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**Datasheet for the decision
of 24 May 2022**

Case Number: T 1098/21 - 3.2.02

Application Number: 14185132.9

Publication Number: 2826436

IPC: A61B18/20, A61B17/00,
A61B90/00, A61B5/00, A61F9/008,
A61F9/009

Language of the proceedings: EN

Title of invention:
Precise targeting of surgical photodisruption

Patent Proprietor:
Alcon Inc.

Opponent:
Johnson & Johnson Surgical Vision, Inc.

Headword:

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

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

Decisions cited:

Catchword:



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 1098/21 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 24 May 2022

Appellant: Johnson & Johnson Surgical Vision, Inc.
(Opponent) 1700 E. Saint Andrew Place
Santa Ana CA 92705 (US)

Representative: Carpmaels & Ransford LLP
One Southampton Row
London WC1B 5HA (GB)

Respondent: Alcon Inc.
(Patent Proprietor) Rue Louis-d'Affry 6
1701 Fribourg (CH)

Representative: Katérle, Axel
Wuesthoff & Wuesthoff
Patentanwälte PartG mbB
Schweigerstraße 2
81541 München (DE)

Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 25 May 2021
rejecting the opposition filed against European
patent No. 2826436 pursuant to Article 101(2)
EPC.**

Composition of the Board:

Chairman M. Alvazzi Delfrate
Members: A. Martinez Möller
C. Schmidt

Summary of Facts and Submissions

- I. The appeal is directed against the decision of the opposition division rejecting the opposition.
- II. Oral proceedings before the board took place on 24 May 2022.

The appellant (opponent) requested that the decision under appeal be set aside and that the patent be revoked.

The respondent (proprietor) requested that the appeal be dismissed (main request) or that the patent be maintained on the basis of one of auxiliary requests 1 to 11, all filed with the reply to the appeal.

- III. Claim 1 of the **main request** (patent as granted) reads as follows:

"A laser surgical system, comprising:

a pulsed laser (1010), configured to produce a laser beam of laser pulses (1012);
an optics module (1020) configured

to receive the laser beam;
to direct the laser beam into a lens of an eye, and
to focus the laser beam in the lens of the eye to cause photodisruption;

an appplanation plate, operable to be in contact with the target tissue to produce an interface and to transmit laser pulses to the target and reflected or

scattered light or sound from the target through the interface;

an Optical Coherence Tomography (OCT) imaging device, configured to create an OCT image of the lens of the eye;

a non-OCT imaging device, configured to generate a non-OCT image; and

a system control module (1040), characterized in that the system control module (1040) is configured to control the optics module (1020) to adjust and focus the laser beam based on positioning information of the eye obtained from images captured before applanation and images captured during a surgical procedure."

- IV. Claim 1 of **auxiliary request 1** differs from claim 1 of the main request in that, immediately after "configured to generate a non-OCT image;", the following wording has been added:

"wherein the OCT imaging device and the non-OCT imaging device are configured to be used to capture images for controlling the laser during a surgical procedure;"

- V. Claim 1 of **auxiliary request 2** differs from claim 1 of the main request in that the characterising portion has been modified by adding the wording underlined below:

"based on positioning information of the eye obtained from images captured by the OCT imaging device before applanation and images captured by the OCT imaging device during a surgical procedure."

- VI. Claim 1 of **auxiliary request 3** differs from claim 1 of auxiliary request 2 in that it further includes the following wording added to the end of the claim:

", wherein the images captured by the OCT imaging device before applanation for calibration establish a relative positioning relationship so that the laser is controllable in position at target tissue with respect to a position associated with images in the OCT image of the target tissue obtained by the OCT".

- VII. Claim 1 of **auxiliary request 4** differs from claim 1 of the main request in that, immediately after "configured to generate a non-OCT image", the following wording has been added:

", wherein the non-OCT imaging device is a camera; wherein the optics module has an objective lens which is configured to direct and focus both the laser beam and an imaging beam to the interface;".

- VIII. Claim 1 of **auxiliary request 5** differs from claim 1 of auxiliary request 4 in that, immediately after "wherein the non-OCT imaging device is a camera;", the following wording has been added:

"wherein the non-OCT imaging device is configured to generate the non-OCT image before the applanation plate is applied;".

