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Datasheet for the decision of 28 May 2019

Case Number: T 2043/15 - 3.2.08

Application Number: 09835875.7

Publication Number: 2367512

IPC: A61F9/01, A61F9/008, A61B18/20, A61F9/007

Language of the proceedings: EN

Title of invention:
PHOTODISRUPTIVE LASER TREATMENT OF THE CRYSTALLINE LENS

Applicant:
Alcon LenSx, Inc.

Headword:

Relevant legal provisions:
EPC Art. 54
RPBA Art. 13(1)

Keyword:
Novelty - (no) - Third and Fourth auxiliary request
Late-filed auxiliary request 5 - admitted (no)

Decisions cited:

Catchword:

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Case Number: T 2043/15 - 3.2.08

D E C I S I O N
of Technical Board of Appeal 3.2.08
of 28 May 2019

Appellant: (Applicant)	Alcon LenSx, Inc. 33 Journey, Suite 175 Aliso Viejo, CA 92656 (US)
Representative:	Hanna Moore + Curley Garryard House 25/26 Earlsfort Terrace Dublin 2, D02 PX51 (IE)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 5 March 2015 refusing European patent application No. 09835875.7.**

Composition of the Board:

Chairwoman	P. Acton
Members:	C. Herberhold
	D. Rogers

Summary of Facts and Submissions

I. By decision posted on 5 March 2015 the Examining Division refused European patent application No. 09835875.7.

II. In its decision the Examining Division held that the subject-matter of claim 1 according to the main request then on file was not novel over the disclosure of prior art D3 (US2007/0173794).

III. The applicant (appellant) lodged an appeal against that decision.

IV. Oral proceedings before the Board were held on 28 May 2019.

At the end of the oral proceedings the requests of the appellant were as follows:

The appellant requested that the decision under appeal be set aside and that a patent be granted upon the basis of either the Third or Fourth Auxiliary Requests, both filed under cover of a letter dated 20 April 2019, or upon the basis of the Fifth Auxiliary Request filed at the oral proceedings before the Board on 28 May 2019.

V. Independent claims:

Note: Underlining has been added by the Board to mark the features which are different in the respective independent claim of each of the requests.

(a) Claim 1 of the Third auxiliary request reads as follows:

"A laser system for fragmenting a crystalline lens of an eye, comprising:

- a pulsed laser (2130) configured to:

generate a laser beam of laser pulses; and an optical delivery system (273), wherein the optical delivery system comprises an X-Y scanner (6410) with a first scanning speed and a Z-scanner (6420) with a second slower scanning speed, the optical delivery system (273) configured to:

apply the laser beam to create an incision in the lens of the eye with a spatial extent along an axis of the eye longer than 2 mm, and a spatial diameter transverse to the axis of the eye larger than 4mm;

characterized in that the optical delivery system is configured to form incisions in a layer-by- layer manner, at least partially along a curved focal plane of the optical delivery system, in any of lines or planar cuts having an orientation non-transverse to the axis of the eye, layers of spirals (267), nested cylinders (262), or crossed planes (265), and

wherein an incision of a layer is formed by a line of cavitation bubbles along the curved focal plane (271) of the optical delivery system without adjusting the Z scanner."

(b) Claim 1 of the Fourth auxiliary request reads as follows:

"A laser system for fragmenting a crystalline lens of an eye, comprising:

- a pulsed laser (2130) configured to:

generate a laser beam of laser pulses, and an optical delivery system (273), wherein the optical delivery system comprises an X-Y scanner (6410) with a first scanning speed and a Z-scanner (6420) with a second slower scanning speed, the optical delivery system (273) configured to:

apply the laser beam to create an incision in the lens of the eye with a spatial extent along an axis of the eye longer than 2 mm, and a spatial diameter transverse to the axis of the eye larger than 4mm;

characterized in that the optical delivery system is configured to form incisions in a layer-by- layer manner, at least partially along a curved focal plane of the optical delivery system, in any of lines or planar cuts having an orientation non-transverse to the axis of the eye, layers of spirals (267), nested cylinders (262), or crossed planes (265), and

wherein an incision of a layer is formed by a line of cavitation bubbles along the curved focal plane (271) of the optical delivery system at the scanning speed of the X-Y scanner and wherein the requirement to adjust the scanning speed of the Z scanner at the scanning speed of the X-Y scanner to compensate for the effect of the curved focal plane is eliminated."

