IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re *Inter Partes* Review of:)
U.S. Patent No. 9,427,356)
Issued: Aug. 30, 2016)
Application No.: 14/451,881)
Filing Date: Aug. 5, 2014)

For: **Photodisruptive Laser Fragmentation of Tissue**

FILED VIA E2E

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 9,427,356

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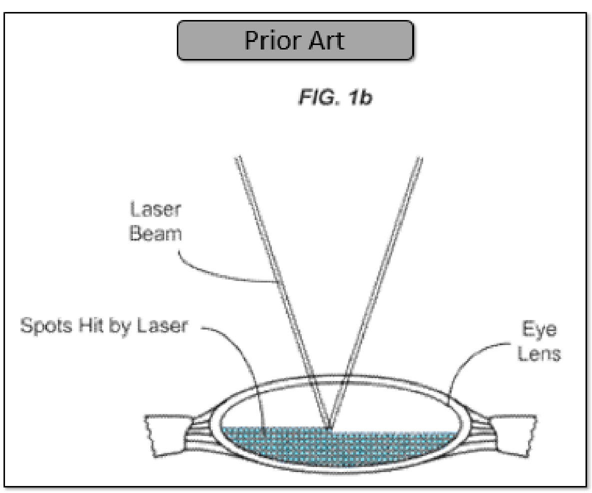
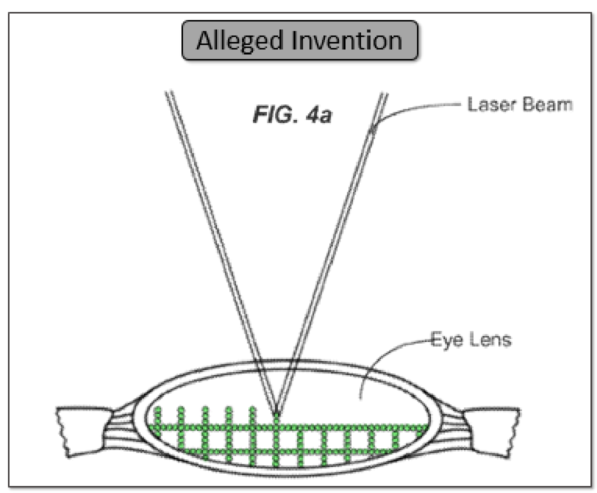
I. Introduction

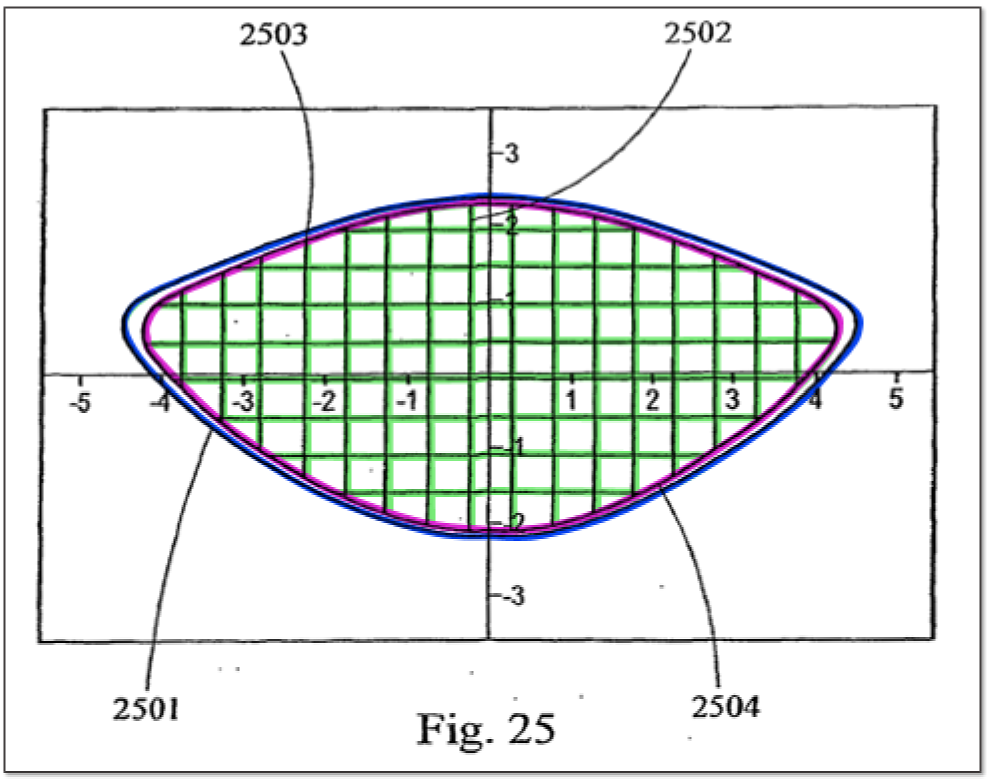
Petitioner Johnson & Johnson Surgical Vision, Inc. ("J&J Vision") requests *inter partes* review of claims 1 and 2 of U.S. Patent No. 9,427,356, titled "Photodisruptive Laser Fragmentation of Tissue" ("'356 patent," Ex. 1001) and assigned to Alcon Inc.("Alcon").

The '356 patent describes laser surgery techniques to "break up the lens" of an eye into small fragments, to remove a cataract. '356 patent, 3:24-30. The '356 patent claims to improve upon a prior art lens fragmentation technique, which had applied a continuous series of laser pulses within the lens (shown below left and highlighted in blue), by "creating layers of photodisrupted bubbles" ('356 patent, 12:12-13) (shown below right, highlighted in green) that divide the lens tissue into a "regular array of cells":





’356 patent, Fig. 1b, Fig. 4a (highlighted). As this Petition demonstrates, a prior art published patent application, WO 2007/084602 A2 (“Frey,” Ex. 1006) likewise applied laser pulses (highlighted in green) to fragment the lens into a regular array of cells:



Frey, Fig. 25 (highlighted).

The ’356 patent also states that the photodisrupted bubble layers may be curved, so as “to accommodate the natural curvature of the lens target region itself[.]” ’356 patent, 7:44-48. But here, too, Frey discloses the same, explaining that “it is preferred that the laser shot patterns generally follow the shape of the lens[.]" Frey, [0093]. Indeed, Frey depicts "shell cut 2504" (highlighted in pink above) which follows the natural curvature of the lens (highlighted in dark blue above). The claims of the '356 patent offer nothing new or nonobvious over the prior art. Thus, J&J Vision requests that the Board institute *inter partes* review and cancel the challenged claims.

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

Ground 1: Claims 1 and 2 are obvious over Frey (Ex. 1006) and the knowledge of a POSA.

Ground 2: Claims 1 and 2 are obvious over Frey in view of Koschmieder (Ex. 1007) and the knowledge of a POSA.

Ground 3: Claims 1 and 2 are obvious over Blumenkranz (Ex. 1008) in view of Frey and the knowledge of a POSA.

Ground 4: Claims 1 and 2 are obvious over Blumenkranz in view of Frey, Koschmieder, and the knowledge of a POSA.

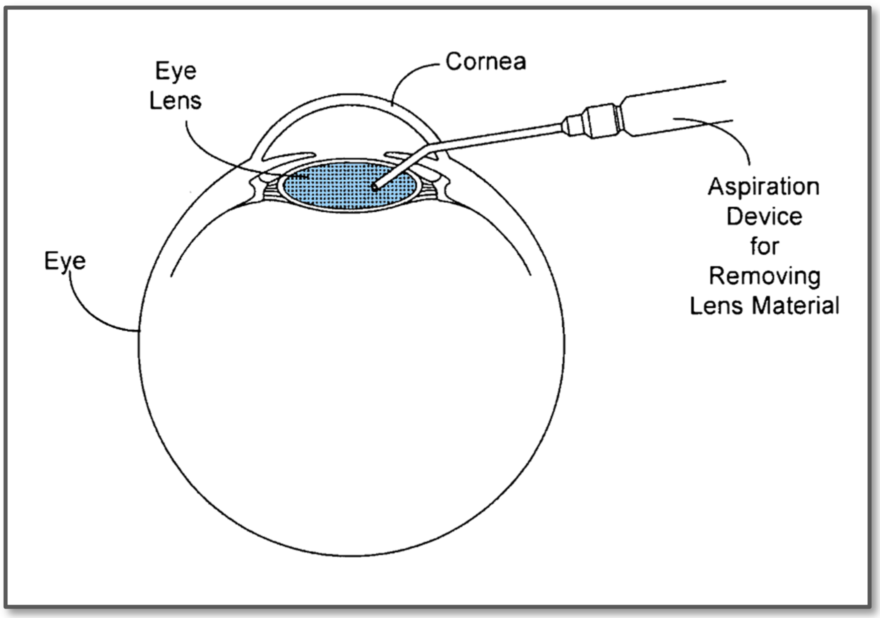
III. Background

A. The '356 Patent (Ex. 1001)

The '356 patent issued from Application No. 14/451,881, filed on August 5, 2014, which is a continuation of abandoned Application No. 12/351,784, which claimed priority to Provisional Application No. 61/020,115, filed on January 9, 2008.

The '356 patent generally relates to laser-based methods for cataract surgery to remove a diseased (clouded) lens of the eye. '356 patent, 3:24-29. The laser fragments the lens into pieces small enough to be removed by aspiration. *Id.*, Abstract, 3:58-4:9; Declaration of Georg Schuele ("Schuele") ¶¶ 14-15.

Figure 2 shows the relevant structures of the eye:

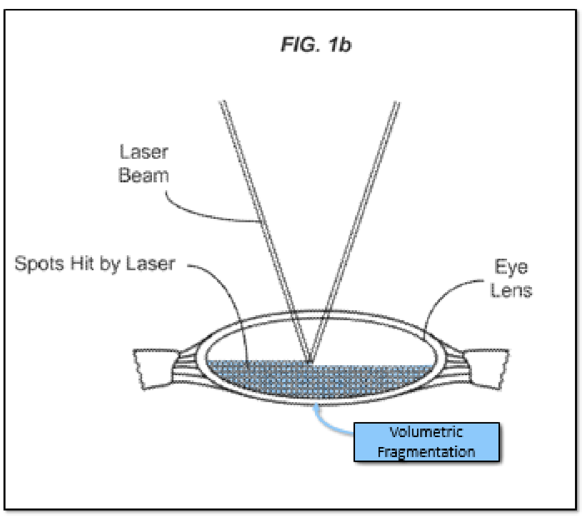


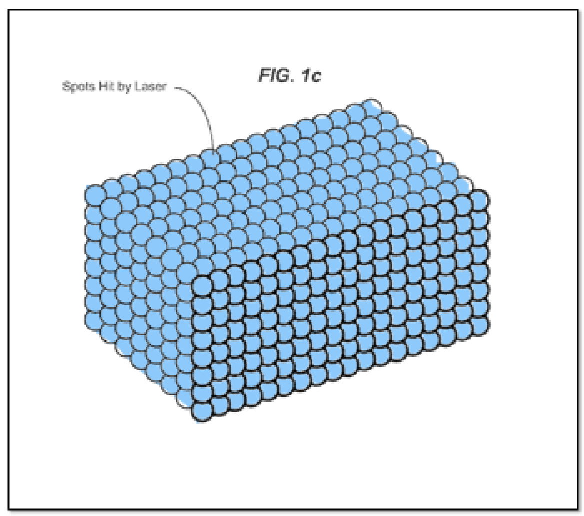
'356 patent, Fig. 2 (highlighted); Schuele ¶ 16. The eye lens (highlighted in blue) is in the interior of the eye, beneath the cornea.[1] In a patient with cataracts, the lens becomes cloudy and must be replaced. *Id.*, 4:10-41. To do so, the laser fragments

[1] This diagram follows the convention of showing a cross section of the eye with the front of the eye at the top (i.e., the eye is looking upwards). Schuele ¶ 16.

the lens, and the resulting pieces are removed by aspiration. *Id.*, 5:47-55; Schuele ¶ 16.

