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.

IPR2021-00846
U.S. Patent No. 10,376,356

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

Petitioners respectfully request that the Board correct a critical mistake committed during prosecution of U.S. Patent No. 10,376,356 ("'356"). The '356 claims are directed to a laser-scanning system to perform ophthalmic (eye) surgeries, yet Patent Owner ("PO") never alleged the system itself was novel. Nor could it, as the system was disclosed in PO's own prior art (among many other references). Rather, PO argued the point of novelty was "programming" the system to apply certain incisions to the eye, specifically "relaxation incisions" that extended for less-than-a-full circle. During examination, the Examiner erroneously relied on the wrong embodiment of a prior art reference (Ex.1021 at Fig. 15R) that used a laser system to deliver a full-circle relaxation incision. The Examiner entirely missed the fact that another embodiment in the same reference (Ex.1021 at Fig. 15W) expressly taught the claimed "relaxation incisions" that extended in less-than-a-full circle.

But even overlooking this error, Swinger is not the only prior-art reference that taught such incisions. Indeed, Petitioners identify additional references, which were not before the Examiner, that show the claimed incisions had been applied manually ***for over a century***. At bottom, PO sought a patent for automating the delivery of well-known incisions using a known laser system. Had the Examiner appreciated that the '356's claims are directed to nothing more than programming a known system to apply known incisions, the claims would never have been allowed.

The Examiner's error affects not just the '356, but also related Patent No. 10,709,548 ("'548"). Both patents are directed to the same system and well-known incisions, and the same Examiner allowed both patents when the claims were amended to require incisions that were less than a full circle. The error committed during prosecution of the '356 was the exact same error committed during prosecution of the '548: a failure to appreciate the full extent of the prior art and maintain what should have been a straightforward rejection.[1]

PO's assertion of the '356 against all 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 Delaware 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. An IPR 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

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[1] Petitioners also challenge two other patents in this family, U.S. Patent Nos. 9,233,023 and 9,233,024, which are also directed to delivering well-known incisions using modern (but known) machines.

request *inter partes* review of ’356 claims 1–15, 17–19 and 21–24 (“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 ’356 against all Petitioners except Alcon Inc. in the Delaware Litigation. Alcon is concurrently filing IPR petitions for four other patents in the same family as the ’356, all of which are asserted in the Delaware Litigation: U.S. Patent Nos. 9,233,023; 9,233,024; 10,109,548.[2] This case may affect, or be affected by, the Delaware Litigation.

[2] 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 ’356 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, 17–19, and 21–24 of the ’356.

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

Alcon challenges the claims based on the following references:[3]

1. U.S. Patent Application No. 2006/0195076 to Blumenkranz et al. (“Blumenkranz”), filed January 9, 2006, is prior art under § 102(b). Blumenkranz was before the USPTO during prosecution of the ’356, but was not applied by the Examiner.

2. Mitchell P. Weikert & Douglas D. Koch, *Refractive Keratotomy: Does It Have a Future Role in Refractive Surgery?*, CATARACT AND REFRACTIVE SURGERY

[3] Each reference qualifies as prior art under 35 U.S.C. §102 regardless of whether the ’356 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.

217–234 (2005) ("Weikert"). Weikert was not before the USPTO during prosecution of the '356.

3. 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 '356.

4. U.S. Patent Application No. 2004/0066489 to Benedikt et al. ("Benedikt"), filed July 18, 2003 and published April 8, 2004, is prior art under § 102(b). Benedikt was not before the USPTO during prosecution of the '356.

5. 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 '356, but was not applied by the Examiner.

Alcon requests IPR on the following grounds:

Ground	Basis	Claims	Reference(s)
1	§ 103	1–2, 4–14, 17–19, 21–24	Blumenkranz in view of Weikert
2	§ 103	2–3, 14–15	Blumenkranz in view of Weikert and Benedikt
3	§ 103	1–8, 14–15, 17–19, 21	Swinger in view of Weikert and Benedikt
4	§ 103	9–12, 22–24	Swinger in view of Weikert, Benedikt, 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.

"cataract incision": PO never argued during prosecution of the '356 that the ability to create "cataract" incisions imparts any distinguishing features over prior art capable of creating incisions in corneal tissue. Ex.1012 at 921 (Examiner found that Sumiya's system for ablating "corneal tissue" teaches "a delivery system for delivering the laser beam to the target tissue to form a cataract incision" and Applicant did not traverse). This is not surprising since the '356 itself broadly defines "cataract incision" as an "incision to allow access for the lens removal instrumentation." Ex.1010 at 10:30–56. Clearly, an intention to use a cut for cataract surgery does not change the cut itself, but, even more importantly, the "cataract" modifier fails to impart any structure that could patentably distinguish the claimed system from prior-art ophthalmic-surgery systems. For example, independent claim 1 recites a structurally complete system for treating target tissue in the cornea, including: (i) a laser source, (ii) an OCT device, (iii) a delivery system, (iv) a scanner, and (v) a controller[4] with programming to make particular incisions. These structures, however, are shared by multifunctional ophthalmic-surgery systems; there is no claimed structure exclusive to performing a "cataract incision." These incisions are not specific to cataract surgery.

The claims' so-called "cataract incisions" are nothing more than incisions that penetrate outer layers of the eye, specifically the cornea, limbus, or sclera, to permit access to the eye chamber. *Id.* at 11:19–43. The "relaxation incisions," likewise made in the cornea or limbus, adjust eye shape to correct refractive error. *Id.* Each incision type can be used in non-cataract procedures, such as corneal transplants (penetrating keratoplasty), lens replacements not spurred by cataracts, glaucoma surgery, and insertion of phakic lenses. Ex.1001 ¶59.

Thus, the word "***cataract***" should not be construed as providing any patentable weight. Nonetheless, Petitioners' prior art teaches scanning systems that could be used for "cataract surgery," so, regardless, the claims are still invalid.

[4] Petitioners reserve the right to challenge the claim term "the controller … programmed to deliver" the first and second treatment patterns as an indefinite means-plus-function term. Nonetheless, Petitioners will apply the prior art as if the claims are definite.

"***a delivery system for delivering the laser beam to the target tissue to form a cataract incision.***" Independent claims 1 and 13 recite a delivery system that delivers a treatment beam "to form a cataract incision." "To form a cataract incision," however, is a functional limitation wrapped in a structural claim, and should not be given patentable weight; it is merely one (of many) possible results that may be achieved by delivering a treatment beam. *See* MPEP 2111.04. At bottom, the claims fail to identify any structure to specifically "form a cataract incision," or explain how the recitation "to form a cataract incision" otherwise implicates or affects the expressly claimed structure. For instance, the claims do not require that the controller is ***configured***, or contains ***programming instructions***, to form a cataract incision and therefore do not contain any structural element.

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 in Section XI. Alcon submits the declaration of Holger Lubatschowski, 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 ’356 Has Not Been Subject to a Prior Petition

The ’356 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 ’356, 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 Blumenkranz and Swinger as base references. While Blumenkranz was never applied, Swinger was, yet was inexplicably distinguished as "fail[ing] to disclose wherein each of the relaxation incision extends in an annular direction for a predetermined length less than a full circle." Ex.1012 at 1430–31. This is wrong, as Swinger plainly shows relaxation incisions (250) that are less than a full circle. *See* Ex.1021 at Fig. 15W, 33:7–23. In any event, the grounds presented in this Petition identify additional art (*e.g.*, Weikert) showing that arcuate, less-than-full-circle relaxation incisions were well-known since the late 1800s.

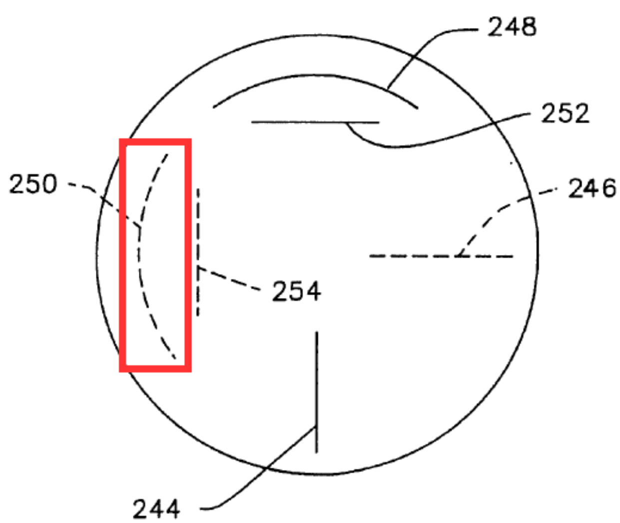
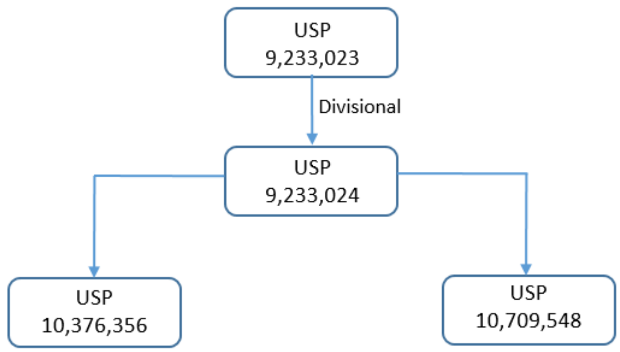


FIG. 15W

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

2. The '356 Claims Are a Subset of Claims Directed to Substantially Overlapping Subject Matter

The '356 issued from application No. 14/668,677 ("'677 application") as part of a family of five applications, four of which issued as patents (the "Culbertson Patents") and are subject to IPR petitions, including this one and the parent '023.



The subject-matter claimed in the four Culbertson patents substantially overlaps. All patents present claims directed to known laser-scanning-system components and the delivery of one or more treatment patterns for forming incisions in optical tissue. The '356 and the '548, in particular, each claim a laser scanning system with OCT that generates treatment patterns including cuts having a less than full circle arcuate extent. In the '356, such cuts are partially penetrating relaxation incisions scanned anteriorly, and in the '548, such cuts are fully penetrating cataract incisions with a beveled edge. The error originating during examination of the '356 recurred during examination of the '548.[5]

The Board is best situated to efficiently and fairly address the Examiner's repeated error that permitted these patents 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, Inc.* 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).

Factor 1: 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

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[5] The other two Culbertson Patents Petitioners are challenging—the '023 and '024—likewise were allowed as a consequence of an Examiner error. Those patents' claimed systems and methods were allowed because the Examiner erred in giving an amendment to the preamble patentable weight.

§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).

Factor 2: 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.1055. 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.1056; *see Apple Inc. v. Seven Networks*, IPR2020-00235, Paper 10 at 8–9 (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*, Paper 15 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*, Paper 11 at 9–12 "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 is scheduled for December 2021. Ex.1056. *See MED-EL Elektromedizinische Gerate 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.1056; *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.1057. 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. Moreover, Petitioners are challenging claims 13–15, 17–19, and 21–24, which are not asserted in the Delaware Litigation.

Factor 5: While four Petitioners are defendants in the Delaware Litigation, Alcon Inc. is not. 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).

