UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ALCON INC., ALCON LENSX, INC., ALCON VISION, LLC, ALCON LABORATORIES, INC., AND ALCON RESEARCH, LLC,
Petitioners

v.

AMO DEVELOPMENT, LLC,
Patent Owner.

IPR2021-00841
U.S. Patent No. 9,474,648

PETITION FOR *INTER PARTES* REVIEW UNDER 37 C.F.R. § 42.101

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*All emphases and coloring added, unless otherwise noted.

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I. INTRODUCTION

U.S. Patent No. 9,474,648 ("'648") is a first-action allowance. The Examiner never rejected the claims, identified the closest prior art, or explained the basis for allowance. Applicants were thus never required to distinguish any prior art or make a single argument in favor of patentability. Yet, as one of twelve child patents to U.S. Patent 8,394,084, the '648 claims the same basic concept of a cataract surgery system that combines a laser with an optical coherence tomography ("OCT") aiming system. Such a combination is not inventive. Since 1984—more than twenty years before the '648's claimed priority date of January 10, 2005—lasers were known to be used for cataract surgery. By 1994, OCT was being used to image cataracts. In the ensuing decade, OCT was used to plan eye surgery. Skilled artisans recognized that OCT could be combined with lasers, and numerous surgical systems combining them had been disclosed.

The '648 is obvious twice over: 1) by taking a laser cataract surgery system (Swinger) and adding an OCT imaging system (Baikoff); and 2) by taking a laser surgery system that already had OCT (Freedman) and using it for cataract surgery (Swinger). Either way, the challenged claims are invalid, and the Examiner erred by relying on past prosecutions to fast track the '648 without a single rejection.

Unfortunately, the Examiner's original error in allowing the '084 created a domino effect. The Examiner allowed the rest of the family in short order, with each prosecution seemingly more cursory than the one before it. In fact, half of the remaining patents, including this one, are first-action allowances. The Examiner's repeated errors culminated in the issuance of several claims that are not only obvious, but also entirely nonsensical.

Patent Owner's ("PO's") assertion of the '648 against Petitioners (except Alcon Inc.) in *AMO Development, LLC et al. v. Alcon LenSx, Inc. et al.*, No. 1:20-cv-00842-CFC (D. Del.), filed June 23, 2020 ("Delaware Litigation"), does not justify denial of this Petition. Trial in that case is set for February 2023, more than four months after the Board would enter a FWD. The Board's institution decision is due by October 2021, two months before the Markman hearing. The PTAB therefore presents the more efficient avenue for hearing Petitioners' invalidity arguments.

Petitioners Alcon Inc., Alcon LenSx, Inc., Alcon Vision, LLC, Alcon Laboratories, Inc., and Alcon Research, LLC (collectively, "Alcon") respectfully request *inter partes* review ("IPR") of '648 claims 1–15 ("Challenged Claims").

II. MANDATORY NOTICES

A. 37 C.F.R. § 42.8(b)(1): Real Parties-in-Interest

The real parties-in-interest are Alcon Inc., Alcon LenSx, Inc., Alcon Vision, LLC, Alcon Laboratories, Inc., and Alcon Research, LLC.

B. 37 C.F.R. § 42.8(b)(2): Related Matters

PO has asserted the ’648 against all Petitioners except Alcon, Inc. in the Delaware Litigation. Alcon is concurrently filing IPR petitions for eleven other patents in the same family as the ’648, all of which are asserted in the Delaware Litigation: U.S. Patent Nos. 8,394,084; 8,403,921; 8,425,497; 8,500,724; 8,709,001; 9,095,415; 9,101,448; 9,107,732; 9,125,725; 9,693,903; and 9,693,904.[1] This case may affect, or be affected by, the Delaware Litigation.

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1 Each patent in the family will be referenced by its last three digits.

C. 37 C.F.R. § 42.8(b)(3) &(4): Lead and Back-up Counsel and Service Information

Lead Counsel	Backup Counsel
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A Power of Attorney accompanies this Petition pursuant to 37 C.F.R. § 42.10(b). Alcon consents to electronic service by email at Alcon_IPR@kirkland.com.

III. PAYMENT OF FEES PURSUANT TO 37 C.F.R. § 42.103

Alcon authorizes the Office to charge the filing fee and any other necessary fee to Deposit Account No. 506092.

IV. CERTIFICATION OF STANDING UNDER 37 C.F.R. § 42.104

Alcon certifies the ’648 patent is available for IPR and that Alcon is not barred or estopped from requesting IPR on the grounds identified herein.

V. OVERVIEW OF CHALLENGE AND RELIEF REQUESTED

A. 37 C.F.R. § 42.104(b)(1): Claims for Which IPR Is Requested

Alcon challenges claims 1–15 of the ’648.

B. 37 C.F.R. § 42.104(b)(2): Grounds for Challenge

Alcon challenges the claims based on the following references:[2]

1. U.S. Patent No. 6,325,792 to Swinger et al. (“Swinger”), filed August 8, 1994, issued December 4, 2001, is prior art under § 102(b). Swinger was before the USPTO during prosecution of the ’648, but was not applied by the Examiner.

2. U.S. Patent No. 6,454,761 to Freedman (“Freedman”), filed January 30, 1995, issued September 24, 2002, is prior art under § 102(b). Freedman was before the USPTO during prosecution of the ’648, but was not applied by the Examiner.

[2] Each reference qualifies as prior art under 35 U.S.C. §102 regardless of whether the ’648 is entitled to the provisional filing date. If PO attempts to prove an earlier date of invention, Petitioners reserve the right to challenge the sufficiency of the provisional application disclosure and any antedating effort.

3. Georges Baikoff et al., *Static And Dynamic Analysis Of The Anterior Segment With Optical Coherence Tomography*, 30 JCRS 1843 (2004) ("Baikoff"), published in September 2004, is prior art under § 102(a). Baikoff was not before the USPTO during prosecution of the '648.

4. Y. Li et al., *Automated Anterior Chamber Biometry With High-Speed Optical Coherence Tomography*, 44 Invest. Ophthalmol. Vis. Sci. 3604 (2003) ("Li"), published in May 2003, is prior art under § 102(b). Li was not before the USPTO during prosecution of the '648.

5. Thomas Hoppeler et al., *Preliminary Clinical Results With The ISL Laser*, 1644 Proc. SPIE, Ophthalmic Technologies II 96 (1992) ("Hoppeler"), published August 14, 1992, is prior art under § 102(b). Hoppeler was not before the USPTO during prosecution of the '648.

6. U.S. Patent No. 4,538,608 to L'Esperance, Jr. ("L'Esperance"), filed June 6, 1984, issued September 3, 1985, is prior art under § 102(b). L'Esperance was before the USPTO during prosecution of the '648, but was not applied by the Examiner.

Alcon requests IPR on the following grounds:

Ground	Basis	Claims	Reference(s)
1	§ 103	1–5, 12–15	Swinger in view of Baikoff and Li
2	§ 103	6–9	Swinger in view of Baikoff, Li, and Hoppeler
3	§ 103	10–11	Swinger in view of Baikoff, Li, and L'Esperance
4	§ 103	1–5, 12–15	Freedman in view of Swinger
5	§ 103	6–9	Freedman in view of Swinger and Hoppeler
6	§ 103	10–11	Freedman in view of Swinger and L'Esperance

C. 37 C.F.R. § 42.104(b)(3): Claim Construction

Claims are construed under the claim-construction principles set forth in *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (*en banc*). 37 C.F.R. § 42.100(b). Alcon reserves the right to respond to any constructions that PO submits.

"***To determine one or more axial locations of the anterior capsule of the lens; and or more anterior capsule axial locations***": (claim 12) Although this claim is indefinite because "and or more anterior capsule axial locations" is a nonsense phrase,[3] the claim may have been intended to recite "one or more anterior capsule axial locations." Under this view, the phrase is synonymous with, and acts as shorthand for, the preceding claim language. The entire limitation could be interpreted thusly: "***to determine one or more axial locations of the anterior capsule of the lens (i.e., one or more anterior capsule axial locations)***."[4] This interpretation is supported by PO's infringement contentions, which ignore the nonsense language in the limitation. *See* Ex.1094 at 14.

D. 37 C.F.R. § 42.104(b)(4): How the Claims Are Unpatentable

Section XI provides a detailed explanation of how the Challenged Claims are unpatentable.

E. 37 C.F.R. § 42.104(b)(5): Evidence Supporting Challenge

A list of exhibits is provided at the end of the Petition. The relevance of this evidence and the specific portions supporting the challenge are provided, *e.g.*, in

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[3] Petitioners acknowledge that section 112(a) challenges are unavailable in IPR.

[4] Although it is not the Board's "function to rewrite claims to preserve their validity," *Allen Eng'g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1349 (Fed. Cir. 2002), Petitioners offer this construction for purposes of applying the prior art.

Section XI. Alcon submits a declaration of Joseph A. Izatt, Ph.D. (Ex.1001) in support of this Petition under 37 C.F.R. § 1.68.

VI. DISCRETIONARY DENIAL IS NOT APPROPRIATE HERE

A. The ’648 Has Not Been Subject to a Prior Petition

The ’648 has not been subject to any prior IPR or PGR petitions. Thus, this is not a “follow-on” petition and there is no basis for the Board to exercise its discretion under 35 U.S.C. § 314(a) and 37 C.F.R. § 42.108(a). *General Plastic Industrial Co. v. Canon Kubushiki Kaisha*, IPR2016-01357, Paper 19 (PTAB Sept. 6, 2017).

Further, Alcon has filed only a single petition challenging the claims of the ’648, avoiding any suggestion that Alcon has placed a substantial and unnecessary burden on the Board. Trial Practice Guide Update (July 2019).

B. The Presented Grounds and Argument Are Dissimilar to the Art and Arguments Previously Presented to the Office

1. *Becton Dickinson* Factors

All factors considered by the Board under 35 U.S.C. § 325(d) weigh in favor of institution. *Becton, Dickinson, & Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8 (PTAB Dec. 15, 2017); *see also Advanced Bionics, LLC v. Med-El Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 at 8 (PTAB Feb. 13, 2020). The Board has consistently “held that a reference that ‘was neither applied against the claims nor discussed by the Examiner’ does not weigh in favor of exercising [] discretion under §325(d)." *Fasteners for Retail, Inc. v. RTC Indus., Inc.*, IPR2019-00994, Paper 9 at 7–11 (PTAB Nov. 5, 2019). The grounds presented in the petition include obviousness challenges applying Swinger and Freedman as base references. Neither Swinger nor Freedman was applied against the Challenged Claims or discussed by the Examiner during prosecution of the '648.[5] The PCT search authority identified Swinger as a "Y" reference in its August 09, 2007 Search Report and further characterized Swinger as showing "first and second pulses [that] are separated by at least 0.1 ps but not more than 10 ns (Fig. 3)" in its May 6, 2007 Written Opinion. Ex.1097 at 1, 7. However, the Examiner never applied Swinger against the '648 claims in any office action at the USPTO.

Additionally, none of the grounds in this Petition were evaluated during prosecution. *Bowtech Inc. v. MCP IP, LLC*, IPR2019-00383, Paper 14 at 5 (PTAB Aug. 6, 2019).