(c) Claim 1 of the Fifth auxiliary request reads as follows:

"A laser system for fragmenting a crystalline lens of an eye, comprising:

- a pulsed laser (2130) configured to:

generate a laser beam of laser pulses, an optical delivery system (273), wherein the optical delivery system comprises an X-Y scanner (6410) with a first scanning speed and a Z-scanner (6420) with a second slower scanning speed, the optical delivery system (273) configured to:

- apply the laser beam to create an incision in the lens of the eye with a spatial extent along an axis of the eye longer than 2 mm, and a spatial diameter transverse to the axis of the eye larger than 4mm;

characterized in that the optical delivery system is configured to form incisions in a layer-by- layer manner, at least partially along a curved focal plane of the optical delivery system, in any of lines or planar cuts having an orientation non-transverse to the axis of the eye, layers of spirals (267), nested cylinders (262), or crossed planes (265),

wherein an incisions of a layer is formed by a line of cavitation bubbles along the curved focal plane (271) of the optical delivery system, the optical delivery system being operated at the X-Y scanning rate wherein only the X-Y scanner is adjusted as the line of cavitation bubbles is formed, and

wherein the optical delivery system is configured to move a focal point of the laser in a posterior to anterior direction of the lens of the eye and wherein the incisions are formed on a layer-by-layer basis

without interrupting the application of the pulsed laser."

VI. The following documents have played a part in the present decision:

D3: US 2007/0173794;

D12: data sheets of SCANLAB hurrySCAN and varioSCAN scan systems, introduced by the examining division on 28 January 2015.

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

Novelty of auxiliary requests 3 and 4 over D3

D3 did disclose in paragraph [0108] and [0109] a system configured for treating and removal of cataracts. As could be seen from the shot pattern reproduced in Figure 25, grid like cuts were employed to carve up the lens material into tiny cube like structures small enough to be aspirated. Figure 25 showed clearly that the cuts were to be placed precisely in a flat plane perpendicular to the z-Axis, not along a curved focal plane of the optical delivery system as claimed. This was done either by using flat field optics, or - if conventional optics with a curved focal plane were used - by operating the Z-scanner such as to compensate for the curvature of the optical system. Indeed, the data sheet of the VarioSCAN Scan system, see D12, which was used in D3 as the Z focusing device, see D3, paragraph [0058], explicitly disclosed that the system was to be used to replace costly flat field objectives. Thus, D3 did not disclose that the incision was formed by a line of cavitation bubbles along the curved focal plane of

the optical delivery system without adjusting the Z-scanner or with the requirement to adjust the scanning speed of the Z scanner at the scanning speed of the X-Y scanner to compensate for the effect of the curved focal plane being eliminated.

Furthermore the system disclosed in D3 did not comprise an X-Y scanner with a first scanning speed and a Z-scanner with a second, slower scanning speed.

Consequently, the subject-matter of claim 1 of the Third and Fourth auxiliary request was novel over the disclosure of document D3.

Admissibility of the Fifth auxiliary request

The Fifth auxiliary request was an attempt to delineate the invention by positive features over the prior art rather than by the negative features employed in the preceding requests. The importance of this had only become clear during the discussion, such that the request could not have been filed earlier. The amendments were based on original claims 12, 36 and 37 and on paragraphs [0017], [0037], [0041] and [0149] of the application as filed, such that the subject-matter was clearly and unambiguously disclosed.

Auxiliary request 5 should thus be admitted into the proceedings.

