IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re *Inter Partes* Review of:)
U.S. Patent No. 9,849,036)
Issued: Dec. 26, 2017)
Application No.: 15/452,252)
Filing Date: Mar. 7, 2017)

For: **Imaging-Controlled Laser Surgical System**

FILED VIA E2E

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 9,849,036

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I. Introduction

Petitioner Johnson & Johnson Surgical Vision, Inc. ("J&J Vision") requests *inter partes* review of all claims of U.S. Patent No. 9,849,036, titled "Imaging-Controlled Laser Surgical System" ("'036 patent," Ex. 1001) and assigned to Alcon LenSx, Inc. ("Alcon").

The '036 patent is directed to a laser surgery system and methods for performing a capsulotomy, a circular incision made in the lens of an eye during cataract surgery. When the patent application that resulted in the '036 patent was filed, laser capsulotomy was well-known in the art, including through US 2011/0202046 A1 ("Angeley," Ex. 1006), a published U.S. patent application.

The purported invention of the '036 patent is to make a tilted capsulotomy incision when the lens of the eye is tilted. But as explained in this Petition, Angeley also discloses such a tilted capsulotomy incision. Thus, it anticipates (and renders obvious) all claims of the '036 patent.

So how did the '036 patent issue? It is because Alcon asserted during prosecution (and the Examiner accepted) that Angeley did not disclose a laser cut that is "tailored to the relative tilt of the target tissue." File History for Application No. 13/110,352 ("'352 FH," Ex. 1003) at 1144 (9/12/2016 Response to Final Office Action). Alcon asserted that "nowhere does *Angeley* suggest or contemplate another way of accounting for lens tilt." '352 FH at 1157 (10/14/2016 Pre-Appeal Brief).

These representations were false. Alcon never identified (and the Examiner did not appreciate) a key disclosure in Angeley that for a tilted lens, "ideally the cut for the capsule will follow this tilt." Angeley, [0090], Fig. 15.

This Petition requests the Patent Office consider, for the first time, the full disclosure of Angeley, including its key teaching in paragraph [0090] that a capsulotomy incision will follow the tilt of the lens.

II. Identification of Challenge (37 C.F.R. § 42.104(b))

Ground 1: Claims 1-17 are anticipated by Angeley (Ex. 1006).

Ground 2: Claims 1-17 are obvious over Angeley.

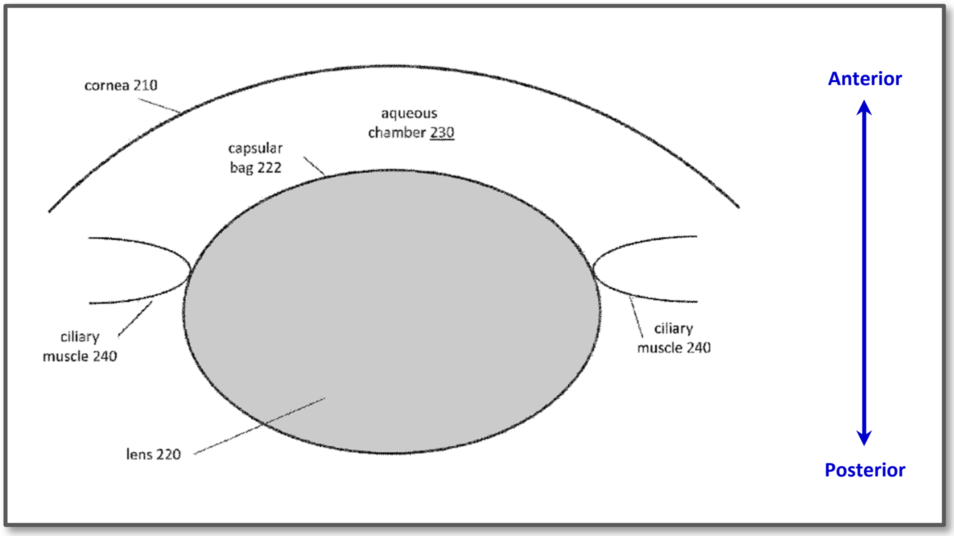
Ground 3: Claims 1-17 are obvious over Angeley in view of the Palanker article (Ex. 1009).

III. Background

A. The '036 Patent (Ex. 1001)

The '036 patent issued from Application No. 15/452,252, filed on March 7, 2017, which is a continuation of Application No. 13/110,352, filed on May 18, 2011.

The '036 patent generally relates to laser cataract surgery, which involves removal of a diseased (clouded) lens of the eye. '036 patent, 1:6-11, 1:44-50; Schuele (Ex. 1004) ¶ 15. Figure 4A shows the relevant structures of the eye:



’036 patent, Fig. 4A (annotated, cropped: showing only eye structures, 220 shaded, anterior/posterior arrow added); Schuele ¶ 15. The lens 220 of the eye (shaded in gray) lies beneath the cornea 210 and is held within the capsular bag 222. Schuele ¶ 16. This diagram follows the convention of showing a cross-section of the eye with the anterior (front) corneal surface at the top (i.e., the eye is looking upwards, as shown on the right). *Id.*

As described in the Background section of the ’036 patent, it was known in the prior art that a laser could be used to perform cataract surgery. ’036 patent, 1:15-20, 1:42-44; Schuele ¶ 17. In particular, lasers were used for two steps in cataract surgery: “capsulotomy” and “fragmentation.” *Id.*, 1:44-45; Schuele ¶ 17. First, the laser makes a circular capsulotomy cut in the anterior lens capsule (front of the capsular bag) to provide access to the lens. *Id.*, 1:50-53; Schuele ¶ 18.

Capsulotomy is also called laser "capsulorhexis."[1] Schuele ¶ 18. Second, the laser is used to fragment (or chop) the clouded lens, so a surgeon may remove the resulting pieces. *Id.*, 1:46-50; Schuele ¶ 18.

The '036 patent concerns laser capsulotomy, the first step in laser cataract surgery. '036 patent, 1:7-11. After imaging the eye, the surgeon "can decide where to direct the cutting laser beam to form the capsulotomy cut 250." *Id.*, 5:56-59. As shown in the '036 patent, a capsulotomy may be performed with cut-cylinder 260-c (shaded in pink), having a height of "Dcut":

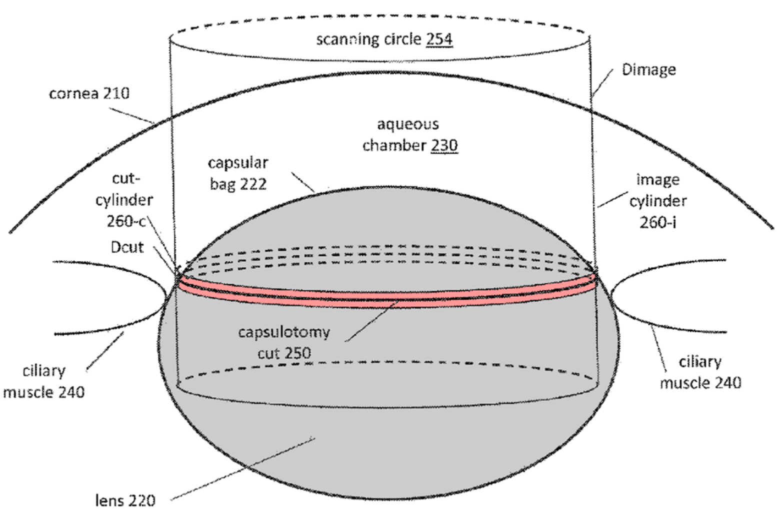


FIG. 4A

[1] *See* Angeley, [0005]. The discussion below generally uses the term "capsulotomy" to describe capsulotomy/capsulorhexis.

’036 patent, Fig. 4A (annotated: 260-c, 220 shaded); Schuele ¶ 19. The height (Dcut) of cut-cylinder 260-c is selected to ensure that the anterior capsular bag is fully transected. *Id.*, 6:17-23; Schuele ¶ 20. The ’036 patent calls this band, where laser pulses are applied, a “tracking band.” ’036 patent, 7:27-29; Schuele ¶ 20.

Figure 4A above shows a non-tilted lens. ’036 patent, 3:9-10. However, in some cases, the lens of the eye can be tilted. *Id.*, 6:24-30. In a tilted lens, the depth into the eye of the anterior lens capsule varies about the circumference of the intended capsulotomy incision, as shown below in Figure 4B:

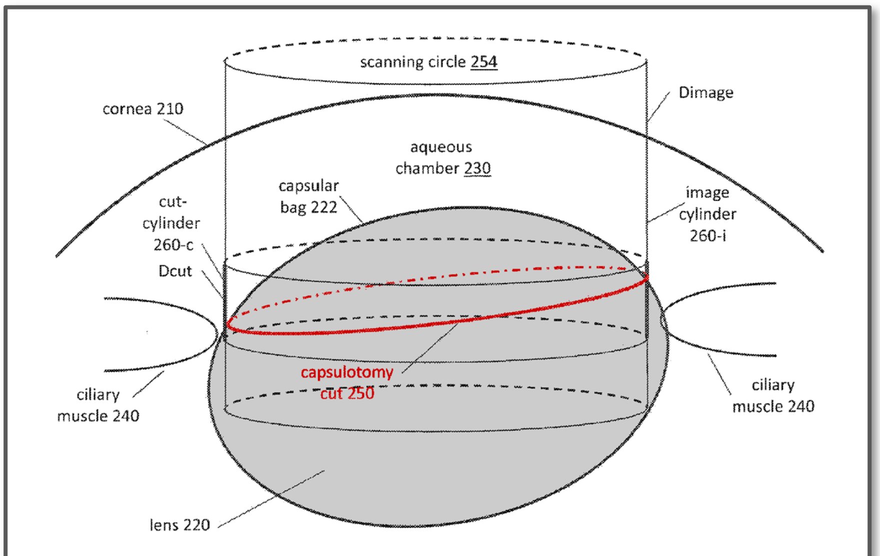


FIG. 4B

Id., Fig. 4B (annotated: 250 highlighted, 220 shaded); Schuele ¶ 21.

The ’036 patent explains that a difficulty with treating a tilted lens is that the height (Dcut) of the capsulotomy incision is increased to ensure that the anterior lens capsule is fully transected. ’036 patent, 6:36-39. It postulates that in such case, the height of the capsulotomy incision may be 4-6 times greater. *Id.*, 6:40-44. This is shown in Figure 4B, where the capsulotomy is performed with cut-cylinder 260-c (shaded in blue) having a larger "Dcut" height:

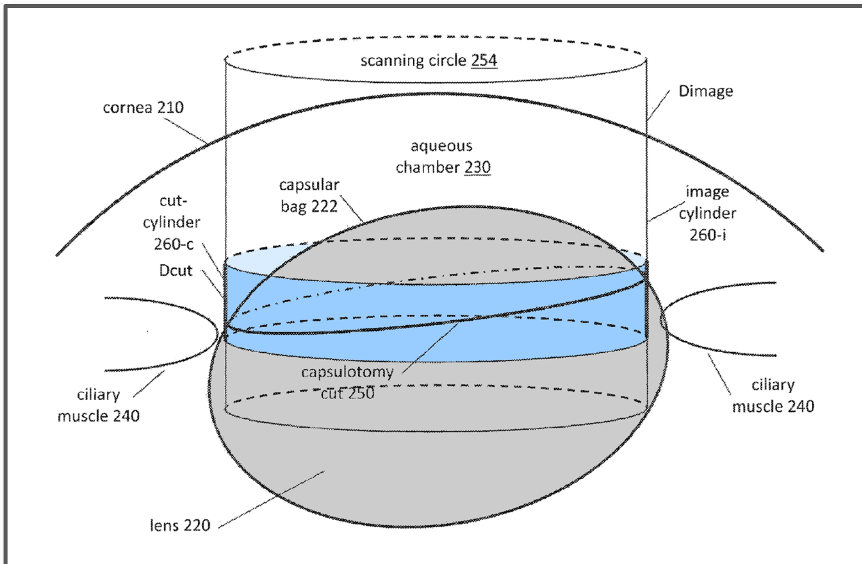


FIG. 4B

Id., Fig. 4B (annotated: 260-c, 220 shaded); Schuele ¶¶ 22-23. As shown, the non-tilted capsulotomy incision (260-c, shaded in blue) has a sufficient height to accommodate the depth variation of the anterior lens capsule to be cut (250). Schuele ¶ 24; *see also id.* ¶¶ 25-26.