- IX. Claim 1 of **auxiliary request 6** differs from claim 1 of the main request in that, immediately after "to cause photodisruption", the following wording has been added:

", the optics module comprising a scanner for scanning the laser beam and a beam conditioner for collimating and focusing the laser beam".

and in that, immediately after "configured to generate a non-OCT image", the following wording has been added:

", wherein the non-OCT imaging device is a camera; wherein the scanner and beam conditioner for the laser beam are separate from optics in the OCT imaging device for controlling an imaging beam for the OCT; wherein the optics module has an objective lens which is configured to direct and focus both the laser beam and an imaging beam to the interface;".

- X. Claim 1 of **auxiliary request 7** differs from claim 1 of auxiliary request 6 in that the wording "focus both the laser beam and an imaging beam to the interface" has been amended to "focus both the laser beam and the imaging beam to the interface" and in that, immediately after "and the imaging beam to the interface;", the following wording has been added:

"a first beam splitter and a second beam splitter to direct the laser beam and the imaging beam for the OCT, the second beam splitter also being used to direct a returned imaging beam into the OCT imaging device;".

- XI. Claim 1 of **auxiliary request 8** differs from claim 1 of auxiliary request 7 in that, immediately after "to direct a returned imaging beam into the OCT imaging device", the following wording has been added:

", and wherein the first beam splitter and the second beam splitter are also configured to direct light from the target to the camera".

- XII. Claim 1 of **auxiliary request 9** differs from claim 1 of auxiliary request 2 in that, immediately after "by the OCT imaging device before applanation", the following wording has been added:

"for calibration of the OCT against the laser".

- XIII. Claim 1 of **auxiliary request 10** differs from claim 1 of auxiliary request 2 in that, immediately after "by the OCT imaging device before appplanation", the following wording has been added:

"that are used to calibrate the OCT against the laser to establish a relative positioning relationship".

- XIV. Claim 1 of **auxiliary request 11** differs from claim 1 of the main request in that it further includes the following wording added to the end of the claim:

", wherein the images captured by the OCT imaging device or the non-OCT imaging device before appplanation to the eye establish a mapping relationship stored as digital calibration data, the laser surgical system being configured to apply the digital calibration data and OCT images of the target tissue captured during the surgery in controlling focusing and scanning of the surgical laser beam during the surgery".

- XV. The appellant's arguments which are relevant to the present decision can be summarised as follows.

Main request - added subject-matter - OCT imaging device and non-OCT imaging device

Claim 1 comprised subject-matter extending beyond the content of the parent application (WO 2009/033111 A2). The parent application did not support the combined use of an Optical Coherence Tomography (OCT) imaging device and a non-OCT imaging device. The first sentence of paragraph [0057] of the parent application disclosed non-OCT imaging devices as an alternative to an OCT

imaging device. It did not disclose - at least not without ambiguity - that a non-OCT device could be used in addition to an OCT imaging device. The specific embodiments could not resolve this ambiguity, because none of them unambiguously disclosed an OCT imaging device and a non-OCT imaging device for controlling the laser.

Main request - added subject-matter - images captured before applanation and during a surgical procedure

Claim 1 also comprised subject-matter extending beyond the content of the parent application due to the control based on positioning information of the eye obtained from images captured before applanation and images captured during a surgical procedure.

The parent application presented the applanation as a step occurring prior to the surgery, whereby there was also a stage after applanation and before surgery. Hence, "before surgery" did not have the same meaning as "before applanation".

Paragraph [0054] emphasised the advantages of using post-applanation images. There were no reasons to combine post-applanation images with pre-applanation images. The second sentence of paragraph [0056] did not provide a basis for such a combination because the imaging times were presented as alternatives ("or").

Passages of the parent application describing specific embodiments could not serve as a basis for the combination either, because claim 1 constituted at best an unallowable intermediate generalisation.

Auxiliary requests - admittance and added subject-matter

The auxiliary requests should have been filed in first-instance proceedings and should thus not be admitted under Article 12(4) RPBA 2020.

None of the auxiliary requests overcame the objections of added subject-matter. Claim 1 of each of auxiliary requests 9 and 10 constituted an unallowable intermediate generalisation based on the embodiment described in paragraph [0101] of the parent application, which indicated that the laser was controlled based on the photodisruption by-product.