The alleged problem. The '356 patent describes a prior art approach for laser cataract surgery called "volumetric tissue fragmentation[.]" '356 patent, 2:65-67. In that technique, laser pulses are applied "essentially uniformly within a surgical region, e.g., the eye lens, to be treated to allow aspiration and removal of the lens material." *Id.*, 4:64-5:5. Each laser pulse interacts with the tissue to create a corresponding cavitation bubble. *Id.*, 3:43-45. The '356 patent shows volumetric fragmentation in Figures 1b and 1c:

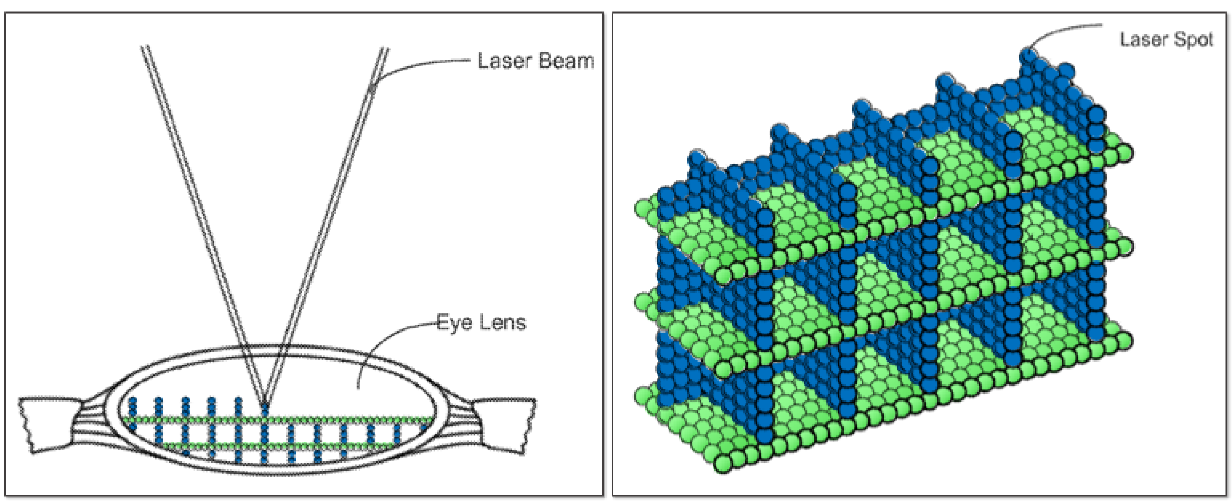




'356 patent, Figs. 1b-1c (highlighted, labeled); Schuele ¶ 17. As shown, the laser pulses (highlighted in light blue) are applied "in an essentially uniform fashion" throughout the lens of the eye. '356 patent, 4:64-5:2.

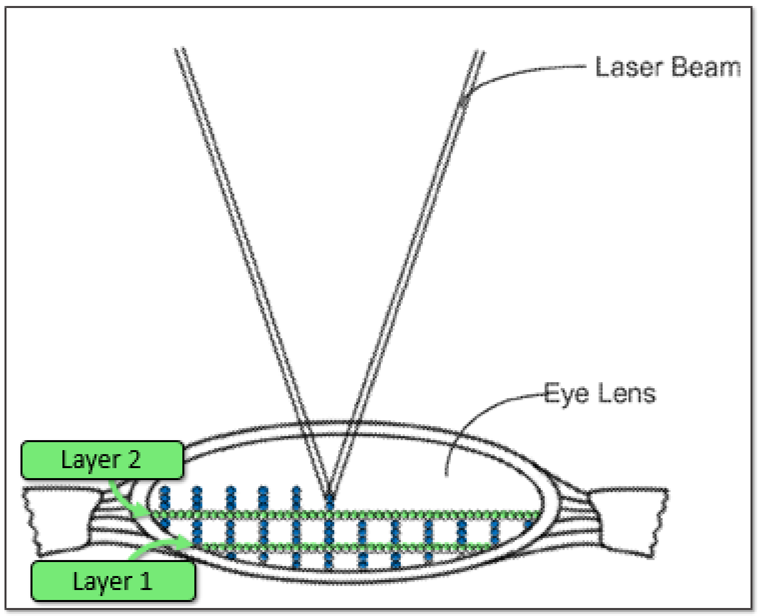
According to the '356 patent, the high density of laser pulses applied in volumetric fragmentation will "generate gas in [the] form of cavitation bubbles and decrease the lens tissue transparency," thereby interfering with the laser treatment. '356 patent, 3:43-52; Schuele ¶ 18. Additionally, the '356 patent asserts that volumetric fragmentation may lead to undesired effects such as heat generation and increased procedure time. '356 patent, 2:65-67, 4:2-6; Schuele ¶ 18.

The alleged solution. To solve the alleged shortcomings of volumetric fragmentation, the '356 patent proposes that the laser cut the lens tissue into "cells of predetermined size, shape and spatial distribution." '356 patent, 5:42-46. The laser pulses thus create a "regular array of cells" as shown in Figures 4a and 4b:



Id., Figs. 4a and 4b (highlighted); Schuele ¶ 19. These figures show how the laser pulses form side walls (highlighted in dark blue) and layers (highlighted in green) comprised of photodisrupted bubbles, to create "cells" (or "granules") of tissue between the laser cuts. '356 patent, 6:48-62. The resulting "granules, or cells, can be cubes." *Id.*, 7:8-9; Schuele ¶ 19.

The '356 patent also explains how this regular array of cells is formed in layers. '356 patent, 7:11-12. This is shown in Figure 4a:



Id., Fig. 4a (highlighted, labeled); Schuele ¶ 20. The laser applies a bottom layer of laser pulses (highlighted in green and labeled "Layer 1") that is transverse to the optical axis of the eye. '356 patent, 7:15-18; Schuele ¶ 20. The laser then creates walls of a predetermined cell height (highlighted in dark blue). '356 patent, 7:24-27. Next, the laser applies another layer of laser pulses (highlighted in green and labeled "Layer 2"), which defines not only the "top" of the first row of cells, but also the "bottom" of the next row of cells. *Id.*, 7:31-34. This process may be repeated until the lens is fully subdivided into cells, which creates a "regular array of cells[.]" *Id.*, 7:34-36; *see also* Schuele ¶¶ 20-21.

The '356 patent also points out that the layers of laser pulses (and resulting photodisrupted bubbles) "can be somewhat curved, to accommodate the natural curvature of the lens target region itself or the natural curvature of the focal plane of the surgical system." '356 patent, 7:44-48. The '356 patent neither provides any further explanation, nor do any of its figures illustrate such a curved layer of photodisrupted bubbles. Schuele ¶ 22.

B. Prosecution History

The parent application to the '356 patent (App. No. 12/351,784) was filed on January 9, 2009 and has since been abandoned. The claims of the abandoned parent recited a method to use a "laser beam to generate cell boundaries" in order to "form cells in the selected target region." '784 FH (Ex. 1003) at 21 (1/9/2009 Provisional Application, claim 1). The Examiner rejected the claims as anticipated in view of US 2007/0173794 A1 ("Gray, " Ex. 1009).[2] '784 FH at 370 (10/29/2012 Office Action).

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[2] Although the first-named inventor is Rudolph Frey, US 2007/0173794 A1 is identified as "Gray" in this Petition to avoid confusion with Frey. Frey claims priority to Gray, and all the disclosures of Gray are included in Frey.

In response, Alcon admitted that Gray "discloses the formation of a cubic lattice of cells with his laser system." *Id.* at 405 (2/28/2013 Response to Office Action). But, Alcon sought to distinguish Gray solely based on the limitation that "cells form a closed packed structure with a cell-to-interstitial volume ratio greater than for a cubic lattice," *id.* at 402. After another rejection, Alcon abandoned the application. *Id.* at 510 (11/7/2014 Notice of Abandonment); Schuele ¶¶ 26-27.

On August 5, 2014, Alcon filed the application for the '356 patent. The original independent claim 1 recited a method to form a regular array of cells with layers of photodisrupted bubbles, "wherein layers are curved." '356 FH (Ex. 1002) at 37 (8/5/2014 Application). The dependent claims recited that the curved layers "accommodate the natural curvature of the focal plane of the surgical system" (claim 2) and "accommodate the natural curvature of the lens" (claim 3). *Id.*

The claims sought during prosecution of the '356 patent did not include the same "cell-to-interstitial volume ratio" limitation that Alcon used to try to distinguish Gray in the abandoned parent application. Nevertheless, the Examiner overlooked Gray (and Frey) during prosecution of the '356 patent, instead rejecting the pending claims based on other prior art that is not at issue in this Petition.

Following two rejections, Alcon amended claim 1 to recite that the layers are created "according to the curvature of the focal plane to track the natural curvature of the lens." '356 FH at 193 (6/8/2015 Response to Final Office Action). Alcon argued that it was "Applicant's inventive insight" that with curved layers, "the risk of cutting into the distal boundary of the lens is greatly reduced." *Id.* at 200.

After another rejection, Alcon amended the claims to recite that "the layers are created by scanning the pulsed laser with the optics module according to ~~the~~ a curvature of the focal plane of the optics module to track the natural curvature of the lens." '356 FH at 258 (10/30/2015 Response to Office Action) (modifications in original). Alcon further argued that the prior art did not disclose the "relevant limitation of 'to track the natural curvature of the lens.'" *Id.* In response, the Examiner allowed the claims. *Id.* at 275 (5/3/2016 Notice of Allowance); Schuele ¶¶ 31.

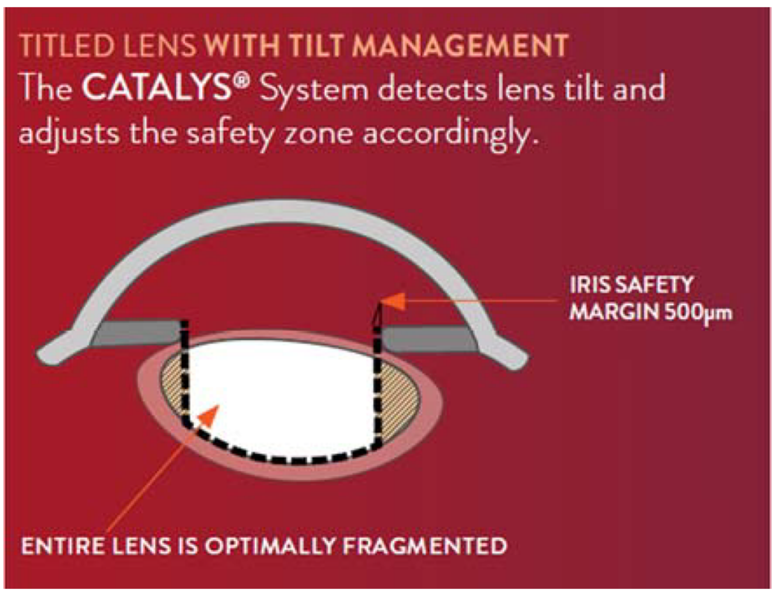
IV. Person of Ordinary Skill in the Art

A person having ordinary skill in the art at the time of the purported invention in or about January 2008 ("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 ¶¶ 32-36. 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

Claims are construed under the same standard used by the courts in litigation. 37 C.F.R. § 42.100(b).

In litigation, Alcon contends that J&J Vision's accused Catalys® system will "track the natural curvature of the lens" because the boundary of the overall pattern of photodisrupted bubbles matches the curvature of the eye lens. *See* Alcon's Initial Infringement Contentions, Ex. D ("Alcon Contentions," Ex. 1013) at 49-81. For example, Alcon points to the following diagram in litigation to allege that the accused Catalys system meets the "track the natural curvature of the lens" limitation:



Alcon Contentions, 65; *see also id.* 64 ("In the Catalys System, the laser photodisruption follows the curvature of the lens."). The white zone shows the region where the photodisrupted bubbles are applied by the accused device, and

Alcon contends that the curved posterior boundary (curved dotted line) tracks the natural curvature of the lens (shown in pink). *Id.* at 64-65; Schuele ¶ 39.

Under Alcon's construction, the boundary of the overall pattern of photodisrupted bubbles must "track the natural curvature of the lens." Because that construction is the basis for Alcon's infringement allegations, J&J Vision accepts and adopts that construction solely for purposes of this *inter partes* review proceeding only. *See, e.g., Liebel-Flarsheim Co. v. Medrad, Inc.*, 481 F.3d 1371, 1380 (Fed. Cir. 2007) (broad claim construction for infringement purposes may ultimately result in a determination of patent invalidity). That construction is the basis for Grounds 1 and 3 in this Petition.

To the extent that the Board requires that the "curvature of the focal plane" must "track the natural curvature of the lens," claims 1 and 2 remain unpatentable. That alternative construction is the basis for Grounds 2 and 4 in this Petition.

All other terms should be given their ordinary and customary meaning.[3] 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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[3] Petitioner reserves the right to argue alternative constructions in other proceedings, and where such a defense is available, that the claims are indefinite.