The purported invention of the '036 patent is the ability to perform a tilted capsulotomy incision on a tilted lens. Alcon asserted in related litigation:

> For example, prior art capsulotomy incisions were made at a constant depth even when the anterior lens surface was uneven due to lens tilt. The patented solution includes imaging the eye and creating a scan

> pattern for the capsulotomy incision that tracks an imaged layer of the eye. At least claim 7 is directed to a method of adjusting for lens tilt.

10/30/2020 Answer and Counterclaims (Ex. 1011) ¶ 427.

This tilted capsulotomy incision has a smaller height (Dcut) because the capsulotomy follows the tilt of the lens. ’036 patent, 7:5-15. As a result, the laser pulses are applied in a tracking band that, like the anterior lens capsule itself, has a non-uniform z-depth.[2] *Id.*, 7:27-29. The depth is “non-uniform” because one edge of the tilted capsulotomy is located deeper in the eye (greater z-depth) than the other edge (shallower z-depth). Schuele ¶¶ 27-28; *see also* ’352 FH at 1053-54 (5/13/2016 Response to Final Office Action). This approach can be shown in annotated Figure 4B. The annotated pink tracking band shows a tilted capsulotomy that follows the tilt of the lens 220:

[2] Depth is called “z-depth” because depth is measured along the z-axis of the laser system (i.e., the vertical direction in the figures). Schuele ¶ 25.

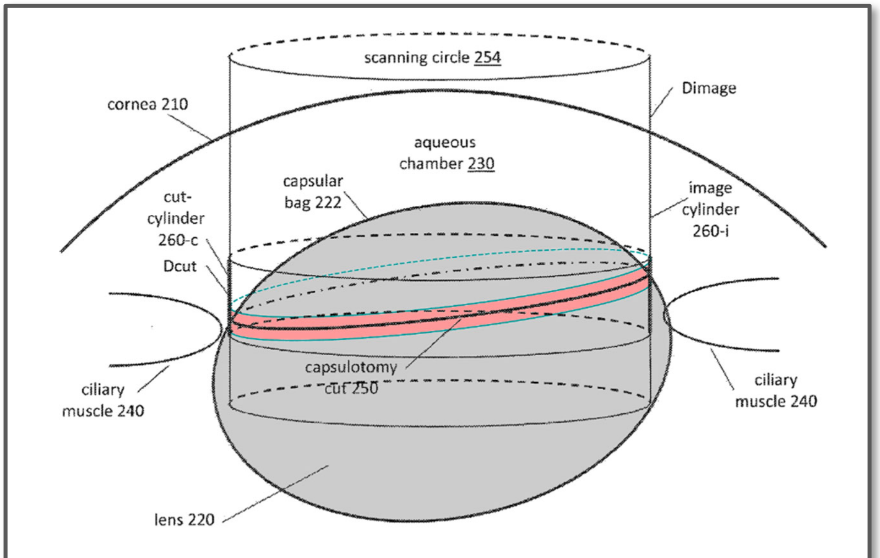


FIG. 4B

Id., Fig. 4B (annotated: pink/green band added, 220 shaded)[3]; Schuele ¶¶ 28-29. In Alcon's words, the "claimed system" defines a "laser cut within the tracking band

[3] The '036 patent shows the tilted tracking band in what it calls "unfolded" representations of the laser scan pattern, for example in Figures 6B and 6C (tracking band 257). *See* '036 patent, 7:25-34; Schuele ¶ 27-29. In those charts, the z-depth of the capsulotomy (vertical axis) is plotted against the angular position about the circumference, from 0° to 360° (horizontal axis). Schuele ¶ 27; *see also id.* ¶¶ 25-26. However, for purposes of illustration, the same tracking band is shown by adding the pink band to Figure 4B. Schuele ¶ 28-29.

that is ***tailored to the relative tilt of the target tissue***." '352 FH at 1144 (9/12/2016 Response to Final Office Action).[4]

B. Angeley (Ex. 1006)

The prior art Angeley reference discloses a system and method for making laser capsulotomy incisions during cataract surgery. Angeley, Abstract, [0078], [0090]. The disclosed system images the eye using optical coherence tomography (OCT) "to produce a 3-dimensional path for the cutting of the capsulorhexis." *Id.*, [0078], [0090], [0064]; Schuele ¶ 37.

Figure 9 of Angeley shows capsulotomy incision 400B:

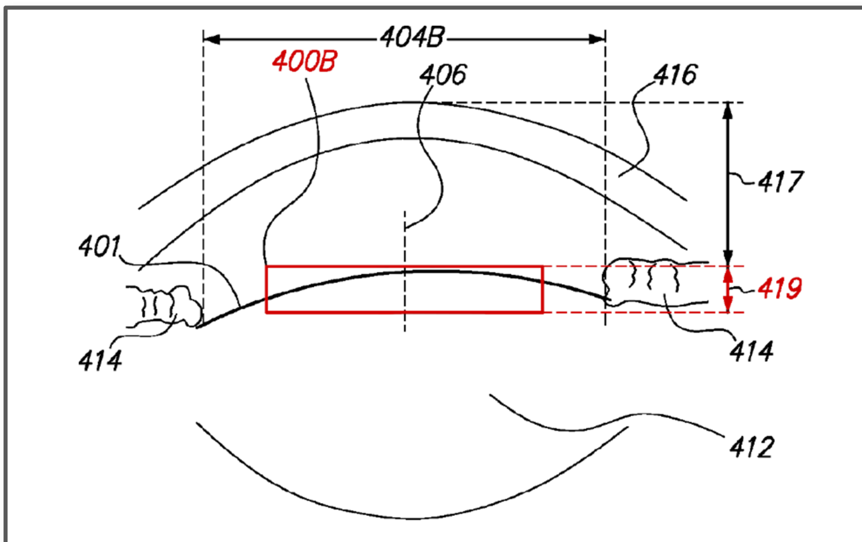


FIG. 9

[4] All emphasis is added unless otherwise noted.

Angeley, Fig. 9 (annotated: 400B, 419 highlighted); Schuele ¶ 38. The incision is not limited to a "flat circle." *Id.*, [0078]. Rather, the capsulotomy "can be described as having a cylindrical shape (extruded circle or ellipse)." *Id.* The laser pulses are applied in a band having "depth thickness 419," as shown in Figure 9 above. *Id.* This depth thickness 419 will "take into account variations in the depth of the targeted capsule cut" and "ensure that the capsule is intersected by the cutting mechanism." *Id.*; Schuele ¶ 39.

Angeley also teaches that a capsulotomy can be performed on a tilted lens. Figure 15 depicts an eye with a "tilted lens" 424 relative to the optical axis 422:

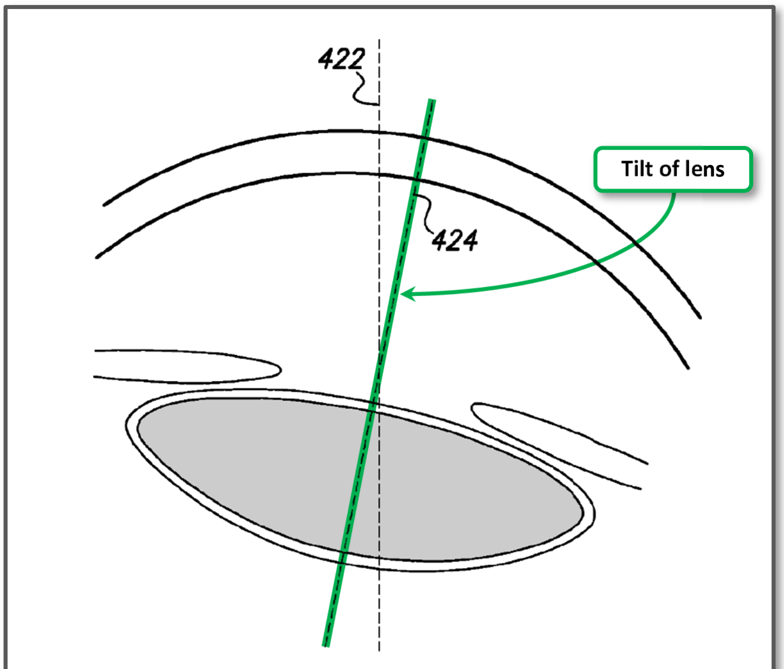


FIG. 15

Id., Fig. 15 (annotated: 424 highlighted and labeled); Schuele ¶ 40. The OCT imaging system of Angeley "can detect this tilt by finding the axis 424 connecting the centers of curvatures of the anterior and posterior lens surface." *Id.*, [0090]; Schuele ¶ 41.

Angeley describes how a capsulotomy can be performed on this tilted lens. Angeley, [0090]; Schuele ¶¶ 41-44. The capsulotomy is in a "tilted capsulorhexis [capsulotomy] incision plane." *Id.* Thus, in this tilted lens, "ideally ***the cut for the capsule will follow this tilt.***" *Id.*

The disclosure of Angeley is discussed by J&J Vision's declarant, Dr. Georg Schuele. Schuele ¶¶ 40-44. Dr. Schuele holds a Ph.D. in Physics from the University of Lübeck (Germany). *Id.* ¶ 3. He was actively working in the field of laser cataract surgery when Alcon filed its application for the '036 patent, and he is familiar with the perspective of a POSA at the time of the invention. *Id.* ¶¶ 3-6, 46-50.

Dr. Schuele explains that the "tilted capsulorhexis incision plane" described in paragraph [0090] of Angeley crosses the tilt of the lens (axis 424) in Figure 15. Schuele ¶ 42. That incision plane is labeled on Figure 15 below. Additionally, when the capsulotomy cut "will follow this tilt," it is made along the incision plane. Schuele ¶ 43. The capsulotomy cut described in paragraph [0090] is also labeled on Figure 15 below:

