IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re *Inter Partes* Review of:)
U.S. Patent No. 9,456,925)
Issued: Oct. 4, 2016)
Application No.: 12/343,418)
Filing Date: Dec. 23, 2008)

For: **Photodisruptive Laser Treatment of the Crystalline Lens**

FILED VIA E2E

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 9,456,925

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I. Introduction

Petitioner Johnson & Johnson Surgical Vision, Inc. ("J&J Vision") requests *inter partes* review of claims 1, 2, 4, 5, 11, 12, 17, 23, 24, 26, and 27 of U.S. Patent No. 9,456,925, titled "Photodisruptive Laser Treatment of the Crystalline Lens" ("'925 patent," Ex. 1001) and assigned to Alcon Inc. ("Alcon").

The '925 patent describes methods of laser cataract eye surgery, in which laser scanning is used to form incisions in the crystalline lens of the eye. The claims require that the laser is scanned along a "curved focal plane" of the laser delivery optics.

Alcon secured allowance of the '925 patent by asserting that the Examiner was "unable to point to an explicit description of a laser optical system with a curved focal plane" in the prior art of record. '925 patent FH 1395 (Ex. 1002). The problem was that Alcon never identified (and the Examiner did not appreciate) that the prior art used "conventional focusing optics"—which has a curved focal plane—to scan the prior art laser system. The Examiner allowed the claims without ever considering that issue.

World Intellectual Property Organization Publication, No. WO 2007/084602 A2 ("Frey," Ex. 1006), is a published patent application that, like the prior art of record, uses conventional focusing optics to scan the laser for laser cataract surgery, in the manner recited by the claims. This Petition requests that the

Patent Office consider, for the first time, the key teaching in paragraph [0065] of Frey that laser scanning can be done with "conventional focusing optics" together with how a person of ordinary skill in the art would have understood such optics to be configured.

U.S. Patent Application Publication No. 2006/0195076 A1 ("Blumenkranz," Ex. 1008) is a published patent application that discloses virtually all the limitations of the '925 patent claims. It was never substantively discussed during prosecution. Combined with Frey and its teaching in paragraph [0065], Blumenkranz likewise renders the claims obvious.

The claims of the '925 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 Challenge (37 C.F.R. § 42.104(b))

Ground 1: Claims 1, 2, 4, 5, 11, 12, 17, 23, 24, and 26 are obvious over Frey (Ex. 1006) and the knowledge of a POSA.

Ground 2: Claims 17 and 27 are obvious over Frey in view of Blumenkranz (Ex. 1008) and the knowledge of a POSA.

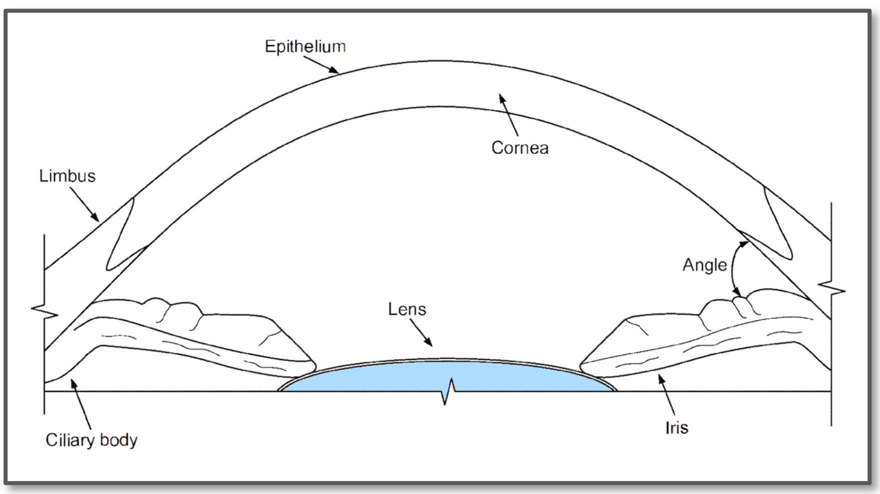
Ground 3: Claims 1, 2, 4, 5, 11, 12, 17, 23, 24, 26, and 27 are obvious over Blumenkranz in view of Frey and the knowledge of a POSA.

III. Background

A. The ’925 Patent

The ’925 patent issued from Application No. 12/343,418, filed on December 23, 2008, a continuation-in-part of abandoned Application No. 12/205,842, which claimed priority to Provisional Application No. 60/970,454, filed September 6, 2007.

The ’925 patent generally relates to laser cataract eye surgery to remove a diseased (clouded) lens of an eye. ’925 patent, 1:21-22, 5:60-6:8. Figure 18 shows the relevant structures in the front portion of the eye:



Id., Fig. 18 (highlighted); Schuele ¶ 15. The lens (highlighted in blue, above) is in the interior of the eye, beneath the cornea.[1] Laser pulses are applied to the lens to produce photodisruption bubbles, which form incisions that can break up the lens into small fragments. ’925 patent, 1:23-26, 1:37-41. The fragments can then be removed via aspiration. *Id.*, 7:49-59. The ’925 patent acknowledges that the method of “[l]aser-induced photodisruption [including lens fragmentation] has been already used in the past in laser ophthalmic surgery.” *Id.*, 1:37-41, 7:43-48; Schuele ¶ 18.

The ’925 patent claims to improve upon the prior art by using the laser to make certain types of “non-transverse” incisions in the lens. *Id.*, 4:6-7, 12:37-13:4. Such non-transverse incisions generally follow the Z axis, which passes through the middle of the eye (vertical direction in Fig. 18 above). *Id.* 11:41-61, 12:38-41; Schuele ¶¶ 18-22. Near the center of the lens, the fibers of the lens are generally transverse (horizontal direction in Fig. 18 above). ’925 patent, 13:6-16; Schuele ¶ 22. The non-transverse incisions will thus cut the transverse fibers, thereby effectively weakening the biomechanical strength of the lens. ’925 patent, 13:6-16; Schuele ¶ 22.

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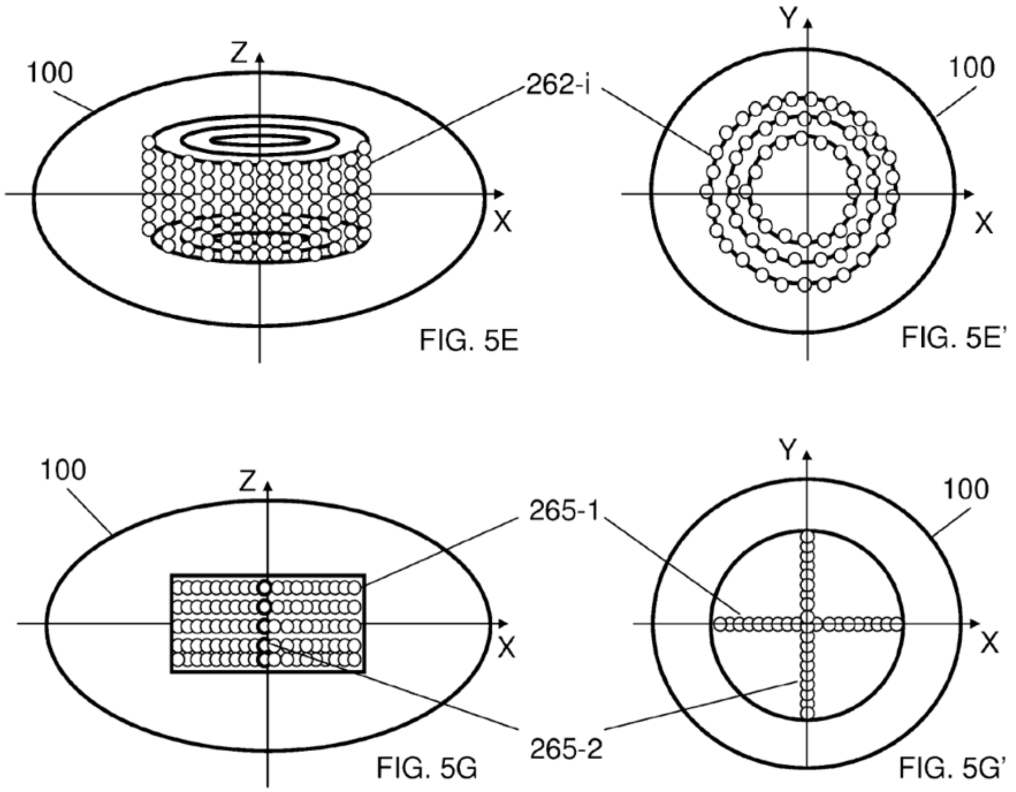
[1] This diagram follows the convention of showing a cross-section of the eye with the front of the eye at the top (i.e., the eye is looking upwards). Schuele ¶¶ 15-17.

Examples of non-transverse incisions are shown below in Figures 5E-5E′ and 5G-5G′, where the figure on the left is a side view (like Fig. 18 above) and the figure on the right is a top-down view (looking at the front of the eye):



’925 patent, Figs. 5E-5E′, 5G-5G′; Schuele ¶ 23. Figures 5E-5E′ show a cylindrical incision, and Figures 5G-5G′ show two crossing vertical planes. ’925 patent, 17:57-58, 18:57.

The ’925 patent explains that the non-transverse (vertical) incisions are created on a layer-by-layer basis, where each layer (horizontal) is formed by moving the XY scanner to laterally scan the laser. *Id.*, 2:54-55, 19:51-55. Thus, for example, the cylindrical incision is formed by layers of rings. *Id.*, 18:9-10, 18:37-41. This approach has the alleged advantage of "reducing or eliminating the need to move the Z servo [scanner] at the rate of the X-Y scanner." *Id.*, 19:51-55. This allows the system to reduce movement of the Z scanner, which is usually heavier and slower than the X-Y scanning mirrors. *Id.*, 16:49-57; Schuele ¶ 24.

In one embodiment where incisions are created on a layer-by-layer basis, the layers "may follow the curvature of the focal plane." '925 patent, 19:51-55. This is shown in Figure 5J′:

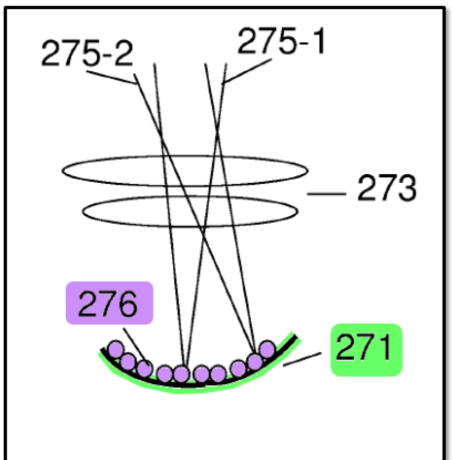


FIG. 5J'

Id., Fig. 5J′ (highlighted); Schuele ¶ 25. As shown above, the focal plane 271 (highlighted in green) is curved, and therefore the incision 276 formed by photodisrupted bubbles (highlighted in purple) follows the same curvature as the laser is scanned in the X-Y plane. '925 patent, 19:44-55. The '925 patent explains that "the focal plane 271 is typically curved in optical systems unless (any suitable portion of) the optics 273 of the laser delivery system is corrected for field curvature." *Id.*, 19:28-31; *see also id.*, 19:31-34.

B. Prosecution History

Claim 1, as originally submitted with the application for the '925 patent, was directed to a method of treating a crystalline lens by applying laser pulses to form non-transverse incisions in the lens. '925 patent FH 65 (Dec. 23, 2008 Appl.). It did not require incisions to be formed on a layer-by-layer basis, or to be formed along a curved focal plane. *Id.*

Following three rejections, Alcon amended claim 1 to recite the following limitation:

> forming an incision in the surgical region on a layer-by-layer basis by scanning a laser beam with an XY scanner of a laser delivery optics ***along a curved focal plane*** of the laser delivery optics to form a line of bubbles without adjusting a Z scanner of the laser delivery optics at a scanning rate of the XY scanner.[2]

[2] All emphasis added unless otherwise noted.