2. The '648 Claims Are a Subset of Claims Directed to Substantially Overlapping Subject Matter

The '648 issued from application 14/949,645 ("'645 application"). The '645 application is one of over twenty child applications to the '084 parent, thirteen of

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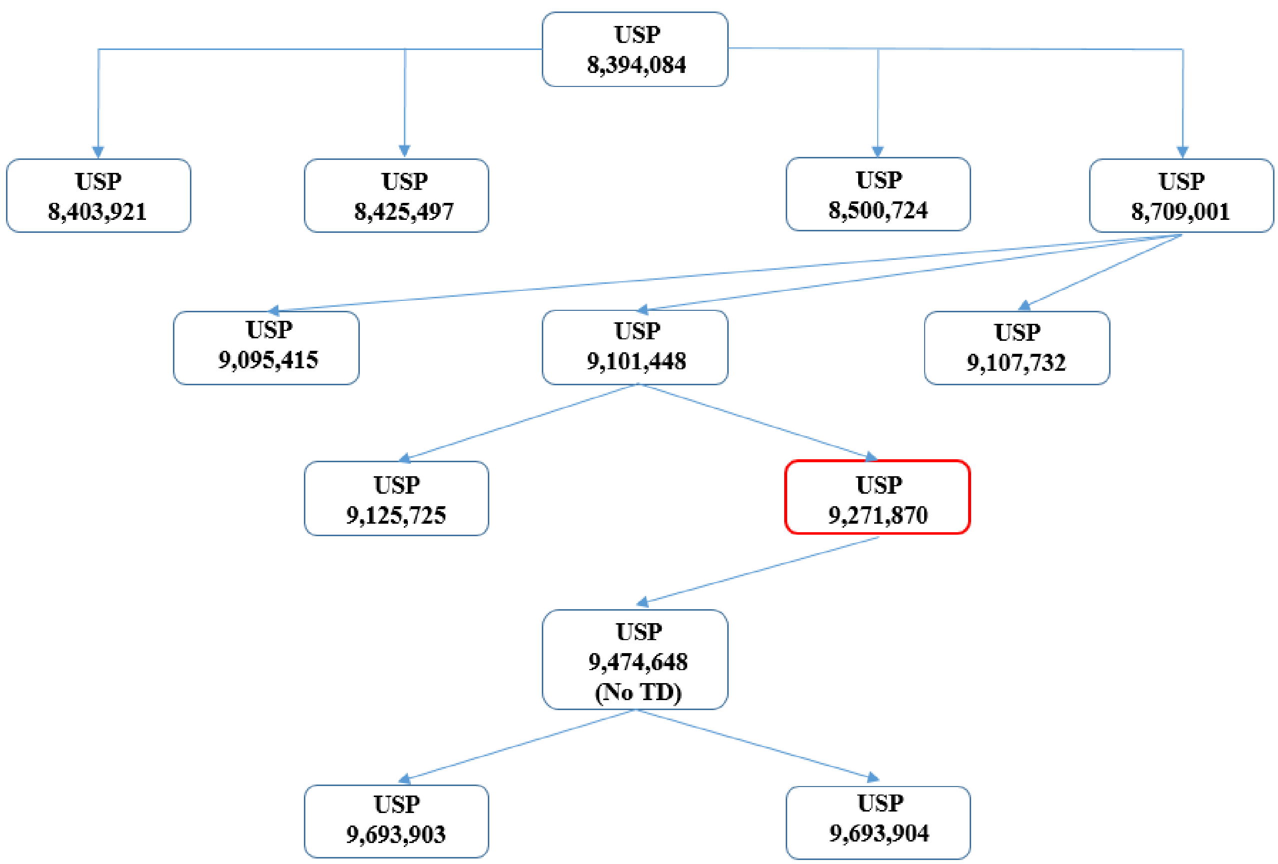
5 Swinger was applied as a secondary reference during prosecution of the '497 and '724, but never in combination with Freedman.

which issued as patents, twelve of which are or will be subject to IPR petitions, including this one. The family of twelve patents (including the ’084 parent) asserted by PO in the Delaware Litigation and consequently targeted by Alcon for IPR is shown below. PO has not asserted the ’870 (highlighted in red) in the Delaware Litigation. Each of the asserted patents, with the exception of ’648, is subject to a terminal disclaimer. The ’648 Examiner also examined all of the related patents, with the exception of ’903 and ’904 (where he nonetheless remained the Signatory Examiner).



After an atypical examination including nine interviews over the course of one year, the Examiner allowed the ’084 on December 12, 2012, with cursory examination. Following the ’084 allowance, the eleven other challenged patents were allowed in haste. Across all eleven challenged patents combined, only five office actions were entered and the Examiner’s arguments in each were quickly abandoned. For example, in each of the ’497, ’724, and ’001 examinations, the Examiner applied U.S. Patent No. 5,098,426 to Sklar as a primary reference, only to immediately withdraw it.

In addition, the ’084’s search history reflects that the Examiner’s searches were limited to U.S. (e.g., US-PGPUB, USPAT, and USOCR) and foreign (e.g., FPRS, EPO, JPO, and DERWENT) patent databases, neglecting guidance in MPEP 904.2 (Rev. 5, August 2006) that non-patent literature (“NPL”) searches “must be considered.” Ex.1005 at 119–34.[6] Thus, unsurprisingly, the Examiner did not have the NPL applied here before him (*e.g.*, Baikoff and Li), although it would have been easy to find if the Office’s NPL search tools had been adequately employed. Searches for NPL directed to ocular applications of OCT imaging would have been of particular importance. *See* MPEP §904.2 (Rev. 5, August 2006) (“Search tool knowledge is particularly important for examiners in arts (*e.g.*, very active, high

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[6] References to “IBM_TDB” in the search history is to the IBM Technical Disclosure Bulletin, which is a collection of defensive publications that ceased being published in 1998.

technology) where patent documents may seriously lag invention and, consequently, represent a reference source of limited value. These examiners ***must take special care*** to ensure that their searches include consideration of NPL and employ the effective use of tools specialized to cover NPL pertinent to their search needs").

The Examiner's errors had a domino effect: after allowing the '084, the Examiner allowed the rest of the family in short order, with each prosecution seemingly more cursory than the one before it. For example, the Examiner entered a first-action allowance to several claims in the '725 patent that are not only obvious, but entirely nonsensical.

The Board is best situated to efficiently and fairly address the Examiner's repeated errors that permitted this large patent family to issue with invalid claims directed to substantially overlapping subject matter.

C. Efficiency, Fairness, and the Merits Support the Exercise of the Board's Authority to Grant the Petition

1. *Fintiv* Factors

Taking "a holistic view" of the six *Apple v. Fintiv* factors demonstrates that the Board should not exercise its discretion under §314(a) in light of the Delaware Litigation. IPR2020-00019, Paper 11 at 6 (PTAB Mar. 20, 2020) (precedential).

<u>Factor 1</u>: Institution will enable the Board to resolve the issue of validity, and a finding of invalidity will relieve the District Court of the need to continue with the majority of the Delaware Litigation. Alcon will move the District Court for a partial

stay of all validity issues, providing the Board the sole opportunity to adjudicate §102/103 issues. The opportunity for such simplification increases the likelihood the court will grant a stay in view of IPR institution. *Bio-Rad Lab'ys. Inc. v. 10X Genomics, Inc.*, No. CV 18-1679-RGA, 2020 WL 2849989, at *1 (D. Del. June 2, 2020) (staying case in view of IPR because of infancy of case and likelihood of simplifying issues for trial set more than a year away); *Ethicon LLC v. Intuitive Surgical, Inc.*, No. CV 17-871-LPS, 2019 WL 1276029, at *3 (D. Del. Mar. 20, 2019) (same, less than seven months before trial); *see also Seven Networks, LLC v. Apple Inc.*, C.A. No. 2:19-cv-00115-JRG, Dkt. 313 (E.D. Tex. Sept. 22, 2020) (same, less than six weeks before trial).

<u>Factor 2</u>: Trial in the Delaware Litigation is currently scheduled for February 13, 2023, four months after the projected statutory deadline for a final written decision (October 2022). Ex.1098. However, the District of Delaware has experienced a backlog of jury trials due to the ongoing COVID-19 pandemic, making the February 2023 date uncertain. Ex.1101; *see Apple Inc. v. Seven Networks*, IPR2020-00235, Paper 10 at 8–9 (PTAB July 28, 2020) (these facts "diminish[] the extent to which this factor weighs in favor of exercising discretion"). In contrast, "the Board continues to be fully operational," and thus the projected statutory deadline for the final written decision will not change. *Sand Revolution II, LLC v. Continental Intermodal Grp.-Trucking LLC*, IPR2019-01393, Paper 24 at 9

(PTAB June 16, 2020). This factor weighs against exercising discretion to deny institution. *See, e.g., Brunswick Corporation v. Volvo Penta of the Americas, LLC*, IPR2020-01512, Paper 15 at 10–11 (PTAB March 11, 2021)(citing *Fintiv* at 12).

Factor 3: Petitioners have acted diligently, filing sixteen petitions within two months of receiving PO's Infringement Contentions, which identify for the first time the claims PO is asserting in the Delaware Litigation. *See Med-El Elektromedizinische Geräte GES.M.B.H., v. Advanced Bionics AG*, IPR2021-00044, Paper 14 at 24–25 (PTAB April 6, 2021)(quoting *Fintiv* at 11 "The Board recognizes, however, that it is often reasonable for a petitioner to wait to file its petition until it learns which claims are being asserted against it in the parallel proceeding"). In contrast, by the institution date in October 2021, the parties and District Court will have invested limited resources in the Delaware Litigation, particularly with regard to invalidity issues. The *Markman* hearing for December 2021 will not have occurred by the institution-decision date. Ex.1098. *See Med-El Elektromedizinische Geräte GmbH v. Advanced Bionics AG*, IPR2020-00190, Paper 15 at 12–14 (PTAB June 3, 2020) (if *Markman* order has not issued at time of institution decision, this factor weighs against exercising discretion). And the deadlines for completing fact discovery, exchanging expert reports, and filing dispositive motions all occur in 2022. Ex.1098; *VMWare, Inc. v. Intellectual*

Ventures I LLC, IPR2020-00470, Paper 13 at 19 (PTAB Aug. 18, 2020) (instituting where "much work remains in the parallel proceeding as it relates to invalidity.").

Factor 4: In the unlikely scenario that the Delaware trial occurs before the FWD, Alcon has stipulated to PO that if this IPR is instituted, Alcon will not pursue invalidity on the specific grounds raised here or on any other ground that reasonably could have been raised in this IPR. Ex.1099. Numerous Board decisions, including the precedential decision *Sotera Wireless, Inc. v. Masimo Corporation*, IPR2020-01019, Paper 12 (PTAB December 1, 2020), confirm that such a stipulation eliminates concerns about the overlap between the district-court case and the IPR, causing this factor to weigh ***strongly against*** the Board exercising its discretion under § 314(a). *Id*. at 18; *see also, e.g., NVIDIA Corp. v. Invensas Corp.*, IPR2020-00602, Paper 11 at 27–28 (PTAB Sept. 3, 2020); *NanoCellect Biomedical, Inc. v. Cytonome/ST, LLC*, IPR2020-00551, Paper 19 at 21–24 (PTAB Aug. 27, 2020); *Sand Revolution*, Paper 24 at 11–12; *Seven*, Paper 10 at 12–16.

Factor 5: While four Petitioners are defendants in the Delaware Litigation, Alcon Inc. is not (but is a counterclaimant). This weighs against exercising discretion to deny the petition, as the PTAB is the only venue where the validity issues raised here can be resolved for each of the five Petitioners including, in particular, Alcon Inc. See *Nalox-1 Pharms., LLC v. Opiant Pharms, Inc.*, IPR2019-00685, Paper 11 at 6 (PTAB Aug. 27, 2019). Further, institution would serve the goal of providing an efficient alternative to litigation, and permit the Board to resolve questions of patentability regarding claims PO might otherwise assert against others later. *See Seven*, Paper 10 at 16 n.7.

Factor 6: As set forth below, the merits of the grounds of this Petition are strong. Where "Petitioner has set forth a reasonably strong case for the obviousness of most challenged claims," this factor weighs ***against*** the Board exercising its discretion under §314(a). *Sand Revolution*, Paper 24 at 13.

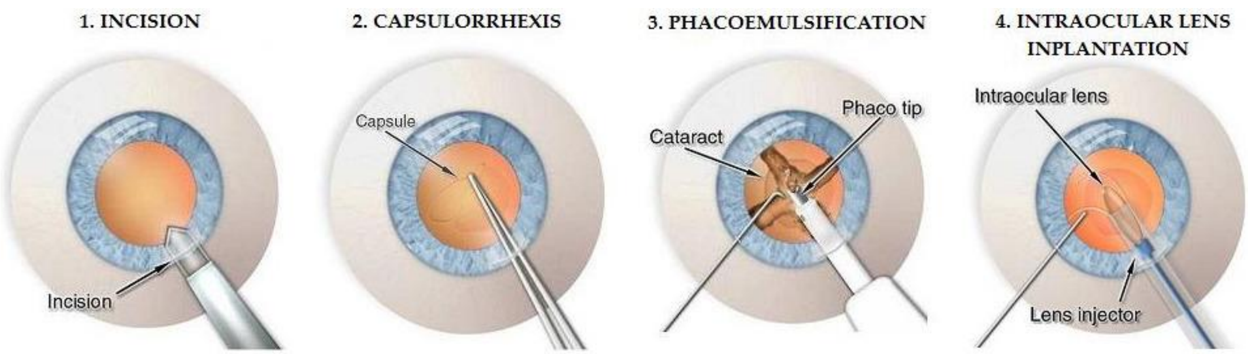
"Considering the *Fintiv* factors as part of a holistic analysis," it would run counter to "the interests of efficiency and integrity of the system" if this Board were "to deny institution of a potentially meritorious Petition." *Id.* at 14. Thus, the Board should decline to exercise its discretion under §314(a).

VII. BACKGROUND OF THE TECHNOLOGY

A. Cataract Surgery

Cataracts are a common eye condition causing blurred vision and can lead to blindness. The standard treatment for cataracts is to replace the natural, clouded lens with an artificial intraocular lens ("IOL"). The lens, however, is deep in the eye—under the cornea and contained within the lens capsule, which is the bag surrounding the lens. A surgeon must first make an incision in either the cornea (a clear corneal incision) or the sclera (a scleral tunnel incision). Next, the surgeon must create an opening in the anterior lens capsule, which is called an anterior capsulotomy or capsulorhexis. The surgeon then breaks apart and removes the lens, typically with the use of ultrasonic energy in a process called phacoemulsification. After removing the lens, the surgeon then implants the IOL. Ex.1001 ¶25.

This video and the figures below illustrate an exemplary procedure.



