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Datasheet for the decision of 2 September 2009

Case Number: T 1000/06 - 3.2.02

Application Number: 01920265.4

Publication Number: 1263364

IPC: A61F 9/007

Language of the proceedings: EN

Title of invention:
Sutureless ocular surgical methods and instruments

Applicant:
JOHNS HOPKINS UNIVERSITY

Opponent:
-

Headword:
-

Relevant legal provisions:
-

Relevant legal provisions (EPC 1973):
EPC Art. 52(1), 54, 56

Keyword:
"Novelty (no)"
"Inventive step (third and fourth auxiliary requests) (no)"

Decisions cited:
-

Catchword:
-

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Case Number: T 1000/06 - 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 2 September 2009

Appellant: JOHNS HOPKINS UNIVERSITY
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Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 23 December 2005 refusing European application No. 01920265.4 pursuant to Article 97(1) EPC 1973.**

Composition of the Board:

Chairman: S. Chowdhury
Members: D. Valle
A. Pignatelli

Summary of Facts and Submissions

I. This appeal is against the decision of the examining division dated 23 December 2005 to refuse European patent application No. 01 920 265.4.

The grounds of refusal were that claim 1 of each of the main request and the first and second auxiliary requests was not clear, the subject-matter of claim 1 of the second auxiliary request was also not novel, and claim 1 of each of the third and fourth auxiliary requests did not involve an inventive step. The following documents were cited:

D1: WO 97/47247
D2: US-A-5 807 244
S1: US-A-5 487 725
S8: US-A-3 659 607

II. On 16 February 2006 the appellant lodged an appeal against the decision and paid the prescribed fee on the same day. On 2 May 2006 a statement of grounds of appeal was filed.

III. The appellant requests that the decision be set aside and a patent be granted on the basis of the claims 1 to 26 filed with its letter dated 20 April 2005. As auxiliary requests the appellant requests that a patent be granted on the basis of the auxiliary requests 1 to 4 filed with its letter dated 28 October 2005.

Following a communication from the Board accompanying an invitation to attend oral proceedings, the appellant

withdrew its request for oral proceedings and requested a decision based on the state of the file.

IV. Claim 1 of the main request reads as follows:

"A device kit including at least one entry alignment device (100a-100g) that is configured for insertion into an eye (2) and so as to provide a through aperture in each of the conjunctiva (4) and sclera (6) of the eye (2) and to maintain the through aperture formed in each of the conjunctiva (4) and sclera (6) aligned during a surgical procedure; and wherein a cross-section of the entry alignment device (100a-100g) is sized such that when the entry alignment device is removed from the eye (2), the through aperture formed in the sclera (6) is sealed without the use of sutures".

Claims 2 to 26 are dependent claims.

Claim 1 of the first auxiliary request additionally specifies that the alignment device is sized such that the through aperture formed in the sclera is self-sealing.

Claim 1 of the second auxiliary request additionally specifies that the cross-section of the device is 22 gauge or less.

Claim 1 of the third auxiliary request additionally specifies that the alignment device comprises an insertion member and a stop member, the insertion member having an outer diameter of about 22-24 gauge.

Claim 1 of the fourth auxiliary request additionally specifies that the alignment device comprises an insertion member and a stop member, the insertion member being made from polyimide and having an outer diameter of about 23-24 gauge, or the insertion member being made from stainless steel and having an outer diameter of about 22-23 gauge.

Reasons for the Decision

1. The appeal is admissible.

2. Scope of claim 1 - main request

Claim 1 relates to a device kit including at least one entry alignment device. Although the term "kit" implies a collection of instruments to be used together, claim 1 defines only an entry alignment device intended to provide an aperture in the eye through which surgical instruments may be passed, but no further surgical instruments forming part of the kit.

The entry alignment device is configured for insertion into an eye so as to provide a through aperture in each of the conjunctiva and sclera of the eye and to maintain the through aperture formed in each of the conjunctiva and sclera aligned during a surgical procedure. Expressed more simply, this is a needle-like device for insertion into the eye for forming an aperture through the conjunctiva and sclera.

