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Datasheet for the decision of 15 January 2015

Case Number: T 2511/12 - 3.2.08

Application Number: 08102896.1

Publication Number: 1977724

IPC: A61F9/00, A61F9/007

Language of the proceedings: EN

Title of invention:
System for treating ocular disorders

Applicant:
Glaukos Corporation

Headword:

Relevant legal provisions:
EPC Art. 76(1)

Keyword:
Divisional application - added subject-matter (yes)

Decisions cited:
G 0010/93, G 0001/06

Catchword:

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Case Number: T 2511/12 - 3.2.08

D E C I S I O N
of Technical Board of Appeal 3.2.08
of 15 January 2015

Appellant: (Applicant)	Glaukos Corporation 26051 Merit Circle Suite 103 Laguna Hills, CA 92653 (US)
Representative:	Maiwald Patentanwalts GmbH Elisenhof Elisenstrasse 3 80335 München (DE)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 2 July 2012 refusing European patent application No. 08102896.1 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman	T. Kriner
Members:	C. Herberhold
	D. T. Keeling

Summary of Facts and Submissions

I. By its decision posted on 2 July 2012 the Examining Division refused European Patent application No. 08102896.1.

II. The appellant (applicant) lodged an appeal against that decision in the prescribed form and within the prescribed time limit.

III. In accordance with the appellant's request, the Board issued a summons for oral proceedings. In the accompanying communication under Article 15(1) RPBA dated 8 May 2014, item 3, it was explained (among others) that there were reasons to believe that the requirements of Article 76(1) EPC were not met and that - in accordance with G 10/93 (OJ EPO 1995, 172) - said ground was to be included in the proceedings.

IV. Oral proceedings before the Board of Appeal were held on 15 January 2015.

At the end of the oral proceedings the appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the claims of the Main Request or, in the alternative, on the basis of one of Auxiliary Requests 1-3, all submitted on 15 December 2014.

V. Claim 1 of the **Main Request** reads as follows (emphasis, also in the following requests, by the Board):

"A system for treating an ocular disorder, comprising **an implant being adapted for allowing aqueous humor to flow from an anterior chamber of a human eye into a uveal scleral outflow**;

the implant comprising **a hollow, elongate tubular element** having an inlet section and an outlet section; a lumen extending between the inlet section and the outlet section and communicating with inlet and outlet ports, the implant sized for a uveal scleral outflow of the eye; and
a delivery device carrying the implant and comprising a handpiece, an elongate tip, a holder and an actuator, the elongate tip having a distal portion made of flexible material or being curved, the delivery device being configured to advance the implant from within the anterior chamber using an ab interno procedure, the delivery device holding the implant with the outlet section leading the inlet section."

Claim 1 of **Auxiliary Request 1** reads as follows:

"A system for treating an ocular disorder, comprising **an implant being adapted for allowing aqueous humor to flow from an anterior chamber of a human eye into a uveal scleral outflow;**
the implant comprising **a hollow, elongate tubular element** having an inlet section and an outlet section; a lumen extending between the inlet section and the outlet section;
and
a delivery device carrying the implant and comprising a handpiece, an elongate tip, a holder and an actuator, the elongate tip having a distal portion being curved, the delivery device being configured to advance the implant from within the anterior chamber using an ab interno procedure, the delivery device holding the implant with the outlet section leading the inlet section."

Claim 1 of **Auxiliary Request 2** reads as follows:

"A system for treating an ocular disorder, comprising **a glaucoma shunt or stent for reducing the intraocular pressure in a human eye, by permitting aqueous outflow from an anterior chamber of an eye through uveal scleral outflow**, the glaucoma shunt or stent comprising **a hollow, elongate tubular member** having an inlet section and an outlet section; and
a delivery device carrying the glaucoma shunt or stent and comprising a handpiece, an elongate tip, a holder and an actuator, the elongate tip having a distal portion being curved, the delivery device being configured to advance the glaucoma shunt or stent from within the anterior chamber using an ab interno procedure, the delivery device holding the glaucoma shunt or stent with the outlet section leading the inlet section, the handpiece comprising a spring that is configured to be loaded when the stent is being held by the holder, the spring being at least partially unloaded upon actuating the actuator, allowing for release of the stent."

Claim 1 of **Auxiliary Request 3** reads as follows:

"A system for treating an ocular disorder, comprising **a glaucoma shunt or stent for reducing the intraocular pressure in a human eye, by permitting aqueous outflow from an anterior chamber of an eye through uveal scleral outflow**, the glaucoma shunt or stent comprising **a hollow, elongate tubular member** having an inlet section and an outlet section;
and
a delivery device carrying the glaucoma shunt or stent and comprising push-pull type plunger, the delivery device further comprising a handpiece, an elongate tip and an actuator, the elongate tip having a distal

portion being curved, the delivery device being configured to advance the glaucoma shunt or stent from within the anterior chamber using an ab interno procedure the delivery device holding the glaucoma shunt or stent with the outlet section leading the inlet section."