B. Lasers in Cataract Surgery

The use of lasers with "ultrashort" pulses of light to cut tissue dates back several decades. Ex.1001 ¶26. By the late 1980s, "[u]ltrashort pulsed lasers [] established themselves as the modality of choice for many surgical procedures where propagating thermal effects are to be suppressed," Ex.1047 at 2:11–15, including for cataract surgery. Ex.1001 ¶26.

As scientists developed lasers with shorter pulses, the applications for such lasers grew. Femtosecond lasers exhibited improved outcomes over lasers with longer pulse lengths, enabling more precise, efficient, and less damaging cuts in optical tissue. *Id.* ¶27. Because of these advantages, by the 1980s, lasers with ultrashort pulses had already been used to perform the anterior capsulotomy procedure that is part of modern cataract surgery and had been used as an alternative to, or in combination with, phacoemulsification to fragment the cataractous lens. *Id.* ¶¶28–29.

C. Optical Coherence Tomography Imaging for Ophthalmology

1. Overview

The precision with which a laser can cut tissue led scientists to seek more precise tools for guiding the laser. *Id*. ¶31. This need to obtain precise positioning information was particularly relevant in the context of anterior capsulotomy. *Id.*

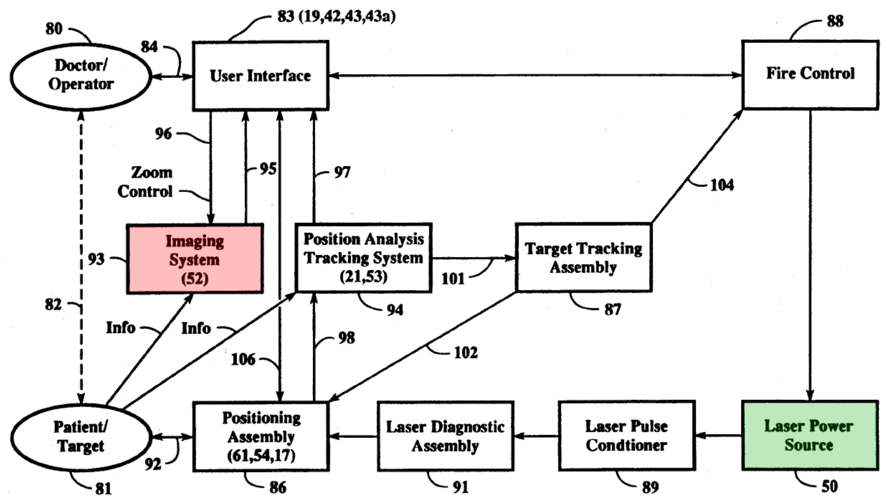
As optical-imaging techniques advanced, such techniques were incorporated into image-guided systems. *Id*. ¶32. For example, OCT was the next evolution of imaging technology being investigated for use in ophthalmology in 2005. The first use of OCT to create "high resolution cross-sectional imaging of structure in the anterior segment" of the eye, including specifically to image cataracts to their full thickness, was published in 1994. *See* Ex.1054 at 1. As described by Dr. Izatt, OCT was a "high-quality tomographic imaging for the measurement of anterior eye structures … and cataract progression in the crystalline lens" and therefore had "potential … as a diagnostic procedure for ophthalmologic examination of the anterior eye." *Id.* at 6. And OCT had been recognized as useful for planning surgery within the anterior segment, such as for sizing an IOL. *See* Ex.1001 ¶¶32–33.

By the late 1990s, OCT was a well-known method of imaging the human eye with more precision than ever before. OCT provided a mechanism for realistic imaging for various applications. *Id.* ¶33. Unsurprisingly, by 2005, there were numerous publications disclosing combinations of OCT with a laser, including for use in cataract surgery. *Id*.

OCT-guided laser surgical systems were also described for use in other optical surgeries. *Id*. By leveraging OCT, optical surgeons could look further and more clearly into the eye, opening up the field to surgical procedures requiring deep and more precise cutting tools, such as cataract surgery. *Id.* ¶34.

2. Integrating Imaging and Treatment into an Automated Approach

Due to the computer-controlled nature of lasers, scientists sought to combine lasers with computerized image-guidance to control the laser precisely during treatment. *Id*. ¶35. In the late 1980s and early 1990s, computerized image-guided laser control systems allowed the cutting process to run automatically, minimizing operator oversight and error, with feedback based on the real-time imaged eye structures. *Id*. For example, ophthalmological surgical systems that used microscopy to guide the laser automatically were known. *Id*. By pairing a laser with a real-time three-dimensional imaging system in a single automated unit, surgeons could exploit diagnostic information about the depth and position at which to fire the laser. *See* Ex.1047 at 3:17–23, Fig. 4 (illustrating combination of imaging and laser assemblies in a single automated system).



These early computer-controlled devices disclosed that laser operation could occur automatically. Ex.1001 ¶36. Another patent, Ex.1076, filed in the late 1980s disclosed a "unique integration of several such diverse aspects (including mapping, imaging, tracking, precision laser cutting and user interface), precisely yet inexpensively, into a fully automated workstation." Ex.1001 ¶37.

Upon the emergence of OCT as an effective imaging tool, scientists soon integrated it into laser control systems to facilitate both the diagnostic and treatment aspects of laser eye surgery. *Id.*

VIII. THE '648

The '648 issued from Application No. 14/949,645, filed November 23, 2015, and claims priority to Provisional Application No. 60/643,056, filed January 10, 2005. Ex.1030. Although the '645 application was filed after March 16, 2013, it claims priority to an application filed before March 16, 2013, and thus patentability is not governed by the amendments to 35 U.S.C. §§ 102 and 103 made by the Leahy-Smith America Invents Act, Pub. L. 112-29, 125 Stat. 284 (2011).[7]

A. Alleged Problem

The ’648 describes a number of supposed problems with manual cataract surgery, such as the “inability of the surgeon to adequately visualize the capsule due to lack of red reflex, to grasp it with sufficient security, to tear a smooth circular opening of the appropriate size without radial rips and extensions or technical difficulties related to maintenance of the anterior chamber depth after initial opening, small size of the pupil, or the absence of a red reflex due to the lens opacity.” Ex.1030 at 2:7–13. The ’648 allegedly overcomes these issues by allowing for “rapid and precise openings in the lens capsule and fragmentation of the lens nucleus and cortex … using 3-dimensional patterned laser cutting.” *Id*. at 3:16–19.

B. Alleged Invention

The ’648 discloses the traditional elements of an ophthalmological laser surgical system: a light source for generating a beam of light, a delivery system for

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[7] To the extent the Board finds any limitation in the ’648 unsupported by the original specification, and that the AIA governs, the outcome remains the same as all art cited in each Ground qualifies as prior art under AIA-§ 102(a) and does not fall within any exception under AIA-§ 102(b).

focusing the beam, and a controller for controlling the light source and the delivery system. *See, e.g.*, Ex.1030 at 4:56–5:15. The '648 also discloses that imaging "may be used to determine the location and measure the thickness of the lens and lens capsule to provide greater precision to the laser focusing methods," *id.* at 8:13–18, and that "[l]aser focusing may also be accomplished using one or more methods including direct observation of an aiming beam, Optical Coherence Tomography (OCT), ultrasound, or other known ophthalmic or medical imaging modalities and combinations thereof." *Id.* at 8:18–22.

Figure 12 discloses an exemplary embodiment incorporating OCT. *See id.* at 13:2–20.

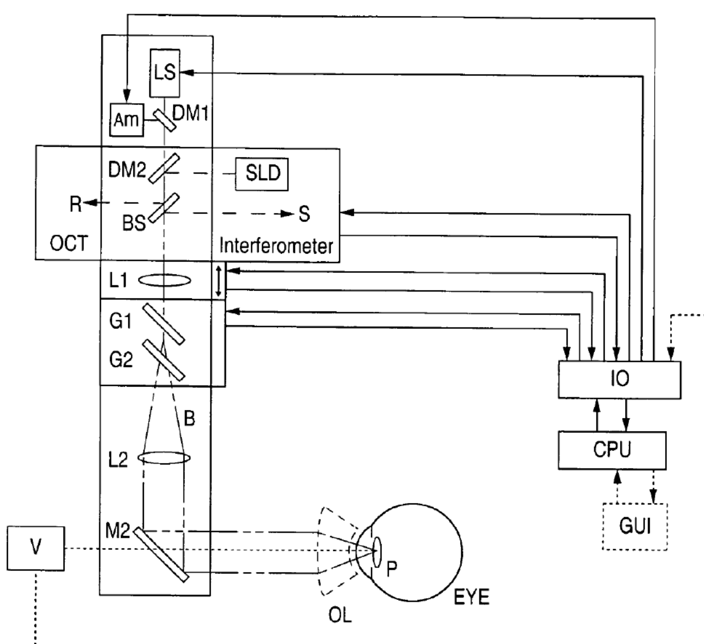


FIG. 12

The light source is laser source LS. *Id*. at 11:34–37. The delivery system consists of: lens L1, used to scan the laser focus along the z-axis; mirrors G1 and G2, used to scan in the X & Y axes; lens L2, which focuses the beam into the patient's eye; and mirror M2, which directs the beam onto the target. *Id*. at 11:48–12:14. The "entire system is controlled by the controller CPU." *Id*. at 12:33–35.

This embodiment also contains an OCT imaging system. The light source for the OCT in this embodiment is designated SLD, which "may be a superluminescent diode … such as the SuperLum SLD-37." *Id*. at 13:11–14. The OCT reference input is designated R and the sample input is designated S. *Id*. at 11:38–42. Figure 13 shows another embodiment where the OCT has been replaced by confocal microscopy. *Id*. at 13:21–22.

The '648 discloses that the system can perform anterior capsulotomy as well as lens fragmentation. *Id*. at 10:27–39.

C. Prosecution History

The record before the PTO is sparse and prosecution proceeded extremely quickly. The file wrapper consists of an initial application, Ex.1032 at 817–70, a preliminary amendment filed the same day replacing all claims, *id.* at 812–17, and a Notice of Allowance issued just over 2 months after filing, *id.* at 774–805. Three months after the Notice of Allowance, Applicants filed a Request for Continued Examination ("RCE") in order to file an Information Disclosure Statement ("IDS").

Id. at 142–763. The Examiner considered the IDS, and issued a second notice of allowance within a month. *Id.* at 89–141. After sorting through a few fee deficiencies with a subsequent IDS, the Examiner issued a third Notice of Allowance. *Id.* at 2–86. In the Notice for Allowances, the Examiner merely summarized the limitations of the independent claims, and stated that "[t]he prior art of record doesn't reasonably teach or suggest this combination of limitations," without ever identifying what the prior art does teach. *Id*. at 779 (original Notice of Allowance), 94 (second Notice of Allowance referring to reasoning in the original), 4 (third Notice of Allowance referring to reasoning in the original). The '648 then issued; prosecution took less than 11 months in total. *Id.* at 1.

IX. LEVEL OF ORDINARY SKILL IN THE ART

A POSA as of January 2005 would have had a Ph.D. in Physics, Biomedical Engineering, or a related science, such as Nuclear Engineering, as well as a basic understanding of ophthalmology, or at least five years of experience in research, manufacturing, or designing medical optics or medical lasers. Additional education or experience in related fields could compensate for deficits in the above qualifications.

X. OVERVIEW OF THE PRIMARY PRIOR ART

A. Swinger

Swinger discloses a computer-controlled laser-surgery system configured to perform various surgical procedures in the eye, including the anterior capsulotomy and lens fragmentation procedures of cataract surgery. Ex.1039 at Fig. 6, 16:60–20:34, 23:13–25. The system comprises a laser unit 100 configured to generate an ultrashort-pulsed laser beam. *Id.* at 17:11–15, 8:34–42. An optical scanning system directs a focal point of the laser beam onto target tissue in three dimensions to create dielectric breakdown of the tissue. *Id.* at 16:62–17:10, 41–45, 20:49–51, 34:52–67. At the system's core, a computer control unit 114 automates the operation of the laser and the optical system. *Id.* at Fig. 6, 17:41–57, 19:17–20. Swinger also describes the use of an imaging device to directly visualize the lens capsule and accurately identify eye components. *Id.* at 34:52–57, 35:59–63.

B. Freedman

Freedman discloses a method and device for laser surgery using OCT to control the treatment laser beam. Ex.1040 at 2:7–10. The treatment laser beam can be used for ablation of "tumors or of cornea tissue" or "other biological tissue," or for "clearing cataracts." *Id.* at 8:31–34, 4:32–35, 1:23–26. The treatment laser beam is a "pulsed laser beam" controlled by a processor "in accordance with [an] ablating plan." *Id.* at 5:45, 5:35–36. Freedman teaches an imaging system using OCT to "three dimensionally image a target" and "evaluate the thickness and the boundary state of each layer of the cornea or other biological tissue." *Id.* at 7:16–17, 4:33–35.

Figure 1 illustrates laser surgical system 14 comprising an interferometer 16 and optical system 18. *Id.* at 4:45–46. Together, the interferometer and optical system constitute an OCT assembly.