’925 patent FH 1093 (June 23, 2014 Resp. to Office Commc’n). The Examiner rejected the claim another three times as anticipated and/or obvious in view of U.S. Patent Application Publication No. 2007/0185475 A1 (“Gray,” Ex. 1020).[3]

In response, Alcon admitted that Gray discloses “forming shot patterns in a ‘layer-by-layer manner’.” ’925 patent FH 1298 (June 23, 2015 Resp. to Office Action). Alcon also conceded that in Gray, layers are “formed without adjusting the Z scanner.” *Id.* 1300. But, Alcon argued that in Gray, “layer-by-layer embodiments clearly show flat shot-layers, not curved ones.” *Id.* 1298; *see also id.* 1395 (Jan. 19, 2016 Resp. to Office Action) (“The Office Action was unable to point to an explicit description of a laser optical system with a curved focal plane by Frey.”).

Alcon’s arguments ultimately persuaded the Examiner to issue the pending claims. *Id.* 1409-11 (May 20, 2016 Not. of Allowance); *see id.* 1404-11. Neither the Examiner nor Alcon addressed or acknowledged Gray’s disclosure that the laser system may include “conventional focusing optics,” which Gray identifies as an alternative to “flat field optics.” Gray, [0064]; *see also* Frey, [0065]. As explained below, when using conventional focusing optics, the layer-by-layer approach

[3] Although the first-named inventor is Rudolph Frey, U.S. Patent Application Publication No. 2007/0185475 A1 is identified as “Gray” in this Petition to avoid confusion with Frey. Gray and Frey have substantially the same disclosure.

described in Gray (and Frey) scans the laser along a curved focal plane. *See* Sections VI.A and VI.B.3.b, *infra.*

IV. Person of Ordinary Skill in the Art

A person of ordinary skill in the art ("POSA") at the time of the purported invention in or about September 2007 or December 2008 would have at least a Bachelor's degree in a laser-related engineering or physics field, and several years of work experience in designing laser-based systems for eye surgery. Schuele ¶¶ 33-37. 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.[4] 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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[4] J&J Vision 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, 2, 4, 5, 11, 12, 17, 23, 24, and 26 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 ’925 patent. Frey is also prior art under pre-AIA 35 U.S.C. § 102(b) because it was published on July 26, 2007, more than one year before the application for the ’925 patent.[5] As noted above, a related published application with substantially the same disclosure (Gray) was discussed during prosecution. However, a key disclosure in Gray was not discussed during prosecution. *See* Section III.B, *supra.* Frey was disclosed in an international search report during prosecution, but was not otherwise discussed. ’925 patent FH 243 (Oct. 14, 2010 International Search Report).

Frey discloses “methods and systems for delivering a laser beam to a lens of an eye in a plurality of sectional patterns [that] results in the shaped structural weakening of the lens.” Frey, Abstract, [0018]. Frey explains that his methods of structural weakening of the lens “address a variety of medical conditions,” (*id.*,

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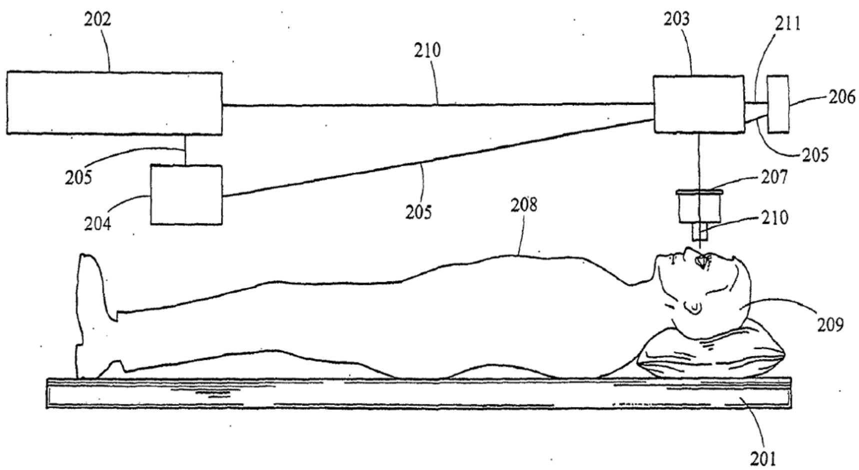
[5] In litigation, Alcon confirmed that it does not claim priority to the earlier provisional or parent applications. Alcon’s 2nd Suppl. Resps. to Interrog. No. 18 (Ex. 1018) at 12.

[0001]), such as "enabling the removal of the clear or cataractous lens material of the natural crystalline lens." *Id.*, [0062]; *see also id.*, Abstract, [0017], [0091], [00115]-[00117], [00123], [00131], Figs. 25, 41.

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



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], Fig. 2. 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.*, [0062]-[0065]; *see also id.*, [0091], [0092], [0093] (laser "spot with an energy sufficient to cause photodisruption … results in individual gas bubbles"), [00115], [0060], [00131], Figs. 2, 2A; Schuele ¶¶ 49-50.

Frey teaches that the laser surgical system 2 delivers the laser beam in a variety of "sectional patterns," including "vertical planes" that are "essentially parallel to the optical axis, i.e., the AP [anterior-posterior] axis." Frey, [00123]; *see also id.*, [0003], [0005], Figs. 1, 1A, 9. Such vertical plane incisions are non-transverse to an axis of the eye. Schuele ¶ 51. One such sectional pattern is a grid-like "shot pattern that cuts the lens into small cubes." Frey, [0091]; *see also id.*, [0115]-[00117]. As shown below in Figure 25 of Frey, the cubic laser pattern includes vertical planar incisions (highlighted in purple) parallel (non-transverse) to the optical axis of the eye, as well as horizontal planar incisions (highlighted in blue):

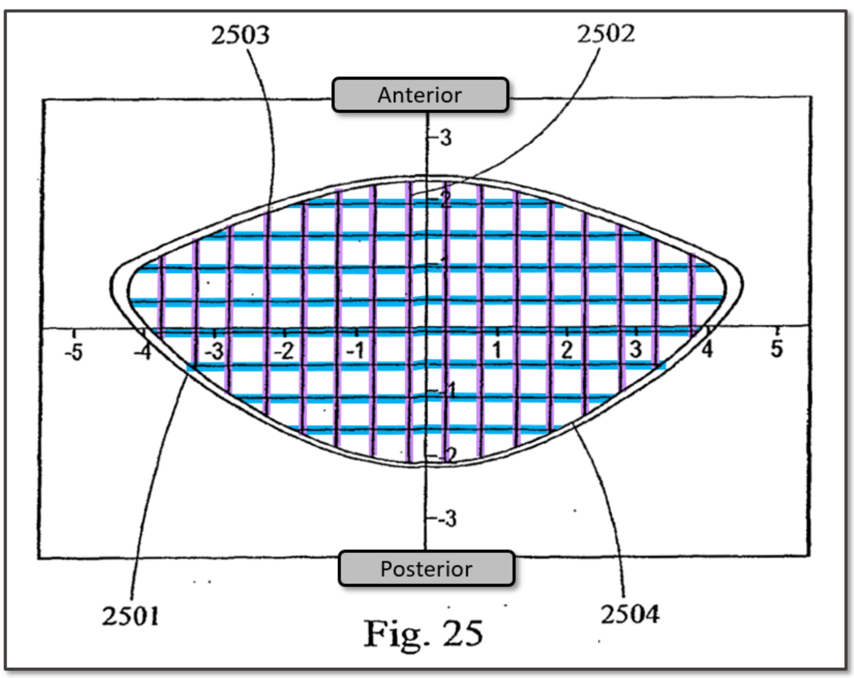


Fig. 25

Frey, Fig. 25 (highlighted, anterior/posterior labeled); Schuele ¶ 52. Each vertical plane in Figure 25 has a height (in the Z direction) from 1-4 mm and width (in an

X-Y plane) up to about 8 mm. Frey, Fig. 25; *see also id.*, [00131], Fig. 41 (describing and depicting non-transverse concentric cylindrical tube incision); Schuele ¶ 52; *see* Sections VI.B.4 and VI.B.5, *infra*.

Frey's laser system forms these incision patterns on a layer-by-layer basis. Frey, [00116], [0094]; Schuele ¶ 53. Indeed, Alcon admitted that substantially the same disclosure in Gray discloses "forming shot patterns in a 'layer-by-layer manner'." '925 patent FH 1298 (June 23, 2015 Resp. to Office Action). Frey teaches firing "laser shots in general from posterior points in the laser pattern to anterior points," or from "anterior to posterior." Frey, [0094]. At a given depth (from anterior to posterior), a layer of laser shots is applied by scanning the laser in a transverse "z plane[]" with an XY scanner ("move in x/y"). *Id.*, [00116]; Schuele ¶ 53.

Frey also discloses creating its laser shot patterns with layers of photodisrupted bubbles using "conventional focusing optics." Frey, [0065]; Schuele ¶ 54. A POSA would have known that conventional focusing optics create a curved focal plane, as illustrated below:[6]

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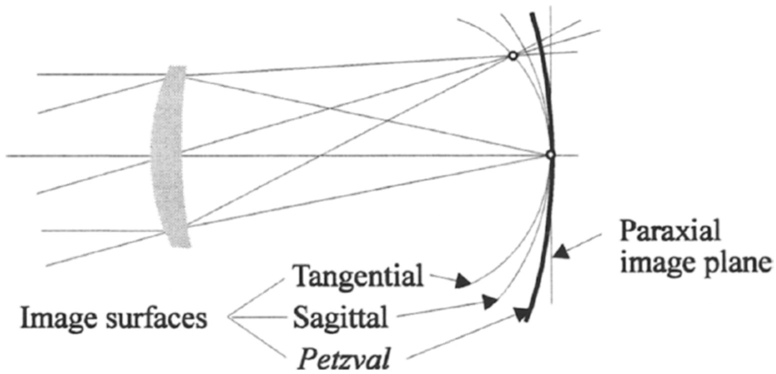
[6] In this figure from Max Riedl's OPTICAL DESIGN FUNDAMENTALS FOR INFRARED SYSTEMS (2d ed. 2001) ("Optical Design Fundamentals," Ex. 1014), the light source originates from the left, and therefore the curved focal plane is oriented



Optical Design Fundamentals at Fig. 3.5; *see also id.* at 40 ("the image surface would be parabolic in shape"); Schuele ¶¶ 55-57. This curvature is called Petzval curvature or field curvature. Optical Design Fundamentals at 40; *see also* John E. Greivenkamp, FIELD GUIDE TO GEOMETRICAL OPTICS (2004) ("Greivenkamp," Ex. 1015) at 79 ("Field curvature characterizes the natural tendency of optical systems to have curved image planes."). 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.

B. Claim 1

1. Preamble

"A method of treating a crystalline lens of an eye with a laser, the method comprising"

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vertically on the right. However, where the light source originates from the top of the diagram (as in Figure 5J′ of the '925 patent and Figure 25 of Frey), the curved focal plane is oriented horizontally at the bottom. Schuele ¶¶ 55-57.

To the extent the preamble is limiting, it is disclosed by Frey. Frey discloses "methods and systems for delivering a ***laser beam to a lens of the eye*** in a plurality of sectional patterns [that] results in shaped structural weakening of the lens."[7] Frey, Abstract; *see also id.*, [0001], Fig. 2, [0026] ("system for delivering a laser beam shot pattern to the lens of an eye"), [0062] ("there is provided a system for delivering a laser beam shot pattern to the lens of an eye"). Frey teaches its "methods for treating the structure of the human crystalline lens with a laser" are used "to address a variety of medical conditions such as presbyopia, refractive error and cataracts[.]" *Id.*, [0001]; *see also id.* [0064], [0065], [0017], [0018], [0091], [0093], [00115]-[00117], [00123]-[00126], [00131], [0044], [0060], Figs. 25, 41, 42; *see also* Frey Overview, Section VI.A, *supra*; Schuele ¶¶ 61-65.