VI. Ground 1: Claims 1 and 2 Are Obvious Over Frey and the Knowledge of a POSA

A. Frey (Ex. 1006)

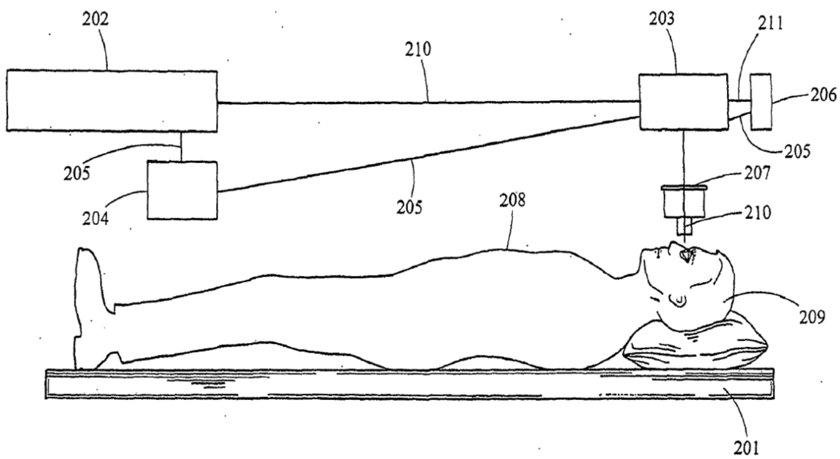
Frey is prior art under pre-AIA 35 U.S.C. § 102(e)(1) because it was filed on January 18, 2007, before the earliest priority date for the ’356 patent. As noted above, a related published application (Gray) was discussed during prosecution of the parent application, and Alcon sought to distinguish it on unrelated grounds before abandoning that application. *See* Section III.B, *supra*. Frey was not cited during prosecution of either the parent application or the ’356 patent.[4]

Frey discloses “treating the structure of the natural human crystalline lens with a laser to address a variety of medical conditions,” including cataracts. Frey, [0001]; *see also id.* [0017], [0062], [0091], [00115]-[00117]. Frey teaches “delivering a laser beam to a lens of an eye in a plurality of sectional patterns” (*id.*, [0018]) thereby

[4] Gray and two other published applications naming Rudolph Frey as an inventor were cited by the Applicant during prosecution of the ’356 application. *See* ’356 FH at 113 (8/14/2014 IDS). And although Gray and the other two published applications contain substantially the same disclosure as Frey, none of Gray or the two other published Frey applications was substantively discussed during prosecution of the ’356 patent.

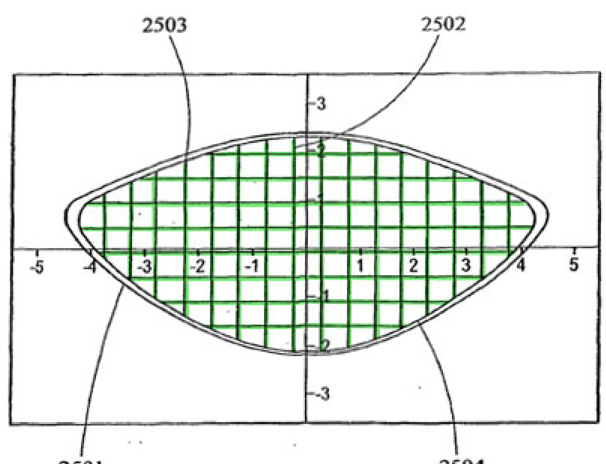
"enabling the removal of the clear or cataractous lens material of the natural crystalline lens." *Id.* [0062]; *see also id.* Abstract, [0091], [00115]-[00117]; Schuele ¶¶ 50-51.

Frey's laser surgical system is shown in Figure 2:

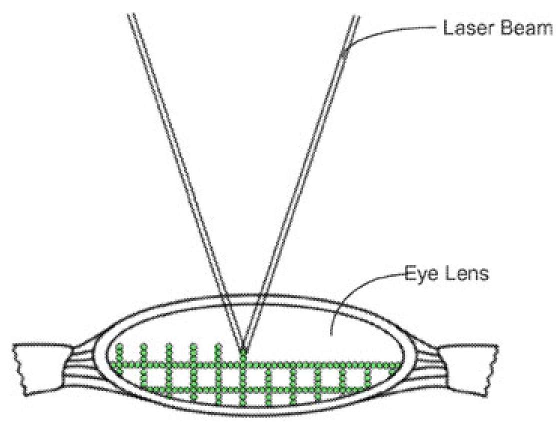


Frey, Fig. 2. Frey's laser surgical system comprises a control system 204 that interfaces and controls a laser 202, an imaging system 206, and optics 203 for delivering a laser beam shot pattern to the lens of the eye. *Id.*, [0062], Figs. 2, 2A. The system delivers laser beam 210, via optics 203 and laser patient interface 207, to apply "a series of [laser] shots" across the eye lens "in a precise and predetermined pattern in the x, y, and z dimension," to produce a series of photodisruption bubbles. *Id.*, [0065], [0062];*see also id.* [0064], [0091], [0093], [00115], Figs. 2, 2A; Schuele ¶ 52.

Frey teaches applying laser pulses to create a "shot pattern that cuts the lens into small ***cubes***."[5] Frey, [0091]; *see also id.* [00115]-[00117], Fig. 25. Frey explains that this shot pattern will "carve up the lens material into tiny cube like structures small enough to be aspirated away." *Id.*, [00115]; *see also id*. [0091], [00116]-[00117], Fig. 25. In fact, Frey's grid-like shot pattern is nearly identical to the regular array of cells disclosed and claimed in the '356 patent. The following side-by-side comparison shows how the '356 patent and Frey both create a regular array of cells in the lens of the eye, by applying the laser to form photodisrupted bubbles (highlighted in green):



Frey

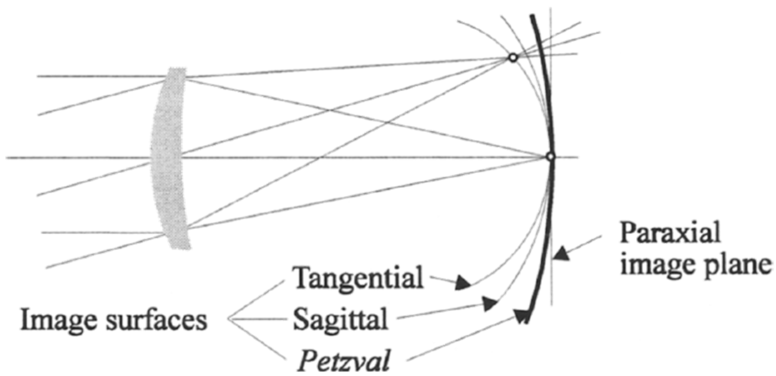


'356 Patent

Frey, Fig. 25 (highlighted); '356 patent, Fig. 4a (highlighted); Schuele ¶ 53.

[5] All emphasis added unless otherwise noted.

The grid-like shot pattern in Frey is made using an x-y scanner (scanning horizontally in Figure 25 above) and z-focusing device (adjusting the depth in Figure 25 above), which may be used with "conventional focusing optics." Frey, [0065], [0069], Figs. 2, 2A; Schuele ¶ 54. A POSA would have known that conventional focusing optics create a curved focal plane, as illustrated below:[6]



MARK RIEDL, OPTICAL DESIGN FUNDAMENTALS FOR INFRARED SYSTEMS Fig. 3.5 (2d ed. 2001) ("Optical Design Fundamentals," Ex. 1014); *see also id.*, 40 ("the image surface would be parabolic in shape"); Schuele ¶ 55-57. This curvature is called

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[6] In this figure from Optical Design Fundamentals, the light source originates from the left, and therefore the curved focal plane is oriented vertically on the right. Optical Design Fundamentals, 1-2, Fig. 1.1; Schuele ¶ 55. However, where the light source originates from the top of the diagram (as in Frey, Fig. 25 and '356 patent, Fig. 4a), the curved focal plane is oriented horizontally at the bottom. Schuele ¶¶ 55-57.

Petzval curvature or field curvature. Optical Design Fundamentals, 40; *see also* JOHN E. GREIVENKAMP, FIELD GUIDE TO GEOMETRICAL OPTICS 79 (2004) ("Greivenkamp," Ex. 1014) ("Field curvature characterizes the natural tendency of optical systems to have curved image planes."). Schuele ¶¶ 55-57. Frey's x-y laser scanning, when using its "conventional focusing optics," will apply laser pulses according to this curvature of the focal plane of its optics. Schuele ¶ 57.

Frey also teaches that the laser shot patterns should also follow the natural curvature of the lens:

> ***In all of the laser shot patterns provided herein*** it is preferred that the laser shot patterns generally ***follow the shape of the lens*** and placement of individual shots with respect to adjacent shots in the pattern are sufficiently close enough to each other, such that when the pattern is complete a sufficiently continuous layer and/or line and/or volume of lens material has been removed[.]

Frey, [0093]; *see also id.* [0083]. Frey discloses specific examples of curved layers that follow the natural curvature of the lens. Schuele ¶¶ 58-59. For example, in addition to the grid-like shot pattern 2502 that cuts the lens into cubes, Frey also provides for a curved layer of photodisrupted bubbles in shell cut 2504 (highlighted in pink):

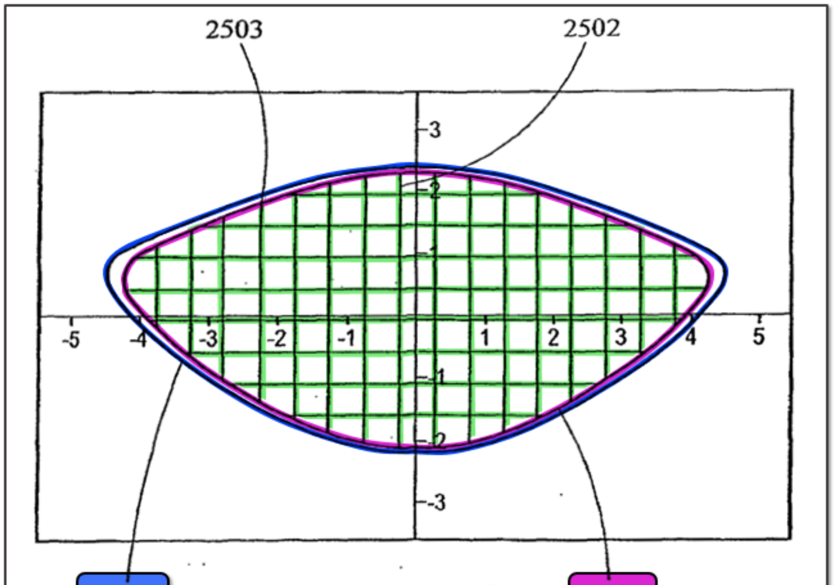


Fig. 25

Frey, Fig. 25 (highlighted); Schuele ¶ 59. The shell cut 2504 tracks the curvature of the outer surface 2501 of the lens of the eye (highlighted in blue). Frey, [0116]; Schuele ¶ 59.

B. Claim 1

1. Preamble

"A method of fragmenting lens tissue of an eye with a laser surgical system, the method comprising"

To the extent the preamble is limiting, it is disclosed by Frey. Schuele ¶¶ 64-68. Frey's laser surgical system is shown in Figure 2 and includes "a patient support 201; a laser 202; optics for delivering the laser beam 203; a control system for delivering the laser beam to the lens in a particular pattern 204 …; a means for determining the position of lens with respect to the laser 206 …; and a laser patient interface 207." Frey, [0062], Fig. 2; *see also id.* [0026] ("FIG. 2 is a block schematic diagram of a type of system for delivering a laser beam shot pattern to the lens of an eye according to the teachings of the present invention."); Schuele ¶¶ 65-66.

Frey's laser surgical system is used to fragment lens tissue of an eye. Frey, [0001], [0062], [0091], [00115]-[00117]; Schuele ¶ 67. Frey explains that its laser shot pattern "***cuts the lens into small cubes***, which cubes can then be removed from the lens capsule[.]" Frey, [0091]; Schuele ¶ 67. The fragmentation pattern is shown, for example, in Figure 25 of Frey. Frey, [0044] ("FIG. 25 is a cross section drawing of a lens showing the placement of a cube laser shot pattern in accordance with the teachings of the present invention."), [0091], [00116]; *see also* Section VI.A, *supra*; Schuele ¶¶ 67-68.

2. Step 1[a]: generating a pulsed laser beam

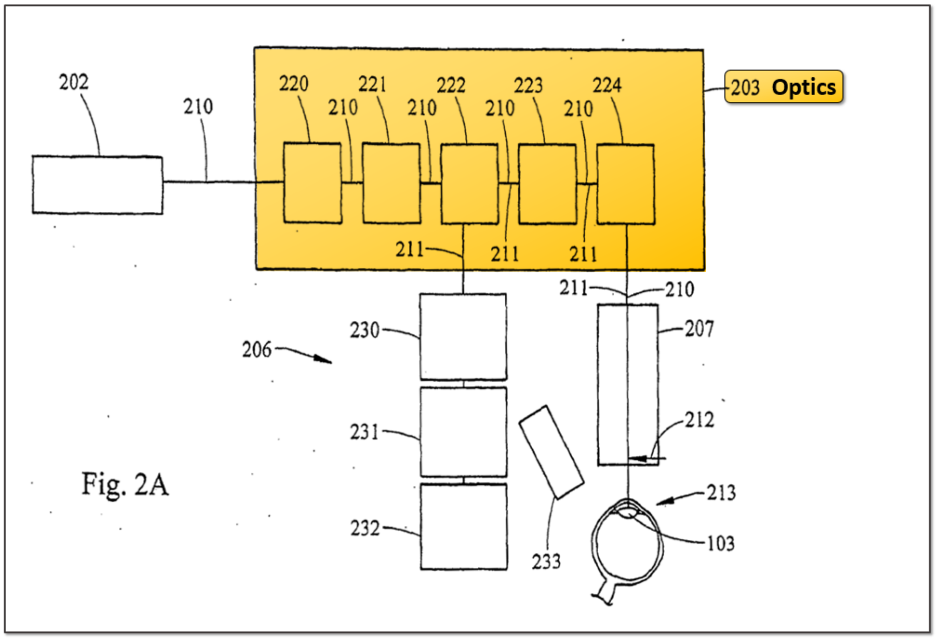
"generating a pulsed laser beam with a pulsed laser"

Frey's laser 202 provides a laser beam with a "***short pulse width***" which is used "together with the energy and beam size, to produce photodisruption" in the lens. Frey, [0064]; *see also id.* [0065], [0044], [0091], [00115]-[00117]. Frey thus discloses this step. Schuele ¶¶ 70-72.