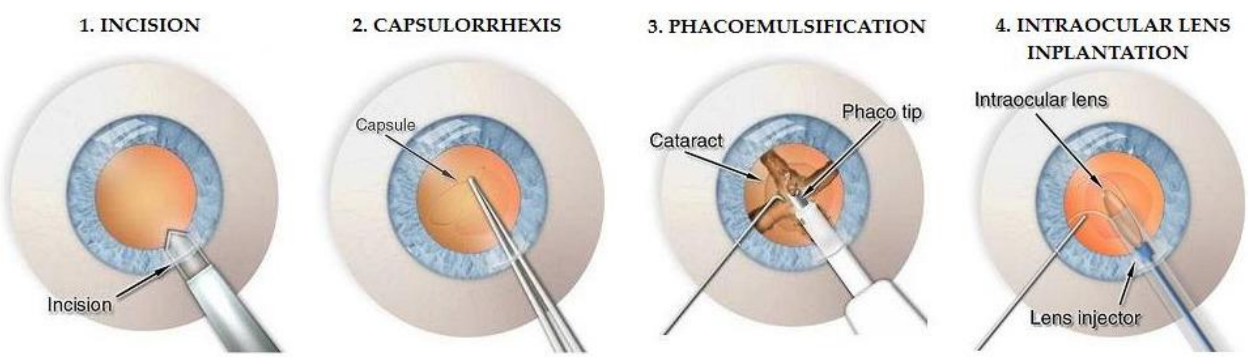
VII. BACKGROUND OF THE TECHNOLOGY

A. Anterior-Segment Surgery

Numerous ophthalmic procedures require access to the anterior chamber of the eye, which is accomplished by making incisions into the corneal or other exterior tissue of the eye, such as the sclera or limbus. Such procedures include, but are not limited to cataract surgery, including refractive lens exchange surgery, corneal transplants (penetrating keratoplasty), glaucoma surgery to increase aqueous outflow or insert valves, or the insertion of phakic anterior chamber lenses (so called ICLs). Ex.1001 ¶22.

1. 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"). A typical cataract surgery comprises several steps: (1) create an incision in the cornea or other exterior tissue, such as the sclera, (2) correct for astigmatism, either pre-existing or surgery-induced from the surgical incision, (3) create an opening in the anterior lens capsule, (4) break apart the lens, either by cutting it into pieces or using ultrasonic phacoemulsification, and remove the lens, and (5) implant the IOL into the lens capsule. Ex.1001 ¶23. This video and the figures below illustrate an exemplary procedure.



2. Correcting Astigmatism

A problem arises when surgeons incise the cornea (or other exterior tissues), though. "[C]orneal incisions (CCIs) made during cataract surgery have been known to induce astigmatism by flattening the meridian on which the incision was centered," and the amount of astigmatism "varies with incision length and placement." Ex.1019 at 11. In other words, any incision in the exterior of the eye changes its shape. Ex.1001 ¶24.

In order to correct these surgery-induced astigmatisms, surgeons have applied additional incisions, termed "relaxing incisions," to the eye to correct the eye's shape. Ex.1019 at 11. These include "partial thickness" incisions, which do not penetrate the eye, but instead allow the corneal tissue to relax to a corrected state. Ex.1001 ¶24.

B. Lasers in Ocular Surgery

The development of laser technology and the benefits it provides to surgeons dates back decades. In the 1970s, scientists had begun exploring the replacement of manual blades with automatic laser systems, and recognized their application for ophthalmic surgical procedures. Ex.1001 ¶25.

By the 1980s, "[u]ltrashort pulsed lasers [] established themselves as the modality of choice for many surgical procedures where propagating thermal effects are to be suppressed," including for cataract surgery. *See* Ex.1025 at 2:11–14. These surgical lasers deliver incisions by emitting short pulses of light at a rapid rate—on the picosecond (10^{-12} s) or femtosecond (10^{-15} s) scale—to disrupt and ablate target tissue. Ex.1001 ¶25. The use of lasers allowed surgeons to deliver incisions with far superior accuracy, and less unintended damage, than prior manual processes. *Id.* ¶26.

In the ophthalmic field, lasers were quickly adopted and used for several surgical procedures. For instance, surgeons performed anterior capsulotomies—part of a cataract procedure where the capsule of the eye that houses the lens is incised—with lasers. *Id.* ¶27.

Scientists had also recognized the benefits of reducing the pulse length of surgical laser beams. By the turn of the twenty-first century, picosecond laser systems had been widely displaced by femtosecond laser systems. *Id.* ¶28. In 2001, the first femtosecond laser was FDA-approved for the "creation of a corneal flap in patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the cornea." *Id.*

VIII. THE '356

The '356 issued from the '677 application, filed on March 25, 2015, and claims priority to application No. 12/048,186, filed on March 13, 2008. Ex.1010. Because the '186 application was filed before March 16, 2013, the '356's 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).[6]

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[6] To the extent any limitation in the '356 are unsupported by the original specification, and that the AIA governs, the outcome remains the same as all art

A. Alleged Problem

In order to access the cataractous lens, the '356 explains that a complete cut of the cornea, limbus, or the sclera (referred to as a "cataract incision" in the '356 specification) may not be desirable when, for example, the cataract incision is made "in an unsterile field where opening the eye to the environment poses further risks of endophthalmitis, for example." Ex.1010 at 10:30–45. The '356 further explains that surgeons often have difficulty in starting the cataract incision at the correct location relative to the limbus when employing manual cutting techniques. *Id*. at 10:50–56.

In addition to describing purported challenges with making a cataract incision, the '356 describes a supposed need for "ophthalmic methods, techniques and apparatus to advance the standard of care of corneal shaping that may be associated with invasive cataract and other ophthalmic pathologies." *Id*. at 1:59–62. In particular, the '356 explains that standard cataract incisions typically induce from 0 to 1.0 D of astigmatism, on average, but does not identify anything novel about the arcuate extent of the incisions. *Id*. at 11:12–15.

cited in each Ground qualifies as prior art under AIA-§ 102(a) and does not fall within any exception under AIA-§ 102(b).

B. Alleged Invention

The ’356 discloses the traditional elements of an ophthalmological laser surgical system: a light source (4) for generating a beam of light, a scanner (40 and 50) for deflecting the light beam to form treatment patterns, and a controller (300) for controlling the light source and scanner to deliver the treatment patterns. *See, e.g., id.* at 3:49–4:13, 5:15–39; Fig. 1.

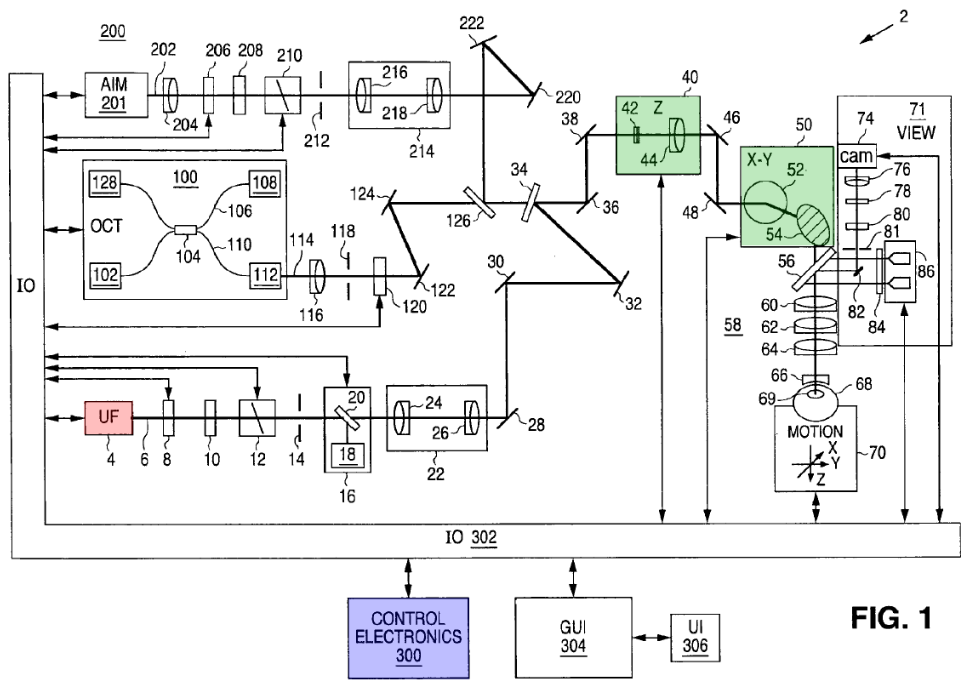

FIG. 1

The ’356 discloses that a cataract incision (402), shown below, can be made using the laser surgical system. And, in order to offset the astigmatism associated with the cataract incision and “achieve a better visual correction,” the ’356 laser surgical system creates a relaxing incision (420) in the cornea (406). *Id*. at 11:16–36. The ’356 describes that the cataract incision (402) and one or more relaxation incisions (420) can be made using the imaging and scanning features of system (2), and explains that a pair of treatment patterns can be generated to form incisions (402) and (420) "providing more accurate control over the absolute and relative positioning of these incisions." *Id.* at 13:38–44.

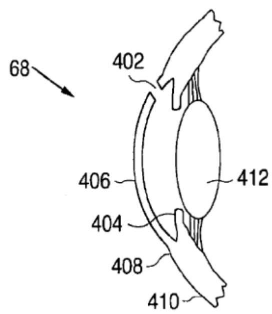

FIG. 5B

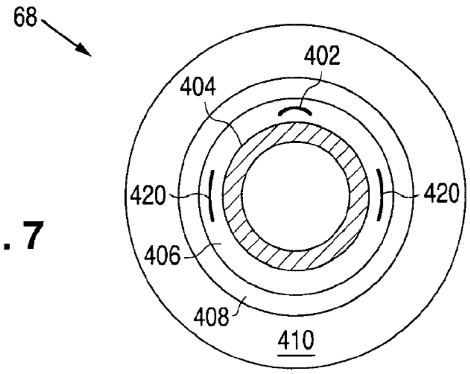

FIG. 7

C. Prosecution History

The prosecution history lays bare the Examiner's mistake. The original application was filed on March 25, 2015. Ex.1012 at 990. The Examiner rejected the structural elements of the claims through a series of prior-art combinations, and noted that the claims' functional limitations of "defining of the incision pattern, scanning the incision pattern, and the performance of the incisions" were obvious because they did not impart any additional structural. *Id.* at 921–22; *see also id*. at 920–30. PO did not press the system itself as a point of novelty, and instead focused arguments on the obviousness of using that system to deliver the claimed incisions. *See id*.

Although PO argued that claim limitations such as "scan the eye tissue," "generate an incision pattern" and "scan the focal point of the laser beam" were "structural limitations" *id.* at 975–976, the Examiner was not convinced and issued a Final Office Action finding the claims obvious over a combination of previously-cited and new references, this time including Swinger. *Id.* at 1012–23. The Examiner again noted that the amended claims do not "positively recite[]" a system that must "create the relaxation incisions," but merely be "capable of" creating the relaxation incisions. *Id.* at 1023–24. The Examiner also stated that the newly added Swinger reference also taught "to incise one or more relaxation incisions into the cornea, wherein at least one of the one or more relaxation incisions is a partially penetrating incision that leaves an un-incised tissue thickness." *Id.* at 1014.

PO amended the claims to add a "controller" "programmed" to "scan the eye tissue," "generate an incision pattern," and "scan the focal point of the laser beam," and argued that this functional language is not merely intended use. *Id.* at 1087–91, 1095–99. PO further argued that Fig. 15R, and other portions of Swinger which the Examiner cited (30:50–62, 31:39–46) did not disclose an "incision pattern that forms a relaxation incision" and "scan[ning] from the posterior to the anterior." *Id.* at 1096.

Not appreciating that Swinger does in fact teach both limitations, the Examiner issued a new ground of rejection that relied on Swinger only secondarily to teach relaxation incisions. *Id.* at 1120–32. However, the Examiner pointed to a single embodiment in Swinger (Fig. 15R) that showed a full-circle relaxation incision. *Id.* at 1122, 1183 (maintaining rejection in view of Swinger).

PO then amended the independent claims to recite that "***each of the relaxation incision [sic] extends in an angular direction for a predetermined length less than a full circle.***" *Id.* at 1204–08. PO argued that the relaxation incision described in Swinger is different from the relaxation incisions recited in the claims because Swinger's relaxation incision forms a complete circle, rather than being "less than a full circle." *Id.* at 1211–15. In making this argument, PO ignored Swinger's other embodiment shown in Figs. 8B and 15W, which clearly teach less-than-full-circle relaxation incisions. *Id.* at 1212. The Examiner overlooked Swinger's other figures as well, agreed with PO, and subsequently issued a notice of allowance on March 13, 2018. *Id.* at 1236–39.