2. Step 1[a]: selecting a surgical region

"selecting a surgical region of the lens"

Frey discloses a laser surgical system that delivers a laser beam to the lens of the eye to structurally weaken the lens. Frey, [0062], [0065] ("providing a series of shots to the natural lens"), [0066], [0070], [0091], [0093], [00115]-[00117], [00123]-[00126], [00130]-[00133], Figs. 2, 2A, 25, 41, 42. "[T]he laser shot pattern is such

[7] The lens of the eye is sometimes called the "crystalline lens." Frey, [0002]; Schuele ¶ 63.

that a ***selected volume and/or shape of lens material*** are removed by photodisruption from the lens." *Id.*, [0092]; *see also id.*, [0001], [0017], [0093]. Frey thus discloses this step. Schuele ¶¶ 66-69.

3. Step 1[b]: forming an incision

> *"forming an incision in the surgical region on a layer-by-layer basis by scanning a laser beam with an XY scanner of a laser delivery optics along a curved focal plane of the laser delivery optics to form a line of bubbles in each layer without adjusting a Z scanner of the laser delivery optics at a scanning rate of the XY scanner"*

Frey discloses this step. Schuele ¶¶ 70-85.

a. Forming an incision on a layer-by-layer basis without adjusting a Z scanner

Frey's laser 202 provides a laser beam with a "short pulse width" which is used "together with energy and beam size, to produce photodisruption" in ocular tissue, including the lens. Frey, [0064]-[0065]. The laser pulses produce photodisruption bubbles that cut or break the lens tissue, i.e., form an incision. *Id.*, [0064]; *see also id.*, [0093] ("when the ***pattern is complete a sufficiently continuous layer and/or line and/or volume of lens material has been removed[] resulting in a structural change***"), [0065], [0091], [0092], [00115]-[00117], [00123]-[00126], [00131], [0044], [0060], Figs. 25 (depicting grid like incision), 41 (depicting concentric cylindrical tube incision); Schuele ¶¶ 72-75.

Frey's laser system delivers the pulsed laser beam to the lens of the eye with optics 203, which include a "z focusing device," "an x y scanner," and "focusing optics" that may be "conventional focusing optics." Frey, [0062], [0065], [0069], Figs. 2, 2A; Schuele ¶ 76. The laser system laterally (e.g., horizontally in Frey Figures 25) scans the laser beam with an XY scanner, which "may be a pair of closed loop galvanometers with position detector feedback." *Id.*, [0065]; Schuele ¶ 76. The Z scanner (called the "z focusing device") changes the depth (e.g., vertical position in Frey Figures 25) at which the laser beam is scanned. Frey, [0065]; Schuele ¶ 76. The "focusing optics," such as "conventional focusing optics," focus the laser beam into a predetermined spot size in the lens to cause photodisruption. Frey, [0065], [0064], [0069]; Schuele ¶ 76.

Frey's laser system forms incisions in the lens on a layer-by-layer basis, where the laser beam is scanned in each layer with an XY scanner:

> 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]; *see also id.*, [0094], [00117]; Schuele ¶ 77. At each z-axis location (from anterior to posterior, or vice-versa), the laser will be scanned in a "z plane" with an XY scanner without adjusting the Z scanner. Schuele ¶ 77. Then, the Z scanner is moved to the next depth and another "z plane" is scanned with the XY scanner. *Id.* ¶ 77. Thus, Frey discloses this portion of Step 1[b].[8] Schuele ¶ 78.

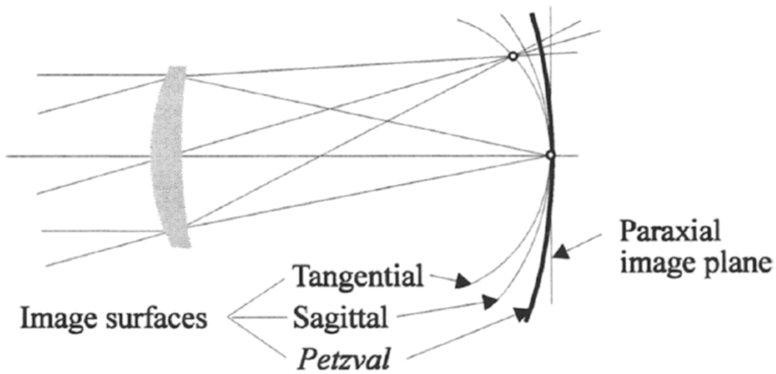
b. Along a curved focal plane

In Frey, each of the layers is scanned along a curved focal plane of the laser delivery optics to form a line of bubbles. Frey, [00116], [0094], [0065]; Schuele ¶ 79-85. The scanning of each layer is controlled by an "x y scanner," and may be done through "***conventional focusing optics***." Frey, [0065], [00116]; Schuele ¶ 79.

Frey's "conventional focusing optics" provides a curved focal plane. Schuele ¶ 80. In fact, Frey acknowledges the curvature in "conventional focusing optics" by separately identifying "flat field optics" (which avoids a curved focal plane) as an alternative type of focusing optics. Frey, [0065]; Schuele ¶ 80.

[8] In fact, Alcon admitted that substantially the same disclosure in Gray discloses "forming shot patterns in a 'layer-by-layer manner'." '925 patent FH 1298 (June 23, 2015 Resp. to Office Action).

That curved focal plane of conventional focusing optics is shown in basic textbooks, such as Optical Design Fundamentals:



Optical Design Fundamentals at Fig. 3.5; Schuele ¶ 81. A POSA would have known that such conventional focusing optics have a curved focal plane. *See, e.g.*, Schuele ¶¶ 81, 55-57; U.S. Pat. No. 4,772,107 ("Friedman," Ex. 1012), 1:16-20 (Petzval curvature present in "conventional optical designs"); G. Molesini, GEOMETRICAL OPTICS, ENCYCLOPEDIA OF CONDENSED MATTER PHYSICS (2005) ("Molesini," Ex. 1016), 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.").[9] Indeed, the '925 patent admits that the focal plane "is

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

typically curved in optical systems unless (any suitable portion of) the optics 273 of the laser delivery system is corrected for field curvature." '925 patent, 19:28-34, Figs. 5J, 5J′; *see also* Schuele ¶ 82.

As a result of this knowledge, it would have been obvious to a POSA to scan Frey's pulsed laser with an XY scanner "along a curved focal plane" to "form a line of bubbles in each layer." Schuele ¶ 83. 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*. Moreover, a POSA would have been motivated to use such conventional optics with a curved focal plane, because it is simpler to design and typically less expensive than other specialized optics. *Id*. For example, flat field

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published in 2001, more than one year before the earliest priority date for the '925 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 '925 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 '925 patent. Greivenkamp is § 102(b) prior art because it was published in 2004, more than one year before the earliest priority date for the '925 patent. None of Optical Design Fundamentals, Friedman, Molesini, or Greivenkamp were cited during prosecution.

optics (which avoid a curved focal plane) require adding several different optical elements that can introduce aberrations and reduce the intensity of the focused laser beam. U.S. Pat. Appl. Publ'n No. 2008/0192783 A1 ("Rathjen," Ex. 1010), [0003], [0009]; Molesini at 265-67; '925 patent, 19:28-34, Figs. 5J-5J'; Schuele ¶ 83. A POSA would have known that conventional focusing optics with a curved focal plane were preferred. Schuele ¶ 83. 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, 1197-98 (Fed. Cir. 2014) (citations omitted), *aff'd*, 624 F. App'x 756 (Fed. Cir. 2015).

A POSA would have had a reasonable expectation of success in incorporating a curved focal plane. Schuele ¶ 84. 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. Frey, [0065]; *see also* '925 patent, 19:28-34 ("the focal plane 271 is ***typically curved***"); Schuele ¶ 84. In fact, it would have required more expertise to avoid a curved focal plane than to implement it. *See* Rathjen, [0003], [0009]; Schuele ¶ 84.

4. Step 1[c]: orientation of incision

"an orientation of a portion of the incisions is one of an orientation intersecting fibers of the lens and an orientation non-transverse to an axis of the eye"

Frey discloses both incision orientations. Schuele ¶¶ 86-92.

First, Frey discloses incisions non-transverse to an axis of the eye. The ’925 patent explains that “non-transverse” incisions are “essentially parallel to the axis of the eye.” ’925 patent, 12:37-44; *see also id.*, 11:40-67; Schuele ¶¶ 19-21. Likewise, Frey discloses vertical incisions that are “***essentially parallel to the optical axis***” of the eye. Frey, [00123]; *see also id.*, Fig. 9 (showing “A/P axis” as the “Z” axis), [0003] (“visual axis”), [0091], [00115]-[00117], [00124]-[00126], [00130]-[00131], [0044], [0060], Figs. 1, 1A, 2, 2A, 25, 41-42.

In Figures 25 and 41, Frey provides examples of these vertical incisions (highlighted in purple):

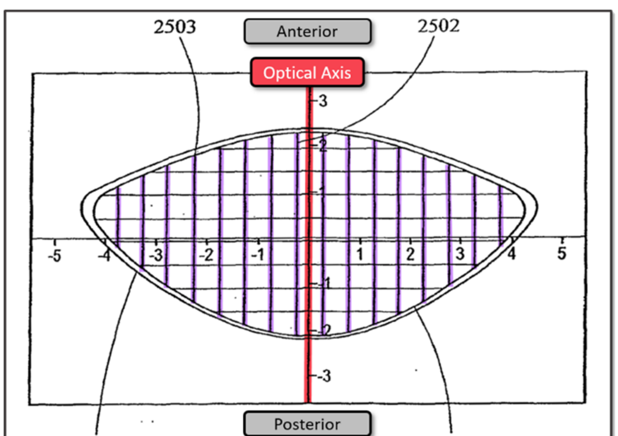

Fig. 25

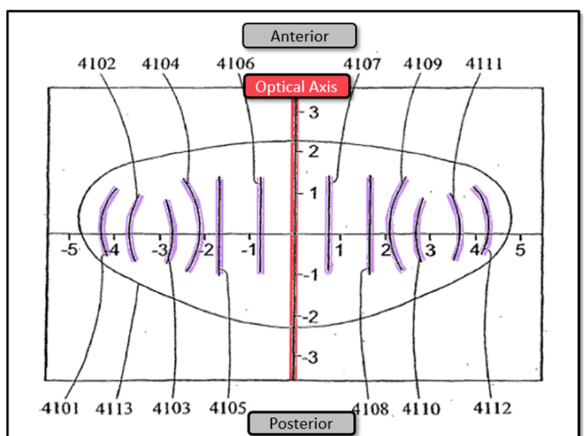

Fig. 41

Frey, Figs. 25, 41 (highlighted, anterior/posterior/axis labeled); Schuele ¶ 88-89, 51-52; *see also* Frey, [00115]-[00117], [00131] (“FIG. 41 [has] primarily vertical patterns”). Figure 25 shows how vertical and horizontal planar cuts fragment the lens into cubes. *Id.*, [00115]-[00116]. Figure 41 shows a side view of laser incisions that form "concentric cylindrical tubes" (*id.*, [00131]), which directly correspond to the cylindrical incisions shown in Figure 5E of the '925 patent. Schuele ¶ 89.

Second, Frey also discloses incisions intersecting fibers of the lens. As the '925 patent recognizes, near the center of the lens, "the fibers and their layers are typically close to transverse to the axis of the eye" (horizontal in the diagrams). '925 patent, 13:5-11; Schuele ¶¶ 17-22. Frey's vertical planar incisions, including the purple-highlighted incisions shown above, are perpendicular to the fibers and thus intersect the fibers of the lens. Frey, [0003]-[0006], [0044], [0060], [0091]-[0093], [00115]-[00117], [00123]-[00127], [00131], Figs. 1, 1A, 3-7C, 25, 41, 42; Schuele ¶¶ 90-91, 17.