3. Step 1[b]: directing the laser beam

"directing the pulsed laser beam with an optics module towards a target region in the lens tissue"

Frey's laser system delivers the pulsed laser beam to the lens of the eye with optics 203. Frey, [0062] ("system for delivering a laser beam shot pattern to the lens of eye comprising … ***optics for delivering the laser beam 203***."); *see also id.* [0069], Figs. 2, 2A. This optics module is shown in Figure 2A:



Id., Fig. 2A (highlighted, labeled); Schuele ¶ 75. Frey's optics deliver the laser pulses "to the natural lens of the eye" with a "predetermined beam spot size to cause photodisruption with the laser energy reaching the natural lens." *Id.*, [0065]; *see also id.* [0044], [00115] ("photodisruption cutting"), [00116].

Frey thus discloses this step. Schuele ¶¶ 73-76.

4. Step 1[c]: form a regular array of cells

"controlling the optics module by a system control module to form a regular array of cells in the target region by creating layers of photodisrupted bubbles to generate cell boundaries"

Frey discloses this step, as explained below. Schuele ¶¶ 77-88.

a. System control module

Frey teaches that a "control system 204" of the laser surgical system controls optics 203 to deliver the laser beam "to the lens in a particular pattern[.]" Frey, [0062]; *see also id.*, [0065], [0066], [0070], [0151], [0152], Figs. 2, 2A; Schuele ¶ 79. The control system 204 interfaces with optics 203 through a connection represented by lines 205 in Figure 2. *Id.*, [0062]; *see also id.* [0066]; Schuele ¶ 79. Frey's control system 204 constitutes a system control module for controlling the optics module (optics 203). Schuele ¶¶ 79-80.

b. Form a regular array of cells in the target region

In Frey, the pulsed laser is applied in a grid-like shot pattern, to fragment the lens into an array of cubes. Frey, [0091] ("A shot pattern that cuts the lens into small cubes, which cubes can then be removed from the lens capsule is provided."); *see also id.*, [0044] ("cube laser shot pattern"), [00115]-[00117]. This shot pattern thus forms a regular array of cells, as shown in Figure 25 of Frey:

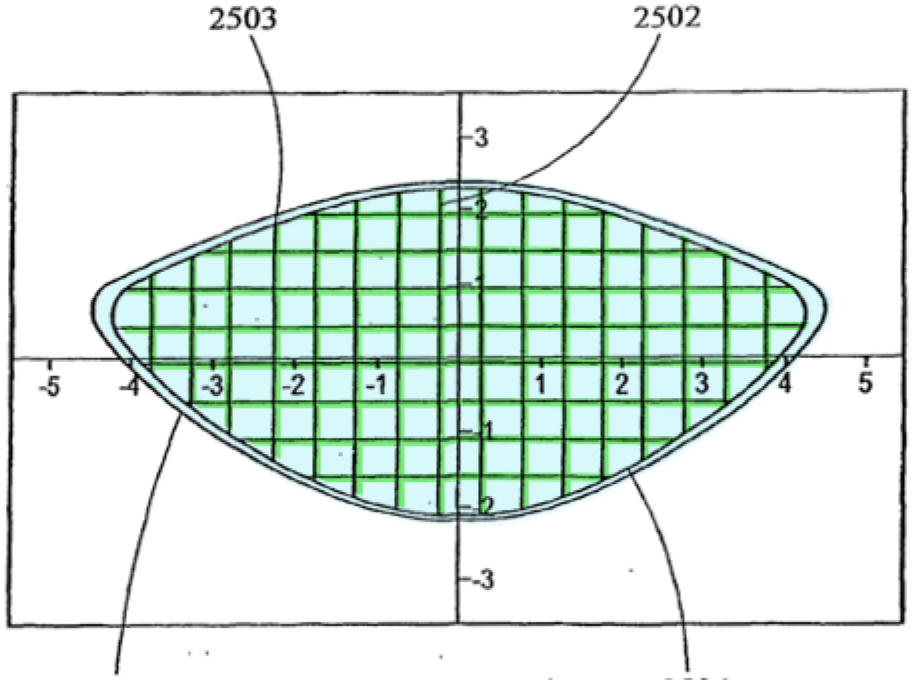


Fig. 25

Frey, Fig. 25 (highlighted); Schuele ¶¶ 81-83. The cells of tissue (shaded in blue) are formed by the grid-like laser shot pattern (highlighted in green). Schuele ¶ 82. In fact, Frey's regular array of cells is nearly identical to that shown in the '356 patent. *Compare* Frey, Fig. 25 *with* '356 patent, Fig. 4a; *see also* Schuele ¶¶ 83-84.

c. Create layers of photodisrupted bubbles to generate cell boundaries

Frey uses its pulsed laser to create layers of photodisrupted bubbles to generate cell boundaries within its grid-like shot pattern 2502. Frey, [0116] ("shot pattern 2502 that creates grid like cuts"), [0091], [00115], [0064], [0044], [0093]; Schuele ¶ 85. Frey's laser system sequentially creates layers of photodisrupted bubbles (called "z planes") at a given z-depth, before moving to the next depth on the z-axis:

> Accordingly, it is proposed to photodissrupt [*sic*] the most anterior sections of the cataract first, then moves posteriorally, shooting through gas bubble remnants of cataractous tissue, to the next layer of cataract tissue below. In addition to ***shooting the laser in anterior z planes*** then moving posterior, it is further provided to essentially drill down anterior to posterior, which we call the z axis throughout this document and then move in x/y and drill down again.

Frey, [00116]; Schuele ¶ 86; *see also* Frey, [0094], [00117]. The layers of photodisrupted bubbles formed by the laser in Frey are shown and labeled below:

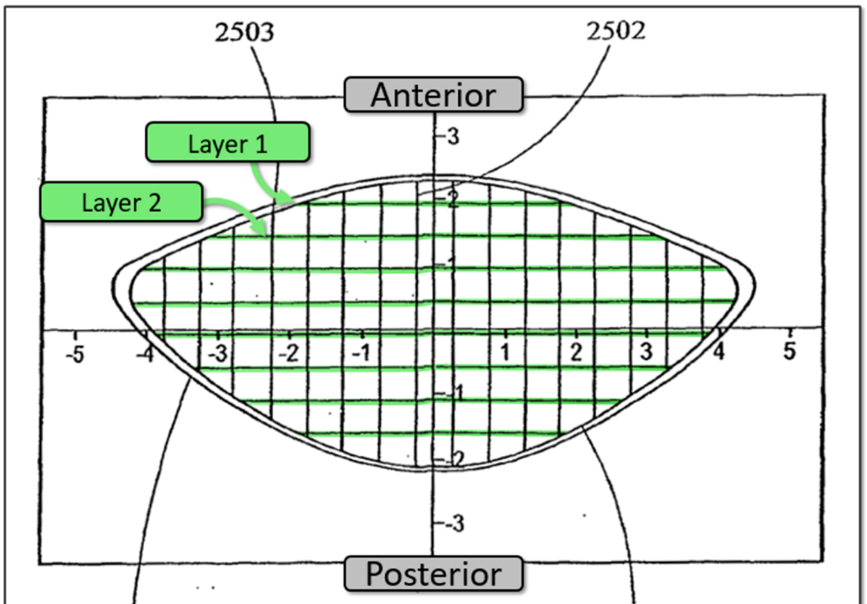


Fig. 25

Frey, Fig. 25 (highlighted, labeled); Schuele ¶ 87. As shown, these layers of photodisrupted bubbles form boundaries between each row of cells. Frey, Fig. 25; *see also id.* [0093], [00114], [00123], [00124]-[00126]; Schuele ¶¶ 87-88.

5. Step 1[d]: curved layers

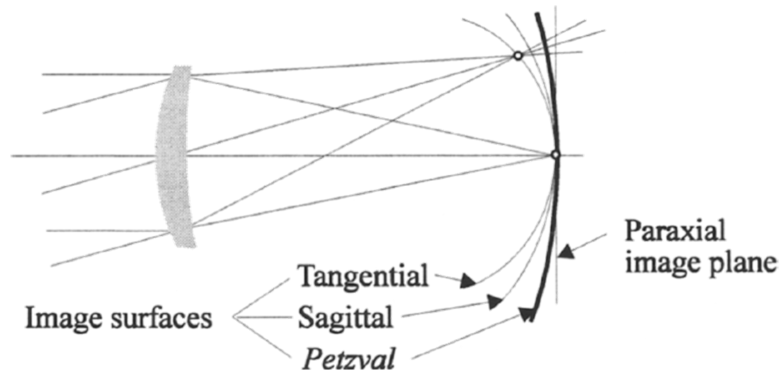
"the layers are created by scanning the pulsed laser with the optics module according to a curvature of the focal plane of the optics module to track the natural curvature of the lens"

Frey discloses this step, either alone or in view of the knowledge of a POSA, as explained below. Schuele ¶¶ 89-100.

a. Scanning the pulsed laser according to a curvature of the focal plane of the optics

As discussed above for step 1[c], Frey creates photodisruption bubble layers by scanning the laser in "z planes." Frey, [00116]. The scanning of each layer is controlled by an "x y scanner," and may be done through "***conventional focusing optics***[.]" Frey, [0065], [00116]; Schuele ¶ 91. To form subsequent layers, a "z focusing device" is used to move to the next depth. Frey, [0065], [00116]; Schuele ¶ 91.

Frey's "conventional focusing optics" would have a curved focal plane. Schuele ¶¶ 92, 55-57. That curvature is shown in basic textbooks, such as Optical Design Fundamentals:



Optical Design Fundamentals, Fig. 3.5; Schuele ¶ 92. A POSA would have known that such conventional focusing optics have a curved focal plane. *See, e.g.*, Schuele ¶¶ 92, 55-57; US 4,772,107 ("Friedman," Ex. 1012), 1:16-20 (Petzval curvature present in "conventional optical designs"); G. Molesini, GEOMETRICAL OPTICS, IN ENCYCLOPEDIA OF CONDENSED MATTER PHYSICS 266 (2005) ("Molesini," Ex. 1016), at 266 ("Every optical system has, associated with it, a basic field curvature, [wherein] the sharpest image is formed on a curved focal surface[.]"); Greivenkamp, 79 ("Field curvature characterizes the natural tendency of optical systems to have curved image planes."); Optical Design Fundamentals, 40 ("the image surface would be parabolic in shape")[7]; Schuele ¶¶ 92; *see also* Section VI.A, *supra*. Indeed, Alcon

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[7] 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). Optical Design Fundamentals is pre-AIA § 102(b) prior art because it was

has admitted in another patent that the focal plane "is ***typically curved*** in optical systems unless (any suitable portion of) the optics 273 of the laser delivery system is corrected for field curvature." US 2009/0171327 A1 ("Kurtz," Ex. 1011), [0178], Figs. 5J, 5J'; *see also* Schuele ¶ 93.

As a result of this knowledge, it would have been obvious to a POSA to scan Frey's pulsed laser with an optics module "according to a curvature of the focal plane of the optics module." Schuele ¶ 94. A POSA would have understood (or at least found it obvious in view of their own knowledge) that the express disclosure in Frey of "conventional focusing optics" would have provided laser scanning along a curved focal plane. *Id.* ¶ 94. Moreover, a POSA would have been motivated to use conventional focusing optics with a curved focal plane because such conventional

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published in 2001, more than one year before the earliest priority date for the '356 patent. Friedman is pre-AIA § 102(b) prior art because it was published on September 20, 1988, more than one year before the earliest priority date for the '356 patent. Molesini is pre-AIA § 102(b) prior art because it was published in 2005, more than one year before the earliest priority date for the '356 patent. Greivenkamp is 102(b) prior art because it was published in 2004, more than one year before the earliest priority date for the '356 patent. None of Optical Design Fundamentals, Friedman, Molesini, or Greivenkamp were cited during prosecution.

focusing optics were recognized by a POSA to be simpler to design and typically less expensive than other specialized optics. *Id.* ¶ 94. For example, flat field optics (which avoid a curved focal plane) require adding several different optical elements that can introduce aberrations and reduce the intensity of the laser beam. US 2008/0192783 ("Rathjen, " Ex. 1010), [0003], [0009]; Kurtz, [0178]; Molesini, 265-67; Schuele ¶ 94. A POSA would have known that conventional focusing optics with a curved focal plane were preferred. Schuele ¶ 94. Such a curved focal plane thus would have been obvious as a "suitable option from which the prior art did not teach away." *Par Pharm., Inc. v. TWI Pharms, Inc.*, 773 F. 3d 1186, 1198 (Fed. Cir. 2014).