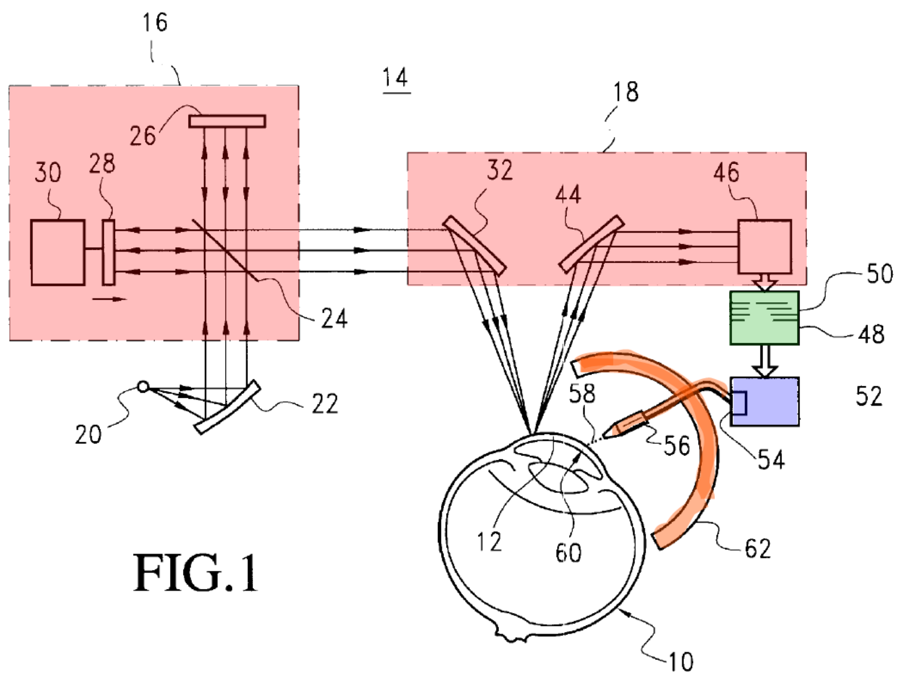


FIG.1

The OCT assembly renders an interferogram by scanning light onto ocular tissue and detecting the reflection. *Id.* at 5:5–23. Processor 48 transforms the interferogram into a spatialgram and "compares spatialgram data to data representing a standard of improved visual acuity to construct an ablating plan." *Id.* at 5:23–31. Processor 48 can also "construct a plan by accepting real time input, for example from a surgeon responding to a signal in the form of an image visually displayed on the screen of a computer." *Id.* at 5:62–67. Freedman discloses that "displacement means 62 displaces ablating light beam 58 across the cornea 12 while focusing the lobe or lobes of beam 58 to complete correction of cornea 12." *Id.* at

5:49–52. Processor 48 thus controls the ablating laser beam 58 through displacement means 62 according to the ablating plan. *Id*. at 5:54–67.

XI. EACH OF THE CHALLENGED CLAIMS IS UNPATENTABLE

A. Ground 1: Claims 1–5 and 12–15 Are Obvious Over Swinger in View of Baikoff and Li

1. Motivation to Combine

a. OCT

Swinger discloses a computer-controlled laser-surgery system configured to perform various surgical procedures in the eye, including the anterior-capsulotomy and lens-fragmentation procedures of cataract surgery. Ex.1039 at Fig. 6, 16:60–20:34, 23:13–25. However, Swinger does not utilize OCT imaging as a diagnostic tool. Swinger's pre-surgical analysis for directing the treatment beam instead employs manual estimation or the use of ultrasound to image ocular tissue. *Id*. at 35:17–36:7 (teaching ultrasound to measure distance between cornea and anterior lens capsule to identify a safe distance to begin phacorefractive ablation of lens); *see* Ex.1001 ¶¶142–44.

Swinger further recognizes the benefit of making accurate and reproducible cataract incisions. Ex.1039 at 34:43–51 ("The ability to open a lens capsule in a regular and controlled manner is of great importance. A smooth and regular opening in the anterior capsule prevents the complications of capsule tear or rupture, or difficulties in inserting the intraocular lens because of an inappropriately sized opening. Also, opening either capsule with the invention significantly reduces the acoustic shock waves within the eye and reduces the possibilities of retinal complications or damage to the prosthetic lens.”). However, as much as computer-guided laser systems like Swinger improve the accuracy of incisions, the art had recognized that accurate incisions are only beneficial to the extent they derive from an accurate understanding of the target anatomy. *See* Ex.1001 ¶¶145–47.

To that end, Baikoff describes the benefits of using OCT, a well-known imaging technique, for ophthalmic procedures. Specifically, Baikoff teaches an OCT assembly configured to provide high-resolution images of the cornea, iris, and crystalline lens to help plan ophthalmic surgical procedures. Ex.1041 at 1, 7. Citing the various drawbacks of known anterior segment imaging techniques such as ultrasound, Baikoff turns to OCT to study biometric modifications of the anterior segment with accommodation and age, and to determine possible applications of OCT in areas of anterior segment surgery. *Id.* Finding that OCT is user-friendly and accurate, Baikoff concludes that OCT is especially useful for pre-surgical anterior segment diagnostics. *Id.* at 7. For example, in one potential application, Baikoff predicts using OCT pre-surgery to identify posterior synechias (adhesion between the iris and lens) and modify the surgical plan accordingly. *Id.*; *see also id.* (“The cross-sectional optical images of the anterior segment will enable us to foresee with a reasonable degree of precision changes in the anatomical relationship of the anterior segment after insertion of an angle-supported or iris fixated AC phakic IOL."); Ex.1001 ¶148.

A POSA would have been motivated to integrate an OCT assembly like Baikoff's into Swinger's system to plan and effect laser cataract surgery with improved accuracy, as taught by Baikoff. Ex.1001 ¶149. As explained above, Swinger recognizes the benefits of pre-surgical diagnostic imaging, and is chiefly concerned with making accurate and reproducible cataract incisions. Ex.1039 at 34:43–51; Ex.1001 ¶149. A POSA would have endeavored to improve the accuracy of laser cataract surgeries by looking at the best available imaging techniques to help generate ideal ablation patterns. Ex.1001 ¶149. It was also known in the art that the path to improving the accuracy of incisions lies in imaging, specifically with regard to lens fragmentation. *Id*. A POSA would have endeavored to improve the accuracy of laser cataract surgeries by looking at the best available imaging techniques to generate ideal ablation patterns based on information previously inaccessible through manual estimation or other imaging techniques. *Id*. Baikoff's OCT assembly represents a sophisticated imaging technique available at the time for obtaining precise measurements of the anterior segment in a fast and user-friendly manner. Ex.1041 at 1. Moreover, Baikoff expressly teaches that OCT imaging is suitable for measuring structures within the anterior segment in preparation for surgery. *Id.* at 7. Therefore, a POSA using Swinger's system would have been motivated to leverage Baikoff's OCT imaging capabilities to plan and execute a more accurate laser cataract surgery. Ex.1001 ¶149.

A POSA would have had a reasonable expectation of success in integrating the OCT systems taught by Baikoff into Swinger's treatment system. *Id.* ¶150. The prior art teaches that integrating diagnostic imaging and treatment functionalities in a single automated system is not only desirable, but also straightforward. *See id.*

Furthermore, a POSA would have found this combination obvious to try because there are a finite number of identified and predictable imaging modalities that a have a reasonable expectation of success. *Id.* ¶152. Indeed, the '648 itself recognizes various alternative imaging modalities to OCT. *See* Ex.1030 at 8:13–22, 11:1–29, 13:21–37; *compare* Fig. 11 (OCT imaging), *with* Fig. 13 (confocal microscopy) ("Laser focusing may also be accomplished using one or more methods including direct observation of an aiming beam, Optical Coherence Tomography (OCT), ultrasound, *or other known ophthalmic or medical imaging modalities* and combinations thereof."). A POSA would also have been motivated to modify Swinger's system to include an OCT system like Baikoff's since doing so merely amounts to a simple substitution of known imaging modalities (Baikoff's OCT in place of Swinger's direct visualization with an HeNe beam or use of ultrasound) that would obtain predictable results. Ex.1001 ¶152.

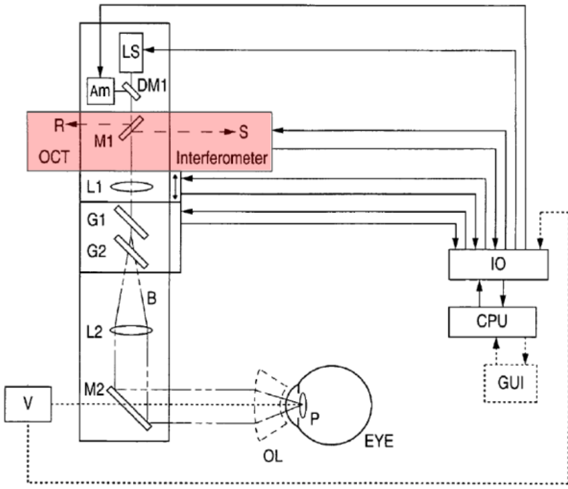


FIG. 11

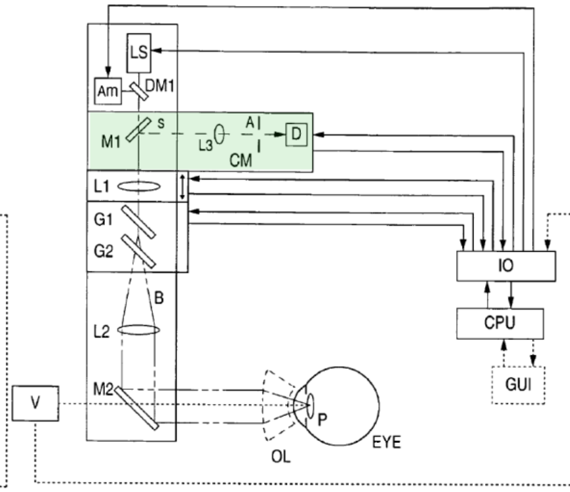


FIG. 13

Ex.1030 at Figs. 11, 13.

b. **Processing Image Data**

The ultrasound and OCT imaging systems disclosed by Swinger and Baikoff require surgeons to make image measurements manually and input those measurements into a computer system. *See* Ex.1039 at 35:59–66 (manual ultrasound measurements are "programmed in . . . before beginning the ablation."); Ex.1041 at 2 (discussing use of software to make measurements between ocular tissue). Swinger and Baikoff do not expressly teach imaging systems with controllers that process image data to determine ocular structures and landmarks without manual intervention.

Li, however, teaches another OCT system like Baikoff's. Ex.1044 at 1–2. But unlike Baikoff, Li recognizes that manual measurements, even those based on image data, can lack precision, and there can often be disagreement among surgeons performing measurements on the same image data. *Id.* Thus, Li employs computer algorithms to make certain measurements automatically, based on the boundaries of the imaged tissue. *Id*.

Upon integrating an OCT imaging system (like Baikoff's) into Swinger's laser system, it would have further been obvious to program Swinger's control system to process image data to identify certain reference points and treatment locations, as envisioned by Li, to improve the accuracy of the measurements and subsequent surgery. Ex.1001 ¶¶154–59. A POSA would have had a reasonable expectation of success in doing so because it merely requires programming the control system with algorithms that automatically evaluate the image data and identify various tissue structures, which is within the skill of a POSA. Ex.1001 ¶159. Indeed, the '648 itself recognizes "the well known and computationally efficient Sobel or Canny edge detection schemes." Ex.1030 at 13:52–53.

This is nothing more than automating a manual activity using well-known components (*e.g.*, controllers and algorithms) in predictable ways, which is obvious to a POSA. *See* MPEP 2144.04 (citing *In re Venner*, 262 F.2d 91, 95, 120 USPQ 193, 194 (CCPA 1958)). Specifically, rather than having a surgeon evaluate images, make measurements, and input those measurements into the system, the controller would be programmed to perform these steps automatically. Such automatic processing of image data eliminates the need for a surgeon to manually make measurements and input them to the system before the controller determines the relevant scanning patterns. Ex.1001 ¶159.

2. Independent Claim 1

a. Limitation 1P[8]

Swinger discloses a laser surgical system for making incisions in ocular tissue during a cataract procedure. Ex.1039 at Fig. 6, 16:60–20:34 (disclosing system), 20:49–21:19 (disclosing incisions performed using the system) 34:30–35:3 (describing anterior capsulotomy procedure).

b. Limitation 1.1

Swinger's system comprises a laser system (*e.g.*, 100) comprising a scanning assembly. Ex.1039 at Fig. 6, 16:60–17:20 ("The laser unit 100 is of the type that can output a beam rapidly deflectable or scannable under electronic control in two dimensions to any location in an area defined by orthogonal X and Y axes"), 20:16–20.

c. Limitation 1.2

Swinger's system comprises a laser (100) operable to generate a laser beam (B) configured to incise ocular tissue. Ex.1039 at 16:60–17:20; *see also id.* at Abstract ("Low-energy, ultra-short (femptosecond) pulsed laser radiation is applied

[8] Ex.1031 is a claim listing that enumerates each claim element.

to the patient's eye in one of a number of patterns such that the exposed ocular tissue is ablated or excised through the process of optical breakdown or photodisruption in a very controlled fashion."), 34:30–35:3 (disclosing cataract procedure comprising incisions in ocular tissue), Figs. 15A1–B1.

d. **Limitation 1.3**

Swinger teaches using an (ultrasound) imaging device configured to acquire image data of the lens. Ex.1039 at 35:17–36:7 (discussing measuring distance between the cornea and anterior lens capsule).