VI. The following documents played a role for the present decision:

Parent application: WO-A-02/080811;
GK1:"The Glaucomas", textbook of R. Ritch et al., second ed., 1996, Chapter 15;
GK2: "Textbook of Glaucoma", textbook of M. B. Shields, M.D., 4th ed., 1997, Chapter 2 "Aqueous humor dynamics";
GK3: "Diagnosis and Therapy of the Glaucomas", textbook of H. D. Hoskins, M. A. Kass, 6th ed., 1989, Chapter 4 "Aqueous humor outflow";
GK5: H. Davson (ed), "The Eye", 3rd edition, 1984, Volume IA, page 296: "Uveoscleral Drainage";
GK6: A. Bill, "Blood Circulation and Fluid Dynamics in the Eye", Physiological Reviews, Vo. 55, No. 3, July 1975, pp. 383-417.

VII. The essential arguments of the appellant can be summarised as follows:

Article 76(1) EPC

As disclosed on page 4, lines 13-20 of the parent application, the main idea of the invention was to bypass the focal resistance to outflow of aqueous only at the point of resistance and to utilize the remaining, healthy aqueous outflow mechanisms downstream. In this context, the cited passage

explicitly mentioned shunts for uveal scleral outflow. As supported by GK1, GK2, GK5 and GK6, the person skilled in the art was well aware of uveoscleral outflow as being aqueous outflow from the anterior chamber through the intramuscular spaces of the ciliary muscle into the supraciliary-suprachoroidal space and out through the substance of the sclera. The person skilled in the art would realize that the problematic tissue to bypass in uveoscleral outflow was the trabecular meshwork of the ciliary muscle and that a bypass stent would thus need to extend into the supraciliary-suprachoroidal space. Such a bypass connection was shown in the embodiment of Figure 43, which according to the description page 26, lines 11-17 illustrated a stent providing a channel for flow between the anterior chamber and the vascular choroid. It was evident for the skilled person, that the outflow mechanism shown in said embodiment was uveoscleral outflow, which implied flow through the supraciliary space. In this context, Figure 43 clearly showed the stent to be positioned in the choroid. While it was true that said stent was described to include a valve or a constriction, the interior of the claimed tube in itself had to be seen as providing a constriction, such that there was no need to explicitly define a constriction or valve in the claims.

Consequently, the earlier application disclosed an implant as claimed and the requirements of Article 76(1) were thus fulfilled.

Reasons for the Decision

1. The appeal is admissible

2. Main Request, Article 76(1) EPC

2.1 Power to examine the requirements of Article 76(1) EPC

In its decision refusing the present patent application, the Examining Division held that the requirements of Article 76(1) EPC were fulfilled. Nevertheless, in accordance with G10/93, the Board of Appeal has the power to examine whether the application or the invention to which it relates meets the requirements of the EPC, including requirements which the Examining Division regarded as having been met.

2.2 The present application has been filed as a divisional of EP application 02728720.0, which originates from international application WO 02/080811.

Article 76(1) stipulates that a divisional application may be filed only in respect of subject-matter which does not extend beyond the content of the earlier application as filed. As pointed out in G1/06 (OJ 2008, 307, HN) in order to comply with said requirement, anything disclosed in the divisional application needs to be directly and unambiguously derivable from what is disclosed in the preceding application as filed, as determined by the totality of its claims, description and drawings when read in context (Case Law of the Boards of Appeal of the EPO, 7th edition, II.F.1.1.1).

In this respect, the appellant has argued that the subject-matter claimed was disclosed by the description of the earlier application, page 4, lines 15 to 20 in conjunction with the embodiment shown in Figure 43 and further described on page 26, lines 11 to 17.

2.3 It was not contested at the oral proceedings that neither the subject-matter claimed in the earlier application as originally filed, nor the implants shown in any of the other specific embodiments (i.e. apart from the embodiment shown in Figure 43) relate to an implant comprising a hollow elongate tubular element and being adapted for allowing aqueous humour to flow from an anterior chamber of a human eye into a uveal scleral outflow path. This is because the embodiment shown in Figure 44 does not show a tubular structure but an osmotic membrane and the outlet of all further other embodiments - again with the exception of the Figure 43 embodiment - resides in Schlemm's canal (labelled No. 22 in the respective drawings) or in one of the collector channels (labelled No. 29 in Figure 41 and 42) directly draining Schlemm's canal, structures belonging to the major outflow route as defined on page 1, lines 18 to 26 of the earlier application. None of those other embodiments is thus adapted for uveoscleral outflow (the "minor route", see page 1, line 26 of the earlier application). Also the claims as originally filed explicitly define the outlet end of the elongated tubular member to reside in Schlemm's canal, i.e. they also relate to shunts for aqueous humour to exit through the major route.

