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.

IPR2021-00845
U.S. Patent No. 9,233,024

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

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*All emphases and coloring added, unless otherwise noted.

TABLE OF AUTHORITIES

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I. INTRODUCTION

Petitioners respectfully request that the Board correct two critical errors committed during the prosecution of U.S. Patent No. 9,233,024 ("'024"), which led to the grant of an invalid patent. First, the Examiner erred in amending the preamble of each independent claim to add "cataract surgery" to "[a] method," ostensibly to distinguish prior-art ophthalmic (eye) surgery methods that did not explicitly mention cataract surgery. In doing so, the Examiner inexplicably missed the fact that the very prior art previously used to reject the claims (Blumenkranz) states that its techniques "may be used during cataract surgery." Second, the Examiner failed to find prior art that taught the allegedly novel feature of the '024: delivering both a partially extending incision in the cornea, limbus, or sclera, and a relaxation incision. Had the Examiner not erroneously given the amended preamble patentable weight, the Examiner would have easily found the prior art identified in this Petition, and would have maintained the obviousness rejection of all claims.

The Examiner's errors in the '024 reflect the exact same errors made in its parent, U.S. Patent No. 9,233,023 ("'023"). Both patents are directed to the same basic system and well-known incisions: the '023 claims the system and the '024 claims the method. At bottom, both the '023 and the '024 are directed to automating an old process using modern—but known—technology (as are related U.S. Patent Nos. 10,109,548 and 10,376,356).

Patent Owner's ("PO's") assertion of the '024 and its familial patents against Petitioners (except Alcon Inc.) in *AMO Development, LLC et al. v. Alcon LenSx, Inc. et al.*, No. 1:20-cv-00842-CFC (D. Del.), filed June 23, 2020 ("Delaware Litigation"), does not justify denial of this Petition. Trial in that case is set for February 2023, more than four months after the Board would enter a FWD. The Board's institution decision is due by October 2021, two months before the Markman hearing. The PTAB therefore presents the more efficient avenue for hearing Petitioners' invalidity arguments.

Petitioners Alcon Inc., Alcon LenSx, Inc., Alcon Vision, LLC, Alcon Laboratories, Inc., and Alcon Research, LLC (collectively, "Alcon") respectfully request *inter partes* review ("IPR") of '024 claims 1–17 and 20–26 ("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 '024 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 '024, all of which are asserted in the Delaware Litigation:

U.S. Patent Nos. 9,233,023; 10,376,356; 10,109,548.[1] This case may affect, or be affected by, the Delaware Litigation.

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

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 ’024 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 1–17 and 20–26 of the ’024.

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

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

[2] Each reference qualifies as prior art under 35 U.S.C. §102 regardless of whether the ’024 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.

1. U.S. Patent Application No. 2006/0195076 to Blumenkranz et al. ("Blumenkranz"), filed January 9, 2006 and published August 31, 2006, is prior art under § 102(b). Blumenkranz was before the USPTO during prosecution of the '024.

2. U.S. Patent Application Publication No. 2008/0058777 to Kurtz et al. ("Kurtz"), filed September 5, 2006, is prior art under § 102(e). Kurtz was not before the USPTO during prosecution of the '024.

3. 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") is prior art under § 102(b). Weikert was not before the USPTO during prosecution of the '024.

4. 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 '024.

5. 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 '024.

Alcon requests IPR on the following grounds:

Ground	Basis	Claims	Reference(s)
1	§ 103	1–17 and 20–26	Blumenkranz in view of Kurtz and Weikert
2	§ 103	**Alternative**: 16	Blumenkranz in view of Kurtz, Weikert, and Swinger
3	§ 103	1–3, 6, 16–17, and 20–26	Kurtz in view of Swinger and Weikert
4	§ 103	4–5 and 7–15	Kurtz in view of Swinger, Weikert, and Benedikt

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.

“A cataract surgery method . . . .” (preamble): It is well settled that “a preamble is not limiting ‘where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention,’” as occurred here. *See Arctic Cat Inc. v. GEP Power Power Prod., Inc.*, 919 F.3d 1320, 1328 (Fed. Cir. 2019). Yet, in order to allow the ’024 over the prior art, the Examiner amended the preamble of each independent claim, originally directed to “[a] method,” to specify a “***cataract surgery*** method.” Ex.1009 at 16–

17. But this amendment merely recites the invention's intended use and fails to impart any patentable weight to the claimed method steps, which can be performed by multifunctional ophthalmic-surgery systems in the prior art.

For example, independent claims 1, 8, 12, and 22 recite methods for treating target tissue in one or more of a cornea, limbus, or sclera of a patient's eye, including: (i) generating a treatment light beam (*e.g.*, a laser beam), (ii) deflecting the beam using a scanner, and (iii) delivering treatment patterns to form particular incisions. Claims 8 and 12 further recite steps for acquiring more data about the patient's eye. These methods, however, include common steps practiced by multifunctional ophthalmic-surgery systems; there is no claimed method step exclusive to "cataract surgery." Indeed, PO tacitly admits the preamble is not limiting when it alleges infringement against Petitioners' multifunctional system, which is capable of making incisions for cataract surgery as well as for other purposes. Ex.1051 at 1–9.

Although PO may argue the claims recite methods for delivering first and second treatment patterns to form incisions in a patient's eye, *see, e.g.*, Sections XI.A.2.d–XI.A.2.e, 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. Ex.1007 at 10:19–21. The "relaxing incisions," likewise made in the cornea or limbus, adjust eye shape to correct general refractive error. *Id*. at 10:66–

11:11. Each incision type can be used in non-cataract procedures such as corneal transplants (penetrating keratoplasty), lens replacements not spurred by cataracts, or glaucoma surgery to increase aqueous outflow or insert valves, or the insertion of phakic anterior chamber lenses (so called ICLs). Ex.1001 ¶¶46–47, 57.