A POSA would have had a reasonable expectation of success in implementing a curved focal plane. Schuele ¶ 95. Such an approach was merely a conventional approach (as Frey acknowledges by referring to it as "***conventional*** focusing optics") that was well within the capabilities of a POSA. *See* Frey, [0065], *see also* Kurtz, [0178]; Schuele ¶ 95. In fact, it would have required more expertise to avoid a curved focal plane than to implement it. Rathjen, [0003], [0009]; Schuele ¶ 95.

b. Track the natural curvature of the lens

Frey discloses scanning the laser "to track the natural curvature of the lens," as required by the claims. Schuele ¶¶ 96-100. Frey explains:

> ***In all of the laser shot patterns provided herein*** it is preferred that the laser shot patterns generally ***follow the shape of the lens*** and placement of individual shots with respect to adjacent shots in the pattern are sufficiently close enough to each other, such that when the pattern is complete a sufficiently continuous layer and/or line and/or volume of lens material has been removed[.]

Frey, [0093]; *see also id.* [0083].

Frey provides specific examples of curved layers of laser pulses that track the natural curvature of the lens. For example, to create the regular array of cells shown in Figure 25, Frey teaches that the laser should form "shell cut 2504" which, it explains, "is integral with the grid like cuts." Frey, [00116]. As shown below, shell cut 2504 (pink) is curved so that it tracks the natural curvature of the lens 2501 (blue):

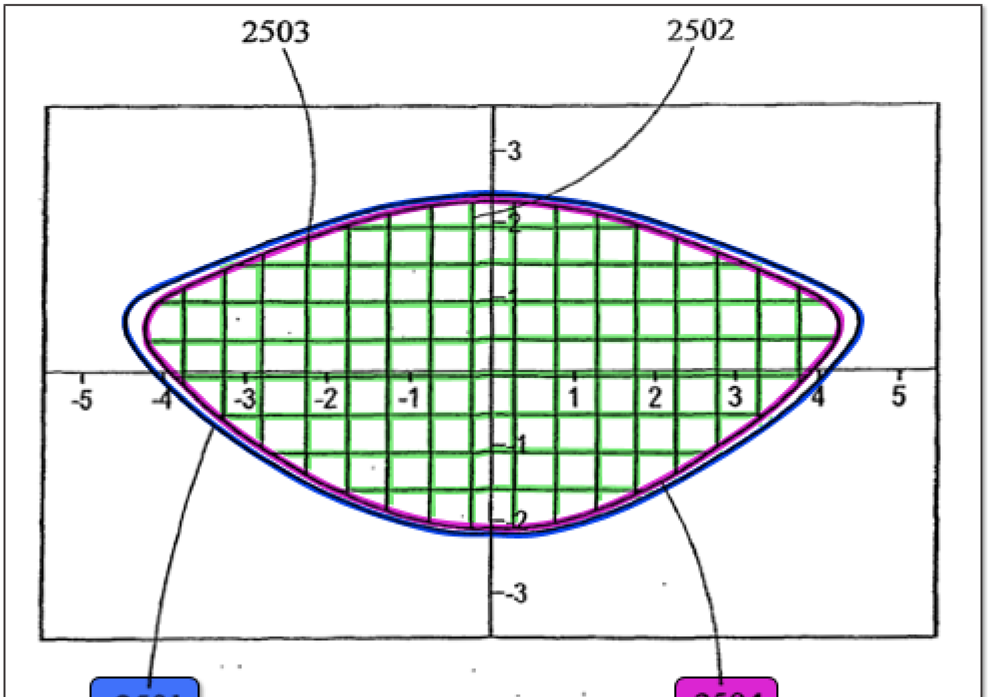


Fig. 25

Frey, Fig. 25 (highlighted); *see also* Schuele ¶ 97.

Frey also includes other examples of "shell cuts." *See, e.g.*, Frey, Figs. 13-17. As Frey explains, preferably "the shells would essentially follow the anterior and posterior curvature of the lens." *Id.*, [0085]. For example, Figure 17 shows "seven essentially concentric shot patterns 1702-1708" (*id.*, [00105]):

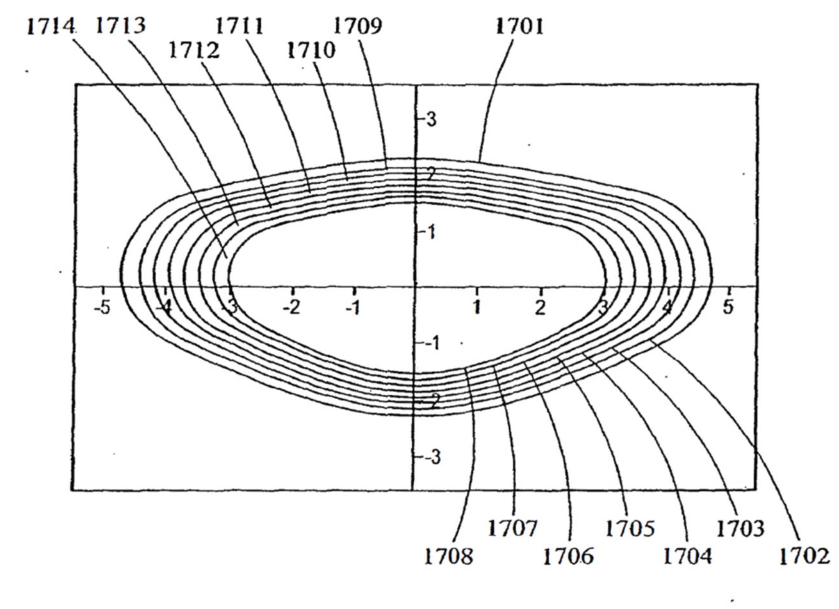


Fig. 17

Id., Fig. 17. As the figure shows, these shell cuts track the natural curvature of the lens. Schuele ¶ 98. Frey also explains that the grid-like cuts of Figure 25 can be made with these shell cuts. It proposes "***combinations***" of various patterns, including "the cube pattern of Fig. 25" and "partial shells and shells[.]" Frey, [0123].

A comparison with the '356 patent itself underscores Frey's broad and detailed disclosure of curved layers. Outside of the claims, the words "curved" and "curvature" only appear in a single sentence of the '356 patent, and that same sentence is also the sole reference to the "natural curvature of the lens[.]" '356 patent, 7:44-48. A side-by-side comparison confirms that this single sentence says nothing more than what was previously disclosed by Frey:

’356 Patent	Frey
In yet other implementations, the layers themselves can be somewhat curved, to ***accommodate the natural curvature of the lens*** target region itself or the natural curvature of the focal plane of the surgical system.	In all of the laser shot patterns provided herein it is preferred that the laser shot patterns generally ***follow the shape of the lens*** and placement of individual shots with respect to adjacent shots in the pattern are sufficiently close enough to each other, such that when the pattern is complete a sufficiently continuous layer and/or line and/or volume of lens material has been removed[.]

’356 patent, 7:44-48; Frey, [0093]; *see also id.* [0083];Schuele ¶ 99. Thus, the entire disclosure of tracking the natural curvature of the lens from the ’356 patent (which is all that supports the claims) is also found in Frey. Schuele ¶ 99.

* * *

In sum, Frey and the knowledge of a POSA renders claim 1 obvious. Schuele ¶ 101.

C. Claim 2

Claim 2 depends from claim 1, and further recites forming the regular array of cells comprising:

> *"forming the cells with a size suitable for extraction by aspiration without additional lens fragmentation."*

Frey discloses this limitation. Schuele ¶¶ 102-105.

As discussed above for step 1[c], Frey discloses forming a regular array of cells, where the cells are cubes. Frey, [0044], [0091], [00115]-[00117], Fig. 25; Schuele ¶ 104. Frey teaches that these cubes are "small enough to be aspirated away with 1 to 2 mm sized aspiration needles." *Id.*, [00115]. This approach will "make it easier to remove" the lens tissue "by ***eliminating*** the high frequency ultrasonic energy used in phaco emulsification today." *Id.* Thus, the cells ("tiny cube like structures") formed by Frey's laser can be aspirated without additional lens fragmentation. Schuele ¶¶ 104-105.

VII. Ground 2: Claims 1 and 2 Are Obvious Over Frey in View of Koschmieder and the Knowledge of a POSA

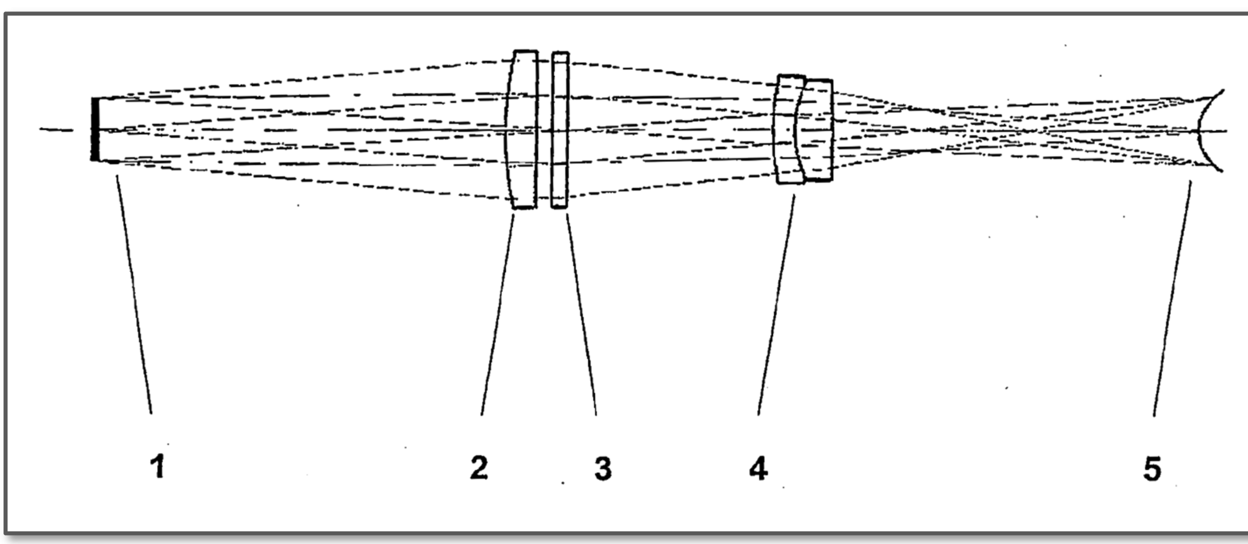
To the extent the Board construes the claims to require that the "curvature of the focal plane" must itself "track the natural curvature of the lens" (*see* Section V, *supra*), claims 1 and 2 would have been obvious over Frey (and the knowledge of POSA) in view of US 2006/0170867 A1 ("Koschmieder," Ex. 1007). Schuele ¶ 106.

A. Koschmieder Discloses a Curved Focal Plane that Tracks the Natural Curvature of the Lens of the Eye

Koschmieder is prior art under pre-AIA 35 U.S.C. § 102(b) because it was published on August 3, 2006, more than one year before the earliest priority date for the '356 patent. Koschmieder was not cited during prosecution of the '356 patent.

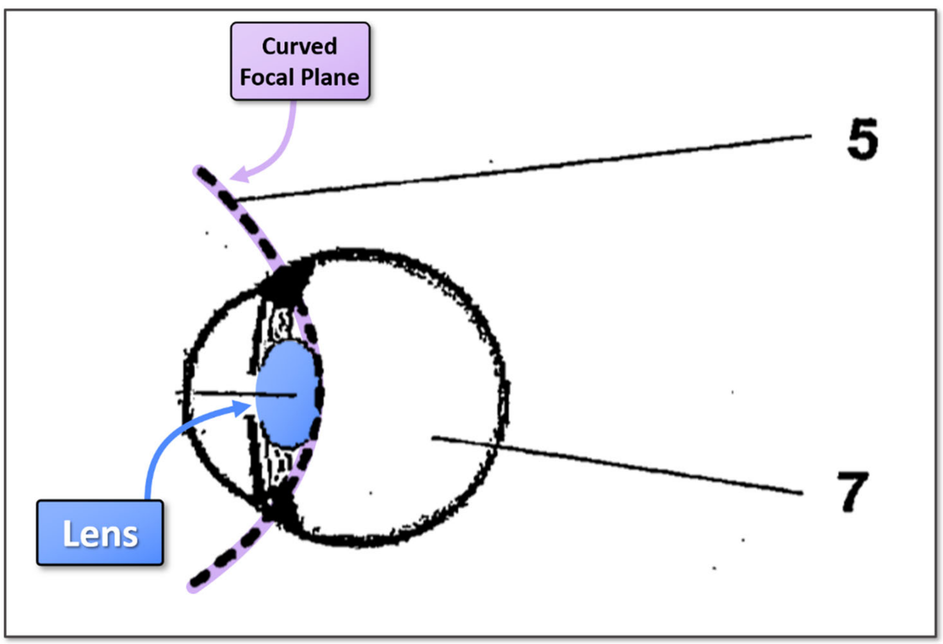
Koschmieder is directed to improved ophthalmic instruments used for diagnosis and treatment of the eye, including laser surgery. Koschmieder, Abstract, [0006], [0034]-[0035]. The beam delivery optics provide "for deliberate ***shaping of the image plane*** in the eye to be irradiated" so that it "can be ***adapted to the spherical contour of the eye***[.]" *Id.*, Abstract, [0015], [0022]-[0023]. In other words, Koschmieder creates a focal plane that tracks the natural curvature of the eye. Schuele ¶¶ 107-108.