5. Step 1[d]: spatial extent of incision

"*the incision has a spatial extent in a Z direction in the range of 0.5-10 mm, and in an X-Y plane in the range of 2-10 mm*"

Frey discloses this step. Schuele ¶ 93-99. Frey shows the spatial extent of the grid-like shot pattern in Figure 25 and the cylindrical shot pattern in Figure 41. The measurement units in both figures are in millimeters (mm). Frey, [0099].

In Figure 25, the vertical planar incisions are highlighted in purple:

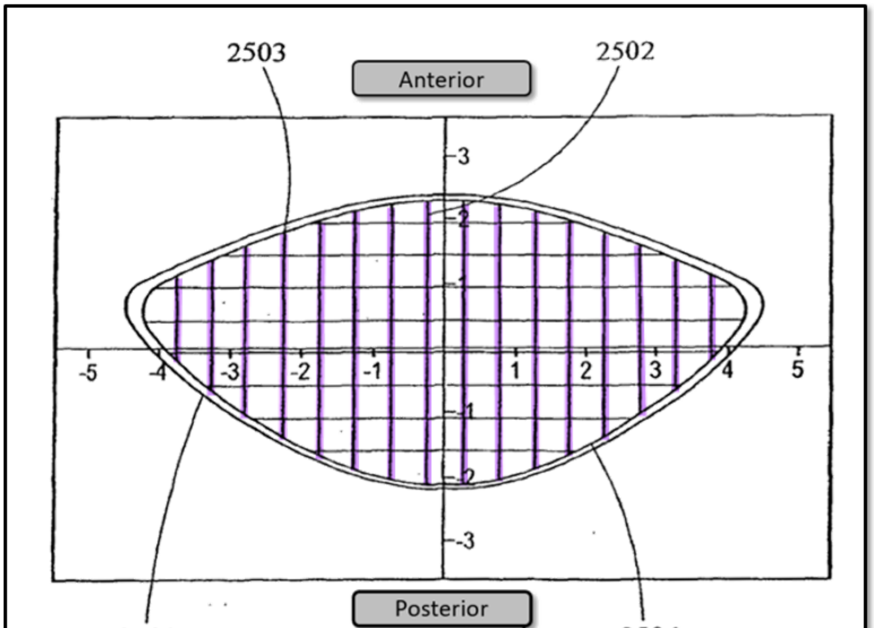

Fig. 25

Frey, Fig. 25 (highlighted, anterior/posterior labeled); Schuele ¶¶ 96-97. Each vertical plane in Figure 25 has a height (in the Z direction) from 1-4 mm, as can be seen from the labels on the vertical axis. Schuele ¶¶ 96-97. The width (in an X-Y plane) is up to about 8 mm.[10] Schuele ¶¶ 95-97.

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[10] As drawn, the vertical planar incisions (highlighted in purple) extend into the plane of the paper. Schuele ¶¶ 95, 97. A POSA would understand that the lens of the eye is round (like an M&M candy). Frey, [0080]-[0081], Figs. 7A, 7B, 7C; Schuele ¶ 95. Thus, the maximum width (in an X-Y plane) of the vertical planar

In Figure 41, the vertical cylindrical incisions are highlighted in purple:

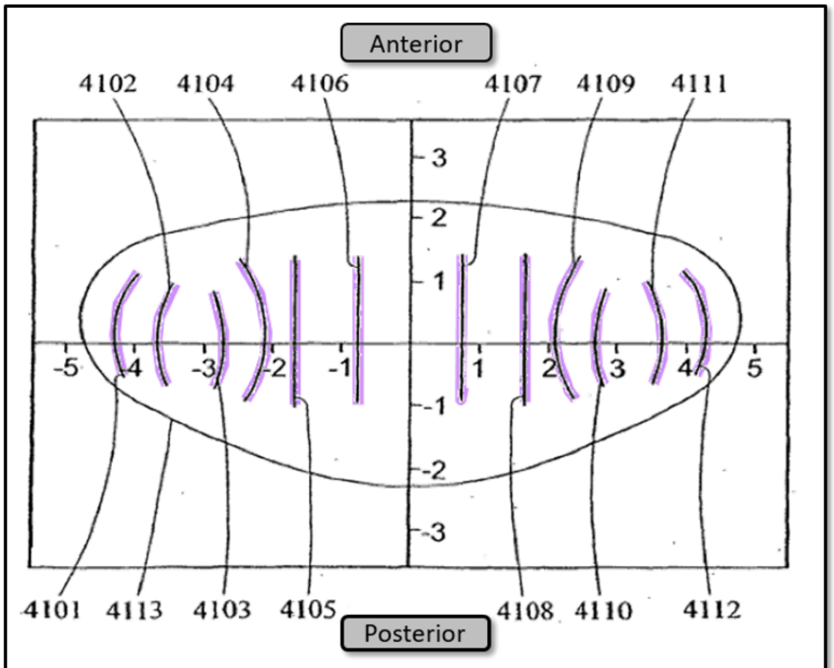

Fig. 41

Frey, Fig. 41 (highlighted, anterior/posterior labeled); Schuele ¶¶ 96, 98. The vertical cylinders are shown in cross-section, and therefore each cylinder is represented by a pair of cuts (e.g., 4106/4107, 4105/4108, etc.). Frey, [00131]; Schuele ¶ 98. Each vertical cylinder in Figure 41 has a height (in the Z direction) of about 2 mm, as can be seen from the labels on the vertical axis. Schuele ¶¶ 96, 98.

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incisions corresponds to the left-right width of the lens as drawn in Figure 25. *Id.* ¶¶ 95,97.

The width (in an X-Y plane) ranges from 2-8 mm, from the narrowest cylinder (4106/4107) to the widest cylinder (4101/4112). *Id.* ¶¶ 96, 98.

Because these values fall within the claimed range, Frey's grid-like shot pattern in Figure 25 and cylindrical pattern in Figure 41 disclose this step. Schuele ¶ 99.

* * *

In sum, Frey and the knowledge of a POSA renders claim 1 obvious. Schuele ¶ 100.

C. Dependent Claims

1. Claim 2

Claim 2 depends from claim 1, and further recites:

> *"the non-transverse orientation of the incision is one of: an orientation substantially parallel to the axis of the eye; and an orientation making a less than 90 degree angle with the axis of the eye"*

Frey discloses this claim. Schuele ¶¶ 102-105. As discussed above for Step 1[c], Frey's vertical incisions are "essentially parallel to the optical axis." Frey, [00123]; *see* Section VI.B.4, *supra*. Both the grid-like shot pattern, Frey, Fig. 25, and the concentric cylindrical shot pattern, *id.*, Fig. 41, include vertical incisions that are substantially parallel to the axis of the eye. Schuele ¶¶ 104, 51-52. As such, they also make a less than 90 degree angle with the axis of the eye. *Id.* ¶ 104.

2. Claim 4

Claim 4 depends from claim 1 and further recites:

> *"the axis of the eye is one of a visual axis, an optic axis, a line of sight and a pupillary axis"*

Frey discloses this limitation. Schuele ¶¶ 106-109, 51-52. Frey discloses that the axis of the eye is the "optical axis" or "visual axis." Frey, [0003], [00123]; *see also id.*, Figs. 9, 1, 1A. These correspond to the "optic axis" and "visual axis" recited in the claim. Schuele ¶¶ 108, 51-52; *see* Section VI.B.4, *supra*.

3. Claim 5

Claim 5 depends from claim 1 and further recites:

> *"the incision cuts the fibers into parts approximately at the intersection of the incision and the fibers; and the modified property of the lens is a weakening of a biomechanical property of the lens"*

Frey teaches this claim. Schuele ¶¶ 110-114.

First, as discussed above for Step 1[c], Frey discloses vertical incisions that cut through and intersect lens fibers, which are generally transverse to the optical axis at the lens center. Frey, [0003]-[0006], [0076]-[0082], [0091], [00115]-[00117], [00123]-[00127], [00131], Figs. 1A, 3-7C, 25, 41. The incision cuts the fibers into parts at the intersection of the incision and the fibers because the photodisruption bubbles are "sufficiently close enough to each other" to result in "cleaving" (i.e., "substantial[] separat[ion]") of the target lens tissue at the points of photodisruption. Frey, [0093]; *see also id.* [0091] (Figure 25 laser shot pattern "cuts the lens into small cubes"), [0092], [00115]-[00117], [00123]-[00127], [00131], Figs. 25, 41; Schuele ¶ 112.

Second, the vertical incisions modify a property of the lens: the incisions structurally weaken the biomechanical structure of the lens by cutting through the fibers, and even cutting the lens into "small cubes" in the case of the grid-like incision. Frey, [0091]; *see also id.*, Abstract ("delivering a laser beam to a lens of an eye in a plurality of sectional patterns results in the shaped ***structural weakening of the lens***"), [00115] ("there is provided a method for the ***structural modification of the lens*** material"), [0092], [0093], [00126], [00127], [00131], Figs. 25, 41, 42; Schuele ¶ 113.

4. Claim 11

Claim 11 depends from claim 1 and further recites:

> *"the incision has a form aligned with the axis of the eye, the form being of at least one of: a cylinder, a set of concentric cylinders, a set of cylinders connected by one or more connecting line, a curved surface, a cone, a spiral, a layered spiral with smooth lines connecting layers of the spiral and a tilted cylinder"*

Frey discloses this claim. Schuele ¶¶ 115-118. As discussed above for Step 1[c], Frey discloses incisions aligned with the axis of the eye, including a cylinder and a set of concentric cylinders as depicted in Figure 41:

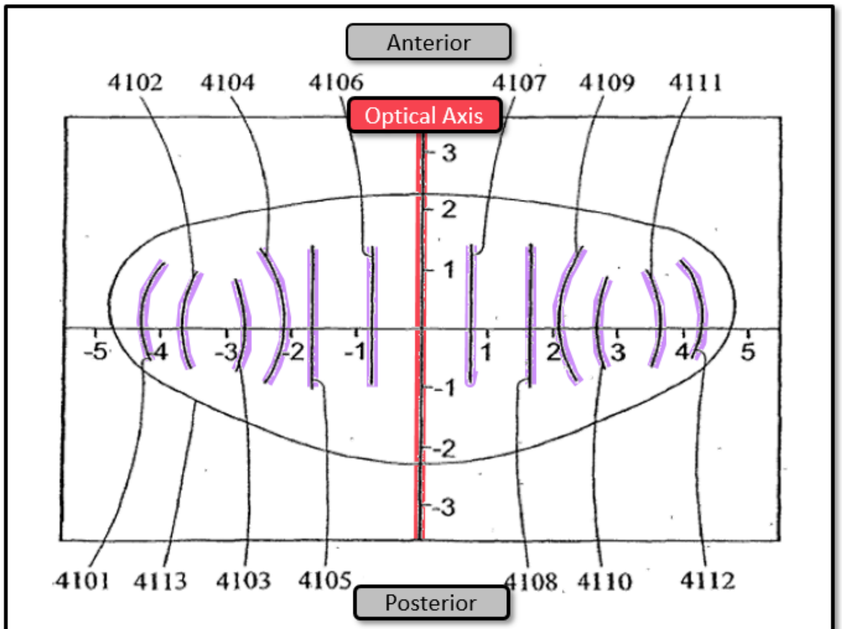

Fig. 41

Frey, Fig. 41 (highlighted, anterior/posterior/axis labeled); Schuele ¶ 117; *see also* Frey, [0060], [00131] ("there is a series of ***concentric cylindrical tubes*** with opposing sides of the tubes being seen as pairs of cuts"), [00132], [00130], [00123] ("patterns would include … concentric cylinders"), Figs. 33, 42; *see also* Section VI.B.4, *supra*.