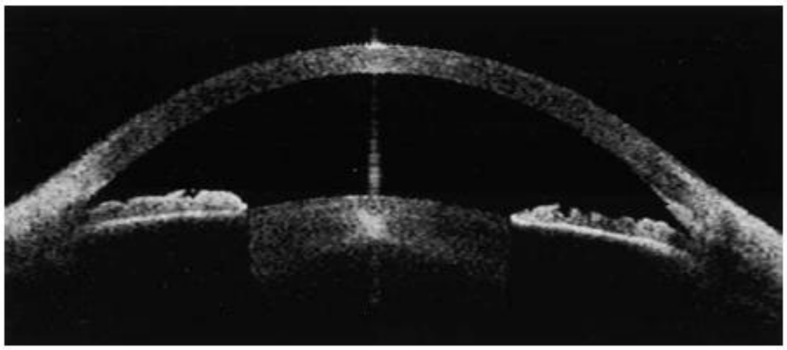
Baikoff likewise teaches an (OCT) imaging device to acquire image data of the lens, Ex.1041 at 2 (OCT allows for measurements of anterior chamber, anterior chamber depth, "corneal pachymetry, radius of curvature of the crystalline lens, ***crystalline lens thickness***, and iridocorneal angle opening"), which a POSA would have integrated into Swinger's system. *See* Section XI.A.1.a; Ex.1001 ¶¶453–55.

e. **Limitation 1.4**

Swinger discloses a control system (114) operably coupled to the laser system (100) and configured for automatic control of the system. Ex.1039 at Fig. 6 (showing operative coupling), 17:41–57 (operative connection between control system and laser system), 19:17–20 (same).

f. **Limitation 1.5**

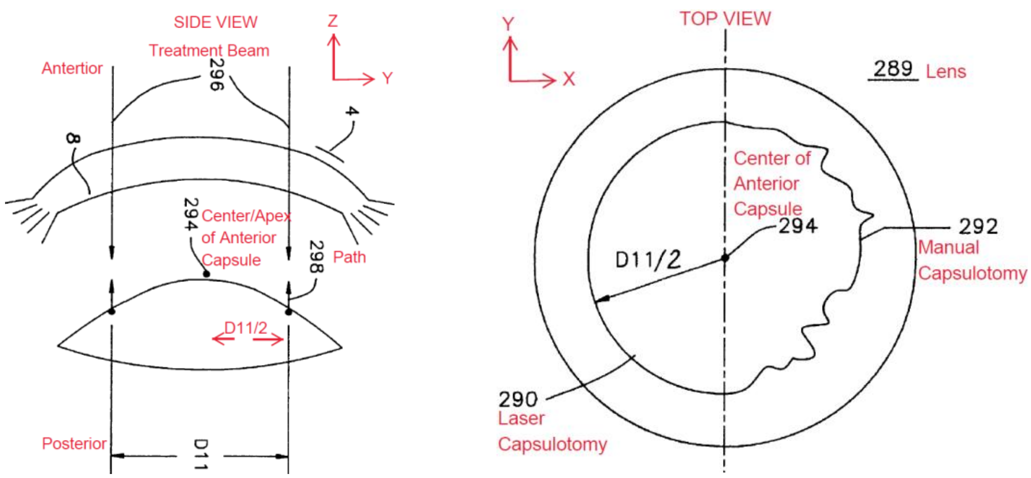
Baikoff describes the controller operates the imaging device to generate image data for ocular tissue of the patient, including the lens. *See* Ex.1041 at 2, Figs. 3, 10; Ex.1001 ¶456.



It would have been obvious to a POSA incorporating an imaging device, as taught by Baikoff, into Swinger's system to do so by operatively coupling the imaging device to Swinger's computer control unit (114) and configuring it to operate the imaging device to generate image data for the patient's crystalline lens. Ex.1001 ¶457. As explained in Section XI.A.1, the benefit of adding an OCT imaging system to Swinger lies in the ability to guide laser ablation based on imaging information. To realize this benefit, a POSA would have understood that the laser system and the imaging device must communicate with one another. Ex.1001 ¶457. As Swinger's system already comprises a computer control unit (114) that communicates among, and automates the processes of, various subsystems, a POSA would have turned to the same computer control unit, or coupled the two controllers, to facilitate communication between the laser system and imaging assembly. *Id.; see also* Ex.1001 ¶457.

g. **Limitation 1.6**

Swinger identifies landmarks within the eye and, once a reference point (294) on the lens capsule has been identified, teaches the use of the laser to perform an anterior capsulotomy (*e.g.*, an anterior capsule incision) under computer control. Ex.1039 at 34:30–35:3 (describing anterior capsulotomy).



Id. at Figs. 15B1, 15A1 (annotations added). Swinger does not disclose the use of an imaging device to identify the landmarks in order to determine an anterior-capsule incision-scanning pattern, or that the controller itself determines an anterior-capsule incision-scanning pattern based on the image data. Rather, Swinger discloses the surgeon manually sets the starting location and depth of the laser (at times, based on image data), and inputs certain cutting parameters before the controller takes over automatic control to ablate the lens capsule. *Id*. at 34:30–35:3, 35:59–66 (describing use of image data to program distances between ocular tissues).

Li teaches another OCT system that processes the OCT image data automatically to identify certain landmarks to make automatic measurements. *See* Ex.1044 at 1–2.

It would have been obvious to a POSA, upon integrating the imaging device taught by Baikoff into Swinger's laser surgical system, to configure Swinger's control system to process the image data, as taught by Li. Ex.1001 ¶¶458–60. Thus, rather than having a surgeon manually identify the reference point (294), and estimate the starting location and depth of the laser, the controller could process the image data[9] to determine these positions, and generate an anterior-capsule incision-

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[9] Claims 1 and 12 of the '648 do not require the control system to be configured to "determine an anterior capsule incision pattern," but only "process the image data" so a pattern can be determined (either by the controller or surgeon). *Compare* Ex.1030 at cl. 1 ("a control system [is] configured to . . . process the image data to determine . . . ."), *with* cl. 13 ("the control system is configured to determine . . . ."). To the extent the Board disagrees, Petitioners treat the limitation as requiring the control system be configured to make each claimed determination.

scanning pattern without requiring a surgeon to manually make measurements and program those measurements into the system. Ex.1001 ¶460. Indeed, automating a previously-manual activity using well-known components in predictable ways would have been obvious to a POSA. *See* MPEP 2144.04 (Rev. 10.2019, June 2020); Section XI.A.1.b. By combining Swinger, Baikoff, and Li, the capsulotomy is based on measured image data to achieve more precise incisions. Ex.1041 at 2; Ex.1001 ¶460.

h. **Limitation 1.7**

Swinger discloses operating a laser surgical system to scan the laser beam's focal zone to perform an anterior capsulotomy, Ex.1039 at Figs. 15B1, 15A1, 34:30–25:3 (describing anterior capsulotomy), and discloses that the controller (114) operates the laser beam and scanner, *id.* at 17:1–10, 17:41–49, 19:44–64; Fig. 6. Moreover, Swinger discloses that "[t]he cutting process can be totally computerized once the reference point on the capsule has been fixed." *Id.* at 34:52–67. In other words, Swinger's controller automatically operates the scanning system after the scanning pattern is programmed. Ex.1001 ¶461.

Although Swinger does not disclose the use of an imaging device to determine an anterior-capsule incision-scanning pattern, for the reasons discussed in Section XI.A.2.g, it would have been obvious to do so. Ex.1001 ¶462. Once the scanning pattern is determined, it would have further been obvious to configure Swinger's control system to operate the laser and the scanning assembly to follow the scanning pattern to accurately deliver the target capsulotomy incision, as shown in Fig. 15A1. Ex.1001 ¶462. And because the scanning pattern is determined based on image data, *see* Section XI.A.2.g, by following the scanning pattern, it naturally follows that positioning of the focal zone is guided by the control system based on the image data. *Id.*

3. Dependent Claim 2

Baikoff teaches an OCT imaging device. Ex.1041 at 1, 2, Fig. 10; Ex.1001 ¶463.

4. Dependent Claim 3

Baikoff teaches that the OCT system generates three-dimensional location data for the anterior capsule of the lens. Ex.1041 at 2–3, 5; Ex.1001 ¶465. A POSA would have known that OCT works by scanning a laser beam[10] relative to the lens

[10] Although the antecedent basis of "laser beam" indicates that "the laser beam" in claim 3, which is intended to image ocular tissue, is the same as "a laser beam" in claim 1, which is "configured to incise ocular tissue," a POSA would have known that a laser beam configured for surgery cannot be used for imaging, as the tissue would be ablated while imaging. Ex.1001 ¶464. Petitioners apply the

to provide the sample input (*e.g.*, the beam sent to the patient's eye and reflected back to the detector) to the OCT imaging device to generate three-dimensional location data[11] for the anterior capsule of the lens. Ex.1001 ¶465.

Thus, when incorporating an OCT system like Baikoff's into Swinger's system, it would have been obvious to a POSA to use an OCT system to scan the ocular tissue to generate three-dimensional location data and determine an anterior-capsule incision-scanning pattern based on that data, as taught by Li. Ex.1001 ¶¶466–67; Section XI.A.2.g. This would have been obvious because the anterior

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prior art as if the laser beams are distinct, either as different light sources, or different configurations of the same light source.

[11] To the extent the Board finds that claims directed to "three-dimensional location data" require true, three-dimensional OCT (though the specification does not teach true 3-D imaging), other prior art teaches the use of an OCT system, like Baikoff's, to perform true, three-dimensional OCT scans. Ex.1042 at 2 ("OCT volume scans were performed by acquiring B-scans parallel to the x-y plane at 10 μm intervals along the z-axis."), Fig. 2A–F. Although OCT in this instance was applied to chicken embryos, a POSA would have known the technique could also be used to image ocular tissue in three dimensions. Ex.1001 ¶468.

capsule is the target tissue for an anterior capsule incision, so a POSA would have known that acquiring three-dimensional location data of that target and processing it to determine a treatment pattern would result in more accurate incisions and eliminate the need for a surgeon to manually measure image data. Ex.1001 ¶¶466–67.

5. Dependent Claim 4

Swinger discloses the laser system uses "a preferred wavelength of about 400 nm to about 1900 nm," Ex.1039 at 8:43–48, which encompasses the claimed range of "800 nm [to] 1,100 nm." Swinger also discloses an embodiment that uses a laser with "an 830 nm wavelength," *id*. at 16:14–16, which falls within the claimed range. Swinger further discloses that the laser has "a low ablation energy density threshold [of] about 0.2 to 5 μJ/(10 μm)^2" and the "cross-sectional area is preferably about 10 μm in diameter," *id*. at 8:37–42. A POSA would have understood Swinger to thus be teaching a pulse energy exceeding, but not significantly higher than, 0.25 to 6.4 μJ, which overlaps with the claimed range of "between 1.0 and 30 micro joules." Ex.1001 ¶470. Moreover, Swinger discloses a pulse duration of "about 10 femptoseconds to about 2 picoseconds per pulse," *id*. at 8:39–40, which overlaps with the claimed range of "about 100 femtoseconds [to] about 10 picoseconds." Lastly, Swinger discloses that the laser beam comprises pulses having a repetition rate between "100 to 100,000 pulses per second," *id*. at 17:11–13, or 0.1 to 100 kHz, which overlaps with the claimed range of "1 kHz [to] about 200 kHz."

6. Dependent Claim 5

Swinger discloses that the anterior-capsule incision-scanning pattern is configured to scan the focal zone starting at a maximum depth and then scanning to sequentially shallower depths. Ex.1039 at 34:61–62 (for anterior capsulotomy "[t]he beam 296 is directed in a circular pattern, ***beginning posteriorly and translating anteriorly*** while following path 298, to ensure complete transection of the capsule.").

7. Dependent Claim 12

Baikoff teaches the control system images axial locations of the anterior capsule of the lens.[12] Ex.1041 at 2; Ex.1001 ¶¶473–75. A POSA would have known that these images are achieved by processing raw interference image data from the detector to generate the image comprising multiple axial locations. Ex.1001 ¶¶473.

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[12] To the extent the Board finds that the controller must "determine one or more axial locations" by automatically identifying the boundaries, which the claim does not expressly require, Li teaches the automatic identification of axial boundaries to make certain measurements. *See* Ex.1044 at 1–2.