Thus, contrary to the Examining Division's opinion (point 1 of the reasons), there is no basis in the earlier application as filed for combining the features of claim 1 of said earlier application with the feature defining the implant as sized or adapted for uveal scleral outflow, i.e. for the minor outflow route.

2.4 With respect to the embodiment relied on by the appellant, which is shown in Figure 43 and further described on page 26, lines 11-17, there is no

disclosure linking this embodiment to uveal scleral outflow. In fact, the sentence on page 4, lines 15-17 - which is the only possible link between uveal scleral outflow and the invention - just states in a very general way, that "various embodiments of glaucoma shunts were disclosed herein for aqueous to exit through the trabecular meshwork (major route) or uveal scleral outflow (minor route) or other route effective to reduce intraocular pressure (IOP)." There is no clear and unambiguous assignment between a particular outflow route and a particular embodiment.
Even if one assumed in the appellant's favour that the skilled person would recognise that - with all other embodiments being for aqueous outflow through the major route - only the embodiments shown in Figures 43 and 44 (which however shows a membrane and not a tubular element) were potential candidates for uveal scleral outflow, an ambiguity would remain because the sentence mentions "uveal scleral outflow" but also "other routes effective to reduce intraocular pressure", without specifying which applies to which embodiment.

2.5 Furthermore, again with respect to the embodiment shown in Figure 43, it is noted that the tissue into which the stent No. 30r is shown to be implanted is not the choroid. As discussed during the oral proceedings, according to the standard definition in the field, the choroid is defined as "the thin, pigmented vascular coat of the eye extending from the *ora serrata* to the optic nerve" (see any medical dictionary, Dorland's Illustrated Medical Dictionary, 29th edition, 2000, being mentioned here merely as an example). The *ora serrata* - and thus the tissue normally referred to as the choroid - is located posterior (i.e. further towards the optic nerve) to the ciliary body, i.e. posterior to the implantation site shown in the

drawing. There is thus an inconsistency between what is shown in Figure 43 and the respective part of the description.

2.6 Even if one assumed that the person skilled in the art would understand that - within the present application- the term choroid was to be given a broader meaning, such as to include the tissue at the scleral basis of the ciliary body, still it cannot be clearly and unambiguously derived that the stent shown in Figure 43 was adapted for uveal scleral outflow. The drawing shows the outflow end of the shunt to be angled away from the interface between said tissue and the sclera and thus away from the supraciliary-suprachoroidal space. Assuming in the appellant's favour that the person skilled in the art was aware of uveal scleral outflow as being through the supraciliary-suprachoroidal space (for the anatomy refer e.g. to GK6, page 406, Fig. 3), for such outflow to be facilitated, the skilled person would expect the outlet to be directed into or at least towards the supraciliary-suprachoroidal space, contrary to what is shown in the drawing.

Instead, the corresponding description refers to the provision of a channel for flow between the anterior chamber and the highly vascular choroid. As can be seen from GK2, page 7, Figure 2.3, the implant when positioned as shown in Figure 43 of the application indeed points towards a highly vascular area close to the major arterial circle. This might well suggest to the skilled person that said implant was for outflow through "[an]other route effective to reduce intraocular pressure" (as defined in the passage on page 4, lines 13-17 of the earlier application), such as e.g. through uveovortex outflow, with aqueous humour

penetrating the vessels of the iris, the ciliary muscle and the anterior choroid by vesicular transport to eventually reach the vortex veins (an outflow mechanism equally known to the person skilled in the art, see GK 2, page 21, "uveovortex outflow").

Thus the embodiment of Figure 43 is not clearly and unambiguously disclosed as being adapted for uveoscleral outflow.

2.7 Finally, the Board notes that the Figure 43 stent is explicitly disclosed to "include a valve with an opening pressure equal to the desired pressure difference between the choroid 17 and the anterior chamber 10 or a constriction that provide the desired pressure drop" (page 26, line 14-17). The valve or constriction has an essential functionality for the tube stent device, because it will prevent ocular hypotony in the event that the pressure level in the tissue around the outlet end is lower than desired for the eye. Due to this explicitly mentioned essential functionality, the features of the stent being a hollow elongate tubular element and the presence of a valve or constriction are inextricably linked. Contrary to the appellant's belief, a tube *per se* does not qualify as a tube including a constriction. Otherwise mentioning the constriction would be superfluous. The omission of the essential characteristic of a valve or constriction from the disclosure of the Figure 43 embodiment thus results in an unallowable intermediate generalization.

2.8 To summarize, for all the reasons given above, the subject-matter 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.

3. Auxiliary Requests 1-3

The above reasoning applies uncontestedly *mutatis mutandis* to the subject-matter of claim 1 of Auxiliary Requests 1-3 which all combine the structural feature of a hollow, elongate tubular element or member being adapted for allowing or permitting aqueous humor to flow from an anterior chamber of a human eye into a uveal scleral outflow or through uveal scleral outflow.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

V. Commare T. Kriner

Decision electronically authenticated