5. Claim 12

Claim 12 depends from claim 1 and further recites:

> *"wherein the incision has a form aligned with the axis of the eye, the form being at least one of: a plane, two or more crossing planes, a combination of planes and connecting arcs, and a combination of planes and cylinders"*

Frey discloses this claim. Schuele ¶¶ 119-122. As discussed for Step 1[c], Frey discloses incisions aligned with the axis of the eye, including a plane and two or more crossing planes as depicted in the Figure 25:

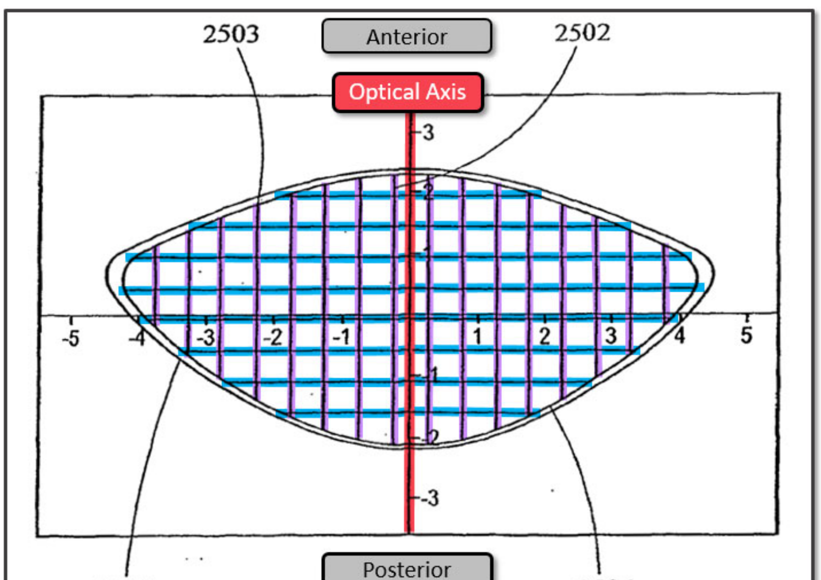

Fig. 25

Frey, Fig. 25 (highlighted, anterior/posterior/axis labeled); Schuele ¶ 121; *see also* Frey, [0091], [00115]-[00117], [0044], [00123] ("patterns would include … radial planes, horizontal planes and ***vertical planes***"), [00124]-[00127]. To cut the lens into "small cubes" as disclosed by Frey, *id.*, [0091], there are two or more crossing vertical planes. Schuele ¶ 121; *see also* Section VI.B.4, *supra*.

6. Claim 17

Claim 17 depends from claim 1 and further recites:

> *"wherein the applying the laser pulses comprises: selecting laser-parameters sufficient to create bubbles in the lens, but insufficient to cause harm to a retina of the eye"*

Frey discloses this claim alone, or in view of the knowledge of a POSA. Schuele ¶¶ 123-128. Frey teaches the laser surgical system creates the sectional shot pattern by directing a pulsed laser beam to the target tissue to create photodisruption bubbles in the lens. Frey, [0064] ("The [laser] beam should be of a short pulse width, together with the energy and beam size, to produce photodisruption," where "photodisruption essentially refers to the conversion of matter to a gas."); *see also id.*, [0065], [0093] (laser "spot with an energy sufficient to cause photodisruption … results in individual gas bubbles"), [0092], [00115]-[00116], [00125]; Schuele ¶ 125.

The '925 patent describes using laser-parameters that are "insufficient to cause harm to a retina of the eye," and it identifies suitable parameters as including "laser pulse energy is in the range of 0.5 microJ to 50 microJ, a duration of a laser pulse is in the range of 0.005 picoseconds to 25 picoseconds, [and] a repetition rate of applying laser pulses is in the range of 1 kHz to 10 MHz." '925 patent, 17:4-22;

id., 3:22-37. Frey discloses using laser-parameters that overlap each of those ranges, including pulse energy "from about a 1 nanojoule to 1 millijoule," pulse duration "from about 1 femtosecond to 100 picoseconds," and pulse rate "from 1 KHz to several GHz." Frey, [0064]. Frey thus teaches using laser-parameters that are insufficient to cause harm to a retina of the eye. Schuele ¶ 126.

Additionally, a POSA would have found it obvious to select laser-parameters sufficient to cause photodisruption, but insufficient to damage the retina of the eye. *Id.* ¶ 127. A POSA would have known that it is important to "avoid retinal damage" when using the laser. Blumenkranz, [0092]; Schuele ¶ 127. That is because the retina, which is essential for vision, lies behind the lens and is only separated from the lens by the clear vitreous of the eye. Schuele ¶ 127. This would have motivated a POSA to select safe laser parameters that are insufficient to cause harm to the retina of the eye. *Id.*; *see also* Blumenkranz, [0089], [0092] ("laser radiant exposure on the retina will not exceed this safety limit"), [0093] ("the laser irradiance on the retina should not exceed the thermal safety limit for near-IR radiation"); U.S. Pat. Appl. Publ'n No. 2009/0012507 A1 ("Culbertson," Ex. 1019), [0028] ("Safety limits with regard to unintended damage to non-targeted tissue bound the upper limit with regard to repetition rate and pulse energy[.]"), [0055][11]. Additionally, a POSA would have had a reasonable expectation of success, since calculations for safe laser-parameters were already described in the prior art. Blumenkranz, [0092]-[0093]; Schuele ¶ 127.

7. Claim 23

Claim 23 depends from claim 1 and further recites:

> *"forming the incision on a layer-by-layer basis, wherein one or more layers are at least partially formed along a curved focal plane of a laser delivery system"*

This claim is disclosed for the reasons explained above for Step 1[b]. Schuele ¶¶ 129-132; *see also* Section VI.B.3.

8. Claim 24

Claim 24 depends from claim 1 and further recites:

> *"a Z directional scanner is adjusted at a slower rate than an X-Y directional scanner when forming a layer of one or more incisions"*

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[11] As discussed *infra*, Blumenkranz is pre-AIA § 102(b) prior art because it published in 2006, more than one year before the earliest priority date for the '925 patent. *See* Section VII.A, *infra*. Culbertson is pre-AIA § 102(e)(1) because it was filed on March 13, 2008, before the earliest priority date for the '925 patent.

This claim is disclosed for the reasons explained above for Step 1[b]. Schuele ¶¶ 133-136. As described above, Frey scans the laser beam in the transverse "z plane" with an XY scanner, without adjusting the Z scanner. Frey, [00116]; *see also* Section VI.B.3.a, *supra*. The Z scanner is only moved after a "z plane" scan is complete. Frey, [00116]; *see also* Section VI.B.3.a, *supra*. As a result, the Z directional scanner is adjusted at a slower rate than an X-Y directional scanner, as recited in the claim. Schuele ¶ 135.

9. Claim 26

Claim 26 depends from claim 1 and further recites:

> *"the incision fragments at least a portion of the lens, the method further comprising: removing the fragmented portion of the lens"*

Frey discloses this claim. Schuele ¶¶ 137-140. Frey discloses incisions that fragment the lens "into small cubes." Frey, [0091]; *see also id.*, [00115]-[00116], [00123], Fig. 25. Frey also teaches that the fragmented cubic lens pieces are removed from the lens using aspiration. Frey, [0091] ("***removal of the sectioned cubes***"), [00115] ("a method for the structural modification of the lens material to make it ***easier to remove***"), *id.*("photodissruption [sic] cutting in a specific shape patterns is utilized to carve up the lens material into tiny cube like structures small enough to be ***aspirated away***"); Schuele ¶ 139.

VII. Ground 2: Claims 17 and 27 Are Obvious Over Frey in View of Blumenkranz and the Knowledge of a POSA

A. Blumenkranz (Ex. 1008)

Blumenkranz 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 asserted priority date for the ’925 patent. Blumenkranz was cited by Alcon in an IDS, *see* ’925 patent FH 135 (Apr. 7, 2010 Info. Disclosure Statement (“IDS”)), but it was not substantively discussed during prosecution.

Blumenkranz discloses a “[s]ystem and method for making incisions in eye tissues at different depths,” including “fragmentation of the lens nucleus and cortex.” Blumenkranz, Abstract, [0009]; *see also id.*, [0045], [0057], [0068]-[0069], [0074], [0078], [0085]-[0086]. Blumenkranz teaches that the 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], [0085]-[0086], [0088]-[0091]; Schuele ¶ 143.

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

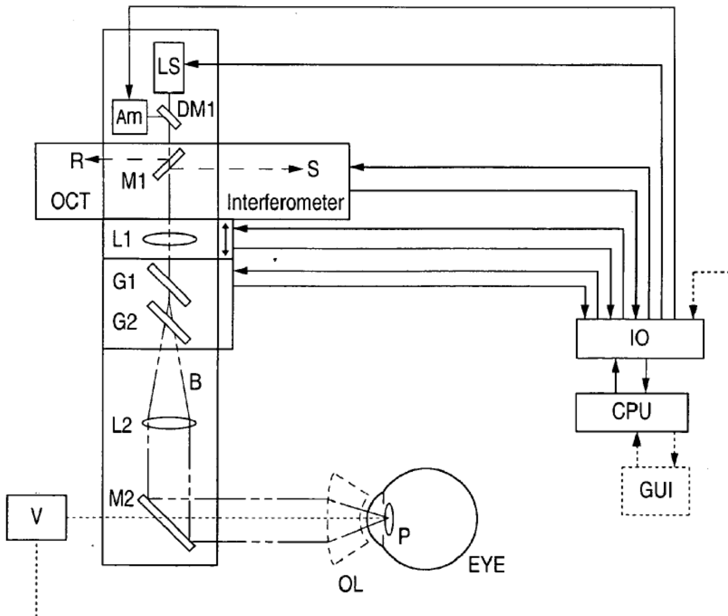


FIG. 11

Blumenkranz, Fig. 11; *see also id.*, 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, 11; Schuele ¶ 144.

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 id.*, Figs. 20, 21; Schuele ¶ 145. The bubble formation is shown in Figure 2:

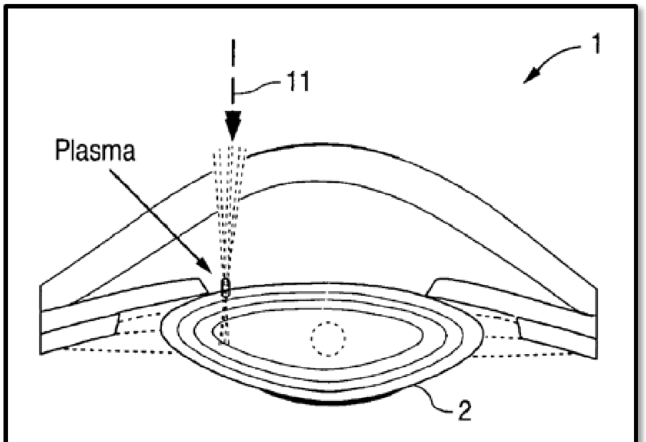


FIG. 2

Blumenkranz, Fig. 2; *see also id.* Fig. 5.

The laser is used to create photodisrupted bubbles to fragment the lens, as Blumenkranz 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], [0085]-[0086], [0088]-[0091], [0099], Figs. 9A-9B, 10A-10C, 20-21; Schuele ¶ 146. Blumenkranz also teaches that the laser creates the fragmentation patterns on a layer-by-layer basis. Blumenkranz, [0013], [0058], [0061]-[0062], [0078], [0085]-[0086], cl. 1; Schuele ¶ 147.

B. Dependent Claim 17

"wherein the applying the laser pulses comprises: selecting laser-parameters sufficient to create bubbles in the lens, but insufficient to cause harm to a retina of the eye."