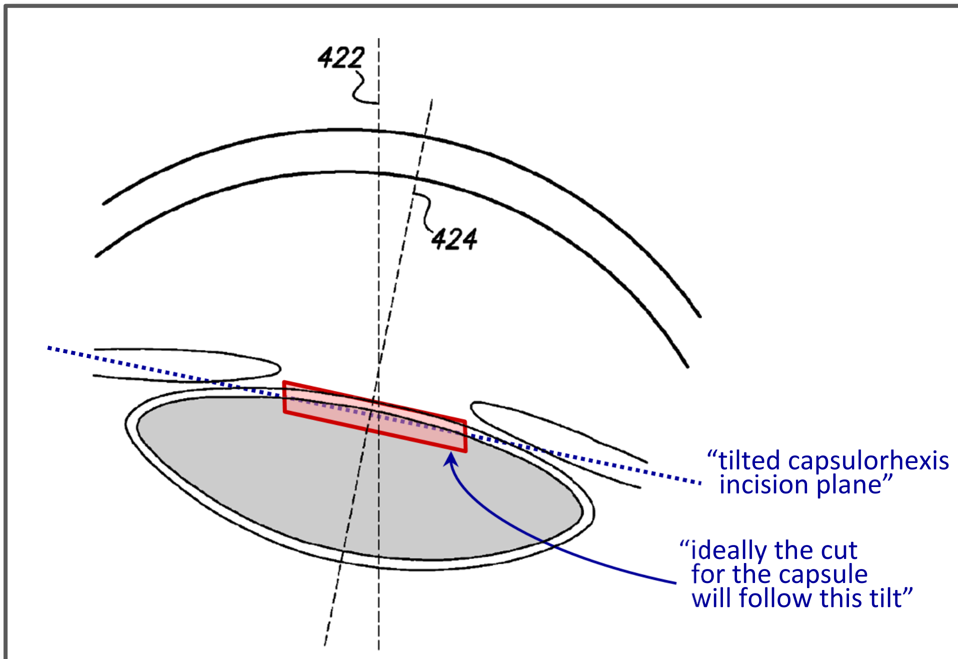
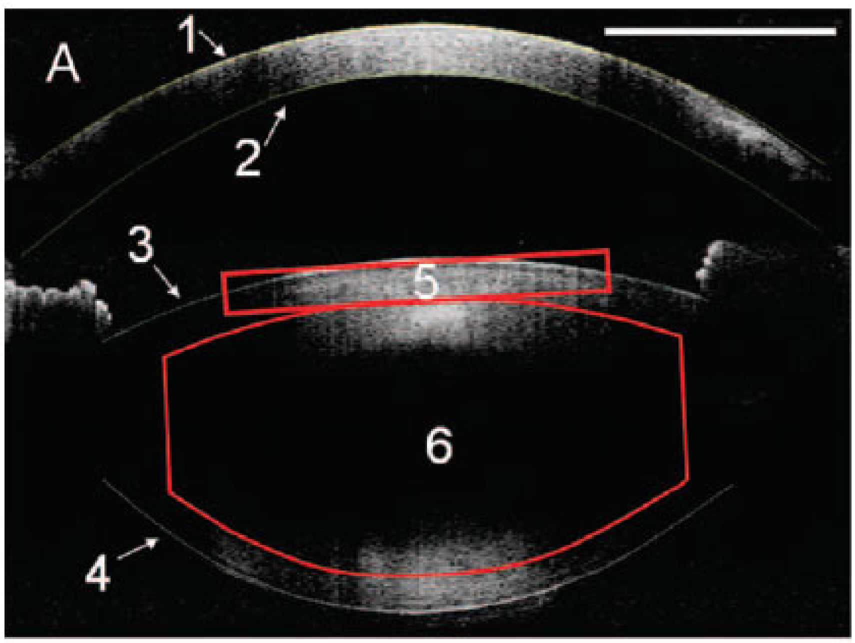


FIG. 15

Angeley, Fig. 15 (annotated: identifying "tilted capsulorhexis incision plane" and where "ideally the cut for the capsule will follow this tilt" of paragraph [0090]); Schuele ¶ 43. As this annotated figure shows, the capsulotomy cut described in paragraph [0090] of Angeley is tilted, i.e., it is defined by a "non-uniform z-depth." *Id.*

Dr. Schuele's understanding of Angeley is confirmed by a contemporaneous article by the Angeley inventors (and co-authored by Dr. Schuele), which was published in Science Translational Medicine in November 2010 ("Palanker article," Ex. 1009)[5]; Schuele ¶¶ 44-45. The Palanker article identifies the provisional application for Angeley (61/297,624) as "the technology described in the paper." Palanker article at 9. In particular, the Palanker article tested the system of Angeley on human and porcine eyes. *Id.* at 2.

Just as described in paragraph [0090] of Angeley, the Palanker article depicts a tilted capsulotomy (tilted red box 5) on a tilted lens (area within the lens capsule 3 and 4), overlaid on a gray scale OCT image of the eye:



[5] The Palanker article was published prior to the filing of the '036 patent. *See* Section VIII.A, *infra.*

Palanker article, Fig. 3A; Schuele ¶ 45. As in Angeley, Figure 3A of the Palanker article has a "tilted capsulorhexis [capsulotomy] incision plane" where "the cut for the capsule will follow this tilt," which the article itself shows as tilted red box (5). Schuele ¶ 45.

C. The Prosecution History

During prosecution of parent Application No. 13/110,352, the Examiner rejected the claims of the parent application as anticipated by Angeley. The Examiner recognized that Angeley discloses "a laser-beam system, configured to generate and scan a beam of laser pulses with an adjustable laser-power parameter to points of a scan-pattern in an eye." '352 FH at 382 (5/6/2013 Non-Final Rejection). Angeley includes "an imaging-based laser-controller" to control the scanning of the laser beam. *Id.* at 383. In particular, Angeley teaches that the laser system can perform capsulotomy, where "the capsulorhexis may be a cylindrical shape." *Id.* at 385.

Throughout prosecution of the parent application, Alcon repeatedly sought to distinguish Angeley by asserting that it does not disclose a tilted capsulotomy (i.e., non-uniform z-depth):

- Angeley "did not describe such 'varying z-depth' tracking bands or cuts." ('352 FH at 446 (9/6/2013 Response to Office Action).)

- "Accordingly, *Angeley* teaches that, to account for tilt of a lens capsule, the thickness of a cut with a uniform lower boundary z-depth is increased—resulting in an undesirably thick incision." ('352 FH at 1108 (5/31/2016 Response and Request for Continued Examination).)
- "Nowhere does *Angeley* suggest or contemplate other ways of accounting for lens tilt, let alone defining 'a lower boundary of [a] tracking band [that] has a non-uniform z-depth that varies according to the determined z-depths of the sequence of points corresponding to the imaged layer.'" ('352 FH at 1146 (9/12/2016 Response to Final Office Action).)

In advancing this argument, Alcon only addressed Figure 9 of Angeley and the accompanying description in paragraph [0078]. Time and again, Alcon attacked just those portions of Angeley as not disclosing a non-uniform z-depth, arguing for example that "***paragraph [0078]*** expressly confirms what ***FIG. 9*** illustrates; namely, that the capsulorhexis cut—which has a lower boundary with a uniform z-depth … has nothing to do with non-uniform z-depth." '352 FH at 1158 (10/14/2016 Pre-Appeal Brief) (underlining in original); *see also* '352 FH at 1145-46 (9/12/2016 Response to Final Office Action,); '352 FH at 1054 (5/13/2016 Response and Request for Continued Examination).

Alcon did not discuss (or even acknowledge) Angeley's disclosure in ***paragraph [0090]*** and ***Figure 15*** that on a tilted lens, "ideally the cut for the capsule will follow this tilt." Angeley, [0090]. Indeed, Alcon represented to the Examiner that ***paragraph [0078]*** "***is the <u>only</u> passage of Angeley*** that describes how cut depth is determined; nowhere does *Angeley* suggest or contemplate another way of accounting for lens tilt." '352 FH at 1157 (10/14/2016 Pre-Appeal Brief) (underlining in original). That statement was false. As described above, paragraph [0090] of Angeley teaches another way to account for lens tilt: to have the cut follow the tilt.

The Examiner overlooked (and Alcon never pointed out) that a tilted capsulotomy with non-uniform z-depth is disclosed elsewhere in Angeley, in paragraph [0090] and Figure 15. Instead, Alcon's focus on paragraph [0078] and Figure 9 ultimately persuaded the Examiner to allow the claims of the parent application. '352 FH at 1167-74 (12/8/2016 Notice of Allowance).

Alcon next pursued claims with substantially the same claim limitation in the continuation application that issued as the '036 patent. *Compare* '352 FH at 1135 (9/12/2016 Response to Final Office Action) (claim 1), *with* File History for Application No. 15/452,252 ("'252 FH," Ex. 1002) at 76 (3/24/2017 Preliminary Amendment) (claim 20). In the initial office action, the Examiner considered the claims allowable, contingent on filing a terminal disclaimer to overcome double-patenting over the parent application. '252 FH at 94 (4/24/2017 Non-Final Rejection). Alcon filed a terminal disclaimer and the claims were allowed. '252 FH at 125-26 (7/20/2017 Terminal Disclaimer); ’252 FH at 132-42 (10/4/2017 Notice of Allowance).

IV. Person of Ordinary Skill in the Art

A person having ordinary skill in the art at the time of the purported invention in or about May 2011 (“POSA”) would have at least a Bachelors’ degree in a laser-related engineering or physics field, and several years of work experience in designing laser-based systems for eye surgery. Schuele ¶ 47. Such a POSA may have worked with an ophthalmologist. *Id.* The experience and education levels may vary: a higher level of education or skill might make up for less experience, and vice versa. *Id.*

V. Claim Construction

All terms should be given their ordinary and customary meaning.[6] J&J Vision reserves the right to respond to any constructions that may be offered by Alcon or adopted by the Board.

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[6] This is the approach taken by Alcon in related litigation. *See* Alcon’s Initial Infringement Contentions, Ex. B (“Alcon Contentions,” Ex. 1012). J&J Vision reserves the right to argue alternative constructions in other proceedings.

VI. Ground 1: All Claims Are Anticipated by Angeley

A. Angeley Is Prior Art to the '036 Patent

Angeley is prior art under pre-AIA 35 U.S.C. § 102(e)(1) because it is a published patent application filed on January 21, 2011, before the '036 patent's earliest claimed priority date.

Should Alcon seek to antedate Angeley's non-provisional filing date, Angeley is also entitled to the January 22, 2010 filing date of U.S. Provisional Application No. 61/297,624 ("Angeley provisional," Ex. 1007). The Angeley provisional has the same relevant disclosures as the Angeley reference discussed in this Petition. *Compare* Angeley provisional 4:23-6:7, 6:15-8:2, 8:15-9:2, 19:13-20:23, 20:24-21:22, 21:23-22:8, 25:6-16, *with* Angeley, [0035]-[0039], [0041]-[0042], [0044], [0072]-[0075], [0077]-[0078], [0080], [0090], respectively; Schuele ¶¶ 62-63.

The provisional application also supports the claims of Angeley. *See Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015). Exemplary support for claim 1 of Angeley is set forth below:

Angeley Claim 1	**Angeley Provisional**
A system for cataract surgery on an eye of a patient, comprising:	2:15-3:11, 17:11-14
a. a laser source configured to produce a treatment beam comprising a plurality of laser pulses;	4:23-5:6

Angeley Claim 1	**Angeley Provisional**
b. an integrated optical system comprising an imaging assembly operatively coupled to a treatment laser delivery assembly such that they share at least one common optical element, the integrated optical system being configured to acquire image information pertinent to one or more targeted tissue structures and direct the treatment beam in a 3-dimensional pattern to cause breakdown in at least one of the targeted tissue structures; and	4:23-5:6, 8:15-9:2, 9:27-10:3, Figs. 1, 3-4, 18
c. a controller operatively coupled to the laser source and integrated optical system, and configured to:	5:7-12, Figs. 1, 3-4, 18
1) adjust the laser beam and treatment pattern based upon the image information, and	7:19-8:2, 8:15-31, 12:11-27, 15:11-20
2) distinguish two or more anatomical structures of the eye based at least in part upon a robust least squares fit analysis of the image information.	19:13-20:23, 21:23-22:8

Schuele ¶ 64.

B. Claims 7 and 13

There are three independent claims in the ’036 patent: claims 1, 7 and 13. Claims 7 and 13 recite steps to create a laser capsulotomy incision on a tilted lens. Claim 1 is directed to an apparatus for performing the steps claimed in claims 7 and 13, plus other limitations. To streamline the discussion, we begin with the broader claims 7 and 13. Claim 1 is discussed separately below. *See* Section VI.C, *infra*.