IX. LEVEL OF ORDINARY SKILL IN THE ART

A POSA as of March 2007 would have had a Ph.D. in Physics, Biomedical Engineering, or a related science, such as Optical Engineering, or at least five years of experience in research, manufacturing, or designing medical optics or medical lasers. In either case, a POSA would have also had a moderate understanding of ophthalmology, and refractive and cataract surgery. Additional education or experience in related fields could compensate for deficits in the above qualifications. Ex.1001 ¶42.

X. OVERVIEW OF THE PRIMARY PRIOR ART

A. Blumenkranz (U.S. Application No. 2006/0195076)

Blumenkranz teaches a system and method for cataract extraction. Specifically, Blumenkranz teaches a light source (10) for generating a treatment light beam (11), a controller (12), and a scanner (*e.g.*, 16). Ex.1017 ¶¶45–46, 56, Fig. 1. The system then delivers a treatment light beam to create an incision in the eye tissue. *Id.* ¶50. Blumenkranz also teaches combining tomography scanning techniques with the controller "to program and control the subsequent laser assisted surgical procedure." *Id.* ¶¶57, 59, 74, 85–86. Moreover, Blumenkranz teaches that when "segment[ing]" the eye lens, cut patterns can be "one or more overlapping or spaced apart spots and/or line segments." *Id.* ¶68. It also notes that "[b]eam scanning with the multifocal focusing and/or patterning systems is particularly advantageous to successful lens segmentation since the lens thickness is much larger than the length of the beam waist axial." *Id.* Blumenkranz teaches that the pattern techniques can be used to "improve existing procedures, including anterior and posterior capsulotomy, lens fragmentation and softening, dissection of tissue in the posterior pole . . . as well as incisions in other areas of the eye such as, but not limited to, the sclera and iris." *Id.* ¶71.

B. Swinger (U.S. Pat. No. 6,325,792)

Swinger discloses a computer-controlled laser-surgery system configured to perform various surgical procedures in the eye, including radial and transverse cuts in the cornea to correct astigmatism. Ex.1021 at Figs. 8B and 15W, 21:12–24, 33:7–22. The system comprises a laser unit (100), a scanner (*see id*. at 19:30–33; 20:16–20) (describing scanner generally, and incorporating by reference specific system), and computer control unit (114) to control the location and intensity of the laser and perform various safety checks. *Id.* at Fig. 8A–B, 17:50–54, 19:30–64. The 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, 17:41–45, 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.

C. Weikert

Although Weikert is a secondary reference, its teachings merit a brief discussion. Weikert is an article titled *Refractive Keratotomy: Does It Have a Future Role in Refractive Surgery*, published as Chapter 14 in CATARACT AND REFRACTIVE SURGERY. Weikert addresses the role of refractive keratotomy in the world of laser ophthalmic systems. Ex.1019 at 1. The article begins by noting that the first refractive keratotomy procedure was conducted in 1885, in which penetrating limbal incisions were made on a patient's eye "to decrease astigmatism following cataract surgery." *Id.* Just a year later, "non-penetrating corneal incisions" were used to "reduce astigmatism by flattening the steep corneal meridian in ten patients." *Id*.

Subsequently, surgeons developed a series of "nomograms"—diagrams with predefined incision patterns—"that incorporated multiple surgical variables to produce more predictable results." *Id*. at 2; *see also* Fig. 14a–d (providing example incision patterns and describing their results).

Weikert then describes the application of refractive keratotomy in certain instances to reduce astigmatism, including "adjusting the cataract incision placement, opposite clear corneal incisions (CCI), arcuate keratotomy (AK), transverse keratotomy (TK), and limbal or peripheral corneal relaxing incisions (LRI/PCRIs)." *Id*. at 11. Specifically, Weikert notes that CCIs "have been known to induce astigmatism." *Id*. To minimize this effect, Weikert suggests using "corneal topography" pre-surgery in order to determine the optimal incision location. *Id*. at 12. But to further offset the effects of a CCI, additional incisions can be administered, such as "[p]artial thickness, arcuate or transverse corneal incisions [to] provide a means for correcting higher levels of astigmatism." *Id*.

XI. EACH OF THE CHALLENGED CLAIMS IS UNPATENTABLE

A. Ground 1: Claims 1–2, 4–14, 17–19 and 21–24 Are Obvious Over Blumenkranz in View of Weikert

1. Motivation to Combine

Blumenkranz teaches a multifunctional laser ophthalmic surgery system fully capable of producing laser incisions of different depths according to various treatment patterns. Ex.1017 ¶¶20, 62, 71, Fig. 8. While Blumenkranz discusses using the system as part of cataract surgery, *id*. ¶¶3, 8, 9, the specification focuses mostly on anterior capsulotomy and fragmentation of the cataractous lens, and does not provide great detail on the initial incisions in the eye tissue to reach the interior chambers. Ex.1001 ¶133. Blumenkranz does not expressly disclose using the system to deliver a cataract incision or relaxation incisions, although it does state that "[t]he techniques described herein may be used to perform new ophthalmic procedures or improve existing procedures," such as making "incisions in other areas of the eye such as, but not limited to, the sclera and iris." Ex.1017 ¶71.

To the extent the term "relaxation incision" imparts any implicit limitations to the claims, such as the purpose of the incision being for "relaxation" of the eye tissue, the combined delivery of penetrating cataract and partial relaxation incisions has been known for approximately 150 years. Ex.1001 ¶¶135–36. Weikert states that the first partially penetrating relaxation incisions "to decrease astigmatism following cataract surgery" were performed in the late 1800s, and the technique has only developed in sophistication since. Ex.1019 at 1–2. While these incisions were historically performed manually using blades, making a centuries-old type of incision using modern technology, such as a laser ophthalmic surgery system, would have been obvious. *See Leapfrog Enters., Inc. v. Fisher-Price, Inc.*, 485 F.3d 1157, 1161 (Fed. Cir. 2007) ("Accommodating a prior art mechanical device that accomplishes [a desired] goal to modern electronics would have been reasonably obvious to one of ordinary skill"); MPEP 2114. As such, it would have been obvious to a POSA to use the system disclosed by Blumenkranz, which is capable of delivering incisions of different depths, Ex.1017 ¶¶20, 62, Fig. 8, to deliver relaxation incisions to correct any pre-existing or surgery-induced astigmatism caused by other incisions, such as "cataract incisions" made to the eye as part of cataract surgery. Ex.1001 ¶¶132–37.

2. Independent Claim 1

a. Limitation 1P

Blumenkranz discloses an optical beam scanning system for cataract and other ophthalmic surgeries used for treating target tissue in a patient's eye. Ex.1017 ¶¶8 (discussing the need to advance standards of care in cataract surgeries), 21 (discussing the "ophthalmic surgical system for treating eye tissue"), 45 (providing structural details of the system), 71 (stating that the system may be used to perform "incisions in other areas of the eye such as, but not limited to, the sclera"), 74, 78 (discussing use for cataracts), 98 (describing use for "any other ocular incision, such as conjunctiva, etc."), 99 ("tiny, self-healing incisions"), cls. 1, 29 (claiming methods and systems for "making an incision in eye tissue").

b. Limitation 1.1

Blumenkranz's system includes a laser source (10) for generating a pulsed laser beam (11). *Id*. ¶¶45–50. The laser beam (11) produces a dielectric breakdown and plasma formation at the focal point. *Id.* ¶¶50, 60; Fig. 2.

c. **Limitation 1.2**

Blumenkranz's system includes an OCT device configured to generate signals (S) used to image tissue of the patient's eye, including the cornea, limbus and sclera. *Id*. ¶¶56–57 (OCT imaging of the anterior chamber), 59, 61, 68 (use of OCT "to obtain additional imaging, anatomical structure or make-up (i.e., tissue density) or other dimensional information about the eye including but not limited to the lens, the cornea, the retina and as well as other portions of the eye."), Figs. 12, 14, 15, cls. 11, 43.

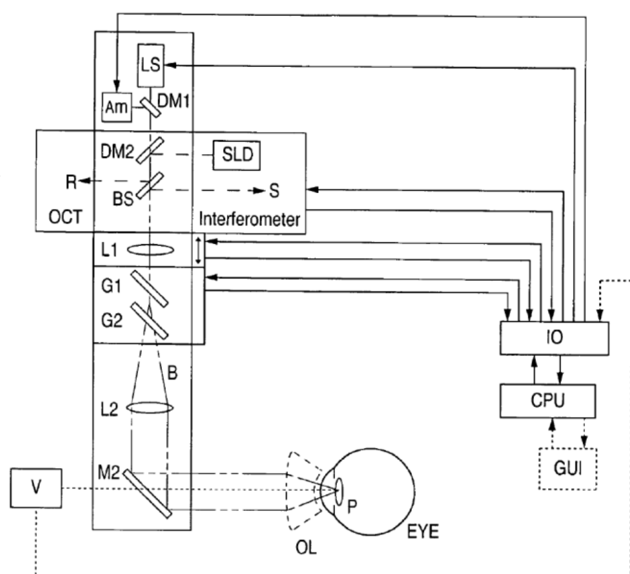

FIG. 12

d. **Limitation 1.3**

Blumenkranz includes a delivery system for delivering the laser beam to the target tissue to form a cataract incision. Ex.1017 at Fig. 12, ¶¶75–77 (treatment beam is guided by optics and mirrors; "entire system is controlled by the controller

CPU"), 76 ("After leaving the scanner, light encounters lens L2 which serves to focus the light onto the target at point P inside the patient's eye EYE. An optional ophthalmic lens OL may be used to help focus the light."), 84–86 (describing laser delivery system and pattern generation), 100 (making incisions for removing lens), Figs. 11, 12.

Additionally, while the phrase "to form a cataract incision" is not a structural limitation deserving of patentable weight, *see* Section V.C, Blumenkranz's system is configured to make various incisions in the eye tissue at varying depths, Ex.1017 at Abstract, ¶100, and Weikert teaches cataract incisions are a well-known aspect of cataract surgery, Ex.1019 at 11. It would have been obvious to configure Blumenkranz's system to deliver cataract incisions. *See* Section XI.A.1.

e. **Limitation 1.4**

Blumenkranz includes a scanner (*e.g.*, 16) for scanning the focal spot of the laser beam to different locations within the patient's eye. Ex.1017 ¶¶45 (scanning elements "controlled by control electronics 12"), 57 (noting the "scanner [is] used to produce the patterns for cutting"), 59 (same), 74 (same), 75–77 (describing interplay between G1, G2, L1, and L2 to achieve scanning; "entire system is controlled by the controller CPU"), 84–86 (describing laser delivery system and pattern generation), Figs. 11, 12.

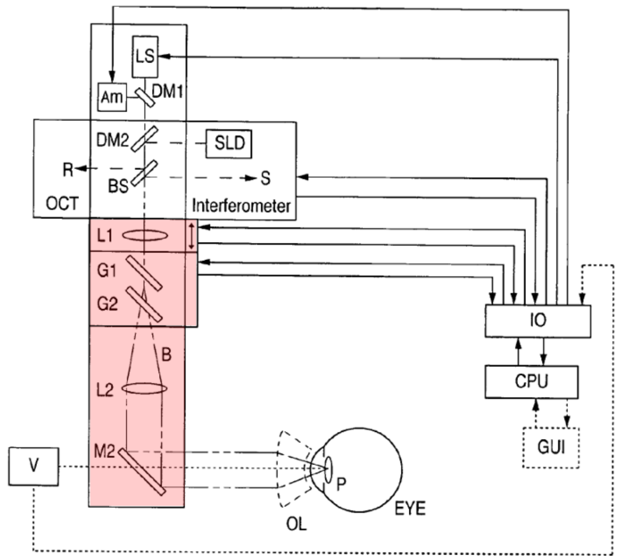

FIG. 12

f. **Limitation 1.5**

Blumenkranz discloses a controller operatively coupled to the laser source, the OCT imaging device, and the scanner.[7] *Id*. ¶¶21, 45 (noting both scanner and laser source are connected to and controlled by control electronics 12), 50, 71, 74, 77 ("entire system is controlled by the controller CPU"), Figs. 11, 12 (illustrating "IO" and "CPU" connected to scanner, laser source, and OCT).