XVI. The respondent's arguments which are relevant to the present decision can be summarised as follows.

Main request - added subject-matter - OCT imaging device and non-OCT imaging device

The parent application disclosed the combined use of an OCT imaging device and a non-OCT imaging device in the first sentence of paragraph [0057]. That sentence disclosed a non-OCT imaging device being "also" used, that is, in addition to the OCT imaging device.

The last sentence of the same paragraph [0057] referred to the embodiments in Figs. 2-10. The disclosure of those embodiments confirmed the intended combination of an OCT imaging device and a non-OCT imaging device. For example, Figure 2 and paragraphs [0062] and [0064] disclosed an imaging system 2200 which could be an OCT including an imaging subsystem 2230. Paragraph [0064] disclosed examples of non-OCT imaging devices as possible subsystems and the use of their images in

controlling the laser. The embodiments of Figures 5-10 comprised an OCT imaging device and visual observation optics such as a camera (in paragraph [0070]), which was a further example of a non-OCT imaging device.

Also the embodiment of Figure 20 included a combination of an OCT imaging device and an ultrasound imaging device, as disclosed in the first sentence of paragraph [0106].

Main request - added subject-matter - images captured before applanation and during a surgical procedure

The applanation defined the start of the surgery, as was clear from the second sentence of paragraph [0054]. Thus, "before applanation" and "before surgery" had the same meaning in the parent application.

The "or" in the second sentence of paragraph [0056] was not an exclusive "or". It was clear to the skilled person that images before applanation were needed in order to take the changes into account.

Hence, paragraphs [0044] and [0056] both disclosed controlling the laser based on positioning information from images acquired before applanation and during surgery. Therefore, claim 1 did not comprise added subject-matter.

The use of pre-applanation images for laser control was also disclosed in paragraphs [0060], [0064], [0088] and [0101] of the parent application.

Auxiliary requests - admittance and added subject-matter

There was no reason to file any auxiliary requests in first-instance proceedings. Thus, the requests should be admitted under Article 12(4) RPBA 2020.

Auxiliary requests 9 and 10 had a basis in paragraph [0101] of the parent application and overcame both objections of added subject-matter. The "or" for the different imaging modalities in paragraph [0101] was a non-exclusive "or". The photodisruption by-products were imaged by the system but did not define a technical restriction of the imaging system itself.

Reasons for the Decision

1. The invention

Recent laser surgical systems, as used for example for eye surgery, operate with laser pulses which are shorter, of lower energy and with higher repetition rates. These systems have increased requirements as regards the precision of the control and aiming of the laser pulse (see paragraphs [0002]-[0003] and [0022]-[0025] of the contested patent).

A more precise laser-pulse localisation can be achieved by having an applanation plate on the tissue during surgery. The applanation plate provides a well-defined interface with the tissue which facilitates transmission and focusing of laser light. Moreover, the applanation plate can be used as a positional reference for the targeted delivery of laser pulses. When using the applanation plate as a positional reference, knowledge of the location of the laser-pulse focus in the target prior to laser firing is necessary. It is also necessary to maintain a constant relative position

between the applanation plate and the internal tissue target during laser firing. When non-superficial structures are targeted, such a use as a positional reference may also require a very precise knowledge of the applanation plate position and thickness (see paragraphs [0026]-[0030] of the contested patent).

The invention relates to an imaging-guided laser surgical system which aims to provide a fast and precise control of the targeted delivery of laser pulses to the lens of an eye when the laser pulses are applied through an applanation plate and which does not have the additional requirements resulting from using the applanation plate as a positional reference (see paragraphs [0031] and [0040] of the contested patent). This problem is addressed in claim 1 of the contested patent by providing a laser surgical system having, among other things, two imaging devices, namely an Optical Coherence Tomography (OCT) imaging device and a non-OCT imaging device, and a system control module configured to control an optics module to adjust and focus the laser beam based on positioning information of the eye obtained from images captured before applanation and images captured during a surgical procedure.

2. Main request - added subject-matter

2.1 OCT imaging device and non-OCT imaging device

2.1.1 The first sentence of paragraph [0057] of the parent application (WO 2009/033111 A2) reads as follows:

The imaging-guided laser surgical systems described below use the OCT imaging as an example of an imaging instrument and other non-OCT imaging

devices may also be used to capture images for controlling the surgical lasers during the surgery.