Claim 7 is directed to a four-step method: (a) imaging a tilted lens capsule; (b) determining the depth of the tilt; (c) generating a tracking band that follows the tilt; and (d) directing the laser to cut a tilted capsulotomy defined by the tracking band. Schuele ¶ 66. Angeley's anticipation of claim 7 can be summarized as follows:

- **Step [a]:** *"generating an image, with an imaging system, of a layer of an eye that is tilted relative to a z-axis of an incision to be made in the eye."* Angeley uses OCT to image a layer of the eye—the anterior lens capsule in which the capsulotomy cut is made. *See, e.g.*, Angeley, [0044], [0074]-[0075]. This can be done in a tilted lens. *Id.*, [0090].
- **Step [b]:** *"determining, with an imaging-based laser-controller, z-depths of a sequence of points in a scan-pattern that correspond to the image of the layer."* Angeley uses a controller (control electronics) to determine the depth of the tilted anterior lens capsule at those points where the laser will be applied for the capsulotomy (scan pattern). *See, e.g.*, *id.*, [0042], [0044], [0048], [0074]-[0075].
- **Step [c]:** *"generating, with the imaging-based laser-controller, a tracking band within the scan pattern defining the incision to be made in the eye, wherein a lower boundary of the tracking band has a non-uniform z-depth that varies according to the determined z-depths of the sequence of points*

corresponding to the image of the layer." Angeley uses the control electronics to generate the capsulotomy pattern. *See, e.g.*, *id.*, [0044]. The tilted capsulotomy forms a tracking band with a non-uniform z-depth. *Id.*, [0090]. The depth of the capsulotomy "varies according to" the determined depth of the tilted lens (in Angeley's words, it "will follow this tilt"). *Id.*

- **Step [d]:** *"directing, with the imaging-based laser-controller, a beam of laser pulses to the points of the scan-pattern to create the incision defined by the tracking band."* Angeley directs laser pulses to points in the determined scan pattern to cut the tilted capsulotomy. *See, e.g.*, *id.*, [0064], [0090].

Claim 13 is directed to a computer-readable medium storing instructions that, when executed, cause a processor of an imaging-based laser system to execute the steps in claim 7.

As shown below, Angeley discloses all steps of claims 7 and 13.

1. Preamble

"A method, comprising" (claim 7)

"A non-transitory computer-readable medium storing instructions that, when executed, cause a processor of an imaging-based laser system to" (claim 13)

To the extent the preambles are limiting, they are disclosed by Angeley. Angeley discloses "[t]he present invention can be implemented by a system that projects or scans an optical beam into a patient's eye 68, such as system 2 shown in FIG. 1 which includes an ultrafast (UF) light source 4 (e.g., a femtosecond laser)." Angeley, [0035]; *see also id.,* Fig. 1. Angeley teaches that "laser 4" and "the entire system" are "controlled by control electronics 300." *Id.*, [0036], Fig. 1. "Control electronics 300 may be a computer, microcontroller, etc." *Id.*, [0036]. They store the instructions that cause Angeley's controller to perform the steps as explained below. *Id.*, [0044]; Schuele ¶ 72.

2. Step 7/13[a]: generate an image

> *"generating an image, with an imaging system, of a layer of an eye that is tilted relative to a z-axis of an incision to be made in the eye"* (claim 7)
>
> *"analyze an image of a layer of an eye that is tilted relative to a z-axis of an incision to be made in the eye"* (claim 13)

The OCT system in Angeley is an imaging system that can generate and analyze an image. Angeley, [0044]; *see also id.*, Fig. 1 (OCT system 100), Fig. 6 (OCT system 100). The imaging system "provides information about the axial location of the anterior and posterior ***lens capsule***." *Id.*, [0044]; *see also id.*, [0064], [0072], [0074], [0075], [0078], [0080], [0090]. Thus, Angeley images the very same layer of the eye that the '036 patent identifies for capsulotomy. '036 patent, 10:2-3 ("the example of the capsulotomy procedure, where the imaged layer is the ***lens capsule***").

In particular, Angeley uses OCT system 100 to generate and analyze an image of the layer of an eye that is tilted relative to the z-axis of an incision to be made in the eye:

> FIG. 15 is a cross-sectional schematic of the eye showing a ***tilted capsulorhexis incision plane***. Its shows a tilted lens and ideally the cut for the capsule will follow this tilt. Here ***OCT system 100 of FIG. 1 is used to discern capsule 401*** by detecting surfaces 408 [anterior capsule] & 410 [posterior capsule] of lens 412. ***The OCT system can detect this tilt*** by finding the axis 424 connecting the centers of curvatures of the anterior and posterior lens surface.

Angeley, [0090].

For these reasons, Angeley discloses an imaging system that generates and analyzes an image of a layer of an eye that is tilted relative to the z-axis, as required by Step 7/13[a]. Schuele ¶¶ 76-78.

3. Step 7/13[b]: determine z-depths in scan pattern

"determining, with an imaging-based laser-controller, z-depths of a sequence of points in a scan-pattern that correspond to the image of the layer" (claim 7)

"determine z-depths of a sequence of points in a scan-pattern that correspond to the layer" (claim 13)

Angeley's "control electronics 300" is an imaging-based laser-controller, as it controls an OCT imaging system and laser treatment based on the imaging. Angeley, [0036] ("laser 4" and "the entire system" are "controlled by control electronics 300"). The controller determines the "aiming and treatment ***scan patterns***" for the laser pulses. *Id.*, [0042]; *see also id.*, [0044] (information loaded to controller "used to program and control the subsequent laser-assisted surgical procedure")*,* [0063], [0064], [0067], [0075], [0078], [0080], [0090], Fig. 1, Fig. 6. The scan pattern is based on the image obtained in Step 7[a]. *Id.*, [0008] ("acquire image information pertinent to one or more targeted tissue structures and direct the ***treatment beam in a 3-dimensional pattern*** to cause breakdown in at least one of the targeted tissue structures").

In particular, Angeley's imaging system determines the "z-depth" of eye structures: "The OCT generates both lateral (XY) and ***depth (Z) information*** (3-dimensional)." Angeley, [0078]. That information includes the z-depth of points that correspond to a layer of the eye (the anterior lens capsule). *Id.*, [0044] (OCT provides "***axial location of the anterior*** and posterior ***lens capsule***"); *see also, id.*, [0063], [0064], [0072] ("[T]he OCT system produces a ***3-dimensional image*** or map of the anterior segment of the human eye."), [0074], [0075], [0078], [0080], [0090].

For these reasons, Angeley discloses using an imaging-based laser-controller to determine z-depths of a sequence of points in a scan-pattern that correspond to the image of the anterior lens capsule. Schuele ¶¶ 81-84.

4. Step 7/13[c]: generate tracking band with non-uniform z-depth

> *"generating, with the imaging-based laser-controller, a tracking band within the scan pattern defining the incision to be made in the eye, wherein a lower boundary of the tracking band has a non-uniform z-depth that varies according to the determined z-depths of the sequence of points corresponding to the image of the layer"* (claim 7)

> *"generate a tracking band within the scan pattern defining the incision to be made in the eye, wherein a lower boundary of the tracking band has a non-uniform z-depth that varies according to the determined z-depths of the sequence of points corresponding to the image of the layer"* (claim 13)

Angeley discloses generating a tracking band as required by this Step 7/13[c]. As described above, this "tracking band" is a cylindrical band that follows the anterior lens capsule in a non-tilted or tilted lens. *See* Section III.A, *supra* at 4, 8 (annotated pink bands); Schuele ¶¶ 27-29, 87. The '036 patent explains that this band has a depth that spans a preselected distance from the anterior lens capsule. '036 patent, 7:27-29 ("A tracking band 257 can be defined as the set of points of the scan-pattern that are within the preselected distance Dcut from the image 256 of the imaged layer.”).

Angeley discloses this tracking band. It describes the capsulotomy cut as “having a cylindrical shape (extruded circle or ellipse).” Angeley, [0078]. This tracking band creates a “3-dimensional path for the cutting of the capsulorhexis [capsulotomy].” *Id.* Angeley specifies that the height of this “extruded circle or ellipse” is “depth thickness 419.”[7] *Id.*; *see also id.*, [0064] (3-dimensional scan pattern has “scan volume” to cut capsule), Fig. 9. The height of the tracking band, “depth thickness 419” in Angeley, corresponds to “Dcut” in the ’036 patent. Schuele ¶ 88; *compare* Angeley, [0078] (“***extent to the cut in Z***, i.e., the depth thickness

[7] As Angeley explains, the capsulotomy is made with a “treatment beam in a 3-dimensional pattern.” Angeley, [0008]. The tilted capsulotomy incision of paragraph [0090] has a “depth thickness 419” as described in paragraph [0078], since the tilted capsulotomy is created using the same laser surgical system 2 and OCT system 100 that is used to generate capsulotomy incisions with depth thickness 419 in paragraph [0078]. *Id.*, [0090] (“Here, OCT system 100 of FIG. 1 [laser surgical system 2]”), [0066]-[0067] (describing generation of Fig. 8 and Fig. 9 using system 2 and “the OCT system”), [0042]; Schuele ¶ 88 n.3.

419"), *with* '036 patent, 7:22-24 ("***z-extent*** of Dcut"). Thus, Angeley discloses a "tracking band within the scan pattern." Schuele ¶ 88.

Angeley also discloses that the tracking band is tilted, i.e., it has a "non-uniform z-depth."[8] Angeley shows a tilted lens in Figure 15, and explains that such a lens has a "tilted capsulorhexis incision plane." Angeley, [0090], Fig. 15. Angeley teaches that "ideally the cut for the capsule will follow this tilt." Angeley, [0090]. Thus, the tracking band that defines the capsulotomy cut has a non-uniform z-depth. Schuele ¶ 89.

The tilted capsulotomy described in paragraph [0090] of Angeley can be shown on the below annotated Figure 15:

---

[8] Alcon confirmed during prosecution that a tilted capsulotomy has a non-uniform z-depth. *See* '352 FH at 1082-83 (5/31/2016 Response and Request for Continuing Examination) ("Further, the laser controller is configured to 'generate a tracking band within the cylindrical scan pattern defining a cut to be made in the eye, wherein a lower boundary of the ***tracking band has a non-uniform z-depth*** that varies according to the determined z-depths of the sequence of points corresponding to the imaged layer,' ***which is tilted*** relative to an optical axis of the laser system. Accordingly, the claimed system can define a laser cut within the tracking band that is ***tailored to the relative tilt*** of the target tissue.") (underlining removed).

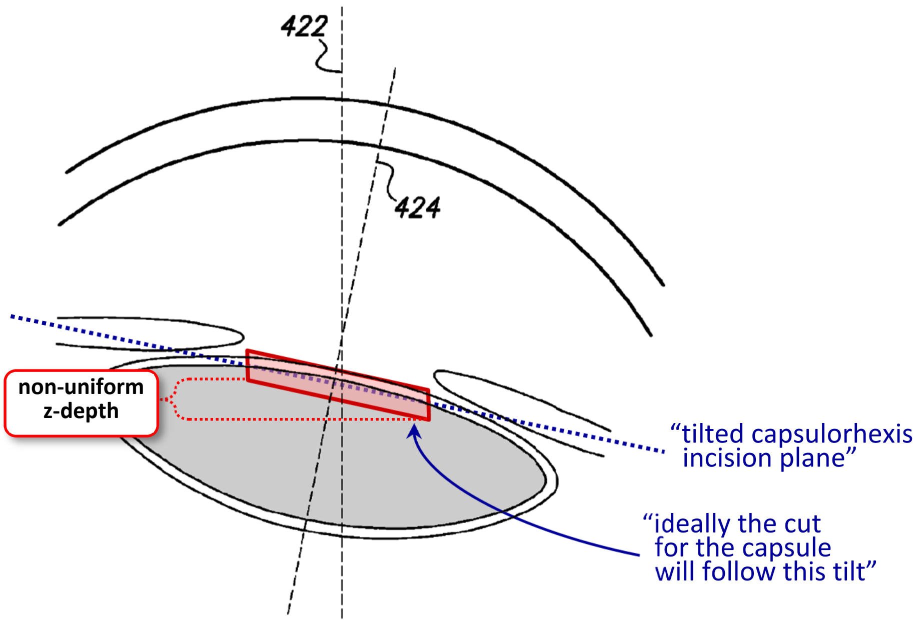


FIG. 15

Angeley, Fig. 15 (annotated: identifying "tilted capsulorhexis incision plane," and where "ideally the cut for the capsule will follow this tilt" of paragraph [0090], non-uniform z-depth labeled); Schuele ¶¶ 89-90. Step 7/13[c] specifically recites that the "lower boundary of the tracking band" has a non-uniform z-depth. As is apparent from the figure, a tilted capsulotomy has a lower boundary with non-uniform z-depth. Schuele ¶ 91. In the case shown above, the z-depth increases from left to right. *Id.*

Finally, the z-depth "varies according to" the determined depth of the anterior lens capsule, the relevant layer of the eye. '036 patent, 10:2-3 ("the example of the capsulotomy procedure, where the imaged layer is the lens capsule"). As Angeley explains, "ideally the cut for the capsule ***will follow this tilt.***" Angeley, [0090]; Schuele ¶ 92.