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[7] It is unclear what the "optical beam scanning" is, or how a controller is coupled to it. Nonetheless, the art will be applied as if the controller is coupled to the scanner of the optical beam.

g. **Limitation 1.6**

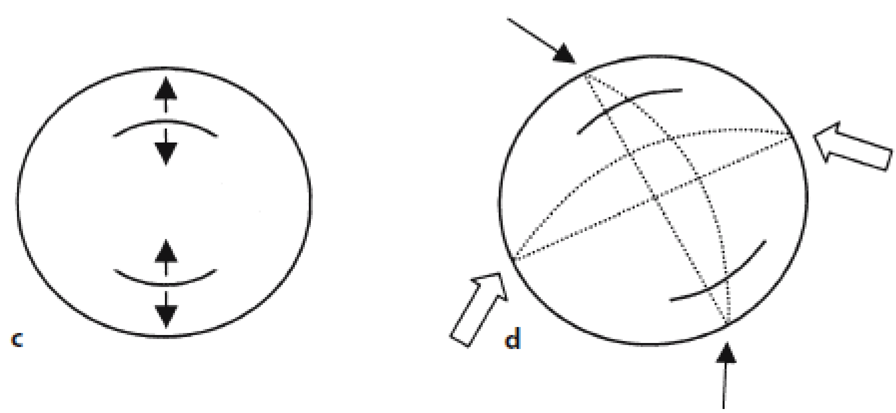
Blumenkranz discloses a controller programmed to scan the eye tissue with the OCT device to generate imaging data for the target tissue that includes imaging data for the cornea. *See* Sections XI.A.2.c (OCT creates image of cornea), XI.A.2.f (describing OCT device as connected to "IO" and "CPU" and generating imaging data for the eye).

h. **Limitation 1.7**

Blumenkranz discloses that the controller is programmed to generate an incision pattern based at least in part on the imaging data. Ex.1017 ¶¶56 (OCT use to create 2D and 3D patterns), 57 (OCT data used to determine procedure parameters), 59 (OCT used as "input into a laser scanning and/or pattern treatment algorithm"), 68, 73 (pattern generator in the control electronics 12), 74 (using OCT data for cutting boundaries), 78, 85, cls. 12, 44.

Blumenkranz's system can also deliver incisions of any length or depth, which may be applied to the cornea. *Id*. ¶¶62 (laser controlled for length and depth), 86 (calculating number of laser pulses based on length and depth), 71 (incisions can be applied to sclera, iris, or "other areas of the eye."); Ex.1001 ¶363. And because the average thickness of the cornea (*e.g.*, 550µm on average) is much greater than the focal spot diameter (*e.g.*, 15µm), each laser pulse would create only partial incisions. *Id*. ¶50; Ex.1001 ¶363. Based on these teachings, a POSA would have understood that the Blumenkranz system is configured to produce partial or full cuts depending on the number of pattern scans run consecutively, and/or based on the relative depths of the scans. Ex.1001 ¶363.

Although Blumenkranz does not expressly disclose relaxation incisions, Weikert teaches that the delivery of relaxation incisions is a routine aspect of cataract surgery. Ex.1019 at 2–3 (describing corneal incisions), 12 (teaching delivery of "[p]artial thickness, arcuate or transverse corneal incisions" to treat astigmatism), 13, 15–16 (arcuate and limbal relaxing incisions combined with cataract surgery). Indeed, partially penetrating relaxation incisions have been performed since the late 1800s "to decrease astigmatism following cataract surgery." *Id.* at 1–2, 11–12. Weikert also discloses relaxation incisions that extend in an angular direction for a predetermined length less than a full circle. *Id.* at 1–4.



It would have been obvious to a POSA to use the system disclosed by Blumenkranz, which is capable of delivering incisions of different sizes and shapes, to deliver relaxation incisions, including to treat astigmatism. *See* Section XI.A.1;

Ex.1017 ¶¶50–53, 60–62; Ex.1001 ¶364. Indeed, the '356 itself recognizes that partially penetrating relaxation incisions "are routinely used to correct astigmatism," and are not a new type of incision. Ex.1010 at 11:16–51.

i. **Limitation 1.8**

Blumenkranz discloses scanning the focal spot of the laser beam in the incision pattern. Ex.1017 ¶¶57 (the "scanner [is] used to produce the patterns for cutting"), 59 (treatment pattern "is used to as a guide in the application of laser energy"), 74 ("automated method" for delivering treatment patterns), 84–86 (pattern generation), Fig. 11.

Blumenkranz also discloses the laser beam focal spot is guided based on imaging data, and scanned in the posterior-to-anterior direction. *Id.* ¶¶59 (using "imaging data . . . as an input into a laser scanning and/or pattern treatment algorithm or technique that is used to as a guide in the application of laser energy . . . ."), 75 (specifics of image-guided treatment beam), 98 ("[A]blating from the posterior to the anterior portion of the lens"). A POSA would have known that laser treatments are generally applied in a posterior-to-anterior direction when the target tissue is transparent (including the cornea), so that the laser does not pass into already-ablated tissue that can scatter the beam and reduce its treatment energy. Ex.1001 ¶367.

Thus, a POSA would have known that, when using Blumenkranz's system to deliver an incision pattern with relaxation incisions (as taught by Weikert), the laser beam focal spot would be guided by image data to ensure an accurate and precise incision. Ex.1001 ¶366. A POSA also would have known that scanning would proceed in the posterior-to-anterior direction to avoid traversing already-ablated tissue. *Id*.

3. Dependent Claims 2 and 14

Claims 2 and 14 have the same limitations, but depend from claims 1 (above) and 13 (below), respectively. Blumenkranz discloses a profilometer[8]—"electro-optical, OCT, acoustic, ultrasound or other measurement," Ex.1017 ¶74—capable of measuring the surface profile of a surface of the cornea of the patient's eye, *id*. ¶56 (describing OCT to locate the surface of ocular tissue), 68 (describing OCT to obtain "dimensional information" about the cornea). Blumenkranz also discloses

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[8] The '356 specification discloses that a "profilometer" "may be a Placido system, triangulation system, laser displacement sensor, ***interferometer***, or other such device, which measures the corneal topography," and that OCT is an interferometer that can "target the surfaces of the targeted structure in the eye." Ex.1010 at 12:4–12. Indeed, PO's infringement allegations claim that an OCT is a profilometer. *See* Ex.1054 at 9. Thus, a single OCT and system can meet both the OCT limitations of claims 1 and 13 and the "profilometer" limitations of claims 2 and 14.

the imaging device defines the incision pattern. *Id.* ¶¶59 (using "imaging data . . . as an input into a laser scanning and/or pattern treatment algorithm or technique that is used to as a guide in the application of laser energy . . . ."), 75 (discussing specifics of image-guided treatment beam),

Although Blumenkranz does not discuss using the surface profile to define the treatment pattern to correct astigmatism, Weikert teaches that "[c]orneal topography [(*e.g.*, imaging)] can be helpful in directing incision placement and relative length," Ex.1019 at 14, and that relaxation incisions are intended to correct astigmatism, *id.* at 12. Moreover, a POSA would have known to use the surface profile to determine the relaxation incision pattern, as surface profiles are known to measure astigmatism, and relaxation incisions are intended to correct astigmatism. Ex.1001 ¶¶371. It would have been obvious to a POSA to use Blumenkranz's system to image the cornea and deliver relaxation incisions to treat astigmatism, as taught by Weikert. *See* Section XI.A.1; Ex.1001 ¶¶368–71.

4. Dependent Claims 4 and 17

Claims 4 and 17 have the same limitations, but depend from claims 1 (above) and 13 (below), respectively. It would have been obvious to a POSA to deliver relaxation incisions based on image data. *See* Section XI.A.3. To that end, a POSA would have known that OCT images not only the surface profile of the cornea, but also its thickness. Ex.1001 ¶372. When delivering partial relaxation incisions, as taught by Weikert, a POSA would have further known to use the OCT image data to control the depth of the incisions to avoid penetrating the anterior chamber, *id.*, and because Weikert states the relative depth of the incision controls its corrective effect, Ex.1019 at 2–3.

5. Dependent Claim 5

Weikert teaches that relaxation incisions only partially extend through the target tissue, *Id.* at 1–3, 12–13, 15–16. Whereas Weikert's relaxation incisions had to penetrate the anterior surface of the cornea (because manual blades cannot initiate incisions from within the eye), a POSA would have known that Blumenkranz's laser system would not be so limited, and incisions generally proceed in a posterior-to-anterior direction. Ex.1001 ¶¶373–74; Ex.1017 ¶98 (describing "ablating from the posterior to the anterior portion of the lens"). Thus, a POSA using Blumenkranz's laser system would have known that incisions could be applied either on the posterior or anterior side of the target tissue, and (because relaxation incisions are partially penetrating) not cross either the anterior or posterior surface of the target tissue, respectively. Ex.1001 ¶374.

6. Dependent Claims 6, 8, and 18

Claims 6, 8, and 18 have related limitations, but claims 6 and 8 depend from claims 1 (above) and claim 18 depends from claim 13 (below). Blumenkranz discloses incisions that can be delivered to the sclera or "other areas of the eye," Ex.1017 ¶71, which a POSA would have known includes the cornea. Ex.1001 ¶¶375–77. Blumenkranz also discloses incision patterns comprising a plurality of discrete incisions in the patient's eye. *Id*. ¶68 ("combinations of scan patterns"), Figs. 10A–10C.

Weikert discloses delivering a plurality of relaxation incisions to the cornea or limbus. Ex.1019 at 1–4, 14, Figs. 14.1, 14.2.

It would have been obvious to a POSA to use the Blumenkranz system, which is capable of delivering different incision patterns, to administer more than one incision in the cornea, limbus or sclera to generate relaxation incisions as taught by Weikert. Ex.1001 ¶377.

7. Dependent Claims 7 and 19

Claims 7 and 19 have the same limitations, but depend from claims 1 (above) and 13 (below), respectively. A POSA would have known that Blumenkranz's anterior capsulotomy and lens ablation procedures also require a cataract incision on an anterior surface of the eye, such as the cornea, limbus, or sclera. *See*, *e.g.*, Ex.1017 ¶100 (noting incision required for IOL implant), Fig. 3; Ex.1001 ¶378. Although Blumenkranz does not expressly state the laser system delivers the cataract incisions, a POSA would have understood that Blumenkranz's system could be used to do so. Ex.1001 ¶378.

Additionally, Weikert teaches the delivery of a corneal cataract incision as part of a relaxation incision. Ex.1019 at 12 (describing opposite clear corneal incisions, which are intended as both cataract incisions and relaxation incisions), 14 (noting that patients with certain astigmatism had the cataract incision ("CCI") "incorporated into" the relaxation incision ("PCRI")). It would have been obvious to a POSA to use Blumenkranz's system to deliver the plurality of discrete incisions (*e.g.*, relaxation incisions) that comprise both cataract incisions and corneal relaxing incisions. *See* Section XI.A.1; Ex.1001 ¶379.

8. Dependent Claims 9 and 22

Claims 9 and 22 have the same limitations, but depend from claims 1 (above) and 13 (below), respectively. Blumenkranz teaches an XY-scanner (G1, G2) to move the beam focus position laterally, and a Z-scanner (L1) to move the beam focus position along the z-axis, wherein the beam goes through the Z-scanner prior to the XY-scanner. Ex.1017 ¶¶65, 75–76, 95, 97, Fig. 12.