Koschmieder's beam delivery optics are shown in Figure 1:



Koschmieder, Fig. 1; Schuele ¶ 109. The illumination beam path begins with the illumination pattern 1, at the left. *Id.*, [0022]. "The shape of the illumination beams is changed by the DOE [diffractive optical element] 3 in such a way that ***an image plane*** 5 ***adapted to the curvature of the respective element to be irradiated*** results in the eye 7 to be irradiated." *Id.*

The spherical image plane 5 "is adapted to the curvature of the eye." Koschmieder, [0023]. These optics are suitable "***for irradiation of the eye lens***" during treatment of the lens, including by "laser scanners." *Id.*, [0034]; *see also id.* [0006], Abstract, [0003], [0035]. Further detail is provided in connection with Figure 2:



Koschmieder, Fig. 2 (highlighted, labeled); Schuele ¶ 110. This figure shows a cross section of the eye, with the front of the eye pointing to the left. Schuele ¶ 110.

Koschmieder depicts "an image plane 5 that is adapted to the rear surface of the eye lens[.]" *Id.*, [0022]. As shown in the figure, the focal plane of the optical system (highlighted in purple) is curved, and that curve tracks the posterior curvature of the lens of the eye (highlighted in blue). Koschmieder, [0022], [0027], [0034];Schuele ¶ 110.

Thus, Koschmieder discloses that the "curvature of the focal plane" will itself "track the natural curvature of the lens." Schuele ¶ 111. To the extent Frey does not disclose this claim limitation, it is disclosed by the combination of Frey (in view of the knowledge of a POSA) and Koschmieder.

B. Motivation To Combine Frey and Koschmieder

A POSA would have found it obvious to incorporate Koschmieder's diffractive optical element (DOE) into Frey's optics 203, to create curved layers according to the curvature of the focal plane of the optics module, which also track the natural curvature of the lens. Schuele ¶ 112.

The motivation to combine is provided by Koschmieder itself. As Koschmieder explains, "the ***straight or even oppositely curved image planes*** of the illumination components and irradiation components ***have a disadvantageous effect***." Koschmieder, [0013]. Those disadvantages are particularly pronounced in "outer areas and edge areas," where the focus will "become blurred and lose intensity to an appreciable extent." *Id.* The curved image planes of Koschmieder provide "a ***uniformly high image quality*** over extensive areas of the eye." *Id.*, [0014]; *see also id.* Abstract, [0003], [0006], [0023], [0032]; Schuele ¶ 113.

A POSA would have understood that Koschmieder's teaching applies to the grid-like shot pattern shown in Figure 25 of Frey, where the horizontal layers of laser pulses may become unfocused near the outer edge when the focal plane curvature does not track the lens curvature. Schuele ¶ 114. A POSA also would have recognized that the diffractive optical element of Koschmieder would improve the laser focus (and resulting delivery of laser power) to the lens when creating the grid-like shot pattern of Frey. *Id.* This combination is particularly suitable because Frey already contemplates that the grid-like shot pattern in Figure 25 may include curved layers. Frey, [00116] (disclosing curved shell cut integral with grid like cuts), [0123] (proposing "combinations" of various patterns, including "the cube pattern of Fig. 25" and "partial shells and shells"); Schuele ¶ 114.

A POSA would have understood Koschmieder's technique was particularly attractive for use with Frey's shell cuts, including shell cut 2504 in Figure 25:

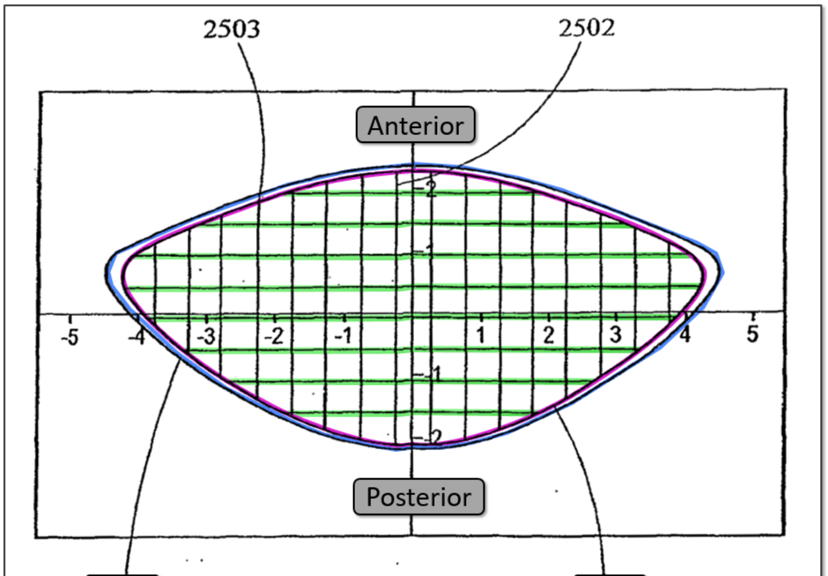


Fig. 25

Frey, Fig. 25 (highlighted, labeled anterior/posterior); Schuele ¶ 115. As shown, shell cut 2504 tracks the posterior curvature of the lens. *Id.* ¶ 115. Koschmieder specifically describes and illustrates a curved focal plane that tracks that posterior curvature of the lens. Koschmieder, Fig. 2; *see also id.*, [0022] ("FIG. 2 shows an image plane 5 that is adapted to the rear surface of the eye lens"); Schuele ¶¶ 115, 110; *see also* Koschmieder [0027] (describing adjusting focus to be on "anterior lens surface," "posterior lens surface," or "intermediate positions").

A POSA would have understood that incorporating Koschmieder's technique into Frey's laser surgical system would allow the laser system to create these curved layers without having to adjust the z focusing device. Schuele ¶ 116. Because the curved layer lies within a single focal plane, the entire shell cut can be scanned by controlling only the x y scanner (which in Frey is a "pair of closed loop galvanometers," Frey, [0065]). Schuele ¶ 116. A POSA would have known that x-y galvanometers act substantially faster than a z focusing device, thus allowing the shell cuts to be made much more quickly when it lies within a single focal plane. *See* Gaddum Reddy & Peter Saggau, *Fast Three-Dimensional Laser Scanning Scheme Using Acousto-Optic Deflectors*, 10(6) J. OF BIOMEDICAL OPTICS 064038-1-2 (Nov./Dec. 2005) ("Reddy," Ex. 1018); *see also* Kurtz, [0151], [0179]-[0180]; Schuele ¶ 116. As a result, a POSA would have been motivated to combine Frey and Koschmieder to compete the shell cuts more quickly and efficiently. Schuele ¶ 116. This combination represents the "mere application of a known technique to a piece of prior art ready for the improvement." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007).

A POSA would have had a reasonable expectation of success to incorporate Koschmieder's diffractive optical element 3 into Frey's optics module 203. Schuele ¶ 117. Koschmieder explains that a diffractive optical element can be added to the surface of existing optics or added as a separate element in the beam path in ophthalmic instruments for treatment of the lens of the eye. Koschmieder, [0022], [0031], Abstract, Fig. 1; *see also* [0025]-[0028], [0034]-[0035]. Koschmieder also explains that the type of beam path for the diffractive optical element is "not relevant." *Id.* Thus, Koschmieder's approach "can be used in a great variety of ophthalmic instruments[,]" including laser systems for "treatment of the human eye." *Id.*, [0034]; *see also id.* [0006], [0035], Abstract, [0031]. These teachings show that the diffractive optical element of Koschmieder is well suited for the optical system of Frey. Schuele ¶ 117.

As explained above, claims 1 and 2 are obvious over Frey and the knowledge of a POSA. *See* Ground 1, Section VI, *supra*. To the extent that the claims are construed to require that the "curvature of the focal plane" must itself "track the natural curvature of the lens" (which is disclosed in Koschmieder, *see* Section VII.A, *supra*), the combination of Frey, Koschmieder, and the knowledge of a POSA also render claims 1 and 2 obvious. Schuele ¶ 118.

VIII. Ground 3: Claims 1 and 2 Are Obvious Over Blumenkranz in View of Frey and the Knowledge of a POSA

A. Blumenkranz (Ex. 1008)

US 2006/0195076 A1 ("Blumenkranz," Ex. 1008) is prior art under pre-AIA 35 U.S.C. § 102(b) because it was published on August 31, 2006, more than one year before the earliest priority date for the '356 patent. Blumenkranz was cited by the Applicant in an IDS, *see* '356 FH at 59 (8/14/2014 IDS), but it was not substantively discussed during prosecution.

Blumenkranz discloses a "system and method for making incisions in eye tissue at different depths[,]" including "fragmentation of the lens nucleus and cortex[.]" Blumenkranz, Abstract, [0009]; *see also id.* [0045], [0068]-[0069], [0074],

[0078]. The Blumenkranz system uses "3-dimensional patterned laser cutting" to dissect the lens "into small segments" that will be "easily removed." *Id.*, [0009]; *see also id.* [0057], [0061]-[0062], [0068]-[0069], [0074], [0078], [0089]; Schuele ¶ 121.

Blumenkranz's laser surgical system is shown in Figure 11:

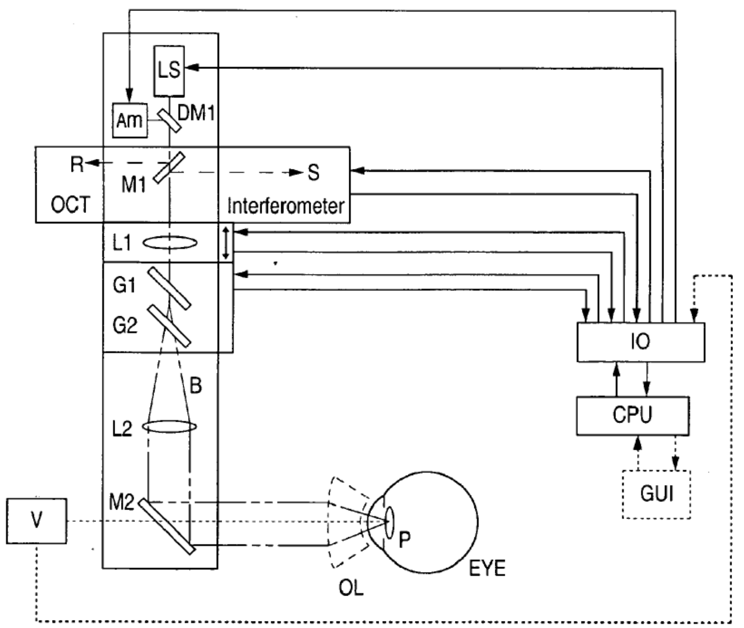


FIG. 11

Blumenkranz, Fig. 11; *see also* Fig. 1. Blumenkranz's system includes "control electronics" that control a "light source 10 [LS] (e.g. laser, laser diode, etc.)" to create an "optical beam 11 [B] (either cw or pulsed)" that the controller scans into the patient's eye using "moveable optical elements[.]" *Id.*, [0045]; *see also* [0075]-[0078], Figs. 1 and 11; Schuele ¶¶ 122-123.