To the extent the Board finds that Frey does not disclose this claim (*see* Ground 1, Section VI.C.6, *supra*), then it is disclosed and rendered obvious by Frey in view of the knowledge of a POSA and Blumenkranz. Schuele ¶¶ 148-153. Blumenkranz teaches laser parameters sufficient to create bubbles in the lens. Blumenkranz, [0050] ("Short 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."), [0046]-[0049], [0053] ("pulse energy should exceed the [dielectric breakdown] threshold by a factor of 2"), *id.* ("cavitation bubble"), [0054], [0058], Figs. 2, 5, 20, 21; Schuele ¶ 149.

The laser parameters selected by Blumenkranz are also insufficient to cause harm to a retina of the eye. Schuele ¶ 150. Blumenkranz teaches that the laser system uses "sub-ps pulses to reduce the threshold energy" exposed to the eye. Blumenkranz, [0083]; *see also* Blumenkranz, [0054]; Schuele ¶ 150. Blumenkranz also explains that:

> ***To avoid retinal damage*** due to explosive vaporization of melanosomes following absorption of the short laser pulse ***the laser radiant exposure on the RPE should not exceed 100 mJ/cm***. Thus NA of the ***focusing optics should be adjusted such that laser radiant exposure on the retina will not exceed this safety limit***.

Blumenkranz, [0092]. Additionally, "to avoid thermal damage to the retina … the laser-irradiance on the retina should not exceed the thermal safety limit for near-IR radiation." Blumenkranz, [0093]; *see also id.* [0074], [0089], [0046]-[0053]; Schuele ¶ 150.

It would have been obvious to incorporate Blumenkranz's laser parameters that are insufficient to harm the retina into Frey's laser surgical system because doing so was using a known technique to improve a similar method (laser treatment of a lens of an eye) in the same way. Schuele ¶ 151. Both Frey and Blumenkranz teach methods of treating the lens with a pulsed laser to create incisions comprised of photodisruption bubbles that fragment the lens into pieces for subsequent removal. Frey, [0091], [0093], [00115]-[00117], [00123], [00131]; Blumenkranz, [0009], [0061]-[0062], [0068]-[0069]; *see also* Ground 1, Section VI and Ground 2, Section VII.A, *supra* and Ground 3, Section VIII, *infra*. A POSA would have been motivated to use Blumenkranz's technique to improve Frey's method of laser treatment because doing so reduces the effect of the laser pulses on surrounding, non-targeted eye tissue. Blumenkranz, [0092]-[0093],[0074]; *see also* Culbertson,

[0028] ("Safety limits with regard to unintended damage to non-targeted tissue bound the upper limit with regard to repetition rate and pulse energy"), [0055] ("Treatment zone 500 has a high density of laser exposures, but a distinct safety zone 502 in the lens 69 between the treatment zone 500 and the posterior capsular bag surface 514 is preferably maintained[.]"), *id.* ("Damage to posterior surface 514 may cause surgical complications, and retinal damage."); Schuele ¶ 152. A POSA would have understood that Blumenkranz's laser parameters increase the overall safety of the laser cataract procedure, which was one of Frey's express design goals. Frey, [00115] ("Thus, there is provided a method for the structural modification of the lens material to make it easier to remove while potentially increasing the safety of the procedure"), [0017]; Schuele ¶ 152.

Frey in view of the knowledge of a POSA and Blumenkranz discloses and renders obvious this claim.

C. Dependent Claim 27

Claim 27 depends from claim 26 and further recites:

> *"the applying the laser pulses comprises: applying laser pulses with laser parameters which do not cause lasting damage to a retina of the eye, wherein the laser pulses fragment the lens to a degree suitable for removal; and the time of the fragmentation is less than a minute"*

As discussed above for claim 17, Frey in view of the knowledge of a POSA, or alternatively in further combination with Blumenkranz, discloses and renders obvious applying laser pulses with laser parameters which do not damage the retina. *See* Sections VI.C.6 and VII.B, respectively, *supra*; Schuele ¶ 156 Moreover, as discussed for Ground 1, claim 26, Frey discloses fragmenting the lens to a degree suitable for removal. *See* Section VI.C.9, *supra*; Schuele ¶ 156. Thus, the only question is whether it would have been obvious that "the time of the fragmentation is less than a minute." It would have been obvious to do so. Schuele ¶ 156.

Blumenkranz expressly discloses fragmenting the lens with a laser in less than a minute:

> Depending on the laser power and repetition rate, the ***patterned cutting can be completed between 5 and 0.5 seconds (or even less)***, using a laser repetition rate exceeding 1 kHz.

Blumenkranz, [0070]; *see also id.*, [0088] ("If a volume of 6×6×4 mm=144 mm^3 of lens is segmented … delivered at 50 kHz, ***it will take 15 seconds***."), [0083], [0091], [0052], [0055]; Schuele ¶ 157. Blumenkranz also teaches that laser-parameters should avoid damage to the retina, Blumenkranz, [0089], [0092], [0093], and that the lens is fragmented to a degree suitable for removal, *id.*, [0009], [0069], [0099].

It would have been obvious to incorporate Blumenkranz's laser parameters into Frey's laser surgical system so that the system fragments the lens in less than one minute and avoids retinal harm. Schuele ¶ 158. Blumenkranz provides the motivation to do so. As Blumenkranz explains, reducing the procedure time can reduce "[c]omplications due to the eye movements." Blumenkranz, [0070]. Blumenkranz also points out the need "[t]o avoid retinal damage." *Id.*, [0092]. Thus, a POSA would have been motivated to use the relevant laser parameters of Blumenkranz (which were intended for laser lens fragmentation) in Frey's system for laser lens fragmentation. Schuele ¶ 158. Such a combination uses Blumenkranz's laser parameters for "'performing the same function it had been known to perform' and yields no more than one would expect from such an arrangement[.]" *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007) (citation omitted). A POSA would have had a reasonable expectation of success, since the laser pulse energy, pulse duration, and pulse rate parameters used by Blumenkranz are available in the system taught by Frey. *Compare* Blumenkranz, [0054], [0070], [0088], [0089], [0092], *with* Frey, [0064]; Schuele ¶ 158.

Accordingly, Frey in view of Blumenkranz (and the knowledge of a POSA) discloses and renders obvious this claim. Schuele ¶¶ 154-159.

VIII. Ground 3: Claims 1, 2, 4, 5, 11, 12, 17, 23, 24, 26, and 27 Are Obvious Over Blumenkranz in View of Frey and the Knowledge of a POSA

Frey and Blumenkranz are described above. *See* Sections VI.A and VII.A, *supra.*

A. Claim 1

1. Preamble

"A method of treating a crystalline lens of an eye with a laser, the method comprising:"

To the extent the preamble is limiting, it is disclosed by Blumenkranz. Schuele ¶¶ 161-166. Blumenkranz discloses a "[s]ystem and method for making incisions in eye tissue at different depths" using a laser. Blumenkranz, Abstract; *see also id.*, [0009], [0045], [0061]-[0062], [0068]-[0069], [0074]-[0075], Figs. 1, 11. Those incisions may be used for "fragmentation of the lens nucleus and cortex" using "3-dimensional patterned laser cutting." *Id.*, [0009]; *see also id.*, [0045], [0057]-[0058], [0068]-[0069], [0073] ("treatment pattern"), [0074], [0078], [0085]-[0086], [0099], Figs. 2, 5, 9A-9B, 10A-10C, 20, 21; *see* Section VII.A; Schuele ¶¶ 161-166.

2. Step 1[a]: selecting surgical region

"selecting a surgical region of the lens"

Blumenkranz discloses a laser system that directs a laser beam to the lens of the eye to fragment the lens. Blumenkranz, [0009], [0045], [0068], [0078], Figs. 1, 9A-9B, 10A-10C, 11. "Specifically, rapid and precise openings in the lens capsule and ***fragmentation of the lens nucleus and cortex*** is enabled using 3-dimensional patterned laser cutting." *Id.*, [0009]; *see also id.*, [0045], [0056]-[0058], [0061]-[0062], [0068]-[0069], [0073], [0074] (identifying "***upper and lower boundaries of cutting***"), [0078], [0085]-[0086], [0088]-[0091], [0099]; Schuele ¶¶ 167-170.

3. Step 1[b]: forming an incision

"forming an incision in the surgical region on a layer-by-layer basis by scanning a laser beam with an XY scanner of a laser delivery optics along a curved focal plane of the laser delivery optics to form a line of bubbles in each layer without adjusting a Z scanner of the laser delivery optics at a scanning rate of the XY scanner"

Blumenkranz in view of Frey and the knowledge of a POSA discloses this step. Schuele ¶¶ 171-184.

a. Forming an incision on a layer-by-layer basis without adjusting a Z scanner

Blumenkranz discloses a method of making "incision[s] in eye tissue" by scanning a laser beam in the eye. Blumenkranz, [0013]; *see also id.*, Abstract, ("method for making incisions in eye tissue"), [0009], [0015], [0073], [0062], [0057], [0061]-[0062], [0068]-[0069], [0074], [0078], [0083], [0085]-[0086], [0088]-[0091], cl. 1, Figs. 5, 9A-9B, 10A-10C, 20, 21; Schuele ¶ 173. The laser pulses produce photodisruption bubbles that cut or break the lens tissue. Blumenkranz, [0050], [0053], [0069].

Blumenkranz's system delivers the laser beam to the lens of the patient's eye with "moveable optical elements," including a z scanner, an xy scanner, and focusing element. *Id.*, [0045]; *see also id.*, [0075]-[0078], Figs. 1 and 11. The laser system laterally scans the laser beam with an XY scanner, which may include "a pair of orthogonal galvanometric mirrors G1 & G2." *Id.*, [0076]. It also includes a Z scanner, which "may be a single element or a group of elements" (lens L1), that can be used to adjust the "location along the z-axis of the beam B disposed to the target at point P." *Id.*, [0075]. The focusing element (lens L2) "serves to focus the light onto the target at point P inside the patient's eye." *Id.*, [0076]; Schuele ¶¶ 174-175.

Blumenkranz discloses forming the segmentation patterns (incision) on a layer-by-layer basis. Schuele ¶ 176. Blumenkranz describes focusing the laser "beam at a first focal point located at first depth in the eye tissue" (a first layer). Blumenkranz, cl. 1. The laser beam is scanned in a "pattern on the eye ***while focused*** at the first depth." *Id.* Next, the laser beam is focused "at a second focal point located at a second depth" (a second layer) and scanned "while focused at the second depth." *Id.* In other words, for each layer, Blumenkranz describes scanning the laser beam with an XY scanner without adjusting a Z scanner. Schuele ¶ 176. Blumenkranz confirms that the Z scanner is not adjusted when it explains that "the depth of the focal point (waist) in the tissue is ***stepped up or down with each consecutive scan***." Blumenkranz, [0062]; *see also id.*, [0013], [0015], [0078], [0057], [0058], [0068]. [0085]-[0086], Figs. 5, 20, 21. Each consecutive scan is performed by the XY scanner (G1 & G2), while stepping up/down is performed by the Z scanner (L1). Schuele ¶ 176.