Reasons for the Decision

1. Novelty of auxiliary requests 3 and 4 over D3

1.1 D3 discloses:
A laser system for fragmenting a crystalline lens of an eye (D3, Figure 2 and 2A; paragraph [0108]: "for treating and removal of cataracts"), comprising:

- a pulsed laser (paragraph [0057]) configured to:

generate a laser beam of laser pulses, and an optical delivery system (paragraph [0058]), wherein the optical delivery system comprises an X-Y scanner (Figure 2A, **223**) with a first scanning speed and a Z-scanner (Figure 2A, **221**) with a second slower scanning speed,

> According to D3, paragraph [0058] the X-Y scanner may be the SCANLAB hurySCAN and the Z focusing device may be the SCANLAB varioScan. Scanning speeds of these scanners are disclosed in the respective data sheets, see D12, page 4 (page 6 of the overlay), left upper table for the hurrySCAN and page 8 (page 10 of the overlay), middle table for the varioSCAN. According to D12, the hurrySCAN has marking speeds of 3.0/2.0 m/s (positioning speed 12m/s) whereas the travel speed of the vario scan is 280mm/s (in the fastest model). Therefore, the Z-scanner of D3 has a slower scanning speed than the XY-scanner.

the optical delivery system configured to: apply the laser beam to create an incision in the lens of the eye with a spatial extent along an axis of the eye longer than 2 mm, and a spatial diameter transverse to the axis of the eye larger than 4mm (see the dimensions

indicated in the laser shot pattern disclosed for cataract removal, D3, Figure 25);

wherein the optical delivery system is configured to form incisions in a layer-by- layer manner (paragraph [0058], last sentence: "...it is further provided to essentially drill down anterior to posterior, which we call the z axis throughout this document and then move in x/y and drill down again"),

at least partially along a curved focal plane of the optical delivery system,

D3 discloses movement in x/y after drilling down in the z-axis, i.e. it discloses applying the incisions (at least partially) without adjusting the Z-scanner. For flat field optics, these incisions are in a flat focal plane. However, D3 also discloses a system using conventional focusing optics (paragraph [0058]), which typically have - uncontestedly - a curved focal plane (see in this respect also the application as filed, paragraph [0174]). Operating the laser with the Z-scanner being stationary, i.e. with a "pure" x/y movement thus inevitably results in incisions along the implicitly curved focal plane of the (conventional optics) optical delivery system.

in any of lines or planar cuts (see Figure 25) having an orientation non-transverse to the axis of the eye (the curved focal plane of the conventional focusing optics optical delivery system is non-transverse to the axis of the eye), layers of spirals, nested cylinders, or crossed planes (see Figure 25), and

wherein an incision of a layer is formed by a line of cavitation bubbles along the curved focal plane (paragraph [0086]) of the optical delivery system without adjusting the Z-scanner (see the last sentence of paragraph [0109] discussed above)."

The subject-matter of claim 1 of the Third auxiliary request is thus not novel.

1.2 The appellant has argued that the shot pattern of Figure 25 disclosed cuts in a flat plane and not in a curved plane of the optical delivery system as claimed. It was thus clear from D3, that any deviation from the flat plane possibly caused by the use of conventional focusing optics was to be compensated by moving the Z-scanner accordingly, a task for which the VarioSCAN Scan system was explicitly designed.

However, D3 is silent on any compensating Z-scanner movements. In paragraph [0109], last sentence, it teaches "pure" x/y movement. Furthermore, while it is true that according to D12, the VarioSCAN Scan system can be run such as to replace costly flat field objectives, there is no disclosure in D3 that the scanner is actually used in this way.

In claiming that the optical delivery system of the invention operates without adjusting the Z-scanner, the appellant essentially defines a negative feature. As D3 does not mention that feature (neither in the positive nor in the negative), there is a priori no reason to assume that it is nevertheless always present. This could be the case, i.e. if according to the common general knowledge the person skilled in the art understood D3 such that it implied Z-scanner adjustment. In other words, the appellant's argument

relies on the alleged common general knowledge. According to established principles, the party that relies on the common general knowledge bears the burden of proof of establishing its content. Consequently, the burden of proof is upon the appellant to convincingly show that according to the common general knowledge the person skilled in the art would have inevitably understood the D3 disclosure to imply adjusting Z-scanner movement in the case of conventional focusing optics. There has, however, not been provided any evidence in this respect. On the other hand, in particular because firstly in most uncorrected optical systems the curvature is anyway positive (application, paragraph [0174]) and secondly because in cataract surgery the lens is anyway destroyed, it appears plausible that in D3 the slight curvature introduced by using conventional optics was simply tolerated. The Board thus sees no reason to consider a feature as being implicit in D3 which is not explicitly disclosed in said document. That feature being claimed as not present thus cannot establish novelty.