Blumenkranz teaches that the "laser light focused into eye tissue 2" cuts the lens tissue into pieces by forming a "photo-induced plasma," which results in photodisruption bubbles, also called "cavitation bubble[s]." Blumenkranz, [0050], [0053]; *see also* Figs. 20 and 21; Schuele ¶ 124. This is shown in Figure 2:

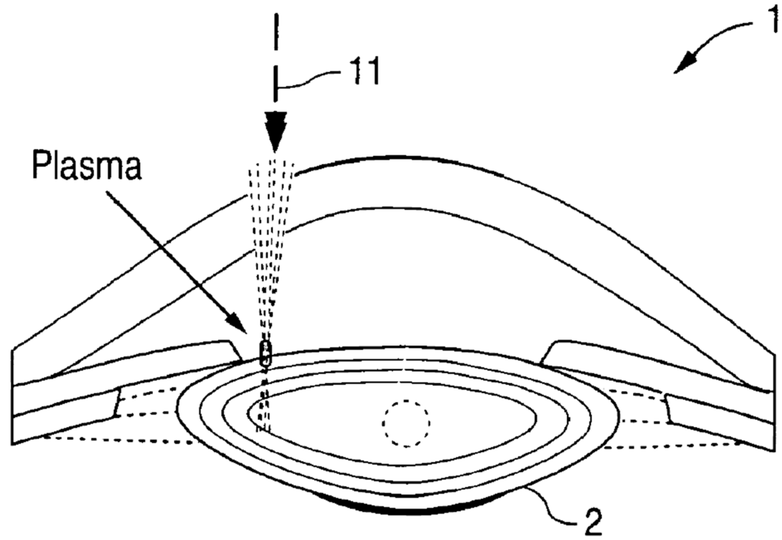


FIG. 2

Blumenkranz, Fig. 2; *see also id.* Figs. 5, 20-21. It explains:

> For segmentation of the eye lens 3, the patterns can be linear, planar, radial, radial segments, circular, spiral, curvilinear and combinations thereof including patterning in two and/or three dimensions. Scans can be continuous straight or curved lines, or one or more overlapping or spaced apart spots and/or line segments.

Blumenkranz, [0068]; *see also id.* [0009] ("fragmentation of the lens nucleus and cortex is enabled using 3-dimensional patterned laser cutting"), [0069] ("exemplary patterns allow for dissection of the lens cortex and nucleus into fragments of such dimensions that they can be removed simply with an aspiration needle"), [0057], [0074], [0078], Figs. 9A-9B, 10A-10C, 20-21; Schuele ¶ 125.

Blumenkranz teaches a grid-like array segmentation pattern of the lens as depicted in Figure 10C, which is a top-down view of the laser cutting pattern:

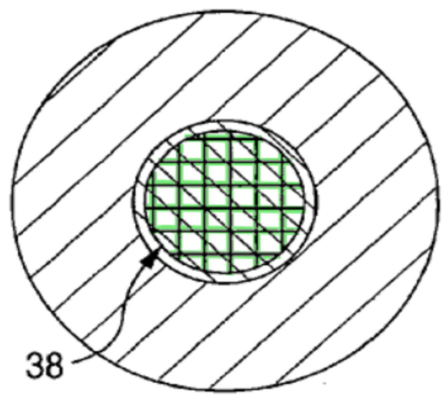


FIG. 10C

Blumenkranz, Fig. 10C (highlighted scan pattern 38); *see also id.*, [0068]; Schuele ¶ 126. In district court, Alcon alleges that the type of grid-like segmentation pattern depicted in Blumenkranz's Figure 10C creates a "regular array of cells" as required by the '356 patent. Alcon Contentions, at 43-44. Blumenkranz also teaches that the laser system fragments the "bulk of the lens…into ***cubic pieces of 1 mm***[.]" Blumenkranz, [0089]. The system thus dissects the lens into an array of cells. Schuele ¶ 127.

Blumenkranz also teaches that the system creates the fragmentation patterns, including the grid-like fragmentation pattern in Figure 10C, on a layer-by-layer basis. Blumenkranz, [0013], [0061]-[0062], [0078]. The system "produc[es] several circular or other pattern scans consecutively at ***different depths***" where the depth of laser focus "is stepped up or down with each consecutive scan." *Id.*, [0062]; *see also id.* ("[W]hen segmenting a lens, the laser can be focused on the most posterior portion of the lens and then moved anteriorly."). "[T]he laser pulses are sequentially applied to the same lateral pattern at different depths of tissue using, for example, [by] axial scanning of the focusing elements[.]" *Id.*; *see also id.* [0013], [0078]; Schuele ¶ 128.

B. Claim 1

1. Preamble

> *"A method of fragmenting lens tissue of an eye with a laser surgical system, the method comprising:"*

To the extent the preamble is limiting, it is disclosed by Blumenkranz. Schuele ¶¶ 129-134. Blumenkranz discloses a laser surgical system and methods for treating a human crystalline lens with its laser surgical system. Blumenkranz, Abstract ("System and method for making incisions in eye tissue at different depths."), [0009], [0045], [0061]-[0062], [0068]-[0069], [0074]-[0075], Figs. 1, 11.

The laser surgical system of Blumenkranz fragments lens tissue by "3-dimensional patterned laser cutting" that dissects the lens into pieces that are then removed using aspiration. Blumenkranz, [0009], [0045], [0057], [0061]-[0062],

[0068], [0069], [0074], [0078], [0099] ("[a]n ***ultrafast laser is used to fragment the lens*** into pieces small enough to be removed"), Abstract; Schuele ¶¶ 131-134.

2. Step 1[a]: generating a pulsed laser beam

"generating a pulsed laser beam with a pulsed laser"

Blumenkranz explains that the "***[s]hort pulsed laser light*** focused into eye tissue 2 will produce dielectric breakdown at the focal point, rupturing the tissue 2 in the vicinity of the photo-induced plasma[.]" Blumenkranz, [0050]; *see also id.* [0046]-[0049], [0051]-[0055], [0073], [0062], [0078], [0083]. Blumenkranz thus discloses this step. Schuele ¶¶ 135-138.

3. Step 1[b]: directing the laser beam

"directing the pulsed laser beam with an optics module towards a target region in the lens tissue"

Blumenkranz teaches that its laser system directs a pulsed laser beam to the target lens tissue with "one or more ***moveable optical elements*** (e.g. lenses, gratings, or as shown in Fig. 1 a mirror(s) 16)." Blumenkranz, [0045]; *see also id.* Fig. 1. The system performs "3-dimensional scanning" by using "Lens L1" to adjust the beam location along the z-axis, a "pair of orthogonal galvanometric mirrors G1 & G2" to scan the beam transversely along the x-y axes, and "lens L2" to focus the beam to a point P in the target lens tissue. *Id*, [0075]-[0076]; *see also id.* Fig. 11; Schuele ¶¶ 141-142. Blumenkranz's optical system delivers the pulsed laser beam to target tissue in the lens of the eye. Blumenkranz, Fig. 11, [0045], [0062], [0050], [0068]-[0069], [0075]-[0076], [0078], [0085].

Blumenkranz thus discloses this step. Schuele ¶¶ 139-143.

4. Step 1[c]: form a regular array of cells

"controlling the optics module by a system control module to form a regular array of cells in the target region by creating layers of photodisrupted bubbles to generate cell boundaries"

Blumenkranz discloses this step, as explained below. Schuele ¶¶ 144-151.

a. System control module

Blumenkranz includes "control electronics" that control the moveable optical elements to scan the pulsed laser beam in a 3-dimensional pattern in the lens tissue. Blumenkranz, [0045], [0009], [0085] ("The pattern to be applied can be selected from a collection of patterns in the control electronics 12"), Fig. 1, Fig. 11. Indeed, Blumenkranz teaches that "the entire system is controlled by controller CPU" through the input/output device IO. *Id.*, [0077]; *see also id.*, [0073] ("the treatment pattern can be rapidly applied to the target tissue using an automated 3 dimensional pattern generator (in the control electronics 12)"), [0074], Figs. 1, 11. Blumenkranz's control electronics constitute a system control module for controlling the optics module (moveable optical elements lens L1, mirrors G1 and G2, and lens L2). Schuele ¶¶ 146-147.

b. Form a regular array of cells in the target region

Blumenkranz controls its moveable optical elements to form a regular array of cells in the target lens region. Blumenkranz, [0009], [0068], [0069], [0085], [0089], [0090], Figs. 9A-9B, 10A-10C. In one such fragmentation pattern, the system cuts the lens into "***cubic pieces*** of 1 mm in size" (i.e., cells), just like those shown in the '356 patent. *Compare* Blumenkranz, [0089] *with* '356 patent, 7:8-13 ("the granules, or cells, can be cubes."); *see also* Blumenkranz, Fig. 10C. These resulting cubic pieces of lens tissue form a regular array of cells. Schuele ¶ 148.

c. Create layers of photodisrupted bubbles to generate cell boundaries

Blumenkranz teaches that the laser system forms the segmentation patterns layer-by-layer, where the laser pulses are "sequentially applied" to "the same lateral pattern at different depths of tissue." Blumenkranz, [0062]; *see also id.* [0013], [0015], cls. 1, 2. For lens segmentation, the system focuses the laser "on the most posterior portion of the lens and then move[s] more anteriorly as the procedure continues." *Id.*, [0062]; *see also id.* [0057], [0074], [0078], [0085]. The laser pulses create "cavitation bubbles." *Id.*, [0053]; *see also id.* [0050], [0051], Figs. 2, 5, 20-21. Schuele ¶ 149.

Blumenkranz provides a specific example of using the laser to form cell boundaries. Blumenkranz, [0089]. To cut the lens "into cubic pieces of 1 mm in size[,]" Blumenkranz creates photodisrupted bubbles that are 15 μm in diameter. *Id.* Because 66 bubbles are required to span 1 mm (1mm/15μm=66), the bottom layer "will require 66×66=4356 pulses" for each cube. *Id.* These laser pulses create layers of photodisrupted bubbles that form cell boundaries. Schuele ¶ 150.

5. Step 1[d]: curved layers

"the layers are created by scanning the pulsed laser with the optics module according to a curvature of the focal plane of the optics module to track the natural curvature of the lens"

Blumenkranz in view of Frey (and the knowledge of a POSA) discloses this step, as explained below. Schuele ¶¶ 152-161.

a. Scanning the pulsed laser according to a curvature of the focal plane of the optics

As discussed above for step 1[c], Blumenkranz creates photodisruption bubble layers, by scanning the laser through its optical elements (lens L1, mirrors G1 and G2, and lens L2).

To segment the lens into pieces, Blumenkranz applies a "lateral pattern at different depths of tissue[.]" Blumenkranz, [0062]. These patterns are applied within "focal planes" for "segmentation of the lens." *Id.*, [0057]; *see also id.* [0074], [0078] ("scanning planes"), [0085]; Schuele ¶¶ 154-155. While Blumenkranz explains that "an appropriate focusing element will be selected from an available set" (Blumenkranz, [0078]), it would have been obvious to select Frey's "conventional focusing optics" for such purpose. Schuele ¶ 155.

Both Blumenkranz and Frey are directed to pulsed laser systems used to fragment lens tissue into cubes, which are removed by aspiration. Schuele ¶ 156. In fact, the two systems share the same basic optical design, with the focusing optics located after the x-y scanner and z focusing device in the optical train. *Compare* Blumenkranz, Fig. 11 (z-focusing lens L1, x y scanning mirrors G1/G2, focusing lens L2) *with* Frey, Fig. 2A (z focusing device 221, x y scanner 223, focusing optics 224); Schuele ¶ 156. It would have been obvious to combine their interrelated teachings related to the laser beam delivery optics to develop a laser system for cataract surgery. *In re Kerkhoven*, 626 F.2d 846, 850 (C.C.P.A. 1980) ("It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose.").

Blumenkranz explains that any suitable focusing optics can be used based on the desired system performance. Blumenkranz, [0078]. A POSA, when selecting the optics for Blumenkranz's laser system, would have been motivated to select the "conventional focusing optics" of Frey. Schuele ¶ 157. Such optics were already applied by Frey for cutting lens tissue, so their use in Blumenkranz simply incorporates "old elements with each performing the same function it had been known to perform." *KSR*, 550 U.S. at 417. Moreover, such conventional optics were recognized by a POSA to be simpler to design and typically less expensive than other specialized optics. Schuele ¶ 157. For example, flat field optics (which avoid a curved focal plane) require adding several different optical elements that can introduce aberrations and reduce the intensity of the laser beam. Rathjen, [0003], [0009]; Kurtz, [0178]; Molesini, 265-67; Schuele ¶ 157. A POSA would have known that conventional focusing optics were preferred. Schuele ¶ 157; *see also* Sections VI.A and VI.B.5.a, *supra*.

The use of Frey's conventional focusing optics in Blumenkranz's laser system would result in scanning the laser in a curved focal plane, as recited in the claims. *See* Sections VI.A and VI.B.5.a, *supra*; Schuele ¶ 158.

b. Track the natural curvature of the lens

It would have been obvious to apply the teachings of Frey to Blumenkranz to apply laser pulses that track the natural curvature of the lens. Schuele ¶ 159. Both Blumenkranz and Frey share the same approach of using a pulsed laser to fragment the lens into cubes. Blumenkranz, [0089], [0068], Fig. 10C; Frey, [0091], [00115]-[00117], Fig. 25; *see* Sections VI.B.4.b-c and VIII.B.4.b-c, *supra*; Schuele ¶ 159. Frey suggests the added step of providing a laser shot pattern that will "follow the shape of the lens." Frey, [0093]; *see also id.* [00116], [0083], Fig. 25. Specifcally, Frey proposes that shell cut 2504 can be added to the grid-like shot pattern that forms the cubes. *Id.*, [00116], Fig. 25; *see also id.* [00123]; Schuele ¶ 159.