The sentence refers to OCT imaging "as an example of an imaging instrument" and then refers to "non-OCT imaging devices" in the plural form. This wording gives rise to reasonable doubts as to whether "may also be used" defines the non-OCT imaging devices as being additional to the OCT imaging device or as an alternative. It follows that the sentence, when considered on its own, does not unambiguously disclose the combination of an OCT imaging device and a non-OCT imaging device as defined in claim 1.

- 2.1.2 Consulting the examples in Figs. 2-10, referred to in the last sentence of the same paragraph [0057], does not help to resolve the ambiguity.

The embodiment of Figure 2 comprises an OCT imaging device, referred to as "imaging system 2200" and also as "OCT module 2200" (see paragraph [0063]). This system comprises an "imaging subsystem 2230", a term which is described in paragraph [0062] as comprising the optical components of the OCT as opposed to other elements such as the control and communication modules. However, it is not disclosed anywhere that the imaging system could comprise further imaging subsystems.

Paragraph [0064] refers to "subsystems or devices", without indicating that those correspond to the previous "imaging subsystem". The second sentence of paragraph [0064] discloses either providing certain diagnostic instruments (such as wavefront aberrometers or corneal topography measuring devices) in the system or using pre-operative information from these devices to augment intra-operative imaging. For the former

option, it is not disclosed how the information from these instruments is used. However, even if it were used to augment intra-operative imaging, as for the latter option, there is no indication that the augmented image is used for controlling the laser.

The embodiments of Figures 5-10 comprise an OCT imaging device and a "visual observation optics unit" presented in paragraph [0070] as providing a direct view or image of the target. A camera for capturing an image of the target is indicated as a possible visual observation optics unit, which can be regarded as a non-OCT imaging device. However, it is not disclosed that images from this non-OCT imaging device are used for controlling the laser. Figures 5-10 suggest the opposite because the visual observation optics unit is not even connected to the control system in contrast with the OCT imaging device.

- 2.1.3 The respondent likewise referred to the first two sentences of paragraph [0106] as representing an example of a combination of an OCT imaging device and a non-OCT imaging device, whereby the ultrasound imaging device in paragraph [0106] is a non-OCT imaging device. Even if this passage describing the embodiment of Figure 20, which shows only one imaging device 2030, were to be used to try to resolve the ambiguity of the first sentence of paragraph [0057], it would not be helpful either. On the one hand, the passage is likewise ambiguous, thereby allowing the meaning that the "imaging device 2030" could be alternatively implemented as an "ultrasound imaging device". On the other hand, also interpreting the paragraph as referring to the combination of OCT and ultrasound, there is no indication that the ultrasound images are used for controlling the laser during surgery.

- 2.1.4 In summary, the first sentence of paragraph [0057], also when read in the context of the application as a whole, does not directly and unambiguously disclose a combination of an OCT imaging device and a non-OCT imaging device as defined in claim 1.
- 2.2 Images captured before applanation and during a surgical procedure
- 2.2.1 The system control module is defined in claim 1 as being configured to control the optics module to adjust and focus the laser beam based on positioning information of the eye obtained from images captured before applanation and images captured during a surgical procedure. It was disputed whether this definition resulted in subject-matter extending beyond the parent application.
- 2.2.2 The second sentence of paragraph [0054] of the parent application reads as follows:

Notably, certain parameters of the target tissue such as the eye measured before the surgery may change during the surgery due to various factor [sic] such as preparation of the target tissue (e.g., fixating the eye to an applanation lens) and the alternation [sic] of the target tissue by the surgical operations.

By indicating that the change occurs "during the surgery", the sentence suggests that preparation including fixation to the applanation lens is part of the surgery. However, the sentence does not specify that the applanation itself defines the start of the surgical procedure.

In fact, the parent application does not specify which steps are encompassed by the term "surgery" and, in particular, it does not consistently establish the temporal relationship between applanation and the start of the surgery. The third sentence of paragraph [0054] already discloses that "measured parameters of the target tissue prior to such factors and/or the surgery may no longer reflect the physical conditions of the target tissue during the surgery". Hence, a different meaning is given to "prior to such factors" (such as fixation to the applanation lens according to the immediately preceding sentence) as compared to "prior to ... the surgery". Other passages such as paragraph [0012] or claim 29 refer to applying information from OCT images (acquired after tissue engaging/applanation) for laser-beam focusing "before or during surgery", suggesting that the term surgery refers to the delivery of surgical pulses.