For these reasons, Angeley discloses generating a tracking band having non-uniform z-depth in accordance with Step 7/13[c]. Schuele ¶¶ 87-93.

5. Step 7/13[d]: direct incision defined by tracking band

> *"directing, with the imaging-based laser-controller, a beam of laser pulses to the points of the scan pattern to create the incision defined by the tracking band."* (claim 7)
>
> *"generate signals to cause an imaging-based laser-controller system to direct a beam of laser pulses to the points of the scan-pattern to create the incision defined by the tracking band"* (claim 13)

Angeley discloses directing laser beam 6 in a scan pattern to create the tilted capsulotomy incision defined by the tracking band. Angeley, [0090] (describing the "tilted capsulorhexis ***incision*** plane" where the "***cut for the capsule*** will follow this tilt" of the lens); *see also id.*, [0035], [0044], [0064], Fig. 1, Fig. 6; Schuele ¶ 96.

Angeley creates an incision with "a beam of laser pulses," as required by Step 7/13[d]. As Angeley explains, its laser source is "configured to produce a treatment beam comprising a plurality of laser pulses." Angeley, [0008]; *see also id.*, [0035], [0078] (laser beam provides "the cutting mechanism (e.g., the plasma)"), [0042], Fig. 1; Schuele ¶ 97.

The laser pulses of Angeley are directed by an "imaging-based laser-controller," controller 300. Angeley, [0008] ("controller operatively coupled to the laser source and integrated optical system" is "configured to adjust the laser beam and treatment pattern based upon the image information"), [0036] ("laser 4 is controlled by control electronics 300"), [0042], [0044], [0078]; Schuele ¶ 98.

For these reasons, Angeley discloses directing the laser beam to create a tilted capsulotomy in accordance with Step 7/13[d]. Schuele ¶¶ 96-99; *see also* Step 7[b] above and Element 1[e] below (discussing the beam scanner controlled by controller 300).

* * *

In sum, Angeley anticipates claim 7 and 13.

C. Claim 1

Claim 1 is directed to an imaging-based laser system configured to perform the steps of claims 7 and 13 discussed above. Claim 1 is anticipated by Angeley for similar reasons. Schuele ¶ 100.

1. Preamble

"An imaging-based laser system, comprising"

To the extent the preamble is limiting, Angeley discloses an imaging-based laser system, specifically, "an integrated optical system comprising an imaging assembly operatively coupled to a treatment laser delivery assembly." Angeley, [0008]; *see also* Figs. 1 and 6, [0044], [0078], [0090]; Schuele ¶ 103.

2. Element 1[a]: laser engine

"a laser engine configured to generate a beam of laser pulses"

Angeley's system includes a "laser delivery assembly" with "a laser source configured to produce a treatment beam comprising a plurality of laser pulses." Angeley, [0008]; *see also id.,* [0035], [0044], Fig. 1; Schuele ¶ 106.

3. Element 1[b]: imaging-based laser controller

"an imaging-based laser-controller configured to" perform elements 1[c]-1[f]

As discussed above for Step 7/13[b], Angeley's controller 300 is an imaging-based laser controller, as it controls Angeley's laser according to a scanned OCT image. Angeley, [0036] ("laser 4" and "the entire system" are "controlled by control electronics 300"), [0044] ("This [OCT image] information is then be loaded into the control electronics 300, and used to program and control the subsequent laser-assisted surgical procedure."), [0008] ("a controller … configured to adjust the laser beam and treatment pattern based upon the image information"), [0042], [0063], [0067], [0080], [0090], Figs. 1, 6; Schuele ¶ 109.

Angeley's controller 300 is thus configured to perform the rest of the claimed steps (as discussed below). Angeley, [0036]; Schuele ¶ 110.

4. Element 1[c]: determine z-depths in scan pattern

"determine z-depths of a sequence of points in a scan-pattern that correspond to a layer of the eye imaged by an imaging system"

This element is substantively identical to Step 7/13[b] discussed above and is disclosed for the same reasons. Schuele ¶ 112.

5. Element 1[d]: generate tracking band with non-uniform z-depth

"generate a tracking band within the scan pattern defining the incision to be made in the eye, wherein a lower boundary of the tracking band has a non-uniform z-depth that varies according to the determined z-depths of the sequence of points corresponding to the imaged layer"

This element is substantively identical to Step 7/13[c] discussed above and is disclosed for the same reasons. Schuele ¶ 114.

6. Element 1[e]: beam scanner

"cause a beam scanner to scan the beam of laser pulses to the points of the scan-pattern"

This element is like Step 7/13[d] discussed above and is disclosed for the same reasons and as further explained below. Schuele ¶¶ 116-119.

Angeley's Z scan device 40 and X-Y scanning device 50 constitute a "beam scanner." Angeley, [0041]. Indeed, Alcon alleges in litigation that the "XY-scan mechanism(s)" and "Z-scan mechanism" allegedly present in the J&J Vision's Catalys® System are the claimed "beam scanner." 10/30/2020 Answer and Counterclaims (Ex. 1011) ¶ 462; *see also* Alcon Contentions (Ex. 1012), Ex. B, at 93 (citing a J&J Vision patent with XY-scanner and Z-scanner disclosures identical to Angeley, U.S. Patent No. 9,233,023 ("'023 patent," Ex. 1013, 4:56-5:49, as evidence of infringement for this element); Schuele ¶ 117.

Angeley's Z scan device 40 and X-Y scanning device 50 are used to "scan the beam of laser pulses to the points of the scan-pattern," as required by Element 1[e]. Angeley, [0042] ("The aiming and treatment scan patterns can be automatically generated by the scanner 50 under the control of controller 300."), [0064] ("For the UF beam 6, lateral movement is achieved via [xy] galvos 52, 54, for example. The axial or z movement of the focus of the UF beam is achieved via a [z] galvo mechanism 40. The focus of the ***UF beam thereby is scanned 3-dimensionally*** throughout a volume within the eye. This ***scan volume enables the UF laser to access and cut the capsule*** given a wide range of biological variation."), Fig. 1; *see also id.*, [0035], [0041], [0047], Figs. 3-4; Schuele ¶ 118.

As discussed in connection with Element 1[b] and Step 7/13[b], Angeley discloses that its "entire system is controlled by the controller 300." Angeley, [0036]; Schuele ¶ 119. Angeley's "controller [is] operatively coupled to the laser source and integrated optical system" and "configured to adjust the laser ***beam and***

treatment pattern based upon the image information." Angeley, [0008]; *id.,* [0036] ("The laser 4 is controlled by control electronics [or controller] 300."), [0044]. This system includes the Z scan device 40 and X-Y scanning device 50, both of which are under the control of the control electronics 300. *Id.*, [0041] ("The ***z-adjust [40]*** is the z-scan device for treatment in the eye 68. It can be ***controlled automatically and dynamically by the system***."); *id.* ("X-Y scanning is achieved by the ***scanning device 50 … under the control of control electronics 300***."), [0042], [0047], [0064], Fig. 1; Schuele ¶ 119.

7. Element 1[f]: beam attenuator

> *"cause a beam attenuator to control the laser-power parameter of the laser pulses such that a laser power parameter of laser pulses in the tracking band is above a photo-disruption threshold, and a laser power parameter of laser pulses outside the tracking band is below the photo-disruption threshold"*

The '036 patent explains that the "beam attenuator" can include "a Pockels cell, a polarizer-assembly, a mechanical shutter, an electro-mechanical shutter, or an energy wheel" that will "modify a laser-power parameter of the laser pulses" such as "a pulse energy, a pulse power, a pulse length or a pulse repetition rate of the laser pulses, among others." '036 patent, 4:8-19.

Angeley discloses "half-wave plate 8 and linear polarizer 10, which together ***act as a variable attenuator for the UF [laser] beam 6***." Angeley, [0037], Fig. 1;

Schuele ¶¶ 122-123. Angeley explains that "***pulse energy, average power, or a combination***" may be attenuated by the "half-wave plate 8." Angeley, [0038]; Schuele ¶ 123. Moreover, Angeley explains that "[t]he system control shutter 12" acts as an "on/off control of the laser for procedural and safety reasons." Angeley, [0038]. The laser system with "half-wave plate 8 and linear polarizer 10" and "shutter 12" generates a range of laser pulse energy and repetition rate Angeley, [0035], [0037]-[0038]. Angeley's half-wave plate 8, linear polarizer 10, and shutter 12 constitute the claimed "beam attenuator" that controls the laser-power parameter (pulse energy and average power) of the laser pulses. Schuele ¶ 123.

Indeed, Alcon alleges in litigation that the "beam attenuator" is met by the same disclosure in another J&J Vision patent, which has the same half-wave plate 8 and linear polarizer 10 found in Angeley system 2. *See* Alcon Contentions (Ex 1012), Ex. B, at 118 (citing '023 patent at 4:7-15 and Fig. 1 for Element 1[f]), Ex. B at 178 (citing '023 patent at 4:7-15 and Fig. 1 for claim 6); *compare* '023 patent, 4:7-15 and Fig. 1, *with* Angeley, [0037] and Fig. 1 respectively. Schuele ¶ 124.

Angeley also discloses that the beam attenuator (half-wave plate 8, linear polarizer 10, and shutter 12) controls the laser-power parameter "such that the laser power parameter of laser pulses in the tracking band is above a photo-disruption threshold, and a laser power parameter of laser pulses outside the tracking band is below the photo-disruption threshold," as recited in this claim element. Angeley's laser-power parameter is above the threshold when the pulses are directed to the scanning pattern that follows the tilt of the lens capsule. *See* Step 7/13[d] and Element 1[e] above; Schuele ¶ 94-99, 115-120. Angeley teaches that system 2 with half-wave plate 8, linear polarizer 10, and shutter 12 can produce a laser pulse energy range in which the "peak power of the focused [laser] spot" is within the "anterior capsule of the eye … sufficient to produce optical breakdown and initiate a plasma-mediated ablation process." Angeley, [0035]; *see also id.* Fig. 1, [0078], [0008]; Schuele ¶ 126. Angeley's laser does not emit any pulses for cutting outside the tracking band so the laser power there is zero, below the photo-disruption threshold. Angeley, [0035], [0038], [0042] ("treatment light is delivered only within the desired target area"), [0044] ("the beam 6 will be focused where appropriate and not unintentionally damage non-targeted tissue"), [0078], [0090]; Schuele ¶ 126. Angeley thus discloses this feature because it teaches that the beam attenuator controls the power of laser pulses to be above the photodisruption level along the 3-dimensional path for cutting the capsulotomy. Angeley, [0044], [0064], [0078], [0090]; Schuele ¶¶ 126-127.