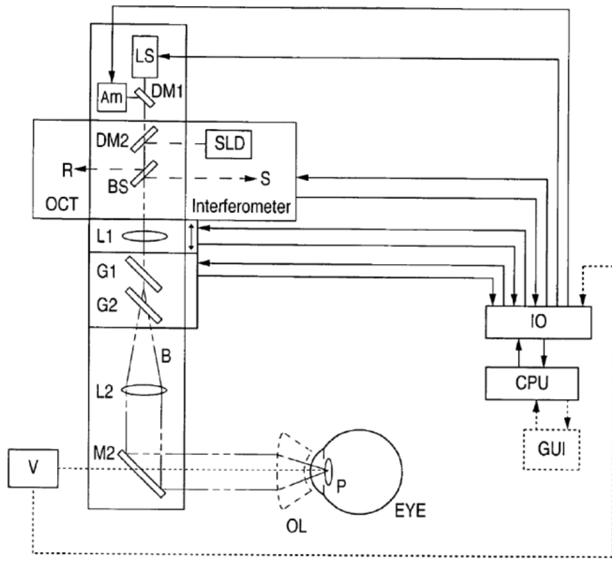


FIG. 12

9. Dependent Claims 10, 11, and 23

Claims 10, 11, and 23 have related limitations, but claims 10 and 11 depend from claims 1 (above) and claim 23 depends from 13 (below). Blumenkranz teaches that the OCT beam that is scanned by an XY- scanner and focused by a Z-scanners. *See* Section XI.A.8; *see also* Ex.1017 ¶57 (OCT scanner is “same scanner used to produce the patterns for cutting”), 75–77, 79, Fig. 12.

10. Dependent Claims 12 and 24

Claims 12 and 24 have the same limitations, but depend from claims 1 (above) and 13 (below), respectively. Blumenkranz discloses the OCT device generating signals used to generate three-dimensional positional data for at least the cornea. *Id*. ¶¶56–57 (describing OCT imaging of the anterior chamber), 59, 61, 68 (describing use of OCT “to obtain additional imaging, anatomical structure or make-up (i.e., tissue density) or other dimensional information about the eye including but not limited to the lens, the cornea, the retina and as well as other portions of the eye."), 74–75 (describing "3-dimensional scanning" of imaging light), Figs. 2, 11, 14. A POSA also would have known that OCT is also capable of imaging the limbus and sclera as well. Ex.1001 ¶382.

11. Independent Claim 13

a. Limitations 13P, 13.1, 13.3–13.5

The combination of Blumenkranz and Weikert renders the claimed scanning system (1P), laser source (1.1), delivery system (1.3), scanner (1.4), and controller (1.5) obvious. *See* Sections XI.A.2.a, XI.A.2.b, XI.A.2.d–XI.A.2.f.

b. Limitation 13.2

Blumenkranz's system includes an Optical Coherence Tomography (OCT) device configured to generate signals (S) used to image tissue of the patient's eye, including the cornea, limbus and sclera. Ex.1017 ¶¶56–57.

Whereas Limitation 1.2 claims OCT imaging of the cornea, Limitation 13.2 claims OCT imaging of the limbus and sclera. However, Blumenkranz notes that imaging can be used to obtain information about "the lens, the cornea, the retina and as well as ***other portions of the eye***." *Id.* ¶68. Blumenkranz also teaches making "incisions in other areas of the eye such as, but not limited to, the sclera and iris." *Id*. ¶71. A POSA also would have known that OCT is also capable of imaging the limbus and sclera, and that in order to make incisions in the limbus and sclera, images of those areas should be taken. Ex.1001 ¶384.

c. **Limitation 13.6**

Blumenkranz discloses a controller programmed to scan the eye tissue with the OCT device to generate imaging data for the target tissue that includes imaging data for the cornea. *See* Sections XI.A.2.c, XI.A.2.g.

d. **Limitation 13.7**

Whereas Limitation 1.7 claims forming incisions in the cornea, Limitation 13.7 claims forming incisions in the limbus or sclera. Blumenkranz, however, teaches incisions in the sclera. Ex.1017 ¶71. Additionally, Weikert recognizes incision location relative the corneal apex merely affects corrective power. Ex.1019 at 4 ("The coupling ratio . . . generally increases with the distance from the limbus (i.e. more anterior incisions produce more flattening relative to steepening)."), 14 (discussing "limbal relaxing incisions"). A POSA would have found it obvious to use Blumenkranz's system to deliver relaxing incisions that extend in an angular direction less-than-a-full circle, and would have known that incisions could be applied to any of the cornea, limbus, or sclera, depending on the type and level of astigmatism to be corrected. *See* Sections XI.A.1, XI.A.2.h; Ex.1001 ¶386.

e. **Limitation 13.8**

Whereas Limitation 1.8 claims posterior-to-anterior scanning of the focal spot, Limitation 13.8 claims scanning the focal spot in the limbus or sclera. *see* Sections XI.A.1, XI.A.2.h, XI.A.11.d, when delivering relaxing incisions to the limbus or sclera, it would have been obvious to a POSA that the focal spot would be scanned, based on image data, *see* Section XI.A.2.i, to incise relaxation incisions into the limbus or sclera. Ex.1001 ¶387.

B. Ground 2: Claims 2–3 and 14–15 Are Obvious Over Blumenkranz in View Weikert, and Further in View of Benedikt

1. Motivation to Combine

Blumenkranz and Weikert collectively teach a surgery scanning system for treating target tissue, including cataracts, by delivering partial and/or complete incisions in eye tissue to gain access to interior chambers. But Blumenkranz and Weikert do not expressly disclose a system with OCT and profiling subsystems.

As much as computer-guided laser systems like Blumenkranz improve the accuracy of incisions, Benedikt recognized that single-measurement systems have inherent deficiencies, and an accurate understanding of the target anatomy is essential to ophthalmic surgery systems. Ex.1020 ¶39. To that end, Benedikt discloses another ophthalmic system with a plurality of imaging or profiling devices that are suitable for automated laser surgery. *Id*. ¶¶6, 13, 15, 16, 39, 41–42. Specifically, Benedikt teaches a combination of a topometer with a light source (16) and CCD array (14), in combination with an additional detector device (such as OCT or a wave front sensor, Figs. 1, 3–4; *id*. ¶23, 25–26). The topometer measures the topographical features of the surface of the eye, *id*. ¶3–4, while the wave-front sensor or OCT measure features below the surface, *id*. ¶14–15. Benedikt teaches that "[a]s a result of the combination of methods, automated laser surgery is provided with a previously unattainable comprehensive topometrical/topographical illustration of the cornea." Ex.1020 ¶39.

A POSA would have been motivated to modify Blumenkranz's ophthalmic-surgery system to have multiple independent imagining and profiling subsystems, as taught by Benedikt, in order to better produce "both the entire substantial surface topography of the cornea and also at least one optical property of the layers of the eye disposed under the cornea," *id*. ¶6, which provides the user a more accurate representation of the patient's eye tissues and layers before, during, and after surgery. Ex.1001 ¶¶142–47. As such, a POSA would have been motivated to integrate Benedikt's imaging assembly into a laser treatment system like Blumenkranz's in order to plan and effect laser surgery with improved accuracy. Ex.1001 ¶146.

Indeed, a skilled artisan would have had a reasonable expectation of success integrating Benedikt's imaging assembly into a laser treatment system like Blumenkranz's. Ex.1001 ¶149. The prior art sets forth that integrating diagnostic imaging and treatment functionalities into a single automated system is not only desirable, but also straightforward. *Id*.

Furthermore, a POSA would have been motivated to modify a laser treatment system to include Benedikt's imaging assembly since doing so merely amounts to a simple substitution (Benedikt's combined-imaging assembly in place of Blumenkranz's OCT and/or other measurement technique) of known imaging modalities that would obtain predictable results.

Moreover, Weikert teaches that eye shape influences the shape and location of both the corneal and relaxation incisions. Ex.1019 at 2 (discussing how nomograms incorporated multiple surgical variables, such as "incisional zone diameter, length, depth and pattern," to produce more predictable results in eye shape for relaxation incisions), Fig. 14.1a–d; *id*. at 12 (discussing using pre-surgery corneal topography to determine corneal incision location). Because Blumenkranz discloses incorporating imaging or profiling subsystems into the controller to determine cutting parameters, *id*. ¶74 ("the data [from the measurement devices] . . . can be loaded into the scanning system to automatically determine the parameters of the cutting"), ¶78, it would have further been obvious to a POSA that a system including both a profilometer and detector, as taught by Benedikt, would use the information obtained therein to determine, at least in part, the first and/or second treatment pattern, as also taught by Weikert. Ex.1001 ¶148.

2. Dependent Claims 2 and 14

PO points to a single OCT system as teaching both the OCT device of claim 1 ***and*** the profilometer of claim 2, Ex.1054 at 2, 9, and thus, Blumenkranz alone meets this limitation. *See* Section XI.A.3. However, to the extent claim 2 requires a distinct profilometer, Benedikt teaches an imaging system with both an OCT and a profilometer. Ex.1020 ¶¶6, 13, 15, 16, 29–31, 32 ("The Placido Topometer . . . allows measurement the surface of the cornea"), 41–42 (describing combined system), Figs 3–4. Benedikt teaches using the surface profile to define the incision pattern. *Id.* ¶39 (automated surgery can be conducted using topometric data obtained from the detector "to introduce the individually optimal ablation pattern for the front surface of the cornea" and "to detach the ablation process from the surgeon's manual dexterity . . . .").

It would have been obvious to a POSA, when integrating a distinct profilometer into Blumenkranz's system, to use the measured corneal surface profile to define the incision pattern so as to treat astigmatism of the eye, as taught by Weikert and Benedikt. Ex.1017 ¶¶74, 78; Ex.1019 at 12 (stating "corneal topography is recommended as part of the standard pre-cataract surgery evaluation" to determine incision location for astigmatism correction), 14 ("Corneal topography can be helpful in directing incision placement and relative length" in the context of incisions to correct for astigmatism); Ex.1017 ¶39; Ex.1001 ¶¶389–90.

3. Dependent Claims 3 and 15

Benedikt describes how the profilometer maintains a relatively unobstructed view by placing elements of the OCT scanner in the dead zone of the profilometer, but does not expressly teach a profilometer entirely distal to the scanner. Ex.1017

¶4, Figs. 3–4. However, it would have been obvious to a POSA to arrange the optical components such that the profilometer is completely distal to the scanner so that the profilometer is completely unobstructed, enabling a more accurate representation of the surface profile of the eye. Ex.1001 ¶391. For instance, Benedikt discloses another embodiment where the profilometer (and wave-front scanner) (14, 93) are placed distally along the central beam path directed to the patient's eye, as well as additional optical components (91) (*e.g.*, where a scanning system would be located) to condition the beam proximal to the profilometer. Ex.1017 ¶¶50–52, Fig. 6; Ex.1001 ¶392.

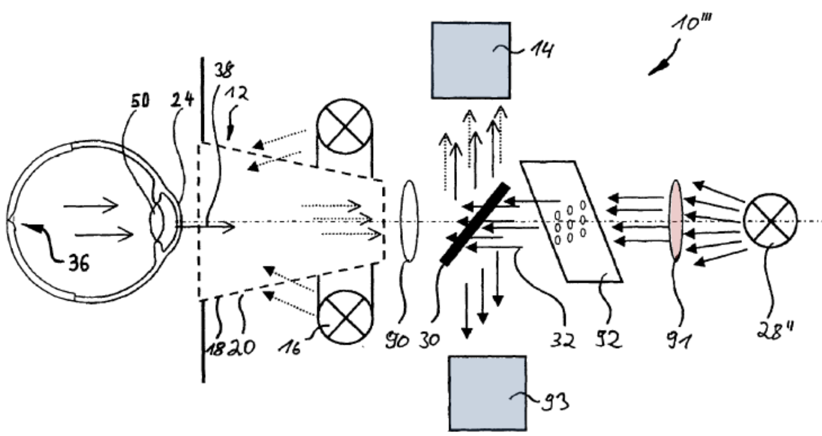


Figure 6

Thus, a POSA integrating Benedikt's dual-imaging device into Blumenkranz's system would have known that the location of the profilometer would be arranged distal to the scanner, so that the scanner is out of the path of the profilometer, using known optical components. Ex.1001 ¶393. This is nothing more than the obvious rearrangement of known parts with predictable results. *See In re Japikse*, 181 F.2d 1019, 86 USPQ 70 (CCPA 1950); MPEP 2144.04.

