing blunt dissection."

Claim 1 of **auxiliary requests 2B to 10B** differ from claim 1 of auxiliary requests 2A to 10A, respectively, in that feature F1 has been substituted for feature F.

Claim 1 of **auxiliary request 2C to 10C** differs from claim 1 of auxiliary requests 2A to 10A, respectively, in that feature E1 has been substituted for feature E.

Claim 1 of **auxiliary request 2D to 10D** differs from claim 1 of auxiliary requests 2A to 10A, respectively, in that feature E2 has been substituted for feature E.

Claim 1 of **auxiliary requests 2E to 8E and 10E** differs from claim 1 of auxiliary requests 2A to 8A and 10A, respectively, in that feature J has been inserted after feature I and before features K to K5, L and M, respectively.

Claim 1 of **auxiliary request 9E** differs from claim 1 of auxiliary request 9A in that feature J has been added at the end.

V. Appellant I's (patent proprietor's) arguments as far as relevant to the decision can be summarised as follows:

The method of insertion of a sharp tipped applier and implant disclosed in the earlier application as filed was irrelevant. The decisive question was whether the earlier application disclosed an applier adapted for inserting the ocular implant through a dissected tissue plane between the ciliary body and the sclera at a location proximate the scleral spur as required by feature E.

Such an applier was disclosed in Figures 17, 20 and 21. Furthermore, an applier adapted for peeling the sclera from the choroid as literally described was also adapted for such an insertion. In particular since appliers with different kinds of blunt tips were disclosed and these could not be inserted through the ciliary body without significant trauma.

The patent as granted, and the auxiliary requests, did thus not extend beyond the content of the earlier application as filed.

VI. Appellant II's (opponent's) arguments as far as relevant to the decision can be summarised as follows:

The earlier application as filed only disclosed insertions of the applier and implant through the ciliary body, not through a dissected tissue plane between the ciliary body and the sclera. The description was clear on this point and Figures 17, 20 and 21 did not show the insertion path in detail.

Furthermore, also the appliers with blunt tips were disclosed as penetrating through the ciliary body. Therefore, an applier according to feature E was not disclosed in the earlier application as filed. The amendments in the auxiliary requests did not overcome this issue.

Reasons for the Decision

1. Articles 100(c) and 76(1) EPC - Extension beyond the content of the earlier application as filed

1.1 The subject-matter of claim 1 of all requests on file extends beyond the content of the earlier application as filed contrary to the requirements of Article 76(1) EPC.

1.2 Features E, E1 and E2 require that the applier is adapted for deployment of the ocular implant through a dissected tissue plane between the ciliary body and the sclera at a location proximate the scleral spur into the deployed location.

It is not disputed that such an applier is not literally disclosed in the earlier application as filed.

Such an applier is also not disclosed in the figures of the earlier application as filed, nor is it implicitly disclosed.

1.3 Appellant I submitted that even if the earlier application as filed described one method of insertion where an inserter with a sharpened tip (page 32, lines 2 to 6) passed through the ciliary body (page 32,lines 22 to 23), the insertion path disclosed in the earlier application as filed was not relevant. This path depended upon the user and additionally going through the ciliary body to the suprachoroidal space was more difficult than going through the dissected tissue plane between the ciliary body and the sclera. The decisive issue was whether the earlier application as filed disclosed an applier adapted for an insertion according to feature E.

Such an applier was disclosed in Figures 17, 20 and 21 of the earlier application as filed. These figures showed the applier and the implant when inserted. The

skilled person knew the anatomy of the eye and its tissues. They thus knew that the ciliary muscle - part of the ciliary body - and the choroid interfaced with the sclera in a dissected tissue plane. Figures 17 and 21 showed a gap at the point SS (suprachoroidal space) which was a dissection of the tissue plane between the ciliary muscle and the sclera. The gap was at the height of the transition between the ciliary muscle, closer to the scleral spur, and the choroid further along the insertion path. The figures showed the sclera on one side of the applier or implant and the ciliary muscle on the other side the applier or implant. Figures 17, 20 and 21 thus clearly showed that both the applier and the implant were inserted in the tissue plane between the ciliary body and the sclera.