The motivation to combine is provided by Frey. Frey explains that laser pulses that follow the shape of the lens help ensure that "a sufficiently continuous layer and/or line and/or volume of lens material has been removed." Frey, [0093]; *see also id.* [0083]. Frey also explains that "by precisely following the individual shape of the layers within the lens more effective cleaving is obtained." *Id.*, [00113]. A POSA would understand from Frey that applying laser pulses that "follow the shape of the lens," including shell cuts, offer the same advantages for Blumenkranz. Schuele ¶ 160. As a result, it would have been obvious to incorporate into Blumenkranz the teaching from Frey of tracking the natural curvature of the lens. *See* Section VI.B.5.b, *supra*.; Schuele ¶ 160.

* * *

In sum, the combination of Blumenkranz, Frey, and the knowledge of a POSA renders claim 1 obvious. Schuele ¶ 162.

C. Claim 2

Claim 2 depends from claim 1, and further recites forming the regular array of cells comprising:

> *"forming the cells with a size suitable for extraction by aspiration without additional lens fragmentation."*

Blumenkranz discloses this limitation. Schuele ¶¶ 163-167.

As discussed above for step 1[c], Blumenkranz discloses forming a regular array of cells, where the cells are cubes. Blumenkranz, [0089]; Schuele ¶ 166. Blumenkranz teaches that its segmentation patterns "allow for dissection of the lens cortex and nucleus into ***fragments*** of such dimensions that they ***can be removed simply with an aspiration needle***." Blumenkranz, [0069]; *see also id.*, [0009] ("The removal of a lens dissected into small segments is performed using a patterned laser scanning and just a thin aspiration needle."), [0099]. Thus, the cells ("cubic pieces") formed by Blumenkranz's laser can be aspirated without additional lens fragmentation. Schuele ¶¶ 166-167.

IX. Ground 4: Claims 1 and 2 Are Obvious Over Blumenkranz in View of Frey, Koschmieder, and the Knowledge of a POSA

To the extent the Board construes the claims to require that the "curvature of the focal plane" must itself "track the natural curvature of the lens" (*see* Section V, *supra*), claims 1 and 2 would have been obvious over Blumenkranz in view of Frey (and the knowledge of a POSA) and Koschmieder. As explained above, Koschmieder discloses a curved focal plane that tracks the natural curvature of the lens of the eye. *See* Section VII.A, *supra*.

A POSA would have found it obvious to incorporate Koschmieder's diffractive optical element (DOE) into Blumenkranz's optical system, to create curved layers according to the curvature of the focal plane of the optics module, and which also track the natural curvature of the lens. Schuele ¶¶ 168-169.

Koschmieder itself provides the motivation to combine. As Koschmieder explains, "the ***straight or even oppositely curved image planes*** of the illumination components and irradiation components ***have a disadvantageous effect***." Koschmieder, [0013]. Those disadvantages are particularly pronounced in "outer areas and edge areas," where the focus will "become blurred and lose intensity to an appreciable extent." *Id.* The curved image planes of Koschmieder provide "a ***uniformly high image quality*** over extensive areas of the eye." *Id.*, [0014]; *see also id.* Abstract, [0003], [0006], [0023], [0032]; Schuele ¶ 170.

A POSA would have understood that Koschmieder's teaching applies to the array of cubes created by Blumenkranz, where the horizontal layers of laser pulses may become unfocused near the outer edge when the focal plane does not track the lens curvature. Koschmieder, [0013]; Schuele ¶ 171. A POSA also would have recognized that the diffractive optical element of Koschmieder would improve the laser focus (and resulting delivery of laser power) to the lens when cutting the lens into cubes in Blumenkranz. *Id.* [0014]; *see also id.* Abstract, [0003], [0006], [0023], [0032], [0034]-[0035]; Schuele ¶ 171. This combination is particularly suitable because Blumenkranz already contemplates using a diffractive optical element. Blumenkranz, [0016], [0021]; Schuele ¶ 172.

A POSA would have understood Koschmieder's technique was particularly attractive for use with Frey's shell cuts, which as explained above, would have been incorporated into Blumenkranz. *See* Section VIII.B.5.b, *supra*. Like shell cut 2504 of Frey, Koschmieder specifically describes and illustrates a curved focal plane that tracks that posterior curvature of the lens. Koschmieder, Fig. 2; *see also id.*, [0022] ("FIG. 2 shows an image plane 5 that is adapted to the rear surface of the eye lens"); Schuele ¶ 173; *see also* Koschmieder [0027] (describing adjusting focus to be on "anterior lens surface," "posterior lens surface," or "intermediate positions"); *see also* Section VII.B, *supra*..

A POSA would have understood that incorporating Koschmieder's technique would allow the laser system to create these curved layers without having to adjust the z focusing lens. Schuele ¶ 174. Because the curved layer lies within a single focal plane, the entire shell cut can be scanned by controlling only the x-y galvanometers (which in Blumenkranz is a "pair of orthogonal galvanometric mirrors[,]" Blumenkranz, [0076]); Schuele ¶ 174. A POSA would have known that x-y galvanometers act substantially faster than a z focusing lens, thus allowing the shell cuts to be made much more quickly when it lies within a single focal plane. *See, e.g.*, Blumenkranz, [0075]-[0076]; *see also* Reddy, 064038-1-2; Kurtz, [0151], [0179]-[0180]; Schuele ¶ 174. As a result, a POSA would have been motivated to combine Blumenkranz in view of Frey with Koschmieder to compete the shell cuts more quickly and efficiently. Schuele ¶ 174. This combination represents the "mere application of a known technique to a piece of prior art ready for the improvement." *KSR*, 550 U.S. at 417.

A POSA would have had a reasonable expectation of success to incorporate Koschmieder's diffractive optical element 3 into Blumenkranz's optical system. Schuele ¶ 175. Koschmieder explains that a diffractive optical element can be added to the surface of existing optics or added as a separate element in the beam path in ophthalmic instruments for treatment of the lens. Koschmieder, [0022], [0031], Abstract, Fig. 1; *see also id.* [0025]-[0028], [0034]-[0035]. Koschmieder also explains that the type of beam path for the diffractive optical element is "not relevant." *Id.* at [0022]. Thus, Koschmieder's approach "can be used in a great variety of ophthalmic instruments," including laser systems for "treatment of the human eye." *Id.*, [0034]; *see also id.* [0006], [0031], [0035], Abstract. These teachings show that the diffractive optical element of Koschmieder is well suited for the optical system of Blumenkranz. Schuele ¶ 175.

As explained above, claims 1 and 2 are obvious over Blumenkranz, Frey, and the knowledge of a POSA. *See* Ground 3, Section VIII, *supra*. To the extent that the claims are construed to require that the "curvature of the focal plane" must itself "track the natural curvature of the lens" (which is disclosed in Koschmieder, *see*

Section VII.A, *supra*), the combination of Blumenkranz, Frey, Koschmieder, and the knowledge of a POSA also render claims 1 and 2 obvious. Schuele ¶ 176.

X. Secondary Considerations

No secondary considerations known to J&J Vision affect, let alone overcome, this strong case of obviousness. In district court, Alcon has asserted that its LenSx® system practices the claims of the '356 patent, and that "[s]econdary considerations supporting non-obviousness include evidence of praise for the patented innovation and commercial success." Alcon's Objections and Responses to Interrogatory No. 15 (Ex. 1017) at 35. These conclusory allegations are legally insufficient to establish nonobviousness. Schuele ¶ 177. 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) (citations omitted). "[T]here is no nexus unless the evidence presented is reasonably commensurate with the scope of the claims." *Id*.

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.

XI. The Board Should Reach the Merits of This Petition

Discretionary denial is unwarranted here.

A. Discretionary Denial Pursuant to Section 325(d) Is Not Warranted

The Board considers discretionary denial under a two-part framework:

> (1) whether the same or substantially the same art previously was presented to the Office or whether the same or substantially the same arguments previously were presented to the Office; and (2) if either condition of first part of the framework is satisfied, whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of challenged claims.

Advanced Bionics, LLC v. Med-El Elektromedizinische Gerate GMBH, IPR2019-01469, Paper 6 at 8 (P.T.A.B. Feb. 13, 2020) (precedential). Analysis under either prong demonstrates that discretionary denial is unwarranted.

First, neither Frey nor Blumenkranz was substantively discussed during prosecution of the '356 patent. Koschmieder was not cited during prosecution, and it is not substantially the same as any art presented during prosecution. The Office was thus never presented with arguments in this Petition. In fact, while Gray was discussed during prosecution of the abandoned parent application, the Examiner never considered whether Gray (or Frey) disclosed a curved focal plane or applying laser pulses that "track the natural curvature of the lens." *See* '784 FH at 367-372 (10/29/2012 Office Action). Thus, the Board should not exercise its discretion to deny institution under § 325(d). *See PEAG LLC v. Varta Microbattery GmbH*, IPR2020-01212, Paper 8 at 11-13 (Jan. 6, 2021), 4-5 (not exercising its discretion to deny institution under the first prong of the *Advanced Bionics* test because references used in combination with previously disclosed primary reference were not previously disclosed to the Office); *Dish Network L.L.C. v. Broadband Itv, Inc.*, No. IPR2020-01359, Paper 15 at 27-30 (Feb. 12, 2021) (declining to exercise discretion when some of the references were not before Examiner).

Second, the Examiner "erred in a manner material to the patentability of the challenged claims." *Advanced Bionics* at 8. Specifically, the Examiner "overlook[ed] specific teachings of the relevant prior art where those teachings impact patentability of the challenged claims." *Id.* at 8 n.9. For example, by failing to apply Frey (or Gray) against the claims of the '356 patent, the Examiner overlooked Frey's disclosure that the laser shot patterns should preferably "follow the shape of the lens." Frey, [0093]. This is a particularly concerning error, since Frey also discloses virtually the same grid-like laser shot pattern forming a regular array of cells as is shown in the '356 patent. *Compare* Frey, Fig. 25 *with* '356 patent, Fig. 4a. Additionally, the Examiner overlooked the relevant teachings in Blumenkranz to cut the lens into cubes, using layers of photodisrupted bubbles. Blumenkranz, [0068]-[0069], [0085], [0089]. The Examiner did not acknowledge Koschmieder at all, or any similar prior art teaching of "shaping of the image plane" so that it "can be adapted to the spherical contour of the eye." Koschmieder, Abstract.

The prosecution history is absolutely "silent" on these teachings; there is no "specific finding of record" addressing them. *Advanced Bionics* at 10-11. The Examiner's failure to examine these teachings in Frey, Blumenkranz, and Koschmieder is an error that materially affects the patentability of the claims.

The Examiner therefore erred by overlooking these teachings of Frey and Blumenkranz, and the Board should decline to exercise its discretion to deny institution under § 325(d). *See Amazon.com v. M2M Sols*, IPR2019-01204, Paper 14 at 16-17 (Jan. 23, 2020) (error to overlook art in an IDS); *Philip Morris Prod., S.A. v. Rai Strategic Holdings, Inc.*, No. IPR2020-00921, Paper 9 at 11 (Nov. 16, 2020) ("Other than initials on a lengthy IDS, nothing in the record indicates that the Examiner substantively considered [the prior art in the petition].").

B. Discretionary Denial Under NHK Spring Is Not Warranted

The *Fintiv* factors confirm that discretionary denial is inappropriate. *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 (P.T.A.B. Mar. 20, 2020) (precedential). Trial in the district court is scheduled well after the Board's final written decision would be expected if trial were instituted (factor 2). If instituted, the Final Written Decision would be expected in or about December 2022. That is at least two 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 or two reference combinations rendering obvious the challenged claims of the '356 patent (factor 6).

XII. 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 ’356 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. filed June 23, 2020).

C. Grounds for Standing

Petitioner certifies that the ’356 patent is available for *inter partes* review and that Petitioner is not barred or estopped from requesting *inter partes* review of the challenged claims of the ’356 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), Petitioner designates the following lead counsel:

- Michael A. Morin (Reg. No. 40,734), michael.morin@lw.com, Latham & Watkins LLP; 555 Eleventh Street, NW, Ste. 1000; Washington, D.C. 20004-1304; 202.637.2298 (Tel.); 202.637.2201 (Fax).

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Pursuant to 37 C.F.R. § 42.10(b), a Power of Attorney from Petitioner is attached. Petitioner 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.

XIII. Conclusion

For the reasons set forth above, Petitioner respectfully requests *inter partes* review of the challenged claims of the ’356 patent.

Respectfully submitted,

Dated: June 7, 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 10,990 words, which is the sum of 10,840 words calculated by Microsoft Word's word-count feature and 150 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. 9,427,356 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 Alcon Inc.'s current litigation counsel:

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