C. Ground 3: Claims 1–8, 14–15, 17–19, and 21 Are Obvious Over Swinger in View of Weikert, and Benedikt

1. Motivation to Combine

Swinger teaches a laser ophthalmic-surgery system intended for various surgical procedures, including corrective keratotomy, in which incisions are delivered to the cornea to correct astigmatism, as well as anterior capsulotomy and lens ablation as part of cataract surgery. Ex.1021 at 5:52–59 (keratotomy), 8:55–67 (other surgical procedures), 10:10–16 (cataract procedures). In other words, Swinger discloses a multifunctional ophthalmic-surgery system to make incisions during cataract surgery.

As part of that process, Swinger teaches that the system "can also easily generate arcuate cuts or transverse cuts ('T-cuts') . . . [so that] the refractive power of the eye is decreased." *Id*. at 21:12–17, Fig. 15W. Such cuts are consistent with Weikert, which teaches that the combined delivery of cataract and relaxation incisions have been known for approximately 150 years. Ex.1019 at 1–2. As such, it would have been obvious to a POSA to use the system disclosed by Swinger, to deliver both relaxation (as both Swinger and Weikert teach) combined with cataract incisions (as Swinger suggests, but Weikert makes explicit) as part of cataract surgery. Ex.1021 at 21:12–17, Fig. 15W; Ex.1001 ¶176.

Neither Swinger nor Weikert expressly disclose a system with an OCT device and profilometer that can be used to determine incision patterns. Instead, Swinger's pre-surgical analysis for directing the treatment beam entails manual estimation or the use of external imaging systems (like ultrasound). *See* Ex.1021 at 35:59–63; Ex.1001 ¶177. Swinger, however, recognizes the benefit of making accurate and reproducible incisions. Ex.1021 at 34:43–51 ("The ability to open a lens capsule in a regular and controlled manner is of great importance.").

As much as computer-guided laser systems like Swinger's improve the accuracy of incisions, Benedikt recognized that an accurate understanding of the target anatomy is essential to ophthalmic surgery systems. Ex.1020 ¶39. To that end, Benedikt discloses another ophthalmic system with a plurality of imaging or profiling devices that are suitable for automated laser surgery. *Id*. ¶¶6, 13, 15, 16, 39, 41–42. Specifically, Benedikt teaches a combination of a topometer with a light source (16) and CCD array (14), in combination with an additional detector device (*i.e.*, an OCT or a wave front sensor), Figs. 1, 3–4; *id*. ¶23, 25–26. The topometer measures the topographical features of the surface of the eye, *id*. ¶3–4, while the wave front sensor or OCT can measure features below the surface, *id*. ¶14–15. Benedikt teaches that, "[a]s a result of the combination of methods, automated laser surgery is provided with a previously unattainable comprehensive topometrical/topographical illustration of the cornea." Ex.1020 ¶39. As such, a POSA would have been motivated to integrate Benedikt's imaging assembly into a system like Swinger's in order to plan and effect laser surgery with improved accuracy. Ex.1001 ¶178.

Indeed, a skilled artisan would have had a reasonable expectation of success integrating Benedikt's imaging assembly into a laser treatment system. Ex.1001 ¶179. The prior art sets forth that integrating diagnostic imaging and treatment functionalities into a single automated system is not only desirable, but also straightforward. *See id*.

Furthermore, a POSA would have been motivated to modify a laser system like Swinger's to include Benedikt's imaging assembly since doing so merely amounts to a simple substitution (Benedikt's combined-imaging assembly in place of Swinger's direct visualization technique or ultrasound) of known imaging modalities that would obtain predictable results. Ex.1001 ¶180.

2. Independent Claim 1

a. **Limitation 1P**

Swinger discloses an optical beam scanning system for ophthalmic surgeries used for incising or treating target tissue in a patient's eye. Ex.1021 at 16:62–20:33,

Fig. 6. Swinger also teaches use for cataract surgery and relaxation incisions. *Id.* at 10:10–15 (cataract surgery, generally), 21:12–17 (relaxation incisions).

b. **Limitation 1.1**

Swinger discloses a laser source (102) for generating a pulsed laser beam (B). Ex.1021 at 17:1–30; Fig. 6. The laser beam (B) produces a dielectric breakdown and plasma formation at the focal point. *Id.* 2:10–15, 13:10–25; Figs. 4–5.

c. **Limitation 1.2**

Benedikt teaches an Optical Coherence Tomography (OCT) device configured for imaging tissue of the patient's eye, including the cornea, limbus and sclera. Ex.1020 at Figs. 3, 4, ¶¶8 (OCT allows for "determination of the optical properties of the entire eye"), 10, 14–16, 19, 42, 44 (OCT scans provide "three-dimensional information"). Benedikt teaches that automated surgery can be conducted using image topometric and OCT data to assist or guide the laser treatment, *e.g.*, "to introduce the individually optimal ablation pattern for the front surface of the cornea" and "to detach the ablation process from the surgeon's manual dexterity[.]" *Id*. ¶39. It would have been obvious to a POSA to integrate an OCT device like Benedikt's into Swinger's laser system. *See* Section XI.C.1; Ex.1001 ¶397.

d. **Limitation 1.3**

Swinger discloses a delivery system for delivering the laser beam to the target tissue to form a cataract incision. Ex.1021 at 16:60–20:34 (describing "computer control unit 114" and laser delivery components), 25:61–26:33 (describing laser delivery system including contact lens), Figs. 6, 15D. Swinger also teaches the system is used for cataract surgery. *Id.* at 8:55–67; 10:10–15.

Additionally, while the phrase "to form a cataract incision" is not a structural limitation deserving of patentable weight, *see* Section V.C, A POSA would have understood that Swinger's system is used for cataract incisions in the cornea. Ex.1021 at 9:64–67 (describing corneal procedures that would include incisions), 10:10–15 (describing cataract procedures that would necessitate anterior incisions in the cornea, limbus, or sclera). Weikert also teaches that cataract incisions are a well-known aspect of cataract surgery, Ex.1019 at 11.

e. **Limitation 1.4**

Swinger discloses a scanner for scanning the focal spot of the laser beam to different locations within the patient's eye under the control of a controller. Ex.1021 at 9:1–6; 16:60–20:34 (describing "scanner" and "computer control unit 114"), 20:49–65 (system "can easily create straight line and curved-line excisions, of any predetermined length and depth, at any location"), 21:9–11, 25:61–26:33 ("means for scanning 74 laser spot 58 in three dimensions"), Figs. 6–7, 15D.

f. **Limitation 1.5**

Swinger discloses a controller operatively coupled to the laser source and the scanner. Ex.1021 at 16:60–20:34 (describing "scanner" and "computer control unit 114"), Fig. 6.

It would have been obvious to a POSA, upon integrating the OCT device taught by Benedikt into the Swinger system, to operatively couple the controller to the OCT imaging device in order to image the target eye tissue prior to ablation, as taught by Benedikt. Ex.1020 ¶¶39 (stating automated surgery can be conducted using image data "to introduce the individually optimal ablation pattern for the front surface of the cornea" and "to detach the ablation process from the surgeon's manual dexterity[.]"), 31 (describing a "PC" or "workstation"), 36 (same), 51(same). Ex.1001 ¶¶402–04.

g. **Limitation 1.6**

Benedikt discloses that the OCT scans the eye tissue to generate imaging data for the target tissue that includes imaging data for the cornea. Ex.1020 ¶¶39 (describing imaging of cornea), 43 (same), Figs. 3–4.

h. **Limitation 1.7**

Benedikt discloses a detector for detecting OCT laser light that generates signals and a controller to receive image data. Ex.1020 ¶¶42 (OCT system includes "photodetector 34'"), 31 (describing a "PC" or "workstation"), 36 (same), 51(same), and using the image data to "automate[] laser surgery" by introducing "the individually optimal ablation pattern for the front surface of the cornea with photo-ablative lasers." *Id*. ¶39. "The data… can be used… to detach the ablation process from the surgeon's manual dexterity and to provide it as a data record for the automated ablation of tissue in the laser per se." *Id*. A POSA would have read Benedikt as teaching a controller programmed to generate incision patterns based on the image data. Ex.1001 ¶406.

Additionally, Swinger and Weikert both disclose relaxation incision patterns extend in an angular direction less than a full circle, and that relaxation incisions are intended to be partially penetrating. Ex.1021 Figs. 8B, 15W (showing "penetrating" (solid line) and non-penetrating (dashed line)), 21:12–24, 33:7–22; Ex.1019 at 2–3 (describing corneal incisions), 12 (teaching delivery of "[p]artial thickness, arcuate or transverse corneal incisions" to treat astigmatism), 13, 15–16 (arcuate and limbal relaxing incisions combined with cataract surgery).

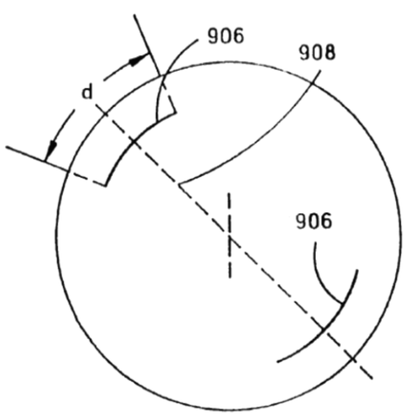


FIG. 8B

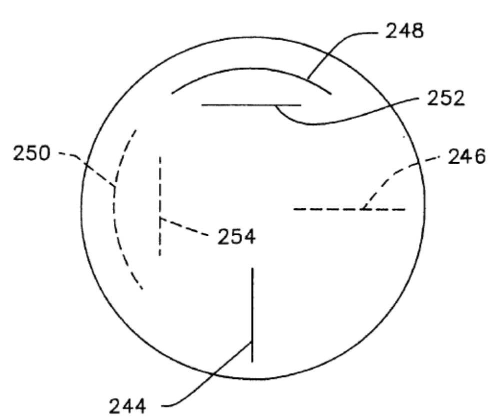
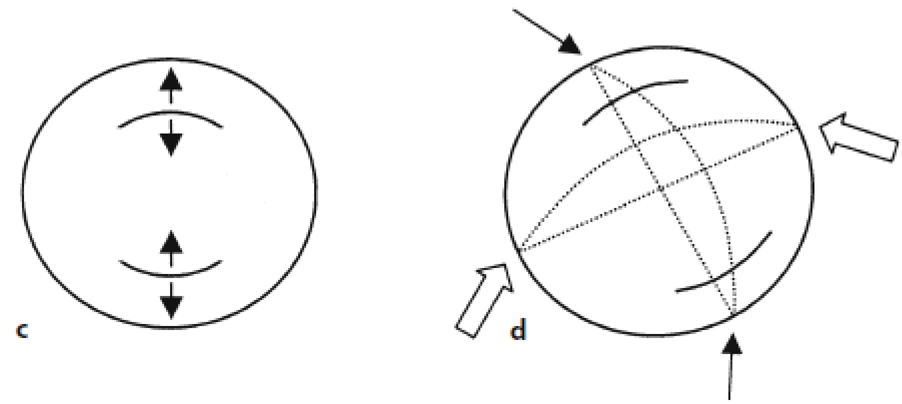


FIG. 15W



Indeed, Weikert teaches that partially penetrating relaxation incisions have been performed since the late 1800s "to decrease astigmatism following cataract surgery". Ex.1019 at 1–2, 11–12.