Furthermore, an applier which was adapted to to peel away or otherwise separate the sclera from the choroid (page 32, lines 22 to 23) was also adapted to pass the dissected tissue plane between the ciliary body and the sclera. It was disclosed that the applier could have an atraumatic or blunt distal tip performing blunt dissection rather than cutting (page 18, lines 27 to 29) and that the tip could have a flat, shovel or spade shape (page 21, lines 27 to 29). A spade shape or blunt end was disclosed to facilitate the creation of a dissection plane (page 33, lines 1 to 4). Appliers with such tips were adapted for an insertion in a dissected tissue plane between the ciliary body and the sclera and would cause significant trauma if passing through the ciliary body.

An applier for an insertion according to feature E was thus disclosed in the earlier application as filed. In particular in combination with a blunt end for

performing blunt dissection as defined in auxiliary request 10A.

1.4 However, appellant I's submission that both Figures 17 and 21 showed the applier and implant as they had been inserted in a dissected tissue plane between the ciliary body and the sclera is not convincing. The figures are schematic and it is thus not possible to deduce the insertion paths in relation to the various eye tissues from the figures alone.

Furthermore, the description contradicts appellant I's argument regarding the insertion path shown in the figures. As pointed out by appellant II, the earlier application as filed describes that the applier penetrates the scleral spur (page 32, lines 1 to 2) and that it is continuously advanced via the ciliary body (page 32, lines 11 to 12). It is also described that one method of approach is to advance the applier through the ciliary body (page 32, lines 22 to 23). Appellant I's assertion that an insertion through the ciliary body would be difficult and that the insertion instead would be made through the dissecting tissue plane between the sclera and the ciliary body is thus not convincing. The description concerning Figure 21 (page 34, lines 18 to 23) declares that the applier and/or the shunt (implant) penetrates tissue and forms a tunnel through the tissue, initially the ciliary body. Figure 21 is thus described as showing an implant which has been inserted through the ciliary body and not through a dissected tissue plane between the ciliary body and the sclera. This directly contradicts appellant I's assertion that Figure 21 shows an implant as inserted in a dissected tissue plane between the ciliary body and the sclera. None of the cited passages are explicitly stated to describe how the applier

reached the position in Figure 17. But in view of the contradictions between the description and Figure 21, the very similar Figure 17, which shows the applier instead of the implant, is also not a direct and unambiguous disclosure that the applier has been inserted through a dissected tissue plane between the ciliary body and the sclera. Consequently, Figures 17, 20 and 21 do not disclose an applier adapted for such an insertion.

Appellant I is correct in that various passages of the earlier application as filed describe that the distal end or tip of the applier can be blunt, atraumatic, spade or shovel shaped instead of sharp. But none of the cited passages relating to these tips describe that they make the applier adapted for passing through a dissected tissue plane between the ciliary body and the sclera. It is disclosed that the applier can peel away the sclera from the choroid (page 32, lines 19 to 21) and that the applier can have a spade shape or a blunt end configured to facilitate creating a dissection plane between the choroid and the sclera (page 33, lines 1 to 4). The latter disclosure is however made in the paragraph bridging pages 32 and 33 in conjunction with the distal tip of the applier passing through the ciliary body (page 32, lines 27 to 28). This contradicts appellant I's assertion that a blunt tip was adapted to pass the dissected tissue plane between the ciliary body and the sclera but could not pass through the ciliary body without creating significant trauma. Additionally, appellant I has not substantiated their assertion that a tip adapted for peeling the sclera from the choroid also is able to pass the dissected tissue plane between the sclera and the choroid body.

1.5 An applier adapted for inserting the ocular implant through a dissected tissue plane between the ciliary body and the sclera at a location proximate the scleral spur into the deployed location is thus not directly and unambiguously disclosed in the earlier application as filed when considered in its entirety. This notwithstanding the fact that appliers with various tip geometries including blunt tips are disclosed.

1.6 It follows that feature E of claim 1 of the main request extends beyond the content of the earlier application as filed contrary to the requirements of Article 76(1) EPC.

The ground for opposition under Article 100(c) EPC thus prejudices the maintenance of the patent as granted.

1.7 The amendments made in features E1 and E2 do not overcome this issue and consequently the extension beyond the content of the earlier application as filed is present also in these features.

Since claim 1 of all auxiliary requests on file includes one of the features E, E1 or E2, they also do not fulfil the requirements of Article 76(1) EPC.

2. The question as to whether auxiliary requests C to E, 2C to 10C, 2E to 10E are admitted into the proceedings or not is therefore irrelevant to the outcome of the proceedings and may be left undecided.

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:

C. Spira M. Foulger

Decision electronically authenticated