Angeley discloses that the imaging-based laser-controller "cause[s]" the beam attenuator to control the laser power parameter of laser pulses. The "entire system is controlled by the controller 300," which generates a tracking band to guide the laser to precise points for the incision. Angeley, [0036]; *see also id.*, [0037]-[0038],

Fig. 1; Schuele ¶ 128. As discussed above, Angeley's controller is "imaging-based" so that it causes the beam attenuator to control the laser power parameter in response to OCT imaging data. Angeley, [0008] ("acquire image information pertinent to one or more targeted tissue structures and direct the treatment beam in a 3-dimensional pattern to cause breakdown in at least one of the targeted tissue structures"), [0013], [0042], [0044], [0078], [0090], Fig. 1; Schuele ¶ 128. The treatment beam generated by the controller is a "plurality of laser pulses." Angeley, [0008]; *see also id.*, [0035], [0036], [0042]; Schuele ¶ 128.

* * *

In sum, Angeley anticipates claim 1.

D. Dependent Claims

1. Dependent Claims 8-12 and 14-17

a. Claim 8/14

Claim 8 (which depends from claim 7) and claim 14 (which depends from claim 13) recite the added step of:

> *"associating a photodisruptive laser-power parameter with points in the scan pattern that are inside the tracking band; and associating a non-photodisruptive laser-power parameter with points in the scan pattern than are outside the tracking band"*

As discussed in connection with Element 1[f] and Step 7/13[d], Angeley's laser system 2 controls the pulse energy and the pulse power of the laser beam so that the laser causes breakdown of the targeted tissue in the scan pattern. Angeley, [0008], [0035], [0064], [0078], [0090]; *see also* Step 7/13[d] and Elements 1[e] and 1[f] above; Schuele ¶¶ 94-99, 115-129. Angeley teaches that the beam attenuator (i.e., half-wave plate 8, linear polarizer 10, and shutter 12) controls the laser pulse power and energy. Angeley, [0037]-[0038]; *see also* Step 7/13[d] and Elements 1[e] and 1[f] above; Schuele ¶¶ 94-99, 115-129, 130-133.

Angeley's laser does not emit any pulses for cutting outside the tracking band, where the laser power is zero (a "non-photodisruptive" laser power level). Schuele ¶ 132. Angeley discloses this step because the beam attenuator controls the laser power parameter of laser pulses to be above the photodisruption level along the 3-dimensional path of the cylindrical capsulotomy incision. Angeley, [0038], [0035], [0078], [0090], [0064]; Schuele ¶ 132.

Thus, Angeley discloses this Step 8/14. Schuele ¶¶ 130-133.

b. Claim 9/15

Claim 9 (which depends from claim 7) and claim 15 (which depends from claim 13) recite the added step of:

> *"wherein determining z-depths of the sequence of points in the scan pattern that correspond to the imaged layer in the eye comprises performing a feature-recognition analysis to identify the imaged layer"*

The ’036 patent indicates that the “feature-recognition analysis” determines the identity and z-depth coordinate of the imaged layer. ’036 patent, 8:50-54. It includes “locating local maxima of the gradient of the spot intensity, ” “an edge-recognition algorithm,” or “a model curve.” *Id.*, 8:54-64.

Angeley teaches that “feature-recognition analysis” is performed using OCT to identify the imaged layer (anterior lens capsule) and its z-depth coordinates. Angeley, [0072] (“The OCT system produces a 3-dimensional image or map of the anterior segment of the human eye.”), [0064] (“OCT can detect structures that include the contact lens, the cornea, the iris, and the lens throughout a volume”), [0074]-[0075], [0078], [0080], [0090]. As discussed above for Step 7/13[b] and Element 1[c], Angeley images the eye using OCT and then detects the location of surfaces in the eye by analyzing “edge pixels” in the OCT images. Angeley, [0074]-[0075]; *see also* citations and discussions for Step 7/13[b] and Element 1[c]; Schuele ¶¶ 79-84, 111-112. Angeley’s system then determines which detected edge pixels belong to the anterior lens capsule and fits them to a sphere representing the anterior capsule. Angeley, [0074]-[0075]. And because each edge pixel has an x, y, and ***z coordinate***, Angeley determines the z-depths of the anterior lens capsule in the 3-dimensional OCT image. *Id.* Angeley thus performs an “edge-recognition algorithm” which, as confirmed by the ’036 patent, is a “feature-recognition analysis" to detect the imaged layer (i.e., the anterior lens capsule). *Id.*; Schuele ¶ 137.

Thus, Angeley discloses this Step 9/15. Schuele ¶¶ 134-138.

c. Claim 10/16

Claim 10 (which depends from claim 9) and claim 16 (which depends from claim 13) recite the added step of:

> *"generating coordinates of the imaged layer corresponding to the scan pattern and the tracking band; signaling the coordinates to a beam scanner; and signaling laser-power parameters to a beam attenuator"*

As discussed in connection with Steps 7/13[b]-[c] and Elements 1[c]-[d], Angeley discloses the generation of coordinates of the imaged layer (i.e., anterior lens capsule) corresponding to the scan pattern and tracking band. *See* citations and discussions for Steps 7/13[b]-[c] and Elements 1[c]-[d]. As discussed in connection with Element 1[e], these coordinates are signaled to the beam scanner so that the laser beam can be directed to the points of the tracking band. *See* citations and discussions for Element 1[e] and Step 7/13[d]. As discussed in connection with Element 1[f], laser power parameters are signaled to Angeley's beam attenuator so that the laser beam creates the capsulotomy incision. *See* citations and discussions for Element 1[f] and Step 7/13[d].

Thus, Angeley discloses this Step 10/16. Schuele ¶¶ 139-141.

d. Claim 11/17

Claim 11 (which depends from claim 10) and claim 17 (which depends from claim 13) recite the added step of:

> *"wherein signaling laser-power parameters to a beam attenuator comprises: signaling a photodisruptive laser-power parameter associated with points in the scan pattern that are inside the tracking band; and signaling a non-photodisruptive laser-power parameter associated with points in the scan pattern than are outside the tracking band"*

This step is substantively identical to Step 8/14 and Element 1[f] discussed above and is disclosed for the same reasons. Schuele ¶¶ 142-143.

e. Claim 12

Claim 12 (which depends from claim 7) recites the added step of:

> *"wherein the incision defined by the tracking band results in a capsulotomy"*

Angeley discloses that the tracking band (*see* Step 7/13[c] and Element 1[d]) corresponds to the intended capsulotomy cut intersecting the lens capsule. Angeley's tracking band defines the "3-dimensional path for the cutting of the capsulorhexis." Angeley, [0078]; *see also id.* [0064]. Angeley's Figure 15 shows a "***tilted*** capsulorhexis incision plane" and teaches that "ideally the cut for the capsule will follow this tilt." Angeley, Fig. 15, [0090]; Schuele ¶ 145. Angeley also discloses directing the laser beam to the points of the tracking band in the treatment scan pattern to create the capsulotomy incision. *See* citations and discussions for Step 7/13[d] and Elements 1[e]-[f].

Thus, Angeley discloses this step. Schuele ¶¶ 144-146.

2. Dependent Claims 2-6

a. Claim 2

Claim 2 depends from claim 1, and further recites:

> *"the layer of the eye imaged by the imaging system is tilted relative to a z-axis of the incision to be made in the eye"*

This element is substantively identical to Step 7/13[a] and Element 1[a] discussed above and is disclosed for the same reasons. Schuele ¶¶ 147-148.

b. Claim 3

Claim 3 depends from claim 2, and further recites:

> *"wherein the imaging system comprises a timedomain optical coherence tomography (OCT) system, a frequency-domain OCT system, or a spectrometer-based OCT system"*

As discussed above in connection with Step 7/13[a] and Element 1[c], Angeley discloses that the imaging system that images the anterior lens capsule is an "Optical Coherence Tomography (OCT)" system. Angeley, [0044], [0072], [0078], [0090], Figs. 1, 6, 9, 15; *see also* citations and discussions for Step 7/13[a] and Element 1[c]. More, Angeley discloses that its "OCT device 100" "employs either ***time domain, frequency*** or single point detection techniques. In FIG. 1, a

frequency domain technique is used with an OCT wavelength of 920 nm and bandwidth of 100 nm." Angeley, [0045]; *see id*., [0049] ("OCT system 100 has an inherent z-range that is related to the detection scheme, and in the case of frequency domain detection it is specifically ***related to the spectrometer*** and the location of the reference arm 106."), [0060] ("There are many possibilities for the configuration of the OCT interferometer, including ***time and frequency domain*** approaches.…").

Angeley discloses both a "time-domain" and a "frequency-domain" OCT system, and thus discloses this element. Schuele ¶¶ 149-151.

c. Claim 4

Claim 4 depends from claim 2, and further recites:

> *"wherein the imaging-based laser-controller is configured to determine the z-depths of the sequence of points in the scan-pattern that correspond to the layer of the eye imaged by the imaging system by performing a feature-cognition analysis of an image of the imaged layer"*

This element is substantively identical to Step 9/15 discussed above and is disclosed for the same reasons. Schuele ¶¶ 152-153.

d. Claim 5

Claim 5 depends from claim 2, and further recites:

> *"wherein the imaged layer is a lens capsule between a lens of the eye and an aqueous chamber of the eye; and the tracking band*

corresponds to an intended capsulotomy cut intersecting the lens capsule"

As discussed above in connection with Element 1[c] and Steps 7/13[a]-[b], Angeley discloses that the imaged layer is the tilted anterior lens capsule, which is between the lens and the an aqueous chamber of the eye. *See* Angeley, [0090] ("OCT system 100 of FIG. 1 is used to discern capsule 401 by detecting surfaces 408 [anterior surface] and 410 [posterior surface] of lens 412."), Fig. 5 (depicting structure of the eye includes capsule 401, lens 412, and anterior chamber), [0044] ("An OCT scan of the eye will provides information about the axial location of the anterior and posterior lens capsule, as well as the depth of the anterior chamber."), [0067] (The OCT system images "the location of the surface of the capsule."), [0075], [0078], Figs. 9, 15; Schuele ¶ 155; *see also* citations and discussions in Element 1[c] and Steps 7/13[a]-[b].

Angeley also discloses that the tracking band (*see* Step 7/13[c] and Element 1[d]) corresponds to the intended capsulotomy cut intersecting the lens capsule. It defines the "3-dimensional path for the cutting of the capsulorhexis." Angeley, [0078]. Angeley's Figure 15 shows a "***tilted*** capsulorhexis incision plane" and teaches that "ideally the cut for the capsule will follow this tilt." Angeley, [0090], Fig. 15; Schuele ¶ 156; *see also* citations and discussions for Steps 7/13[c]-[d], Claim 12 and Elements 1[d]-[f].

Thus, Angeley discloses this element. Schuele ¶¶ 154-157.

e. Claim 6

Claim 6 depends from claim 2, and further recites:

> *"wherein the beam attenuator comprises at least one of a Pockels cell, a polarizer-assembly, a mechanical shutter, an electro-mechanical shutter, and an energy wheel"*

As discussed in connection with Element 1[f], Angeley's "half-wave plate 8 and linear polarizer 10" and "shutter 12" is "a beam attenuator [that] control[s] the laser-power parameter of the laser pulses." Angeley, [0037]-[0038]. Angeley's "half-wave plate 8 and linear polarizer 10" constitute a polarizer-assembly, as required by this element. Schuele ¶ 159. Angeley also discloses "an electro-mechanical shutter" in the form of a "system controlled shutter 12" that "ensures on/off control." *See* Angeley, [0038]; Schuele ¶ 159.

Thus, Angeley discloses this element. Schuele ¶¶ 158-160.

VII. Ground 2: All Claims Are Obvious Over Angeley

In addition to anticipation, the challenged claims would have been obvious over Angeley. "[A] single prior art reference can render a claim obvious." *SIBIA Neurosciences, Inc. v. Cadus Pharm. Corp.*, 225 F.3d 1349, 1356 (Fed. Cir. 2000). That is the case here.