In summary, the parent application neither discloses that the applanation defines the start of the surgery nor indicates that the terms "before applanation" and "before surgery" have the same meaning.

For this reason alone, the first sentence of paragraph [0044] referring to "before and during a surgical procedure" cannot provide a basis for the images captured "before applanation".

- 2.2.3 The second sentence of paragraph [0056], also argued by the respondent to provide a basis for the disputed combination, reads as follows:

The positional reference information provided by the imaging prior to applanation and/or fixation of

the eye, or during the actual surgery reflects the effects of changes in the eye and thus provides an accurate guidance to focusing and positioning of the surgical laser beam.

The sentence refers to imaging prior to applanation or imaging during the surgery.

The argument that the word "or" is intended to be a "non-exclusive or" and thus also discloses "and" is not convincing. Indeed, the same sentence includes a "non-exclusive or" before ("and/or"), meaning that "or" is not to be understood here as also referring to "and/or". Moreover, there is no indication that pre-applanation images are necessary in order to address the positional changes of the eye. Instead, the benefits of image-guided surgery based on post-applanation images are highlighted (see, for example, the first sentence of each of paragraphs [0054] and [0056]).

Hence, the second sentence of paragraph [0056] does not directly and unambiguously disclose control based on positioning information of the eye obtained from images captured before applanation and images captured during a surgical procedure.

2.2.4 The last sentence of paragraph [0060] as well as paragraphs [0064], [0088] and [0101] were also discussed as a potential basis for the disputed combination.

Paragraphs [0060], [0064] and [0088] do not refer to images captured before applanation. Instead, they refer to pre-operative measurements or imaging before surgery. As explained in section 3.2.1, "before

surgery" cannot be equated to "before applanation". For this reason alone, these paragraphs do not provide a valid basis for the combination contained in claim 1.

Moreover, the paragraphs mentioned above do not disclose pre-operative imaging in general. In fact, they refer to specific aspects and/or uses of pre-operative measurements, not necessarily images, which are not included in claim 1: pre-operative measurements of lens thickness (paragraph [0060]), pre-operative information used to augment intra-operative imaging (paragraph [0064]) and OCT calibration (paragraph [0088]). Also for this reason the paragraphs do not define a valid basis for the combination of imaging before applanation and imaging during surgery as defined in claim 1.

Paragraph [0101] refers to the capture of images "either before or after (or both) the applanation plate is applied". This is disclosed in a particular embodiment in which the captured imaging data is processed by the laser system control module to determine the desired target tissue position, and in which the laser system control module moves or adjusts the laser in such a way that the centre of laser-induced photodisruption by-product overlaps with the target tissue position (see paragraph [0100] and the last three sentences of paragraph [0101]). These features define technical restrictions of the laser system control module which are closely related to the imaging and to its timing, because images of the photodisruption by-product can only be captured after firing the laser. These features have not been included in claim 1. Hence, at least for this reason, claim 1 is at best an unallowable intermediate generalisation of the embodiment described in paragraph [0101].

2.3 It follows that claim 1 of the main request comprises subject-matter extending beyond the content of the parent application as filed.

3. Auxiliary requests

3.1 The respondent did not argue why auxiliary requests 1-8 and 11 overcame both issues of added subject-matter. The board is also unable to see how those requests could overcome both issues.

3.2 The respondent argued that the combination of features defined by claim 1 of each of auxiliary requests 9 and 10 overcame both issues of added subject-matter and had a basis in paragraph [0101] of the parent application.

As explained above in the last paragraph of point 2.2.4, paragraph [0101] refers to an embodiment in which further technical features of the system control module closely related to the imaging and to its timing are present. Claim 1 of each of auxiliary requests 9 and 10 does not comprise those features. Hence, at least for this reason, paragraph [0101] does not define a valid basis for the subject-matter of claim 1.

3.3 It follows that, irrespective of the question of their admittance, none of auxiliary requests 1-11 overcome both issues of subject-matter extending beyond the content of the parent application as filed.

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:



D. Hampe

M. Alvazzi Delfrate

Decision electronically authenticated