Internal distribution code:

(A) [-] Publication in OJ
(B) [-] To Chairmen and Members
(C) [-] To Chairmen
(D) [X] No distribution

Datasheet for the decision of 25 March 2021

Case Number: T 2592/17 - 3.2.08

Application Number: 09795867.2

Publication Number: 2379031

IPC: A61F9/007, A61M1/00

Language of the proceedings: EN

Title of invention:
SYSTEM TO IDENTIFY VISCOSITY OF ASPIRATED MATERIAL DURING OPHTHALMIC SURGERY

Applicant:
Bausch & Lomb Incorporated

Relevant legal provisions:
EPC Art. 54(2), 56

Keyword:
Novelty - (yes)
Inventive step - (yes)

Europäisches Patentamt
European Patent Office
Office européen des brevets

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 2592/17 - 3.2.08

D E C I S I O N
of Technical Board of Appeal 3.2.08
of 25 March 2021

Appellant: (Applicant)	Bausch & Lomb Incorporated One Bausch & Lomb Place Rochester, NY 14604-2701 (US)
Representative:	Vossius & Partner Patentanwälte Rechtsanwälte mbB Siebertstrasse 3 81675 München (DE)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 27 June 2017 refusing European patent application No. 09795867.2 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairwoman	P. Acton
Members:	G. Buchmann
	Y. Podbielski

Summary of Facts and Submissions

I. With decision posted on 27 June 2017, the examining division refused European patent application No. 09 795 867.2.

The examining division held that the subject-matter of claim 1 according to the main request lacked novelty with regard to document D1.

II. The applicant filed an appeal against that decision.

III. The appellant (applicant) requested that the decision under appeal be set aside and a patent be granted on the basis of the main request filed with letter dated 20 October 2017, which corresponds to the main request on which the decision of the examining division was based.

IV. In the present decision, reference is made to the following documents which were cited in the International Search Report as being relevant in view of claim 1 of the application:

D1 US 2008208207 A1
D3 WO 0226016 A2

V. Claim 1 of the main request reads as follows.

The amendments compared to claim 1 as originally filed are indicated.

"An ophthalmic surgical system for detecting a change in a viscosity of a material being aspirated from an eye, comprising:

at least a control module connected to an aspiration pump, and a flow meter connected to the control module and the aspiration pump, the flow meter for providing a flow rate of material aspirated from the eye by the aspiration pump;
a surgical handpiece connected to the aspiration pump and the control module to be inserted into the eye during surgery; and
wherein the control module is configured to detect during surgery ~~detects~~ a step change in the flow rate of material aspirated from the eye and upon detecting said step change the control module further causes the surgical system to alert a surgeon that a change in viscosity of the material being aspirated has been detected indicating that the handpiece has moved from a material of a first viscosity to a material of a second viscosity."

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

D1 did not disclose a system wherein a step change of the aspirated fluid flow rate was used to determine a change in viscosity of the fluid.

D1 determined the media type being aspirated using several parameters (fluid flow, pressure, operation and configuration of the instrument). D1 did not measure a step change of the fluid flow, but calculated, using the mentioned parameters, the location of the fluid in a particular region of a diagram.

The system of D1 was dependent on the measurement of several parameters whereas the claimed system exclusively used a step change of a single parameter.

The system of D1 did not detect the movement of the handpiece between vitreous and BSS, but it detected which type of medium was currently aspirated.

Therefore, the subject-matter of claim 1 was novel and inventive.

Reasons for the Decision

1. **Main Request - Novelty - Article 54(2) EPC**

1.1 The examining division had decided that the subject-matter of claim 1 lacked novelty over the disclosure of D1.

1.2 D1 discloses (see paragraphs [0022]-[0026]) an ophthalmic surgical system for characterising a medium by detecting the viscosity of a material being aspirated from an eye, comprising:

- at least a control module (150) connected to an aspiration pump (vacuum generator 165), and a flow meter (175) connected to the control module and the aspiration pump, the flow meter for providing a flow rate of material aspirated from the eye by the aspiration pump;

- and a surgical handpiece (vitrector 105) connected to the aspiration pump and the control module to be inserted into the eye during surgery.