Alcon may argue that the tilted capsulotomy incision of paragraph [0090] does not expressly disclose a "tracking band" with "non-uniform z-depth." Even if

Alcon's argument were accepted, it would have been obvious to combine or modify the tilted capsulotomy incision disclosed in Angeley paragraph [0090] with the disclosed "depth thickness 419" described in paragraph [0078] to arrive at the claimed tracking band with non-uniform z-depth.

The suggestion or motivation to modify a single reference "may be derived from the prior art reference itself." *SIBIA*, 225 F.3d at 1356. Angeley teaches that there must be a depth thickness to a capsulotomy cut—and not just a "flat circle"—"to ensure that the capsule is intersected by the cutting mechanism." Angeley, [0078]; *see also id.,* [0064]. As Angeley explains, the "depth thickness" accounts for "variations in the depth of the targeted capsule cut locations throughout the entire cutting procedure." *Id.*, [0078]. This teaching equally applies to a tilted capsulotomy, where a tracking band provides a margin of error around the tilted capsulotomy incision plane to account for such variations. Schuele ¶ 163. A POSA would also know that such margin of error should follow the tilt of the lens. *Id.*

Based on this teaching, a POSA would make a tilted capsulotomy with "depth thickness 419," which forms a "cylindrical shape (extruded circle or ellipse)" as disclosed in paragraph [0078]. Schuele ¶ 164. This results in a tilted capsulotomy having a tracking band with non-uniform z-depth. *Id.*

The suggestion or motivation to modify a single reference may also come from "the knowledge of one of ordinary skill in the art, or from the nature of the problem to be solved." *SIBIA*, 225 F.3d at 1356. Here, a POSA would have known that a tilted (non-uniform z-depth) tracking band would have been preferred for a tilted capsulotomy. Schuele ¶ 165. This knowledge is corroborated by the prior art, including WO 2012/134986 A1 ("Frey," Ex. 1008), US 2011/0184395 A1 ("Schuele application," Ex. 1010), and Palanker article (Ex. 1009).[9]

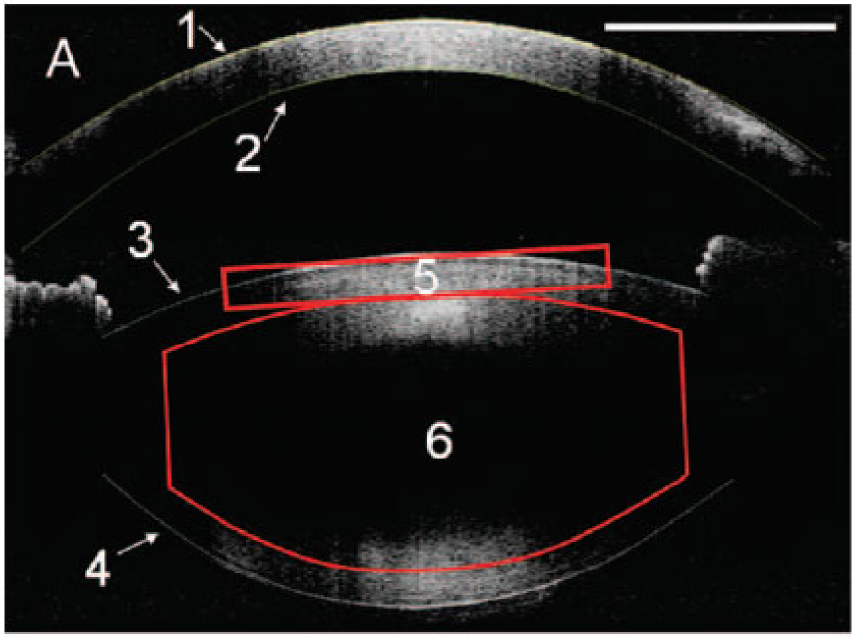
For example, a POSA would have known (as Frey confirms) that in a tilted lens, "the ideal capsulotomy will be tilted." Frey, [0040]. In such a case, "[t]he beam guidance system of the laser should follow the three-dimensional trajectory of the ideal capsulotomy pattern," where "the edge height of the capsulotomy can be

[9] It is permissible to rely on the prior art to corroborate the knowledge of a POSA. *See Koninklijke Philips N.V. v. Google LLC*, 948 F.3d 1330, 1337-38 (Fed. Cir. 2020). Frey is pre-AIA § 102(e)(1) prior art because it claims priority to and incorporates by reference a provisional application filed March 25, 2011 ("Frey provisional," Ex. 1016), which contains the same relevant disclosures and which support at least claim 1 of Frey. *See, e.g.*, Frey provisional, [0014], [0023], [0025], [0026]-[0030], Figs. 6, 7, 8. The Schuele application is pre-AIA § 102(e)(1) prior art because it was filed on December 23, 2010. The Palanker article is pre-AIA prior art under 35 U.S.C. § 102(a) because it appeared in a printed publication before the effective filing date of the '036 patent. *See* Section VIII.A, *infra*.

very small." *Id.* The capsulotomy pattern should have sufficient height to avoid missing the lens capsule "due to slight errors in the measurement of the lens," but it must also be closely tailored to the incision plane to avoid unnecessary laser pulses and to "reduce the surgery time." Frey, [0004]. A tilted capsulotomy with "small edge height" that is closely tailored to the incision plane has a tracking band with non-uniform z-depth. Schuele ¶ 167.

Similarly, a POSA would have also known (as the Schuele application confirms) that the "axial extent" of a capsulotomy pattern should be "limited to the vicinity of the anterior capsule/surface of lens." Schuele application, [0057]. This would motivate a POSA to implement a tilted capsulotomy with a narrow "depth thickness 419" that follows the tilt of the lens (i.e., has non-uniform z-depth). Schuele ¶ 168.

The POSA would have known (as confirmed by the contemporaneous Palanker article) that a capsulotomy pattern on an eye with a tilted lens should be applied within a band that follows the tilt of the lens. Such a tilted tracking band is shown in Figure 3A of the Palanker article, where the tilted red box (5) represents the capsulotomy pattern:



Palanker article, Fig. 3A; Schuele ¶ 169. As shown, capsulotomy pattern (5) has a lower boundary with a non-uniform z-depth.

For all of these reasons, a POSA following Angeley would have made Angeley's tilted capsulotomy of paragraph [0090] with a depth thickness and non-uniform z-depth as described in paragraph [0078]. Schuele ¶ 170.

VIII. Ground 3: All Claims Are Obvious Over Angeley in View of the Palanker Article

Applying a tracking band with non-uniform z-depth to the tilted capsulotomy of Angeley would have been obvious in view of the Palanker article. Schuele ¶ 171.

A. The Palanker Article Is Prior Art to the '036 Patent

The Palanker article was published in the November 17, 2010 issue of Science Translational Medicine. *See* Palanker article at 1, 9 ("Published 17 November

2010"). A press release, dated November 17, 2010, contemporaneously announced its publication. Ex. 1014 (OptiMedica News Release); Schuele ¶ 172. This issue was accessible to the public no later than November 22, 2010 from the Science Magazine website. Ex. 1015 at 11-13 (Wayback Decl.). The lead author, Dr. Palanker, personally downloaded the Palanker article from the website on December 2, 2010. Palanker article at 10; Ex. 1018 (Palanker Decl.). The Palanker article is thus pre-AIA prior art under 35 U.S.C. § 102(a) because it appeared in a printed publication before the effective filing date of the '036 patent.

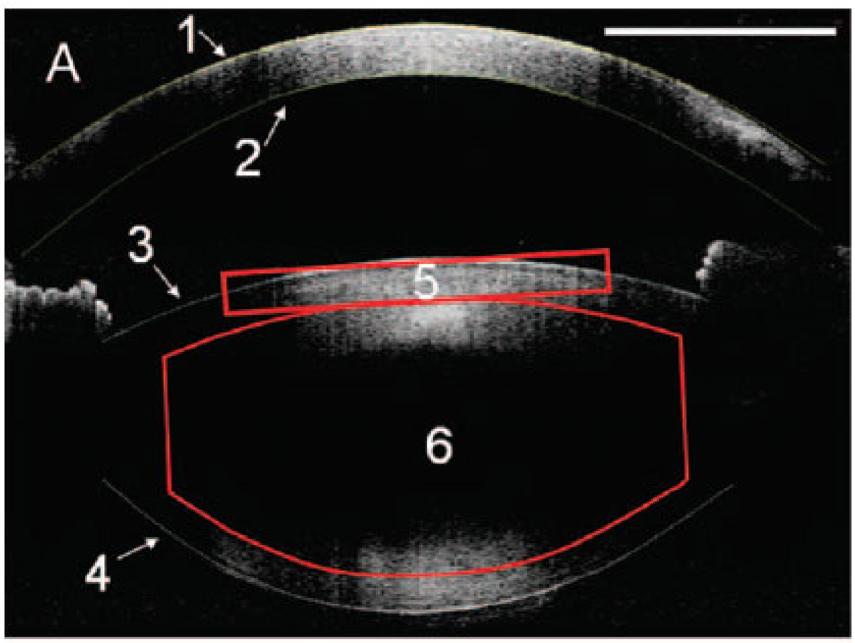
B. The Palanker Article Discloses Generating a Tracking Band with Non-Uniform Z-Depth

The Palanker article teaches the use of OCT imaging to precisely perform a laser capsulotomy. It describes:

> a technique that improves the precision and reproducibility of cataract surgery by performing anterior capsulotomy, lens segmentation, and corneal incisions with a femtosecond laser. The placement of the cuts was determined by imaging the anterior segment of the eye with integrated ***optical coherence tomography***. ***Femtosecond laser produced continuous anterior capsular incisions***, which were twice as strong and more than five times as precise in size and shape than manual capsulorhexis.

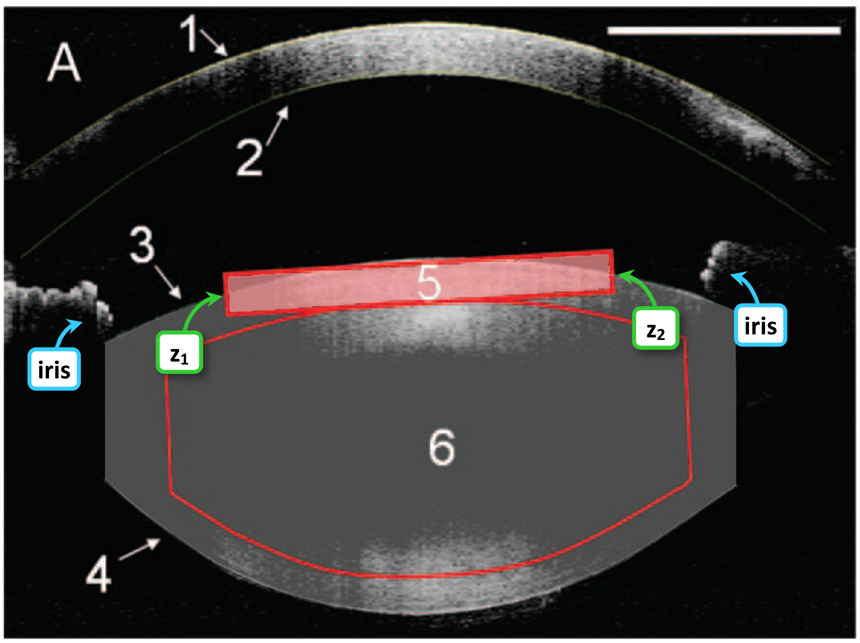
Palanker article at 1.

The Palanker article's laser-based system includes an OCT imaging device that produces a "three-dimensional map of the lens," and "automatically identifies the ***anterior*** and posterior surfaces of the lens and cornea, as well as the iris." Palanker article at 3. The software then "overlays the prospective capsulotomy and the lens segmentation patterns onto the OCT data for the physician's review on a graphical user interface (GUI) (Fig. 3A)." *Id.* The Palanker article's Figure 3A is shown below:



Palanker article Fig. 3A; Schuele ¶ 174. The Palanker article describes this figure as: "OCT image of the eye with outlined boundaries of the cornea (1 and 2) and lens capsule (3 and 4). ***The capsulotomy pattern (5)*** and lens segmentation pattern (6) are shown in solid red." Palanker article at 3; Schuele ¶ 175.