The cross-section of the entry alignment device is sized such that when the entry alignment device is

removed from the eye, the through-aperture formed in the sclera is sealed without the use of sutures. This feature states that the diameter of the device must be so small that, upon removal thereof from the eye, the aperture through the sclera can be sealed without the use of sutures. An example is given of the largest permissible outer diameter of about 23-24 gauge (page 16, lines 18 to 21 of WO 01/68016). This is presumably with respect to the human eye since the application does not touch on this (see point 3 below) and the appellant, in the grounds of appeal, mentions the use of the device with the human eye.

3. Novelty - main request

D1 discloses a device kit including at least one surgical sealing sleeve 1 which is suitable to act as an entry alignment device in that it is suitable for insertion into an eye so as to provide a through aperture in each of the conjunctiva and sclera of the eye and to maintain the through aperture formed in each of the conjunctiva and sclera aligned during a surgical procedure.

Moreover, the sleeve of D1 has a diameter such that upon removal thereof from the eye, the aperture through the sclera can be sealed without the use of sutures. The appellant argues that the prior art surgical instrument of document D1 would not be suitable for the present purpose (self-sealing of the sclera) because it is too large in diameter for the human eye (1-1.5 mm or 17 to 20 gauge, D1: page 3, lines 8 to 12). This argument is not relevant because claim 1 is not limited

to a device for use with humans. In fact the entire application does not contain such a restriction.

For large mammals much larger diameters of the device, compared to the 23-24 gauge used in the application, would provide a through aperture in each of the conjunctiva and sclera and yet be small enough so that, upon removal thereof from the eye, the aperture through the sclera would seal without the use of sutures. The diameter of the D1 device is such that it would perform as required by claim 1 in an elephant, for example.

The device of claim 1 lacks novelty in view of D1, accordingly.

3.1 S1 discloses a surgical instrument 10 (Figure 1A) for the eye, having an elongate probe 12 including an outer tube 14 and an inner 20 tube slidable in the outer tube. The tube 20 has a cutting edge 26 and suction can be applied through it. Figure 5 shows the instrument inserted through the sclera S. Figure 11 shows a probe 202 and a cannula 240 for gas passage and having a size of 20 to 30 gauge (S1: column 10, lines 35 to 39).

Therefore, S1 also demonstrates the lack of novelty of the claimed device.

4. Novelty - auxiliary requests

4.1 The above arguments regarding the novelty of the subject-matter of claim 1 of the main request also apply to claim 1 of the first and second auxiliary requests because S1 discloses a probe size of less than 23 gauge.

4.2 S1 does not disclose the material of the probe or a stop member, so the subject-matter of claim 1 of the third and fourth auxiliary requests is novel.

5. Inventive step

Claim 1 of the third auxiliary request additionally specifies that the alignment device comprises an insertion member and a stop member, the insertion member having an outer diameter of about 22-24 gauge, and claim 1 of the fourth auxiliary request additionally specifies that the alignment device comprises an insertion member and a stop member, the insertion member being made from polyimide and having an outer diameter of about 23-24 gauge, or the insertion member being made from stainless steel and having an outer diameter of about 22-23 gauge.

Regarding the diameter of the insertion member, the claimed range overlaps with the range disclosed in S1 and close to the preferred diameter of S1 (S1: claims 2 and 12) so that diameter is not a distinguishing feature. Moreover, it is obvious to provide a stop member to ensure that the device does not fully enter into the eye, and this is also routinely provided, see D1, Figure 4. Therefore, the provision of a stop member does not involve an inventive step.

As regards the materials polyimide and stainless steel, these are well known materials in the art and their use in the present context brings no unexpected advantage, for which reason they do not involve an inventive step.

For these reasons the subject-matter of claim 1 of the third and fourth auxiliary requests does not involve an inventive step.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar | The Chairman

D. Sauter | S. Chowdhury