It would have been obvious, when combining an OCT imaging device as taught by Baikoff into Swinger's system, to configure Swinger's controller (114) to process the image data and determine one or more axial (depth) locations of the anterior capsule of the lens, because identifying the anterior capsule is necessary when performing anterior capsulotomy and lens ablation. Ex.1039 at 7:51–58 (discussing ablating "interior substance" of lens for cataract surgery), 34:30–35:3 (describing anterior capsulotomy to access lens interior); Ex.1001 ¶474.

8. Dependent Claim 13

Swinger discloses that a surgeon determines the posterior cutting boundary by manually placing the ablating beam just posterior to the anterior capsule. Ex.1039 at 34:52–61 ("[T]he surgeon displaces the HeNe positioning beam ***just posteriorly to the [anterior] capsule*** [ ], or a selected distance can be programmed into the beam control computer, and photodisruption begins."). Ablation then proceeds in the posterior-to-anterior direction until the capsule is transected, at which point the controller automatically, or surgeon manually, terminates ablation. *Id*. at 34:30–67 ("The cutting process can be totally computerized once the reference point on the capsule has been fixed, or the surgeon can terminate the process when the capsule has been visibly cut for 360 degrees."). Thus, Swinger teaches the cutting boundaries for an anterior capsulotomy. Ex.1001 ¶476.

Upon incorporating an imaging system like Baikoff's into Swinger's system, it would have been obvious to a POSA to configure Swinger's controller to process image data (as taught by Li) to identify reference points, such as the boundaries of the anterior capsule. *See* Section XI.A.2.g. From there, a POSA would have known to configure the controller to determine a posterior cutting boundary (*e.g.*, the most posterior starting position of the ablating laser) defined by a preset distance posterior to the posterior surface of the capsule to ensure a complete incision is delivered while avoiding prematurely ablating the lens. *See* Ex.1001 ¶477. Such a boundary would be based on the anterior capsule axial (depth) location measured by the imaging system (*e.g.*, the axial location of the posterior capsule surface), rather than the surgeon's manual measurement. Ex.1001 ¶477.

However, to the extent the claims require a distinct "boundary" (as opposed to an axial limit of the scanning pattern) to serve as a safety check, that would have been obvious to a POSA as well, in view of Swinger. Ex.1001 ¶478.

9. Dependent Claim 14

Swinger discloses the controller is configured to terminate scanning once the incision is completed. Ex.1039 at 34:30–67. As discussed above, upon incorporating an imaging system like Baikoff's into Swinger's system, it would have been obvious to a POSA to configure Swinger's controller to process image data (as taught by Li) to measure the thickness of the capsule. *See* Section XI.A.8. From there, a POSA would have known to configure the controller to determine an anterior cutting boundary (*e.g.*, the most anterior ending position of the ablating laser) defined by a preset distance anterior to the anterior surface of the capsule to ensure a complete incision is delivered while avoiding damaging tissue anterior to the capsule. *See* Ex.1001 ¶¶479–80. Such a boundary would be based on the anterior capsule axial (depth) location measured by the imaging system (*e.g.*, the axial location of the anterior capsule surface), rather than the surgeon's manual measurement. Ex.1001 ¶¶479–80.

However, to the extent the claims require a distinct "boundary" (as opposed to an axial limit of the scanning pattern) to serve as a safety check, that would have been obvious to a POSA as well, in view of Swinger. Ex.1001 ¶481.

10. Dependent Claim 15

Swinger discloses a control system (114) configured to receive various inputs from a user input interface. Ex.1039 at 33:36–43, 34:58–67; Ex.1001 ¶482. For example, the surgeon may select an intended starting point for an incision, input this location parameter into the control system, then initiate the anterior capsulotomy in accordance with the input. Ex.1039 at 34:58–67. A POSA would have understood that Swinger discloses that the control system configures the incision-scanning pattern based in part on an input from a user interface. Ex.1001 ¶482.

B. Ground 2: Claims 6–9 Are Obvious Over Swinger in View of Baikoff, Li, and Hoppeler

1. Motivation to Combine

Whereas Swinger, Baikoff, and Li collectively teach ablating and liquefying a cataractous lens, Hoppeler specifies particular ablation patterns for ***fragmenting*** the lens.

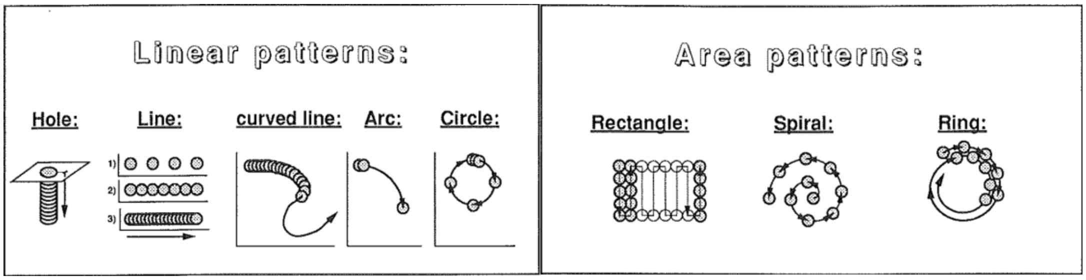
Swinger discloses that the system can ablate and liquefy a cataractous lens by applying any known scanning pattern before implanting the IOL. Ex.1039 at 23:17–25, 35:66–37:2. Although Swinger uses the term "liquefy," a POSA would have known that discrete pieces of the lens still remain after "liquefying" the lens. Ex.1001 ¶¶169–70. A POSA would have understood that, when applying an ablating laser beam to a tissue, the tissue is heated to form a plasma. *See, e.g.*, Ex.1039 at 15:59–63 (application of laser "is completely absorbed by the generated plasma").

However, a POSA would have known that a laser generally is not applied to the entire volume of the lens to convert the entirety of the lens into plasma. Indeed, scanning the entire volume of the lens would be time consuming and potentially damaging, as plasma takes up more volume and can create shocks to surrounding capsule tissue. *See, e.g.*, Ex.1039 at 15:55–63 (discussing acoustic shocks), 35:50–66 (discussing "safety zone" during lens ablation to avoid damaging lens capsule);

Ex.1001 ¶138. Instead, a POSA would have understood that "liquefying" the lens still leaves at least some discrete pieces of the lens intact. Ex.1001 ¶139.

Alternatively, to the extent Swinger cannot be read as disclosing fragmenting the lens into segments, doing so would have been obvious. *Id*. Because Swinger's system can create a pattern of tissue breakdown to segment the tissue in the context of other procedures, it follows that it can do so for lens fragmentation. *See, e.g.*, Ex.1039 at 36:15–17 ("Any pattern, aspheric or spheric, can be programmed into the computer to control the ablation geometry for a desired result."), 35:18–42 (directing the treatment beam in a pattern for phacorefractive ablation of the lens), 34:61–67 (directing the treatment beam in a circular pattern for anterior capsulorhexis); Ex.1001 ¶170.

Hoppeler shows that directing treatment beams in a pattern to segment a cataractous lens into discrete fragments in preparation for IOL placement was known. Ex.1043 at 1–4. Specifically, Hoppeler teaches a computer-controlled system for directing laser beams in various three-dimensional patterns. Figures 2 and 3 illustrate the various linear and area patterns for fragmenting cataracts. Using these patterns to fragment a cataract at lower energies and with computer-guided precision improves patient outcomes by significantly reducing phacoemulsification time in the ensuing cataract surgery. *Id.* at 4. Therefore, it would have been obvious to direct Swinger's treatment beam in a pattern that segments the lens into discrete fragments in accordance with Hoppeler, to reduce phacoemulsification time. Ex.1001 ¶170.



A POSA would have been motivated to use Swinger's system to fragment the lens into discrete pieces during cataract surgery, rather than completely liquefy it, because doing so reduces the time and energy required to prepare the cataract lens for aspiration, while significantly reducing phacoemulsification time in the ensuing cataract surgery. Ex.1043 at 4; Ex.1001 ¶170. Moreover, a POSA would have had a reasonable expectation of success in fragmenting the lens because a POSA would only need to select one of several well-known incision patterns taught by both Swinger and Hoppeler. Ex.1039 at 35:66–36:2 (discussing application of "any of several patterns as previously described" to ablate lens); Ex.1001 ¶170.

2. Dependent Claim 6

To the extent Swinger does not teach this limitation, Hoppeler teaches scanning the focal zone of the laser beam to segment the lens into discrete fragments by scanning the focal zone in a lens fragmentation scanning pattern. Ex.1043 at 4 ("The idea of fragmentation is to significantly reduce phacoemulsification [(or ultrasound)] time in the following cataract surgery.").

3. Dependent Claim 7

Hoppeler teaches that laser systems can be used to perform anterior capsulotomies, including creating a "well-defined opening of the anterior capsule of the lens . . . for aspiration of the whole lens through a small opening." Ex.1043 at 3. Hoppeler also teaches the application of lasers for cataract fragmentation in the lens. *Id*. at 4. Based on these teachings, it would have been obvious that, when using Swinger's system for lens fragmentation, the laser would fragment the lens in sizes suitable to be aspirated through the lumen of an aspiration probe in order to clear the cataractous lens as intended, so that an IOL could be implanted. Ex.1001 ¶486.

4. Dependent Claim 8

Swinger discloses several example scanning patterns comprising a linear pattern, (609, 611, 613), a planar pattern (617), a radial pattern (615), a spiral pattern (619). Ex.1039 at 20:52–65; Fig. 7.

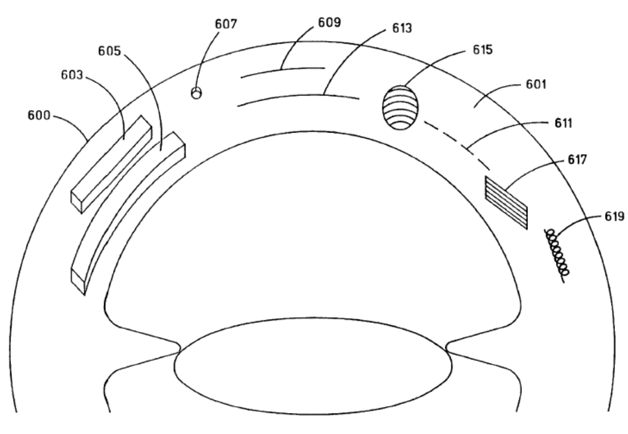


FIG. 7

Swinger also states that these patterns can be applied to any target tissue, *id.*, including the lens during a lens fragmentation procedure, *id.* at 35:66–36:2.

However, to the extent Swinger does not disclose segmenting the lens into discrete fragments, doing so would have been obvious in view of Hoppeler, who teaches several exemplary scanning patterns that can be applied to ophthalmic tissues, including to fragment the lens. Ex.1043 at 2–3, Figs. 2, 3.

5. Dependent Claim 9

Swinger discloses that the system scans the focal zone in fragmentation scanning patterns by sequentially applying laser pulses to different depths, first starting at a maximum depth and then sequentially shallower depths. Ex.1039 at 8:34–40 (pulsed laser), 36:3–5 ("Ablation proceeds from posterior to anterior to avoid absorption of the beam energy by the plasma already formed"). While Swinger describes lens ablation in the context of phacorefractive ablation (for vision correction), it would have been obvious to a POSA that all of the same teachings apply to lens fragmentation for cataract surgery, as the only difference is the amount of the lens being ablated. Ex.1001 ¶¶489–90.

Moreover, Hoppeler teaches that to fragment the lens, scanning should occur by applying laser pulses "in the depth of the lens, working its way anteriorly as gas bubbles form [to] separate the nuclear layers and prevent laser effects in the tissue behind them." Ex.1043 at 4. Hoppeler shows an example of different depth scanning patterns where laser pulses are sequentially applied at different depths. *Id.* at 3.

C. Ground 3: Claims 10 and 11 Are Obvious Over Swinger in View of Baikoff, Li, and L'Esperance

1. Motivation to Combine

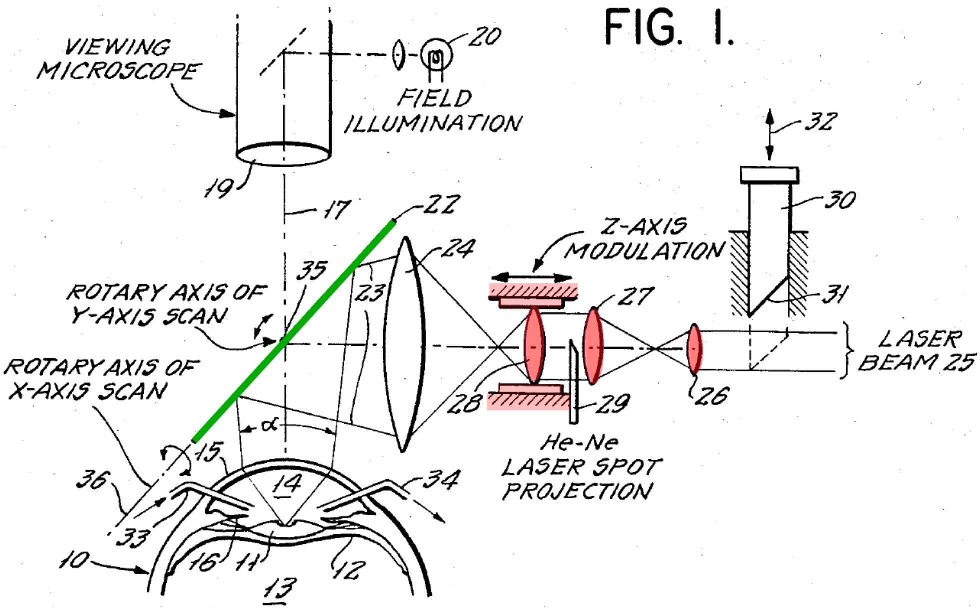
The motivation to combine Swinger with Baikoff and Li is discussed above. *See* Section XI.A.1. A POSA would have further been motivated to combine Swinger, Baikoff, and Li with L'Esperance.