An example of layer-by-layer scanning is shown in Figure 5:

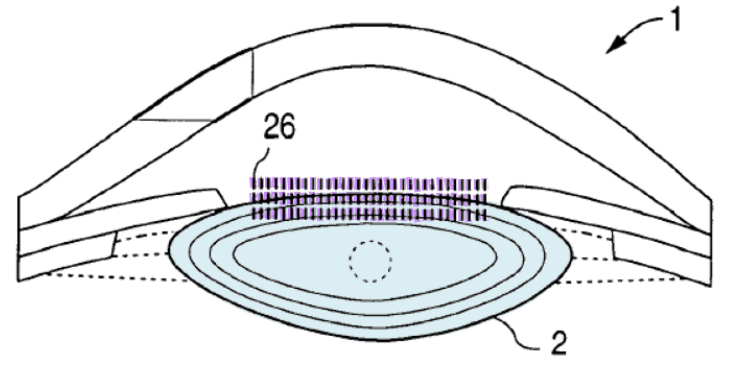


FIG. 5

Blumenkranz, Fig. 5 (highlighted); Schuele ¶ 177. This illustrates how in Blumenkranz Figure 5, there are three layers of laser energy pulses 26 (highlighted in purple) to create an incision in the lens 2 (highlighted in blue). Schuele ¶ 177. Each layer is created by scanning the laser beam with an XY scanner, and the Z scanner is only adjusted to step up/down the depth of laser focus after each layer is completed. Blumenkranz, [0062]; *see also id.*, [0078], [0058]; Schuele ¶ 177.

b. Along a curved focal plane

To create incisions, Blumenkranz applies a "lateral pattern [of laser pulses] at different depths of tissue." Blumenkranz, [0062]. These patterns are applied within "focal planes" of the focusing optics for "segmentation of the lens." *Id.*, [0057]; *see also id.*, [0078], [0086]; Schuele ¶ 179. While Blumenkranz explains that "an appropriate focusing element will be selected from an available set," *id.*, [0078], it would have been obvious to select Frey's "conventional focusing optics" for such a purpose. Schuele ¶ 179.

Both Blumenkranz and Frey are directed to pulsed laser systems used to fragment lens tissue into pieces, which are removed by aspiration. *See* Section VI.A and Section VII.A; Schuele ¶ 180. 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 ¶ 180. It would have been obvious to combine their interrelated teachings related to 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.") (citations omitted).

Blumenkranz explains that any suitable focusing optics can be used based on the desired system performance. Blumenkranz, [0078]; *see also id.*, [0085]-[0086]. A POSA, when selecting the optics for Blumenkranz's laser system, would have been motivated to select the "conventional focusing optics" of Frey. Schuele ¶ 181. 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 (citation omitted); *see* Sections VI.A and VI.B.3.b; Schuele ¶ 181. Moreover, such conventional optics were recognized by a POSA to be simpler to design and typically less expensive than other specialized optics. Schuele ¶ 181. 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 focused laser beam. Rathjen, [0003], [0009]; Molesini at 265-67; '925 patent, 19:28-34, Figs. 5J-5J'; Schuele ¶ 181. A POSA would have understood that conventional focusing optics were preferred. Schuele ¶ 181. At the very least, a POSA would have recognized that Frey's conventional focusing optics (with curved focal planes) are suitable options. Schuele ¶¶ 182; *see Par Pharm.*, 773 F.3d at 1197-98 (obvious combination with "a suitable option from which the prior art did not teach away") (citations omitted).

The use of Frey's conventional focusing optics in Blumenkranz's laser system would result in scanning each layer in a curved focal plane, as recited in the claims. *See* Sections VI.B and VI.B.3.b, *supra*; Schuele ¶ 183.

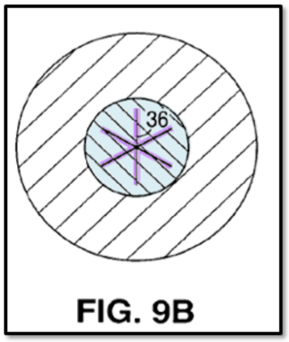
4. Step 1[c]: orientation of incision

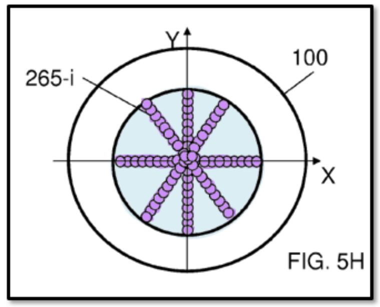
"an orientation of a portion of the incisions is one of an orientation intersecting fibers of the lens and an orientation non-transverse to an axis of the eye"

Blumenkranz discloses both incision orientations. Schuele ¶¶ 185-192.

First, Blumenkranz teaches that the laser system creates the segmentation patterns, in which a portion of the incisions are non-transverse to an axis of the eye. The '925 patent explains that "non-transverse" incisions are "essentially parallel to the axis of the eye." '925 patent, 12:37-44; *see also id.*, 11:40-65. Likewise, Blumenkranz discloses such non-transverse incisions. Blumenkranz, [0061]-[0062], [0058], [0068]-[0069], [0078] ("depth along the z-axis"), [0085]-[0086], Figs. 1, 2, 5, 9A-9B, 10A-10C, 11, cl. 1; Schuele ¶¶ 187-190. In fact, Blumenkranz's non-transverse segmentation incisions are nearly identical to those incisions shown in the '925 patent. This can be seen with a side-by-side comparison of the incisions (in top-down views[12]):

[12] This refers to the view from the top of figures such as '925 patent, Figs. 5E and 5G. In this orientation, the optical axis of the eye extends into the plane of the paper (i.e., looking at the front of the eye). Schuele ¶¶ 189-190.





<u>Blumenkranz</u> **<u>’925 Patent</u>**

Blumenkranz, Fig. 9B (highlighted); ’925 patent, Fig. 5H (highlighted); Schuele ¶¶ 187-189. These figures show a top-down view of crossing planes (highlighted in purple), which as illustrated extend into the plane of the paper (i.e., non-transverse). Schuele ¶¶ 189-190; *see also* Blumenkranz, [0058], [0061]-[0062], [0068]-[0069], [0078], [0085]-[0086], [0088]-[0090], Figs. 5, 9A, 10A-10C, 20, 21 (depicting non-transverse incisions), Figs. 1, 11,.

Second, Blumenkranz also discloses incisions intersecting fibers of the lens. Because portions of Blumenkranz’s orientations are vertically orientated (as shown above), these vertical portions at the center of the lens cut through lens fibers. Blumenkranz, [0059], [0068], Figs. 2, 5, 9A-9B, 10A-10C, 20, 21; Schuele ¶ 191. This is shown, for example, by Figure 5 of Blumenkranz, where the non-transverse incision (highlighted in purple) intersects the fibers of the lens (highlighted in blue):

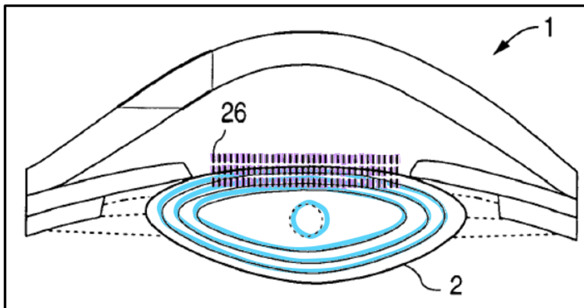


FIG. 5

Blumenkranz, Fig. 5 (highlighted); Schuele ¶ 191; *see also* Schuele ¶¶ 17, 22.

5. Step 1[d]: spatial extent of incision

"the incision has a spatial extent in a Z direction in the range of 0.5-10 mm, and in an X-Y plane in the range of 2-10 mm"

Blumenkranz discloses this step. Schuele ¶¶ 193-196. When cutting the lens cortex, Blumenkranz teaches that the system fragments "a volume of 6×6×4 mm" of lens tissue using the segmentation patterns. Blumenkranz, [0088]; *see also id.* [0009], [0069], [0057], [0089], [0090]; Schuele ¶ 195. The incisions in Blumenkranz's segmentation patterns thus have a height (in the Z direction) of 4 mm, and a width (in an X-Y plane) of 6 mm. Schuele ¶ 195.

* * *

In sum, Blumenkranz in view of Frey and the knowledge of a POSA renders claim 1 obvious. Schuele ¶ 197.

B. Dependent Claims

1. Claim 2

Claim 2 depends from claim 1, and further recites:

> *"the non-transverse orientation of the incision is one of: an orientation substantially parallel to the axis of the eye; and an orientation making a less than 90 degree angle with the axis of the eye"*

Blumenkranz discloses this claim. Schuele ¶¶ 199-203. As discussed above for Step 1[c], Blumenkranz discloses segmentations patterns with incisions that are substantially parallel to the axis of the eye. Blumenkranz, [0068]-[0069], Figs. 9A-9B, 10A-10C; Schuele ¶ 201. In fact, they are nearly identical to the incisions disclosed by the '925 patent:

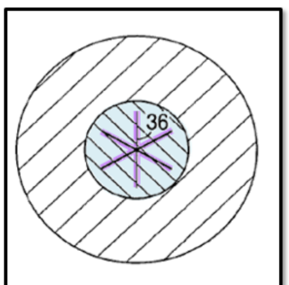
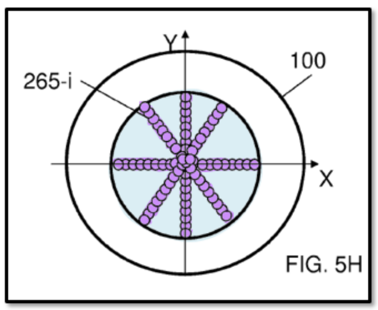


FIG. 9B



Blumenkranz **'925 Patent**

Blumenkranz, Fig. 9B (highlighted); '925 patent, Fig. 5H (highlighted); Schuele ¶ 201. Because Figure 9B of Blumenkranz is a top-down view where the axis of the eye extends into the plane of the paper, just like Figure 5H of the '925 patent, it shows that the incision (highlighted in purple) is parallel to the axis of the eye. *See* Step 1[c], Section VIII.A.4, *supra*; *see also* Blumenkranz, Figs. 5, 9A, 10A-10C, 20, 21. Schuele ¶¶ 201-202. As such, they also make a less than 90 degree angle with the axis of the eye. Schuele ¶¶ 201-202.

2. Claim 4

Claim 4 depends from claim 1, and further recites:

> *"the axis of the eye is one of a visual axis, an optic axis, a line of sight and a pupillary axis"*

Blumenkranz discloses this limitation. Schuele ¶¶ 204-208. Blumenkranz illustrates that the laser incisions are made parallel to the optic axis of the eye. *See, e.g.*, Blumenkranz, Fig. 5 (vertically aligned through optical centers of the lens and cornea); Schuele ¶ 206. Additionally, the vertical incisions disclosed by Blumenkranz are non-transverse to the axis of the eye regardless of which of the recited axes is used. *Id.* ¶ 207; *see also* Section VIII.A.4, *supra*.

3. Claim 5

Claim 5 depends from claim 1, and further recites:

> *"the incision cuts the fibers into parts approximately at the intersection of the incision and the fibers; and the modified property of the lens is a weakening of a biomechanical property of the lens"*

Blumenkranz teaches this claim. Schuele ¶¶ 209-213.

First, as discussed above for Step 1[c], Blumenkranz discloses forming segmentation patterns with vertical incisions that cut through and intersect lens fibers, which are orientated generally transverse to the optical axis at the lens center. *See* Blumenkranz, Figs. 2, 5, 9A-9B, 10A-10C; *see also* Section VIII.A.4, *supra*. These segmentation patterns cut the lens fibers into parts at the intersection of the incision and the fibers because the laser pulses forming the incision "will produce dielectric breakdown" that "rupture[es] the tissue [] in the vicinity of photo-induced plasma." Blumenkranz, [0050]; *see also id.*, [0060] ("axial extent of the cutting zone"), [0086] ("rupture zone"), [0051] ("continuous cutting"), [0062], Figs. 2, 5, 9A-9B, 10A-10C; Schuele ¶ 211.

Second, Blumenkranz's segmentation patterns modify a property of the lens: the segmentations patterns weaken the biomechanical structure by "dissect[ing] [the lens nucleus and cortex] into small segments" for subsequent removal. Blumenkranz, [0009] ("The removal of a lens dissected into small segments is performed using a patterned laser scanning."), [0061]-[0062], [0068]-[0069], [0074], [0078], [0085]-[0086], [0088]-[0090]; Schuele ¶ 212.