As shown, the "capsulotomy pattern (5)" is ***tilted*** relative to the z-axis and follows the tilt of the lens. Schuele ¶ 176. For example, the iris on the left is lower than the iris on the right, a clear indication of lens tilt. *Id.* As the result of a tilted lens, the system generates a 3-dimensional capsulotomy incision pattern based on the determined z-depths of the anterior lens capsule (e.g., $\mathbf{z_1}$ and $\mathbf{z_2}$ below) that follows the tilt of the lens, just as described for the "ideal" cut by Angeley. *Id.*



Palanker article Fig. 3A (annotated: capsulotomy and lens shaded, iris and z points labeled); Schuele ¶ 176. Because "capsulotomy pattern (5)" is tilted, the lower boundary of this capsulotomy pattern has a non-uniform z-depth. In short, the Palanker article discloses a tracking band with a non-uniform z-depth that tracks the tilt of the eye image. Schuele ¶¶ 177-178.

In related litigation, Alcon has pointed to the Palanker article and this same figure as evidence that J&J Vision's product, Catalys®, performs capsulotomy on a tilted lens where the "tracking band has a non-uniform z-depth." *See* Alcon Contentions (Ex. 1012), Ex. B at 57-58. The same analysis applies to invalidity. *Peters v. Active Mfg. Co.*, 129 U.S. 530, 537 (1889) ("That which infringes, if later, would anticipate, if earlier.").

C. Motivation to Combine Angeley and the Palanker Article

Each of the named inventors of Angeley is also an author of the Palanker article. *Compare* Angeley, *with* Palanker article. The Palanker article specifically identifies the Angeley provisional by number (61/297,624) as an application that covers "the technology described in the [Palanker] paper." Palanker article at 9. In fact, they both arose from the same project at OptiMedica, J&J Vison's predecessor. Schuele ¶ 179. The Palanker article thus discloses the commercial embodiment of Angeley's laser-based system for cataract surgery. *Id.*

It would have been obvious to combine Angeley with the Palanker article. Because the Palanker article specifically identifies the Angeley provisional as covering "the technology described in the paper" (Palanker article at 9), a POSA would have been motivated to reference Angeley for details on how to design the laser system described in the Palanker article. Schuele ¶ 180. Additionally, the references would have been combined because they both arise from the same company, share the same authors, and describe the same laser cataract surgery system. *Ex Parte Mettke,* No. 2008-0610, 2008 WL 4448201, at *17 (B.P.A.I. Sept. 30, 2008) (finding motivation to combine four prior art references to invalidate the claim because they are "***from the same corporation***" and "expressly teach modifications, variations, and improvements to a pay-for-use public communications terminal"), *aff'd*, 570 F.3d 1356 (Fed. Cir. 2009). Indeed, the Palanker article describes test results from the commercial embodiment of Angeley's system and thus the teachings of both references ***were combined***. Schuele ¶ 180.

Both Angeley and the Palanker article describe how the laser cataract surgery system can perform capsulotomy on a tilted lens. Schuele ¶ 181. Angeley teaches that its OCT-imaging system can detect a tilted lens and that "ideally the cut for the capsule will follow this tilt." Angeley, [0090], Fig. 15. The Palanker article shows a capsulotomy that follows this tilt in the red box of Figure 3A, which has a non-uniform z-depth. Palanker article Fig. 3A; Schuele ¶ 181. A POSA seeking a "more optimized targeted capsulotomy pattern" (*see* Schuele application, [0057]) on a tilted lens would have combined the two references with a reasonable expectation of success (as the engineers at OptiMedica did). Schuele ¶ 181.

IX. Secondary Considerations

There are no secondary considerations known to J&J Vision that affect, let alone overcome, this strong case of obviousness. In the district court, Alcon has asserted that its LenSx® system practices the claims of the ’036 patent, and that “[s]econdary considerations supporting non-obviousness include evidence of praise for the patented innovation and commercial success.” Ex. 1017 at 35. These conclusory allegations are not anywhere near enough. Among other things, for “objective evidence of secondary considerations to be accorded substantial weight, its proponent must establish a nexus between the evidence and the merits of the claimed invention.” *ClassCo, Inc., v. Apple, Inc.*, 838 F.3d 1214, 1220 (Fed. Cir. 2016). “[T]here is no nexus unless the evidence presented is reasonably commensurate with the scope of the claims.” *Id.* (cleaned up).

Should Alcon proffer any relevant evidence to support its conclusory allegations of secondary considerations in its preliminary response, J&J Vision will request leave to file a reply.

X. The Board Should Reach the Merits of this Petition

A. Section 325(d) Provides No Basis for Discretionary Denial

While Angeley was cited during the prosecution of the parent application, this Petition presents different arguments. The Office erred in a manner material to the patentability of the challenged claims by overlooking key portions of Angeley.

The 35 U.S.C. § 325(d) analysis follows a two-part framework. *See Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper No. 6 (“*Advanced Bionics*”) at 8 (PTAB Feb. 13, 2020) (precedential). The

Board first considers whether "the same or substantially the same" art or arguments were previously presented to the Office. *Id.* If so, the Board then considers whether "the Office erred in evaluating the art or arguments." *Id.; see also id.* at 8-11 (applying *Becton-Dickinson* factors (a), (b), and (d) for part one, and factors (c), (e), and (f) for part two); *Becton, Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper No. 8 (PTAB Dec. 15, 2017) (precedential as to section III.C.5, first paragraph).

Here, the same art (Angeley) was before the Examiner during prosecution of the parent application. *See* Section III.C, *supra.* But under the second *Advanced Bionics* prong, the Examiner clearly erred in evaluating the art because he did not consider Angeley's crucial disclosure in paragraph [0090]. *See Volkswagen Grp. of Am., Inc. v. Mich. Motor Techs. LLC*, IPR2020-00452, Paper 12 ("*Volkswagen*") at 31-33 (PTAB Sept. 9, 2020); *see also Advanced Bionics*, at 8 n.9 ("An example of a material error may include misapprehending or ***overlooking specific teachings*** of the relevant prior art where those teachings impact patentability of the challenged claims.").

In *Volkswagen*, "the Examiner erred during examination by overlooking a highly pertinent additional embodiment of [prior art reference] Kerns, namely, the Figure 7 embodiment" which anticipated the claims. *Id.* at 31-33 (recognizing that "neither the Examiner nor the Applicant addressed this embodiment during prosecution"). Because the Board recognized that Figure 7 disclosed the disputed limitation, it determined that "Petitioner has sufficiently shown how the Examiner erred in a material manner during prosecution of the application resulting in the [challenged] patent by failing to fully consider the embodiment illustrated in Kern's Figure 7 and the corresponding disclosure of this embodiment in columns 10 and 11." *Id.* at 33; *see also NRG Energy, Inc. v. Midwest Energy Emissions Corp.*, IPR2020-00834, Paper 18 at 40 (PTAB Oct. 26, 2020) (reference was the basis of a rejection during prosecution but the examiner "failed to fully consider the [other] aspects" of the reference that were not considered during prosecution); *Comcast Cable Commc'ns, LLC v. Rovi Guides, Inc.*, IPR2020-00806, Paper 10 at 11 (PTAB Oct. 6, 2020) (Examiner overlooked specific teaching in a reference that were the basis for allowing the challenged claims); *Google, LLC v. Personalized Media Commc'ns, LLC*, IPR2020-00721, Paper 11 at 15-17 (PTAB Oct. 2, 2020).

The same is true here. Angeley was cited during the prosecution of the parent application. But the Examiner failed to fully consider the key disclosure of paragraph [0090] and Figure 15. That failure was directly a result of Alcon's misrepresentation that paragraph [0078] "is the <u>only</u> passage of *Angeley* that describes how cut depth is determined; nowhere does *Angeley* suggest or contemplate another way of accounting for lens tilt." '352 FH at 1157 (10/14/2016

Pre-Appeal Brief) (underlining in original); *see also* '352 FH at 1146 (9/12/2016 Response to Final Office Action).

J&J Vision relies on paragraph [0090] and Figure 15 as the most relevant teaching of Angeley, which discloses a tilted lens and a capsulotomy that follows the tilt of the lens. As in *Volkswagen*, "the Examiner erred in a material manner during prosecution … by failing to fully consider" paragraph [0090] and Figure 15 of Angeley. *Volkswagen*, at 33.

J&J Vision also offers a combination of Angeley and the Palanker article. As described above, the Palanker article shows a tilted capsulotomy pattern with non-uniform z-depth in Figure 3A, which Alcon argued was missing from Angeley. The Palanker article is new art that the Examiner never considered.

The Board should reach the merits of this Petition.

B. *NHK/Fintiv* Provide No Basis for Discretionary Denial

The *Fintiv* factors confirm that discretionary denial is inappropriate. *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 (PTAB Mar. 20, 2020) (precedential). Trial in the district court is scheduled well after the Board's decision is expected (factor 2). If instituted, the Final Written Decision would be expected in or about November 2022. That is at least three months ***before*** the trial in the district court, which is scheduled for February 2023.

J&J Vision filed this Petition shortly after learning which claims are being asserted against it in litigation, and well before any claim construction briefing or proceedings in the district court (factor 3). Finally, the merits of this Petition are exceptionally strong, with a single reference anticipating all claims of the ’036 patent (factor 6).

XI. Mandatory Notices under 37 C.F.R. § 42.8

A. Real Parties-in-Interest

The real parties-in-interest Johnson & Johnson Surgical Vision, Inc., and its subsidiaries AMO Development, LLC, AMO Manufacturing USA, LLC, and AMO Sales and Service, Inc.

B. Related Matters

The ’036 patent is asserted in the following case that may be affected by a decision in this proceeding: *AMO Development, LLC et al. v. Alcon LenSx, Inc. et al.*, No. 1:20-cv-00842-CFC (D. Del.). The ’036 patent was added to the litigation through counterclaims filed on October 30, 2020.

C. Grounds for Standing

J&J Vision certifies that the ’036 patent is available for *inter partes* review and that J&J Vision is not barred or estopped from requesting *inter partes* review of the challenged claims of the ’036 patent on the grounds identified herein.

D. Lead and Backup Counsel and Service Information

Pursuant to 37 C.F.R. §§ 42.8(b)(3), 42.8(b)(4), and 42.10(a), J&J Vision designates the following lead counsel:

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Pursuant to 37 C.F.R. § 42.10(b), a Power of Attorney from J&J Vision is attached. J&J Vision consents to electronic service.

E. Fee for *Inter Partes* Review

The Director is authorized to charge the fee specified by 37 C.F.R. § 42.15(a) to Deposit Account No. 506269.

XII. Conclusion

For the reasons set forth above, J&J Vision respectfully requests *inter partes* review of all claims of the '036 patent.

Respectfully submitted,

Dated: May 3, 2021

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CERTIFICATE OF COMPLIANCE WITH 37 C.F.R. § 42.24

I hereby certify that this Petition complies with the word count limitation of 37 C.F.R. § 42.24(a)(1)(i) because the Petition contains a total of 11,648 words, which is the sum of 11,459 words calculated by Microsoft Word's word-count feature and 189 words hand-counted in the figures. This total excludes the cover page, signature block, and the parts of the Petition exempted by 37 C.F.R. § 42.24(a)(1).

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CERTIFICATE OF SERVICE

The undersigned certifies that a complete copy of this Petition for *Inter Partes* Review of U.S. Patent No. 9,849,036 and all Exhibits and other documents filed together with this Petition were served on the official correspondence address for the patent shown in PAIR and a courtesy copy to Patent Owner's current litigation counsel:

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