It would have been obvious to a POSA to use Swinger's system, which is capable of delivering incisions of different sizes and shapes, in combination with the OCT device of Benedikt, to deliver relaxation incisions taught by Swinger and Weikert that are based on imaging data, including OCT. Ex.1001 ¶¶407–08. It would have further been obvious to a POSA, upon integrating an imaging system like Benedikt's with Swinger's system, to program the controller to generate incision patterns based on the image data. This is nothing more than automating the process of a surgeon determining an incision plan after manually observing image data using a controller and algorithms. Ex.1001 ¶408; *see In re Venner*, 262 F.2d 91, 95, 120 USPQ 193, 194 (CCPA 1958); MPEP 2144.04.

i. Limitation 1.8

Swinger discloses scanning the laser beam focal spot in various incision pattern on the cornea. Ex.1021 at 33:7–23. A POSA would have known these patterns are programmed into the system to automate the delivery of the incisions. *See, e.g.*, *id*. at 34:64–67 (stating incision to anterior capsule is "totally computerized" to ensure a smooth incision), Fig. 15A1 (showing difference between manual and computer-controlled laser incisions); Ex.1001 ¶409. Additionally, Swinger discloses corneal incisions that are delivered in a posterior-to-anterior direction. Ex.1021 at 33:7–23 ("[I]ncision begins deep in the cornea and exits by penetrating the anterior corneal surface."); Ex.1001 ¶410 (noting posterior-to-anterior direction typically utilized in transparent tissue). At bottom, a POSA would have known, based on Swinger, Weikert, and Benedikt, that once an incision pattern is generated (based on image data), *see* Section XI.C.2.h, to scan the laser beam focal spot in the incision pattern in the posterior-to-anterior direction. Ex.1001 ¶¶410–11. Thus, because the scanning pattern was based on image data, delivering the pattern with a laser would also be based on image data. Ex.1001 ¶411.

3. Dependent Claims 2 and 14

Claims 2 and 14 have the same limitations, but depend from claims 1 (above) and 13 (below), respectively. Benedikt discloses a profilometer comprising a Placido topometer (14) for measuring the surface profile of a surface of the cornea of the patient's eye. Ex.1020 ¶¶6, 13, 15, 16, 29–31, 32 ("The Placido Topometer . . . allows measurement the surface of the cornea"), Figs. 3–4 (including both OCT device and profilometer). Benedikt also teaches using image data to automate treatment. *Id.* ¶39 (automated surgery can be conducted using topometric data obtained from the detector "to introduce the individually optimal ablation pattern for the front surface of the cornea").

Weikert teaches using a surface profile, like the one acquired by Benedikt's Placido topometer, to define the incision pattern to treat astigmatism of the eye. Ex.1019 at 12 ("If available, corneal topography is recommended" to determine astigmatism), 14 ("Corneal topography can be helpful in directing incision placement and relative length.").

Thus, it would have been obvious to a POSA integrating Benedikt's imaging devices into Swinger's system to use the surface profile from the profilometer to define the incision pattern for the relaxation incisions, because the profilometer is intended to measure astigmatism, and relaxation incisions are intended to correct astigmatism. Ex.1001 ¶¶412–14.

4. Dependent Claims 3 and 15

Claims 3 and 15 have the same limitations, but depend from claims 1 (above) and 13 (below), respectively. Benedikt describes how the profilometer maintains a relatively unobstructed view by placing elements of the OCT scanner in the dead zone of the profilometer, but does not expressly teach a profilometer entirely distal to the scanner. Ex.1020 ¶4, Figs. 3–4. However, it would have been obvious to a POSA to arrange the optical components such that the profilometer is completely distal to the scanner so that the profilometer is completely unobstructed, enabling a more accurate representation of the surface profile of the eye. Ex.1001 ¶415. For instance, Benedikt discloses another embodiment where the profilometer (and wave-front scanner) (14, 93) are placed distally along the central beam path directed to the patient's eye, with a light splitter (30) to direct the light distally, as well as additional optical components (91) (*e.g.*, where a scanning system would be located) to condition the beam proximal to the profilometer. Ex.1020 ¶¶50–52, Fig. 6; Ex.1001 ¶415.

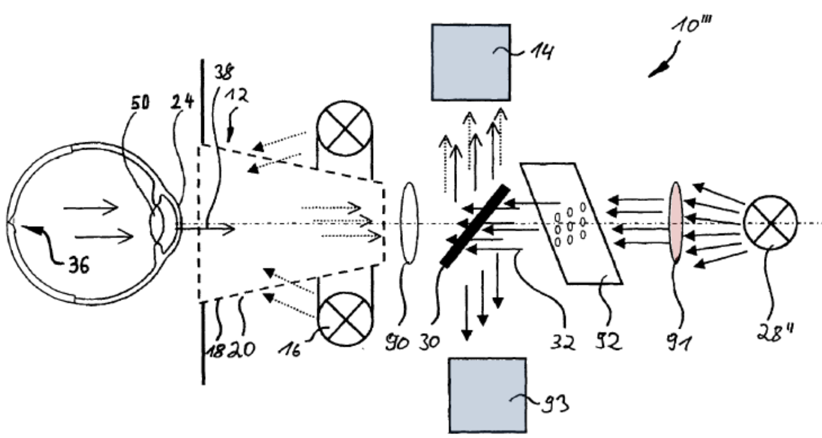


Figure 6

Thus, a POSA integrating Benedikt's dual-imaging device into Swinger's system would have known that location of the profilometer would be arranged distal to the scanner, so that the scanner is out of the path of the profilometer using known optical components. Ex.1001 ¶415. This is nothing more than the obvious rearrangement of known parts with predictable results. *See In re Japikse*, 181 F.2d 1019, 86 USPQ 70 (CCPA 1950); MPEP 2144.04.

5. Dependent Claims 4 and 17

Claims 4 and 17 have the same limitations, but depend from claims 1 (above) and 13 (below), respectively. It would have been obvious to a POSA to deliver relaxation incisions based on image data. *See* Section XI.C.3. To that end, a POSA would have known that OCT images not only the surface profile of the cornea, but also its thickness. Ex.1001 ¶416. When delivering partial relaxation incisions, as taught by Weikert, a POSA would have further known to use the OCT image data to control the depth of the incisions to avoid penetrating the anterior chamber, Ex.1001 ¶416, and because Weikert states the relative depth of the incision controls its corrective effect, Ex.1019 at 2–3.

6. Dependent Claim 5

Swinger discloses the delivery of partial relaxation incisions from a posterior surface, not penetrating an anterior surface. Ex.1021 at 32:1–12. Weikert teaches that relaxation incisions only partially extend through the target tissue, Ex.1019 at

1–3, 12-13, 15–16. Whereas Weikert's relaxation incisions had to penetrate the anterior surface of the cornea (because manual blades cannot initiate incisions from within the eye), a POSA would have known that Swinger's laser system would not be so limited, and incisions generally proceed in a posterior-to-anterior direction. Ex.1001 ¶¶417–18; Ex.1021 at 33:7–23. Thus, a POSA using Swinger's laser system would have known that incisions could be applied either on the posterior or anterior side of the target tissue, and (because relaxation incisions are partially penetrating) not cross either the anterior or posterior surface of the target tissue, respectively. Ex.1001 ¶419.

7. Dependent Claims 6, 8, and 18

Claims 6, 8, and 18 have related limitations, but claims 6 and 8 depend from claims 1 (above) and claim 18 depends from claim 13 (below). Swinger discloses relaxation incisions comprising a plurality of discrete incisions within the cornea. Ex.[Swinger] at 33:7–23, Fig. 15W. Weikert likewise discloses delivering a plurality of relaxation incisions to the cornea or limbus. Ex.1019 at 1–4, 14, Figs. 14.1, 14.2.

8. Dependent Claims 7 and 19

Claims 7 and 19 have the same limitations, but depend from claims 1 (above) and 13 (below), respectively. Swinger teaches both "penetrating" (solid line) and non-penetrating (dashed line), or partial, cuts in the cornea for relaxation. Ex.1021 at Figs. 8B, 15W; 21:12–24, 33:7–22.

Additionally, Weikert teaches the delivery of a corneal cataract incision as part of a relaxation incision. Ex.1019 at 12 (describing opposite clear corneal incisions, which are intended as both cataract incisions and relaxation incisions), 14 (noting that patients with certain astigmatism had the cataract incision ("CCI") "incorporated into" the relaxation incision ("PCRI")). It would have been obvious to a POSA to use Swinger's system to deliver the plurality of discrete incisions (*e.g.*, relaxation incisions) that comprise both cataract incisions and corneal relaxing incisions. *See* Section XI.C.1; Ex.1001 ¶¶420–22.

9. Independent Claim 13

a. Limitations 13P, 13.1, 13.3–13.5

The combination of Swinger, Weikert, and Benedikt renders the claimed scanning system (1P), laser source (1.1), delivery system (1.3), scanner (1.4), and controller (1.5) obvious. *See* Sections XI.C.2.a, XI.C.2.b, XI.C.2.d–XI.C.2.f.

b. Limitation 13.2

Benedikt's imaging device includes an Optical Coherence Tomography (OCT) device configured to generate signals used to image tissue of the patient's eye, including the cornea, limbus and sclera. Ex.1020 ¶43.

Whereas Limitation 1.2 claims OCT imaging of the cornea, Limitation 13.2 claims OCT imaging of the limbus and sclera. However, a POSA also would have known that OCT is also capable of imaging the limbus and sclera as well. Ex.1001 ¶426.

c. **Limitation 13.6**

Benedikt teaches a controller programmed to scan the eye tissue with the OCT device to generate imaging data for the target tissue that includes imaging data for the cornea. *See* Sections XI.C.2.c, XI.C.2.g.

d. **Limitation 13.7**

Whereas Limitation 1.7 claims forming incisions in the cornea, Limitation 13.7 claims forming incisions in the limbus or sclera. Swinger teaches making incisions in the limbus. Ex.1021 at 34:17–21. Weikert, however, recognizes incision location relative the corneal apex merely affects corrective power. Ex.1019 at 4 ("The coupling ratio . . . generally increases with the distance from the limbus (i.e. more anterior incisions produce more flattening relative to steepening)."), 14 (discussing "limbal relaxing incisions"). A POSA using Swinger's system to deliver relaxing incisions that extend in an angular direction less-than-a-full circle would have known that incisions could be applied to any of the cornea, limbus, or sclera, depending on the type and level of astigmatism to be corrected. *See* Sections XI.C.1, XI.C.2.h; Ex.1001 ¶428.

e. **Limitation 13.8**

Whereas Limitation 1.8 claims posterior-to-anterior scanning of the focal spot, Limitation 13.8 claims scanning the focal spot in the limbus or sclera. As discussed above, *see* Sections XI.C.1, XI.C.2.h, XI.C.9.d, when delivering relaxing incisions to the limbus or sclera, it would have been obvious to a POSA that the focal spot would be scanned, based on image data, *see* Section XI.C.2.i, to incise relaxation incisions into the limbus or sclera. Ex.1001 ¶429.