4. Claim 11

Claim 11 depends from claim 1, and further recites:

> *"wherein the incision has a form aligned with the axis of the eye, the form being of at least one of: a cylinder, a set of concentric*

cylinders, a set of cylinders connected by one or more connecting line, a curved surface, a cone, a spiral, a layered spiral with smooth lines connecting layers of the spiral and a tilted cylinder"

Blumenkranz discloses this claim. Schuele ¶¶ 214-217. As discussed above for Step 1[c], Blumenkranz discloses segmentation patterns (i.e., incisions), that are aligned with the axis of the eye, including "circular, spiral, [and] curvilinear" segmentation patterns and "combinations thereof." Blumenkranz, [0068]; *see also id.*, [0069]. Cylinder and concentric cylinder incisions (highlighted in purple) are shown in Blumenkranz:

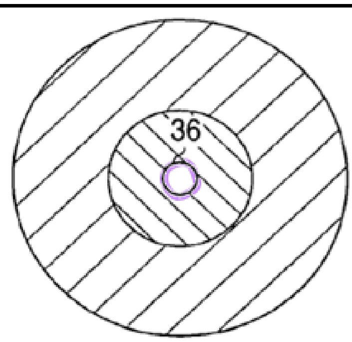


FIG. 9A

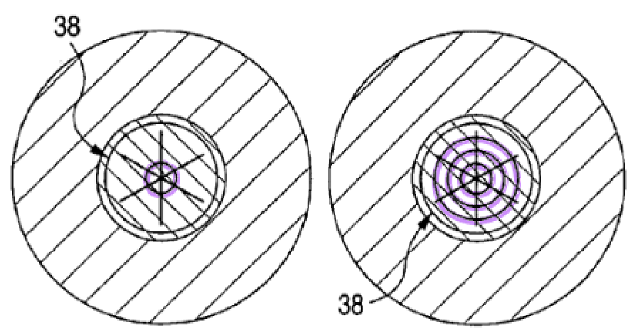


FIG. 10A FIG. 10B

Blumenkranz, Figs. 9A, 10A-10B (highlighted); Schuele ¶ 216; *see* Section VIII.A.4, *supra*.

5. Claim 12

Claim 12 depends from claim 1, and further recites:

> *"wherein the incision has a form aligned with the axis of the eye, the form being at least one of: a plane, two or more crossing planes, a combination of planes and connecting arcs, and a combination of planes and cylinders"*

Blumenkranz discloses this claim. Schuele ¶¶ 218-221. As discussed in connection with Step 1[c], Blumenkranz discloses segmentation patterns (i.e., incisions), that are aligned with the axis of the eye, including "linear, planar, radial, radial segments, circular, spiral, [and] curvilinear" segmentation patterns and "combinations thereof." Blumenkranz, [0068]; *see also id.*, [0069]. Plane and crossing plane incisions (highlighted in purple), are shown in Blumenkranz:

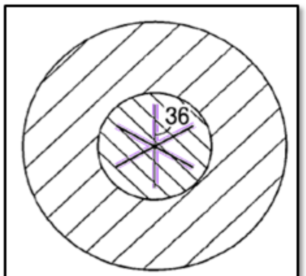


FIG. 9B

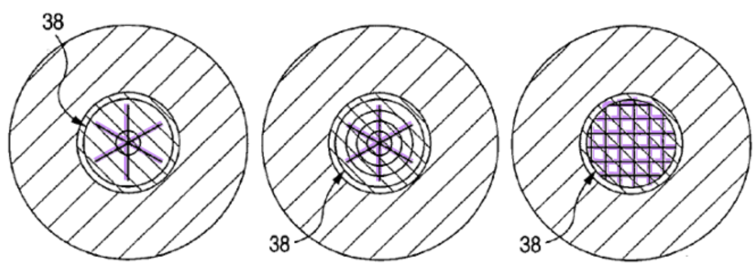


FIG. 10A FIG. 10B FIG. 10C

Blumenkranz, Figs. 9B, 10A-10C (highlighted); Schuele ¶ 220; *see* Section VIII.A.4., *supra*.

6. Claim 17

Claim 17 depends from claim 1, and further recites:

> *"wherein the applying the laser pulses comprises: selecting laser-parameters sufficient to create bubbles in the lens, but insufficient to cause harm to a retina of the eye"*

Blumenkranz discloses this claim. Schuele ¶¶ 222-225. As discussed above for Ground 2, claim 17, Blumenkranz discloses selecting laser-parameters sufficient to create bubbles in the lens. Blumenkranz, [0050], [0042]-[0046], [0053] ("cavitation bubble"), [0054], [0058], Figs. 2, 5, 20, 21; *see* Sections VII.A and VII.B, *supra*. Additionally, Blumenkranz discloses selecting laser parameters insufficient to cause harm to a retina. *Id.*, [0083], [0054], [0092]-[0093]; *see also id.* [0074], [0089], [0046]-[0053]; Schuele ¶ 224; *see also* Section VII.B, *supra*.

7. Claim 23

Claim 23 depends from claim 1, and further recites:

> *"forming the incision on a layer-by-layer basis, wherein one or more layers are at least partially formed along a curved focal plane of a laser delivery system"*

This claim is disclosed for the reasons explained above for Step 1[b]. Schuele ¶¶ 226-229; *see also* Section VIII.A.3, VI.A, VI.B.3, *supra*.

8. Claim 24

Claim 24 depends from claim 1, and further recites:

> *"a Z directional scanner is adjusted at a slower rate than an X-Y directional scanner when forming a layer of one or more incisions"*

This claim is disclosed for the reasons explained above for Step 1[b]. *See* Section VIII.A.3.a, *supra*. As described above, Blumenkranz scans the laser beam with an XY scanner in a "pattern on the eye while focused at the first depth." Blumenkranz, cl. 1. The Z scanner is only "stepped up or down with each consecutive scan." *Id.*, [0062]. As a result, the Z directional scanner is adjusted at a slower rate than the X-Y directional scanner, as recited in the claim. *See* Section VIII.A.3.a; Schuele ¶¶ 230-233.

9. Claim 26

Claim 26 depends from claim 1, and further recites:

> *"wherein the incision fragments at least a portion of the lens, the method further comprising: removing the fragmented portion of the lens"*

Blumenkranz discloses this claim. Schuele ¶¶ 234-237. Blumenkranz explains that the "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." Blumenkranz, [0069]; *see also id.*, [0009] ("removal of a lens dissected into small segments"), [0088] (lens "nucleus may be chosen to be segmented to ease its removal"), [0090], [0017], [0018], cl. 25 ("removing the pieces of lens"); Schuele ¶ 236.

10. Claim 27

Claim 27 depends from claim 26, and further recites:

> *"wherein the applying the laser pulses comprises: applying laser pulses with laser parameters which do not cause lasting damage to a retina of the eye, wherein the laser pulses fragment the lens to a degree suitable for removal; and the time of the fragmentation is less than a minute"*

Blumenkranz discloses this claim. Schuele ¶¶ 238-240. As discussed above for Grounds 2 and 3, claim 17 and Ground 3, claim 26, Blumenkranz discloses applying laser pulses with laser parameters that do not damage the retina, to form segmentation patterns that fragment the lens into pieces suitable for removal. *See* Sections VII.B, VIII.B.6, and VIII.B.9, *supra.* Additionally, as discussed above for Ground 2, claim 27, Blumenkranz also discloses that the time of fragmentation for the segmentation patterns in less than a minute. Blumenkranz, [0070]; *see also* Section VII.C, *supra*; Schuele ¶ 240.

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 ’925 patent, and that "[s]econdary considerations supporting non-obviousness include evidence of praise for the patented innovation and commercial success." Alcon's Objs. & Resps. to J&J's 1st Set of Interrogs., Nos. 1-17," (Ex. 1017) at 35 (Internet references omitted). These conclusory allegations are legally insufficient to establish nonobviousness. 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*. (citations omitted).

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

The Board should institute this Petition on its strong merits rather than issue a discretionary denial.

A. Discretionary Denial Under 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) (footnote omitted). Analysis under either prong reveals that discretionary denial is unwarranted.

Although Gray (which has substantially the same disclosure as Frey) was discussed by the Examiner and Alcon during prosecution, the Examiner erred by "overlook[ing]" a critical teaching "in the relevant prior art where those teachings impact patentability of the challenged claims." *Id.* at 8 n.9, 10. Specifically, the Examiner overlooked and failed to consider Gray's disclosure of "conventional focusing optics," which provides a curved focal plane. Alcon provided only cursory denials that Gray disclosed a curved focal plane. *See, e.g.*, '925 patent FH 1298 (June 23, 2015 Resp. to Office Action) ("layer-by-layer embodiments clearly show flat shot-layers, not curved ones"). The Examiner accepted those assertions with no discussion of Gray's conventional focusing optics. That oversight led to patent issuance.

Indeed, even though Alcon admitted during prosecution that Gray taught "that flat shot-layers are being formed without adjusting the Z scanner," it argued that "does not mean that the individual layers would have been curved while formed without adjusting the Z scanner." *Id.* 1299-1300. In other words, the only limitation that Gray was allegedly missing was creating layers using a curved focal plane. Schuele ¶¶ 31-32. And the Examiner, in the Notice of Allowance, specifically identified Step 1[b] (which includes the curved focal plane) as allegedly missing from Gray. '925 patent FH 1409-11, 1404-11 (May 20, 2016 Not. of Allowance). That prosecution history makes the Examiner's oversight particularly critical.

Thus, the Examiner "erred in a material manner … by failing to fully consider" the focusing optics configuration of Gray, and particularly the disclosure corresponding to paragraph [0065] of Frey. *Volkswagen Grp. of Am., Inc. v. Mich. Motor Techs. LLC*, IPR2020-00452, Paper 12 at 33 (P.T.A.B. Sept. 9, 2020); *see also NRG Energy, Inc. v. Midwest Energy Emissions Corp.*, IPR2020-00834, Paper 18 at 40 (P.T.A.B. 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 (P.T.A.B. Oct. 6, 2020)

(Examiner overlooked specific teaching in a reference that was the basis for allowing the challenged claims).

Although Blumenkranz was presented in an IDS to the Examiner, "[o]ther than initials on a lengthy IDS, nothing in the record indicates that the Examiner substantively considered" it. *Philip Morris Prods., S.A. v. Rai Strategic Holdings, Inc.*, IPR2020-00921, Paper 9 at 11 (P.T.A.B. Nov. 16, 2020) (no § 325(d) denial where the examiner did not discuss reference during prosecution). Hence, the "record does not reflect any substantive consideration of" Blumenkranz during prosecution of the '925 patent, "including any consideration of [Blumenkranz] in combination with [Frey], as presented in the Petition." *Solvay USA Inc., v. WorldSource Enters. LLC*, IPR2020-00768, Paper 12 at 8-9 (P.T.A.B. Sept. 25, 2020); *PEAG LLC v. Varta Microbattery GmbH*, IPR2020-01212, Paper 8 at 11-13 (P.T.A.B. Jan. 6, 2021) (no § 325(d) denial when references used in combination with previously disclosed primary reference were not previously disclosed to the Office).

Thus, § 325(d) denial is not warranted here.

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 decision is expected (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 render obvious the challenged claims of the ’925 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 ’925 patent is asserted in the following case that may be affected by a decision in this proceeding: *AMO Development, LLC v. Alcon LenSx, Inc.*, No. 1:20-cv-00842 (D. Del. June 23, 2020).

C. Grounds for Standing

Petitioner certifies that the ’925 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 ’925 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:

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Petitioner also designates the following backup counsel:

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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.

XII. Conclusion

For the reasons set forth above, Petitioner respectfully requests *inter partes* review of the challenged claims of the ’925 patent.

Respectfully submitted,

Dated: June 11, 2021 By: / Michael A. Morin /

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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 12,143 words, which is the sum of 12,039 words calculated by Microsoft Word's word-count feature and 104 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. 9,456,925 and all Exhibits and other documents filed together with this Petition were served on the official correspondence address for the patent shown in PAIR:

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