The control module according to claim 1 of the application is configured to detect a step change in the flow rate of the fluid aspirated from the eye, i.e. a variation of the flow rate over time. Upon detecting

said step change the control module causes the surgical system to alert a surgeon that a change in viscosity of the fluid being aspirated has been detected.

In contrast to that, in the system of D1, the controller determines the type of the aspirated medium using information about the vacuum force, the aspiration flow rate and other parameters like infusion flow rate and instrument operation (paragraphs [0042]-[0046]). Based on the measured data, each measurement results in a point in a coordinate system formed by said parameters (Figures 4-5). Depending on the location of this point in a certain region of the diagram, the controller determines the type of medium being aspirated at a given point in time. A visual indication of the media type is provided to the surgeon by green or blue flashes (see [0027]).

No comparison of two values measured at different times is disclosed in D1. Such a comparison is, however, required for the claimed detection of the step change of the flow rate.

Therefore, the subject-matter of claim 1 is novel over D1.

2. **Main Request - Inventive Step - Article 56 EPC**

2.1 The system of claim 1 allows to provide the surgeon with the necessary information about effective aspiration of vitreous by detecting a step change of the flow rate of aspirated material.

The technical problem to be solved by the invention is regarded as providing an ophthalmic surgical system with simple and reliable means to give the surgeon an

indication whether vitreous or saline solution is aspirated.

2.2 This problem is solved by the system according to claim 1 because the detection of the step change of the flow rate is sufficient to indicate to the surgeon, that a change of viscosity of the material being aspirated has taken place. From this information the surgeon can conclude which type of material is currently aspirated.

The prior art neither discloses nor suggests the detection of a step change of the flow rate.

2.3 None of the other documents cited in the International Search Report discloses or suggests a system which detects a step change in the flow rate of the aspirated fluid. They all determine the type of the material being aspirated based on the measurement of instantaneous values.

2.4 Document D3 which was cited as being relevant in view of claim 1, discloses an ophthalmic surgical system comprising (pages 4-5) at least a control module (CPU 18) connected to an aspiration pump (20), and an infusion fluid flow sensor (32) and an aspiration pressure sensor (30) connected to the control module.

A surgical handpiece (16) is connected to the aspiration pump and the CPU, to be inserted into the eye during surgery.

In an initialisation step, the fluidic resistance of the system for the infusion fluid is determined (page 4, lines 14-25).

During operation, the CPU uses this fluidic resistance,

the instantaneous aspiration fluid flow and the infusion fluid pressure in order to calculate an expected value ($P_{threshold}$) of aspiration fluid pressure which applies for the infusion fluid.

The system measures the instantaneous aspiration fluid pressure (P_{asp}) and compares it to the expected value. If the aspiration pressure (P_{asp}) is greater than the value expected for an infusion fluid, the surgeon is informed about an occlusion or a viscoelastic agent being present in the aspiration path.

Only instantaneous values are used by the CPU for the calculations. Depending on the instantaneous comparison of the aspiration pressure and the expected pressure, the system indicates the presence or absence of a viscoelastic agent in the flow path (page 5, lines 12-13). The CPU of D3 does not detect the change of the flow rate of the aspirated material.

Therefore, the subject-matter of claim 1 is neither disclosed by D3 nor is it obvious in view of D3.

3. The Board has not identified any deficiencies of the claims regarding the requirements of the EPC, in particular regarding Articles 84 and 123(2) EPC.

Order

For these reasons it is decided that:

The decision under appeal is set aside.

The case is remitted to the examining division with the order to grant a patent with the following claims and a description to be adapted thereto:

Claims:
No. 1-7 of the main request filed with the letter of 20 October 2017.

The Registrar: The Chairwoman:

C. Moser P. Acton

Decision electronically authenticated