While Swinger, Baikoff, and Li collectively teach a system that images and ablates ocular tissue across three-dimensional space, none specify the particular arrangement of optical components to achieve multi-directional scanning. However, various arrangements of optical and motor systems to achieve multi-directional scanning were well known for decades. Ex.1001 ¶¶182–83. Indeed, a POSA would have known that achieving two- or three-dimensional scanning merely requires moving the optical components or target in two (*e.g.*, X, Z) or three (*e.g.*, X, Y, Z) dimensions relative to each other. *Id.* ¶182.

While there are numerous ways to achieve three-dimensional scanning, a POSA would have preferred utilizing optical components to control the focal spot because their small size is suitable for precise control. *See id.* ¶186.

For instance, Swinger teaches that "[t]he laser unit 100 is of the type that can output a beam rapidly deflectable or scannable under electronic control in two dimensions to any location in an area defined by orthogonal X and Y axes," which is a transverse scanning device. Ex.1039 at 17:2–5. Swinger also teaches a z-scanner to perform incisions at prescribed depths in tissue. *See, e.g.*, *id.* at 25:62–67 ("means for scanning 74 laser spot 58 in three dimensions"); 34:52–64 (scanning laser in three dimensions to create anterior capsulotomy). Swinger does not specify how its scanning assembly effects scans in the z-dimension.

L'Esperance, however, teaches a laser surgical system for treating cataracts, similar to Swinger. Ex.1046 at Fig. 1, 1:13–15. Specifically, L'Esperance teaches a computer-controlled scanning assembly comprising a z-axis scanning device (26, 27, 28), and a transverse scanning device (22). *Id.* at 2:39–61, 3:39–4:23, 6:25–49. The z-axis scanning device changes the location of the focal zone of the laser beam (25) parallel to the direction of propagation of the laser beam, while the transverse scanning device scans the location of the focal zone transverse to the direction of propagation of the laser beam. *Id.* Furthermore, the z-axis scanning device scans the laser beam before the transverse scanning device does. *Id.*



Because Swinger implies that its system comprises a z-scanner disposed at some location along the optical path, a POSA would have naturally looked to other prior art for the specifics of such systems. Ex.1001 ¶184. It would have been obvious to a POSA, based at least on the teachings of L'Esperance, that a z-scanner could be placed prior to the transverse scanner. A POSA also would have had a reasonable expectation of success in combining L'Esperance's scanning assembly with Swinger's ophthalmic surgery system, as well as incorporating the scanning assembly functionality into Swinger's controllers, because these scanning subsystems are self-contained and interchangeable; they can be wholly incorporated into Swinger's systems to accomplish scanning along three dimensions. Ex.1001 ¶186.

2. Dependent Claim 10

L'Esperance teaches a scanning assembly comprising a z-axis scanning device (26, 27, 28) and a transverse scanning device (22), the z-axis scanning device being operable to change the location of the focal zone of the laser beam parallel to the direction of propagation of the beam (*e.g.*, along the z-axis), Ex.1046 at 2:50–55 ("[E]lement 28 is mounted for axial displacement, to permit Z-axis manipulation (or modulation) of the depth position of the focal spot . . . ."), the transverse scanning device being operable to scan the location of the focal zone transverse to the direction of propagation of the beam (*e.g.*, along the x-y plane), *id*. at 3:39–47 ("[M]irror 22 is a component part of a two-dimensional scanning system for causing the focal spot [ ] to sweep a regular pattern of coverage . . . . The swept field is thus generally transverse or normal to the axis 17 and is also therefore generally normal to the Z-axis displacement capability . . . ."), the scanning assembly being configured such that the beam is acted upon by the z-axis scanning device before being acted upon by the transverse scanning device, *id.* at Fig. 1.

3. Dependent Claim 11

L'Esperance teaches the z-axis scanning device comprises one or more movable lenses (28), and the transverse scanning device comprises one or more controllable scanning elements (22). Ex.1046 at 2:50–55, 3:39–47, Fig. 1.

D. Ground 4: Claims 1–5 and 12–15 Are Obvious Over Freedman in View of Swinger

1. Motivation to Combine

Freedman discloses a combined laser system and OCT imaging system to perform certain surgical procedures on a patient's cornea. Ex.1040 at 2:7–13. However, Freedman does not disclose using the system to perform an anterior capsulotomy, or the specific parameters of the laser system for tissue ablation.

Swinger, however, teaches that laser surgical systems like Freedman's are suitable for numerous types of surgical procedures. Ex.1001 ¶163. Thus, a POSA would have known that Freedman's combined OCT-and-laser-surgery system is not limited to corneal procedures, but can be used for a number of other ophthalmic-surgery procedures, including cataract surgery. Ex.1001 ¶162. When using Freedman's system for other surgical procedures involving tissues other than the cornea, it would have been obvious to a POSA to use Freedman's OCT imaging system to image the target tissue. *Id*. Indeed, a POSA would have known that Freedman's OCT imaging system is fully capable of imaging any target tissue that other OCT systems are capable of imaging, including the cornea, anterior chamber, iris, and lens. Ex.1001 ¶164. Thus, when using Freedman's system to perform an anterior capsulotomy (as taught by Swinger), a POSA would have found it obvious to use Freedman's OCT system to image at least a part of the lens. *Id*.

Swinger also teaches specific parameters intended to provide a "low energy density" laser that "inflict[s] less trauma to the underlying tissue" than prior-art lasers. Ex.1039 at 2:46–50. Freedman's failure to disclose specific parameters for the surgical laser naturally would have driven a POSA to look to other prior art, such as Swinger, that teaches such parameters. Ex.1001 ¶166. A POSA would have found it obvious to use the parameters taught by Swinger to perform ophthalmic surgeries, such as anterior capsulotomies, to induce less trauma to surrounding eye tissues. Ex.1039 at 7:50–8:6. A POSA also would have had a reasonable expectation of success in using Swinger's laser parameters in the system disclosed by Freedman because all that is required is a particular laser source and programming to control the pulse rate. Ex.1001 ¶167.

2. Independent Claim 1

a. **Limitation 1P**

Freedman discloses a laser surgical system (14) for making incisions in ocular tissue. Ex.1040 at 5:29–40. Although Freedman does not expressly disclose using the system for a cataract surgical procedure, Freedman states the system is suitable for various surgical procedures. *See id.* at 1:23–25 ("[b]iomedical applications" of lasers include "clearing cataracts").

Swinger discloses another laser surgical system, like Freedman's, for making incisions in ocular tissue during a cataract procedure. Ex.1039 at Figs. 6, 15A1, 15B1, 16:60–20:34 (disclosing the system), 20:49–21:19 (disclosing incisions performed using the system).

Thus, it would have been obvious to a POSA to use Freedman's multifunctional ophthalmic-surgery system for cataract surgery. Ex.1001 ¶¶162, 493.

b. **Limitation 1.1**

Freedman's system comprises a laser system (*e.g.*, 52), Ex.1040 at 5:37–40 (noting use of "[a]blating laser . . . to form an incision"), further comprising a scanning assembly to direct a focal zone of the laser beam to locations within a patient's eye. Ex.1040 at 5:49–52 (describing "displacement means 62 ***displaces*** ablating light beam 58 ***across the cornea***"), cl. 6 (describing a method of "detecting the limits of a surface plan of biological tissue by ***scanning*** the tissue. . . ."); Ex.1001 ¶496.

c. **Limitation 1.2**

Freedman comprises a laser (54) operable to generate a laser beam (58) configured to incise ocular tissue. Ex.1040 at 5:37–40 ("Ablating laser device 52 includes [a] laser generator . . . for applying a laser beam from the laser generator . . . to an ablating target region 60 of the cornea 12 to form an incision.").

d. **Limitation 1.3**

Freedman discloses an imaging device (16 and 18, or 66) configured to acquire image data of at least a portion of the eye. Ex.1040 at 2:7–9 ("method and device for laser surgery wherein a treatment laser beam is controlled by interferometry, preferably by optical coherence tomography."), 4:46–50, 6:12–19, cl. 3, Figs. 1, 3. When using Freedman's system to perform an anterior capsulotomy and lens fragmentation, *see* Section XI.D.1, it would have been obvious to a POSA to use Freedman's imaging system to image at least a portion of the lens. Ex.1001 ¶¶497–98.

e. **Limitation 1.4**

Freedman discloses a control system (48) operably coupled to the laser system (52, 54, and 56), and programmed for automatic control of the system. Ex.1040 at Figs. 1, 3, 5:29–36 (discussing function of processor (48) operatively connected to laser and photodetector (46) to construct an image), 6:66–7:8 (same), 8:30–51 (discussing specifics of processor (48) to image target tissue).

f. **Limitation 1.5**

Freedman discloses a control system (48) configured to operate the imaging device (16, 18, or 66) to generate image data of the patient's ocular tissue. Ex.1040 at Figs. 1, 3, 5:29–36 (processor (48) operatively connected to components including photodetector (98) to construct an image), 8:30–51, Fig 3.

When using Freedman's system to perform an anterior capsulotomy and lens fragmentation, *see* Section XI.D.1, it would have been obvious to a POSA to use Freedman's OCT imaging system to image the lens. Ex.1001 ¶500.

g. **Limitation 1.6**

Freedman discloses the controller is configured to process image data to determine an ablating-scanning pattern for scanning a focal zone of the laser beam to perform an ophthalmic surgical procedure. Ex.1040 at 5:60–67, ("the processor 48 constructs an ablating plan for ablating incisions into the target . . . . Processor 48 controls the ablating laser device 52 according to the ablating plan"), 8:41–46 ("The computer can construct an ablating plan by comparing information from the interferometer [(imaging device)] 16 or 66 to a standard of information . . . ."), 9:21–26 (imaging device applicable to "other optically transmissive tissue"). When using Freedman's system to perform an anterior capsulotomy, *see* Section XI.D.1, a POSA would have known to configure Freedman's controller to process the image data from the lens to determine an anterior-capsule-scanning pattern, as taught by Swinger. Ex.1001 ¶501.

h. **Limitation 1.7**

Freedman discloses operating the laser and scanning assembly to scan the focal zone of the laser beam in the scanning pattern to create an incision, wherein positioning of the focal zone is determined in part by the control system based on the image data. Ex.1040 at Figs. 8:66–9:2 ("Ablation can be controlled by both setting the ablation according to the plan and adjusting the ablation during laser surgery by comparing the ablation to the plan and adjusting the ablation according to the comparing step."). When using Freedman's system to perform an anterior capsulotomy and lens fragmentation, *see* Section XI.D.1, it would have been obvious to a POSA that the laser would scan the laser in the anterior-capsule incision-scanning pattern to perform an anterior capsule incision. Ex.1001 ¶502. And because the scanning pattern is determined based on image data, *see* Section XI.D.2.g, by following the scanning pattern, it naturally follows that positioning of the focal zone is guided by the control system based on the image data. *Id.*

3. Dependent Claim 2

Freedman discloses that the imaging device comprises an OCT imaging device. Ex.1040 at 2:7–9, 4:58–5:28, cl. 3.

4. Dependent Claim 3

Freedman discloses that the control system is configured to scan the laser beam[13] relative to the ocular tissue to provide the sample input to the OCT imaging device, Ex.1040 at 5:10–36 ("interference light beam" is used as a sample input to image data), to generate three-dimensional location data of the ocular tissue; and the control system is configured to determine the scanning pattern based on the three-dimensional data, *id*. at 4:58–5:36 (after receiving interference light, "[p]rocessor 48 can construct a virtual or real time display three dimensional image of the cornea

[13] *See supra* n.10.

film from the spatialgram and construct an ablating plan.”).[14] Although Freedman does not expressly disclose that the controller also controls the scanning assembly to scan the laser beam, a POSA would have known that Freedman’s controller necessarily controls a scanning assembly. Ex.1001 ¶¶503–5; Ex.1040 at 4:58–5:36 (describing imaging of three-dimensional image of the cornea), cl. 6 (describing scanning).

5. Dependent Claim 4

Swinger discloses exemplary beam parameters for anterior capsulotomies. *See* Section XI.A.5. It would have been obvious to use the parameters taught by Swinger in Freedman’s system. *See* Section XI.D.1.