1.3 The situation is analogous with respect to the subject-matter defined in claim 1 of the Fourth auxiliary request, which states that an incision of a layer is formed by a line of cavitation bubbles along the curved focal plane of the optical delivery system at the scanning speed of the X-Y scanner and wherein the requirement to adjust the scanning speed of the Z scanner at the scanning speed of the X-Y scanner to compensate for the effect of the curved focal plane is eliminated.

As discussed above, D3 discloses "pure x/y" movement i.e. it discloses that an incision of a layer is formed by a line of cavitation bubbles along the curved focal

plane of the (conventional focusing optics) optical delivery system at the scanning speed of the X-Y scanner. D3 is silent on any requirement to adjust the scanning speed of the Z-scanner at the scanning speed of the X-Y scanner to compensate for the effect of the curved focal plane. It would have been upon the appellant to provide convincing evidence that according to the common general knowledge such requirement was indeed present and thus implicitly disclosed in D3. Without evidence, D3 cannot be understood to imply a requirement which is simply not mentioned therein. The requirement to adjust the scanning speed of the Z-scanner at the scanning speed of the X-Y scanner to compensate for the effect of the curved focal plane thus has to be considered not present, i.e. "eliminated" in D3.

Consequently, the subject-matter of claim 1 of the Fourth auxiliary request is likewise not novel over the disclosure of prior art D3.

2. Admissibility of the Fifth auxiliary request

The Fifth auxiliary request was filed extremely late, namely at the end of the oral proceedings in appeal. Its admission in the proceedings is thus subject to the discretion of the Board (Articles 13(1) and (3) RPBA).

With respect to original disclosure of claim 1 of the Fifth auxiliary request, the appellant has pointed to original claims 12, 36 and 37 and to paragraphs [0017], [0037], [0041] and [0149] of the original description. Claim 12 as filed does, however, further define that no more than one incision is formed. It does also not mention forming incisions in a "layer-by-layer" manner (a feature which is only defined in claim 15 as filed,

which is, however, not linked by any dependency to claim 12). Claim 36 defines a system which works without interrupting the application of the laser. Neither it, nor its dependent claims , however define the formation of incisions in a "layer-by-layer" manner, at least partially along a curved focal plane of the optical delivery system. Paragraph [0017] essentially corresponds to claim 12 as filed, paragraph [0041] essentially corresponds to claim 36 as filed, such that the above considerations apply *mutatis mutandis*. Paragraph [0037] discloses scanning the laser pulses without interrupting the application of the laser pulses, however without reference to the particular layer-by-layer manner and with the further restriction that said scanning takes place "in the entire nucleus of the lens". Lastly, paragraph [0149] comprises a general statement about laser scanners, which can scan the laser beam across the entire surgical region without interruption or repositioning, again without any link to the particular layer-by-layer incisions claimed. It is furthermore not *a priori* apparent (nor did the appellant provide any reasoning in this respect) that the subject-matter of the cited passages may be combined *ad libitum* with the disclosure in original paragraphs [0176] and [0177], on which the hitherto claimed subject-matter was essentially based.

The passages mentioned by the appellant thus do not provide clear and unambiguous support for the claimed subject-matter. Rather the amendment introduces further problems under Article 123(2) EPC.

Consequently, in view of the late stage of the proceedings and the fact that the request was not clearly allowable, the Board decided not to admit the

Fifth auxiliary request into the proceedings (Article 13 (1) and (3) RPBA).

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairwoman:

D. Magliano P. Acton

Decision electronically authenticated