D. Ground 4: Claims 9–12 and 22–24 Are Obvious Over Swinger in View of Weikert, and Benedikt, Further in View of L'Esperance

1. Motivation to Combine

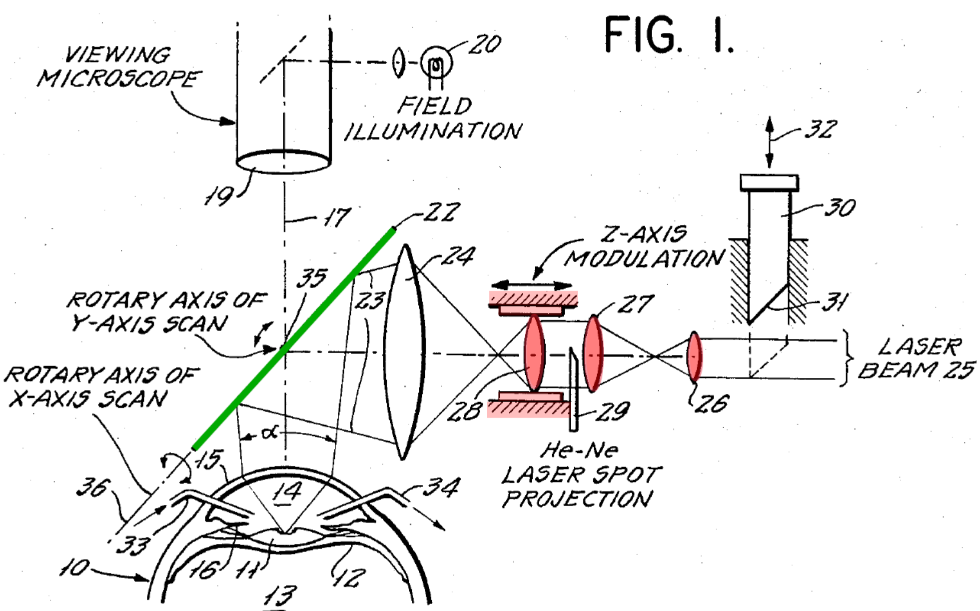
While Swinger, Weikert, and Benedikt collectively teach a system that images and ablates ocular tissue across three-dimensional space, none specifies the particular arrangement of optical components to achieve multi-directional scanning. However, various arrangements of optical and motor systems to achieve multi-directional scanning were old and well known. Ex.1001 ¶182. 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*.

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* Ex.1001 ¶183.

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.1021 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.1022 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 system, as well as incorporating the scanning assembly functionality into Swinger's controllers, because these scanning subsystems are relatively interchangeable; they can be wholly incorporated into Swinger's systems to accomplish scanning along three dimensions. Ex.1001 ¶¶186, 188.

2. Dependent Claims 9 and 22

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.1022 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 sweet 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 propagates through the z-axis scanning device prior to the transverse scanning device, *id*. at Fig. 1.

3. Dependent Claims 10, 11, and 23

Swinger discloses the laser system comprises a scanning system, but does not specify the components of the scanning system. Ex.1021 at 20:16–20.

Benedikt discloses an OCT device that produces an OCT beam that is focused by a Z-scan device (60, 62) and scanned by an X-Y scan device (42'), but does not provide a surgical laser. Ex.1020 ¶¶42–44, Figs. 3–4.

L'Esperance, however, teaches another, substantially similar scanning system to Benedikt's, but adapted to also be used with surgical lasers. *See* Section XI.D.2. It would have been obvious to a POSA to incorporate L'Esperance's scanning system into Swinger's laser system in order to provide three-dimensional scanning, as Swinger itself envisions incorporating any suitable scanning system. Ex.1021 at 20:16–20; Ex.1001 ¶433. It would have further been obvious to a POSA that, upon incorporating Benedikt's imaging devices, that the OCT would use the same scanning system as the surgical laser so that a separate scanning system would not be required, and because integrated scanners for both OCT and surgical lasers were known in the art. Ex.1001 ¶433. Moreover, integrating structures in a predictable way with predictable results is obvious. *See In re Larson*, 340 F.2d 965, 968, 144 USPQ 347, 349 (CCPA 1965); MPEP 2144.04. A POSA would have known to select L'Esperance's surgical scanning system over Benedikt's OCT scanning system because, when providing an integrated scanning system, a POSA would have preferred the more accurate z-axis focal depth control offered by L'Esperance's system. Ex.1001 ¶433.

4. Dependent Claims 12 and 24

Benedikt's imaging device includes an OCT device configured to generate signals used to image tissue of the patient's eye, including the cornea, limbus and sclera. Ex.1020 ¶43. Whereas Claim 12 claims OCT imaging of the cornea, Claim 24 claims OCT imaging of the limbus and sclera. However, a POSA also would have known that OCT is also capable of imaging the limbus and sclera as well. Ex.1001 ¶434.

XII. NO SECONDARY CONSIDERATIONS WEIGH IN PO'S FAVOR

Although PO may contend that its Catalys® Precision Laser System practices the Challenged Patent, has found commercial success, and received industry praise, Ex.1032 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). For instance, each of the Challenged Patents claims "relaxation incision." But this is an optional procedure that does not have to be performed as part of cataract surgery. Ex.1001 ¶496. In order to establish a nexus, PO must show that those using the Catalys® system were also performing optional relaxation incisions. Additionally, 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; the Red Herring 100 award is an award granted to startup companies, not products, which was granted to the developer of Catalys, not for the device itself. 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 26, 2020

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 14,000 (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 26th day of April, 2021, via FedEx® directed to the Patent Owner at the correspondence address of record:

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TABLE OF EXHIBITS

Exhibit No.	Description
Exhibit 1001	Declaration of Holger Lubatschowski, Ph.D.
Exhibit 1002	Curriculum Vitae of Holger Lubatschowski, Ph.D.
Exhibit 1003	U.S. Patent No. 6,099,522 ("Knopp")
Exhibit 1004	U.S. Patent No. 9,233,023
Exhibit 1005	Claim Listing of U.S. Patent No. 9,233,023
Exhibit 1006	File History of U.S. Patent No. 9,233,023
Exhibit 1007	U.S. Patent No. 9,233,024
Exhibit 1008	Claim Listing of U.S. Patent No. 9,233,024
Exhibit 1009	File History of U.S. Patent No. 9,233,024
Exhibit 1010	U.S. Patent No. 10,376,356
Exhibit 1011	Claim Listing of U.S. Patent No. 10,376,356
Exhibit 1012	File History of U.S. Patent No. 10,376,356
Exhibit 1013	U.S. Patent No. 10,709,548
Exhibit 1014	Claim Listing of U.S. Patent No. 10,709,548
Exhibit 1015	File History of U.S. Patent No. 10,709,548
Exhibit 1016	U.S. Provisional Application No. 60/906,944
Exhibit 1017	U.S. Application No. 2006/0195076 ("Blumenkranz")
Exhibit 1018	U.S. Application No. 2008/0058777 ("Kurtz")

Exhibit 1019	Mitchell P. Weikert & Douglas D. Koch, "Refractive Keratotomy: Does It Have a Future Role in Refractive Surgery?," CATARACT AND REFRACTIVE SURGERY, 217–234 (2005) ("Weikert").
Exhibit 1020	U.S. Application No. 2004/0066489 ("Benedikt")
Exhibit 1021	U.S. Patent No. 6,325,792 ("Swinger")
Exhibit 1022	U.S. Patent No. 4,538,608 ("L'Esperance")
Exhibit 1023	R. Huber, et al., *High speed frequency swept light source for Fourier domain OCT at 20 kHz A-scan rate*, 5690 SPIE 96 (2005)
Exhibit 1024	Krasnov, *Laser-Phakopuncture in the Treatment of Soft Cataracts*, 59(2) Brit. J. Ophthal. 96 (1975)
Exhibit 1025	U.S. Patent No. 5,098,426 to Sklar et al. ("Sklar")
Exhibit 1026	David Stern, *Corneal Ablation by Nanosecond, Picosecond, and Femtosecond Lasers at 532 and 625 nm*, Arch. Ophthalmol. (1989)
Exhibit 1027	F.H. Loesel, *Non-thermal ablation of neural tissue with femtosecond laser pulses*, 66 Appl. Phys. B. 121, 125 (1998)
Exhibit 1028	Paul M. Woodward et al., *Anterior Capsulotomy Using A Neodymium YAG Laser*, 16 Annals of Ophthalmology 6, 534, 538–39
Exhibit 1029	Daniele Aron-Rosa et al., *Use of pulsed ps NdYag laser in 6664 cases*, Am. Intra-Ocular Implant Soc. J., Vol. 10 (1984)
Exhibit 1030	Carmen A. Puliafito et al., Laser Surgery of the Lens: Experimental Studies, 90 American Academy of Ophthalmology 8, 1007, 1011 (1983)
Exhibit 1031	https://www.jjvision.com/sites/default/files/media_center/History_of_Refractive_Surgery.pdf
Exhibit 1032	Plaintiff's Responses to First Set of Interrogatories

Exhibit 1033	Liu Z et al., *Evaluation of corneal thickness and topography in normal eyes using the Orbscan corneal topography system*, BRITISH JOURNAL OF OPHTHALMOLOGY 83:774–78 (1999)
Exhibit 1034	I. Howard Fine, et al., *Refractive Keratotomy: Does It Have a Future Role in Refractive Surgery?*, CATARACT AND REFRACTIVE SURGERY, 217–234 (2005) ("Fine").
Exhibit 1035	Samuel Masket and Shaleen Belani, *Proper wound construction to prevent short-term ocular hypotony after clear corneal incision cataract surgery*, J. CATARACT REFRACT SURGERY, 33:383–86 (2007)
Exhibit 1036	Carlos E. Martinez, MD & Stephen D. Klyce, PhD, *Corneal topography in cataract surgery*, CURRENT OPINION IN OPHTHALMOLOGY, 7-1:31–38 (Feb. 1996)
Exhibit 1037	LJ Maguire & WM Bourne, *Topographical analysis of the effects of corneal relaxing incisions on high postkeratoplasty astigmatism*, DEVELOPMENTS IN OPHTHALMOLOGY, 18:197–202 (1989)
Exhibit 1038	Harry S. Geggel, MD, *Arcuate Relaxing Incisions Guided by Corneal Topography for Postkeratoplasty Astigmatism: Vector and Topographic Analysis*, CORNEA, 25-5:545–57 (June 2006)
Exhibit 1039	Helen Seward, et al., *Management of cataract surgery in a high myope*, 85 Controversies in Ophthalmology 1372 (2001)
Exhibit 1040	Stephen A. Boppart, *Surgical Diagnostics, Guidance, And Intervention Using Optical Coherence Tomography*, Ph.D Thesis (1998) (Massachusetts Institute of Technology), *available at* https://dspace.mit.edu/handle/1721.1/9889 ("Boppart")
Exhibit 1041	U.S. Patent Pub. No. 2004/0102765 ("Koenig")
Exhibit 1042	Irina S. Barequet, et al., *Astigmatism outcomes of horizontal temporal versus nasal clear corneal incision cataract surgery*, 30 J. Cataract Refract. Surg. 418, 422 (2004)
Exhibit 1043	Clemens Vass, et al., *Comparative study of corneal topographic changes after 3.0 mm beveled and hinged clear corneal incisions*, 24:11 J. Cataract Refract. Surg. 1498 (1998)

Exhibit 1044	Paul H. Ernest, et al., *Relative stability of clear corneal incisions in a cadaver eye model*, 21:1 J. Cataract Refract. Surg. 39 (1995)
Exhibit 1045	Rengaraj Venkatesh et al., Manual Small Incision Cataract Surgery in Eyes with White Cataracts, Indian J. Ophthalmology 53-3:173-76 (2005)
Exhibit 1046	U.S. Patent Application No. 2007/0282313
Exhibit 1047	T.R. Steele, et al., *Broadly tunable high-power operation of an all-solid-state titanium-doped sapphire system*, 16:6 Optics Letters 399 (1991)
Exhibit 1048	B. Frei & J. E. Balmer, *1052-nm wavelength selection in a diode-laser pumped Nd:YLF laser*, 33:30 Applied Optics 6942 (1994)
Exhibit 1049	V.M. Gelikonov et al., *A Decade Of Optical Coherence Tomography In Russia: From Experiment To Clinical Practice*, 47 Radiophysics and Quantum Electronics 10 (2004) ("Gelikonov")
Exhibit 1050	Bin Rao, et al., *Imaging and investigating the effects of incision angle of clear corneal cataract surgery with optical coherence tomography*, 11:24 Optics Express 3254 (2003)
Exhibit 1051	'023 Infringement Contentions
Exhibit 1052	'024 Infringement Contentions
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