[14] To the extent the Board finds that claims directed to “three-dimensional location data” require true, three-dimensional OCT (though the specification does not teach true 3-D imaging), Freedman discloses another embodiment that accomplishes three-dimensional OCT through a series of X-Z planar scans along the y-axis. Ex.1040 at 7:15–60, Fig. 3. A POSA would have known this method could be employed with the first embodiment (Fig. 1) to generate true, three-dimensional OCT images. Ex.1001 ¶506.

6. Dependent Claim 5

Swinger discloses the anterior-capsule incision-scanning pattern is configured to scan the focal zone at different depths, starting at a maximum depth and then scanning to sequentially shallower depths. Ex.1039 at 34:61–62. When using Freedman's system to perform an anterior capsulotomy, *see* Section XI.D.1, a POSA would have known to configure Freedman's controller to begin scanning at a maximum depth (*e.g.*, most posterior) to sequentially shallower depths (*e.g.*, in the posterior-to-anterior direction) so that the beam is continuously moving into unablated tissue, as taught by Swinger. *See, e.g.*, Ex.1039 at 36:3–5.

7. Dependent Claim 12

Freedman discloses the control system (48) is configured to process the image data to determine tissue boundaries at different axial locations or depths. Ex.1040 at 4:33–45 ("[A] sequence of detection can be used to evaluate the thickness and the boundary state of each layer of the cornea or other biological tissue."). Thus, Freedman's controller and imaging device process image data to determine one or more axial locations of the target tissue. Ex.1001 ¶509–10. When using Freedman's system to perform an anterior capsulotomy, *see* Section XI.D.1, it would have been obvious to a POSA to process the image data to determine one or more axial locations of the lens, because that is the target tissue of the anterior capsulotomy. Ex.1001 ¶¶509–10.

8. Dependent Claim 13

Freedman discloses the imaging device is capable of imaging both the posterior and anterior boundaries of a target ocular tissue, and that the ablation plan is based on the boundaries identified by the image data. Ex.1040 at 4:33–35 (image data comprises evaluation of boundary states), 5:29–36 (creation of "ablating plan" based on image data).

Swinger discloses that, when performing an anterior capsulotomy, a surgeon determines the posterior cutting boundary by manually placing the ablating beam just posterior to the anterior capsule. *See* Section XI.A.8.

When using Freedman's system to perform an anterior capsulotomy, *see* Section XI.D.1, a POSA would have known, consistent with Swinger, to configure the control system to determine a posterior cutting boundary (*e.g.*, the initial reference point just posterior to the anterior capsule) to ensure a complete incision is delivered while avoiding prematurely ablating the lens. Ex.1001 ¶¶512–13.

However, to the extent the claims require a distinct "boundary" (as opposed to an axial limit of the scanning pattern) to serve as a safety check, that would have been obvious to a POSA as well, in view of Swinger. *Id.* ¶514.

9. Dependent Claim 14

Freedman discloses the imaging device is capable of imaging both the posterior and anterior boundaries of a target ocular tissue, and that the ablation plan is based on the boundaries identified by the image data. Ex.1040 at 4:33–35 (noting image data comprises evaluation of boundary states), 5:29–36 (describing creation of "ablating plan" based on image data).

Swinger discloses that, when performing an anterior capsulotomy, ablation terminates anterior to the capsule once the incision is complete. *See* Section XI.A.8.

When using Freedman's system to perform an anterior capsulotomy, *see* Section XI.D.1, a POSA would have known, consistent with Swinger, to configure the control system to determine an anterior cutting boundary (*e.g.*, the ending position of the beam just anterior to the anterior capsule) to ensure a complete incision is delivered while avoiding damaging tissue anterior to the capsule. Ex.1001 ¶¶516–17. And as discussed with respect to Dependent Claim 13, the scanning pattern and boundaries would have been determined based on image data from one or more anterior capsule axial locations.

However, to the extent the claims require a distinct "boundary" (as opposed to an axial limit of the scanning pattern) to serve as a safety check, that would have been obvious to a POSA as well, in view of Swinger. *Id.* ¶517.

10. Dependent Claim 15

Freedman discloses that the control system can configure the incision-scanning pattern based in part on an input from a user interface. Ex.1040 at 5:60–67 ("[T]he processor 48 constructs an ablating plan for ablating incisions into the target [tissue] or the processor 48 can construct a plan by accepting real time input, for example from a surgeon responding to a signal in the form of an image visually displayed on the screen of a computer. Processor 48 controls the ablating laser device 52 according to the ablating plan. . . ."). Although Freedman's example focuses on corneal incisions rather than an anterior capsule incision, it would have been obvious to apply the general teachings of Freedman to anterior capsule incisions as well, as taught by Swinger. Ex.1001 ¶519.

E. Ground 5: Claims 6–9 Are Obvious Over Freedman in View of Swinger and Hoppeler

1. Motivation to Combine

Whereas Freedman in view of Swinger broadly disclose ablating and liquefying a cataractous lens, Hoppeler specifies particular ablation patterns for ***fragmenting*** the lens, as discussed above. *See* Section XI.B.1.

A POSA would have been motivated to use Freedman's system to fragment the lens into discrete pieces during cataract surgery, as Hoppeler does, because doing so reduces the time and energy required to prepare the cataractous lens for aspiration, while still significantly reducing phacoemulsification time in the ensuing cataract surgery. Ex.1043 at 4; Ex.1001 ¶¶172–73. Moreover, a POSA would have had a reasonable expectation of success in fragmenting the lens because a POSA would only need to select one of several well-known incision patterns taught by both

Swinger and Hoppeler. Ex.1039 at 35:66–36:2 (discussing application of "any of several patterns as previously described" to ablate lens); Ex.1001 ¶173.

2. Dependent Claim 6

To the extent Swinger does not teach this limitation, Hoppeler teaches segmenting the lens into discrete fragments. *See* Section XI.B.2.

3. Dependent Claim 7

Hoppeler teaches discrete fragments sized to be removable through a lumen of an ophthalmic aspiration probe. *See* Section XI.B.3. It would have been obvious that, when using Freedman's system for lens fragmentation, the laser would fragment the lens in sizes suitable to be aspirated by a probe in order to clear the cataractous lens as intended, so that an IOL could be implanted. Ex.1001 ¶522.

4. Dependent Claim 8

Swinger and Hoppeler both teach exemplary scanning patterns including at least a linear pattern, a planar pattern, a radial pattern, and a spiral pattern. *See* Section XI.B.4. Based on these teachings, it would have been obvious that, when using Freedman's system for lens fragmentation, the laser would fragment the lens using any known fragmentation scanning pattern, including those taught by Swinger and Hoppeler. Ex.1001 ¶523.

5. Dependent Claim 9

Freedman discloses that scanning occurs in three dimensions, which necessarily requires scanning at a plurality of depths, but does not expressly teach scanning the lens by sequentially applying laser pulses to different depths of the lens, starting with a maximum depth. However, Swinger and Hoppeler both teach laser-scanning systems that apply laser pulses in the posterior-to-anterior direction (*e.g.*, starting at a maximum depth). *See* Section XI.B.5. When using Freedman's system for lens fragmentation, it would have been obvious to a POSA that ablation would start by applying laser pulses at a maximum depth, and sequentially applying pulses at shallower depths, so that the beam always moves into unablated tissue, as taught by Swinger. *See id.*; Ex.1001 ¶524.

F. Ground 6: Claims 10 and 11 Are Obvious Over Freedman in View of Swinger and L'Esperance

1. Motivation to Combine

While Freedman and Swinger teach systems that ablate and/or image ocular tissue across three-dimensional space, neither specifies the particular arrangement of optical components to achieve multi-directional scanning. Freedman, for instance, describes that the ablating laser is translated by "displacement means," but does not specify what constitutes the "displacement means." Ex.1040 at 5:49–53. Nor does Freedman specify how the imaging beam is displaced. Likewise, while Swinger teaches that the system can achieve three-dimensional scanning, Swinger does not specifically disclose how its scanning assembly effects scans in the z-dimension. *See* Section XI.C.1. However, L'Esperance teaches a specific arrangement of optical components to achieve three-dimensional scanning. *See id*.

Because Freedman and Swinger both imply that their system comprise three-dimensional scanning systems, a POSA would have naturally looked to other prior art for the specifics of such systems. Ex.1001 ¶188. It would have been obvious to a POSA, based at least on the teachings of L'Esperance, to utilize a z-scanner placed prior to a transverse scanner. A POSA also would have had a reasonable expectation of success in combining L'Esperance's scanning assembly with Freedman's ophthalmic surgery system, as well as incorporating the scanning assembly functionality into Freedman's controllers, because these scanning subsystems are self-contained and interchangeable; they can be wholly incorporated into Freedman's systems to accomplish scanning along three dimensions. Ex.1001 ¶189.

2. Dependent Claim 10

For the reasons discussed above, L'Esperance teaches a scanning assembly comprising a z-axis scanning device and transverse scanning device. *See* Section XI.C.2.

3. Dependent Claim 11

For the reasons discussed above, L'Esperance teaches the z-axis scanning device comprises one or more movable lenses, and transverse scanning device comprises one or more controllable scanning elements. *See* Section XI.C.3.

XII. SECONDARY CONSIDERATIONS OF NON-OBVIOUSNESS

Although PO may contend that its Catalys® Precision Laser System practices the Challenged Patent, has found commercial success, and received industry praise, Ex.1096 at 46–47, such evidence of secondary considerations does not weigh in favor of non-obviousness. Critically, PO cannot establish a nexus between its product and the Challenged Claims. *ClassCo, Inc., v. Apple, Inc.*, 838 F.3d 1214, 1220 (Fed. Cir. 2016) (discussing nexus requirement). First, no industry praise can be tied to any particular feature of the Catalys; the R&D 100 award was granted for the system generally with no explanation for why it was given, and the Red Herring 100 award is an award granted to startup companies, not products, which was granted to OptiMedica, the original developer of Catalys. Moreover, PO cannot identify any compelling commercial success attributable to any particular claimed feature. For this reason alone, evidence of commercial success is not probative. But even if PO could establish evidence of secondary considerations, it would not outweigh the strong showing of obviousness.

XIII. CONCLUSION

For the foregoing reasons, Alcon respectfully requests that the Board institute *inter partes* review and cancel the Challenged Claims.

Date: April 23, 2021

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This Petition complies with the type-volume limitations as mandated in 37 C.F.R. § 42.24. According to the word processing system used to prepare this document, the brief contains 13,967 (14,000 limit) words.

/s/ *Noah S. Frank*
Noah S. Frank

CERTIFICATE OF SERVICE

In compliance with 37 C.F.R. §§ 42.105, 42.6(e), the undersigned hereby certifies that a copy of the foregoing Petition and supporting exhibits were served on the 23nd day of April, 2021, via Federal Express® directed to PO at the correspondence address of record:

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TABLE OF EXHIBITS

Exhibit No.	Description
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Exhibit 1040	U.S. Patent No. 6,454,761 (“Freedman”)
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Exhibit 1050	Yoshiaki Yasuno et al., *Three-Dimensional And High-Speed Swept-Source Optical Coherence Tomography For In Vivo Investigation Of Human Anterior Eye Segments*, 13 Opt. Express 10652 (2005) (“Yasuno”)
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Exhibit 1054	Joseph Izatt et al., *Micrometer-Scale Resolution Imaging Of The Anterior Eye In Vivo With Optical Coherence Tomography*, 112(12) Arch. Ophthalmol. 1584 (1994) ("Izatt")
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Exhibit 1059	Donna J. Williams et. al., *A Fast Algorithm For Active Contours And Curvature Estimation*, 55(1) CVGIP: Image Understanding 14 (1992) ("Williams")
Exhibit 1060	Volker Westphal et al., *Correction Of Geometric And Refractive Image Distortions In Optical Coherence Tomography Applying Fermat's Principle*, 10 Opt. Express 397 (2002) ("Westphal")
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Exhibit 1065	P.M. Woodward et al., *Anterior Capsulotomy Using A Neodymium YAG Laser*, 16 Annals of Ophthalmology 534 (1984)

Exhibit 1066	D.S. Aron-Rosa et al., *Use Of Pulsed Ps Ndyag Laser In 6,664 Cases*, 10 Am. Intra-Ocular Implant Soc. J. 35 (1984)
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Exhibit 1069	Michael Moretti, *Solidstate Refractive Lasers Evolve Slowly*, 7 Refractive & Corneal Surgery 273 (1991)
Exhibit 1070	A. Casumano et al., *Three-Dimensional Ultrasound Imaging: Clinical Applications*, 105 Ophthalmology 300 (1998) ("Casumano")
Exhibit 1071	Stephen A. Boppart et al., *High-Resolution Optical Coherence Tomography-Guided Laser Ablation of Surgical Tissue*, 82 J. of Surgical Research, 275 (1998) ("Boppart II")
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Exhibit 1101	District Court Jury Trial Notice
Exhibit 1102	Georges Baikoff et al., *Assessment Of Capsular Block Syndrome With Anterior Segment Optical Coherence Tomography*, 30 JCRS 2448 (2004) ("Baikoff III")
Exhibit 1103	RESERVED