Thus, recitation of a "***cataract surgery*** method" in the preamble of claims 1 8, 12 and 22 should not be construed as limiting. Nonetheless, Petitioners' prior art teaches "cataract surgery" scanning systems, so regardless of whether the preamble is given patentable weight or not, the claims are still invalid.

"The first and second treatment patterns are delivered simultaneously": Claims 3, 9, 13 and 24 depend from claims 1, 8, 12 and 22, respectively, and further provide that "the first and second treatment patterns are delivered simultaneously." The '024 states that combining treatment patterns amounts to "***simultaneously***" applying those treatment patterns. Ex.1007 13:26–29 ("[t]he pair of treatment patterns can be applied sequentially, or ***simultaneously*** (i.e. the pair of treatment patterns can be ***combined*** into a ***single treatment pattern*** that forms both types of incisions).").

Thus, based on the specification, one possible construction is that the first and second treatment patterns must be delivered "simultaneously." Ex.1001 ¶¶53, 58. The '024 incorporates by reference Provisional Application No. 60/906,944, which explains that simultaneous delivery can be achieved by using a "[m]ulti-segmented lens." Ex.1016 at 38.

Another possible construction is that the treatment patterns are combined and delivered as part of a single execution of the controller's programming. Ex.1001 ¶54. Such execution can also be accomplished in multiple ways. For instance, a POSA would have known that laser incisions are formed by delivering a treatment pattern at multiple depths. *Id*. ¶55. Thus, treatment patterns can be combined into a single treatment plan such that the treatment patterns are delivered together at each depth. *Id*. ¶56. In other words, at each depth, the scanner will deliver two treatment patterns before moving to the next depth.

Alternatively, multiple incisions can be formed sequentially during a single execution of the controller's programming. Thus, the treatment pattern for one incision will be applied at multiple depths before a second treatment pattern for a second incision is applied. In the Delaware Litigation, PO's contentions appear consistent with this view, as evidenced by allegations regarding "single treatment pattern" language found in claims 2 and 13 of the '023. Ex.1051 at 4 (alleging infringement of claim 2 because "the pattern . . . will be executed in the following ***sequence***: 1. Capsulotomy 2. Lens fragmentation 3. Arcuate incisions 4. Primary incision 5. Secondary incision").

Because these claims are subject to multiple interpretations, and it is unclear which interpretation controls, Petitioners will apply the prior art as if all are correct (despite believing the claims to be indefinite).

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 '024 Has Not Been Subject to a Prior Petition

The '024 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 '024, 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

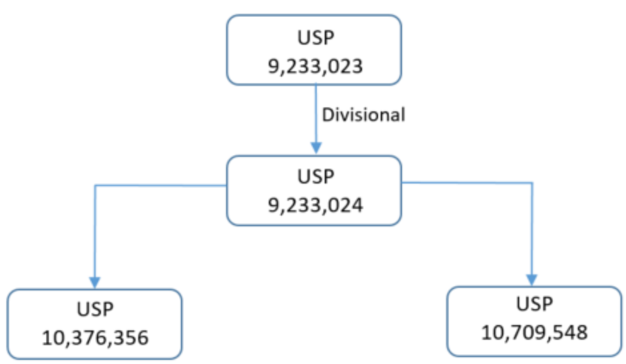
1. *Becton Dickinson* Factors

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 Kurtz as base references. Kurtz was not applied against the Challenged Claims or discussed by the Examiner during prosecution of the '023. While Blumenkranz was applied against the Challenged Claims, the Examiner inexplicably distinguished it by amending the preamble to recite "a ***cataract surgery*** method," Ex.1009 at 16–17, despite the fact that Blumenkranz expressly discloses a cataract surgery method. Ex.1017 ¶11 ("The techniques disclosed herein may be used during cataract surgery . . . ."). But even if the preamble is limiting, the Examiner failed to explain why it would not have been obvious to a POSA to use multifunctional ophthalmic-surgery systems to perform cataract surgery. *See id*. While PO also argued during prosecution that no prior art taught a partially penetrating "cataract incision" or "relaxation incision," *see id.*, the prior art cited in this petition shows that such incisions have been applied as part of cataract surgeries since the late 1800s.

Additionally, 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 '024 and '023 Claims Are Directed to Substantially Overlapping Subject Matter

The '024 is a divisional application of application no. 12/048,186 ("'186 application"), which issued as the '023. The '186 application is the parent to five applications, four of which issued as patents (the "Culbertson Patents") and are subject to IPR petitions, including this one.



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 '023 and '024, for instance, both require a first treatment pattern to form a cataract incision that is partial, but which is subsequently completed to provide access to a chamber of the patient's eye, and a second treatment pattern to form a relaxation incision. Whereas the '023 claims the system's structure, the '024 (a divisional of the '023) claims a method of using that system to deliver the claimed incisions. The error that originated during examination of the '023 recurred during examination of the '024.[3]

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

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[3] The other two Culbertson Patents Petitioners are challenging—Patent Nos. 10,376,356 and 10,109,548—likewise were allowed as a consequence of an Examiner error. Those patents' claimed systems were allowed because the Examiner overlooked prior art disclosure of incisions that are less than a full circle in arcuate extent, which was alleged to be the inventive aspect.

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 §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.1056. 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.1055; *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 claim 3, 9, 13, and 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).

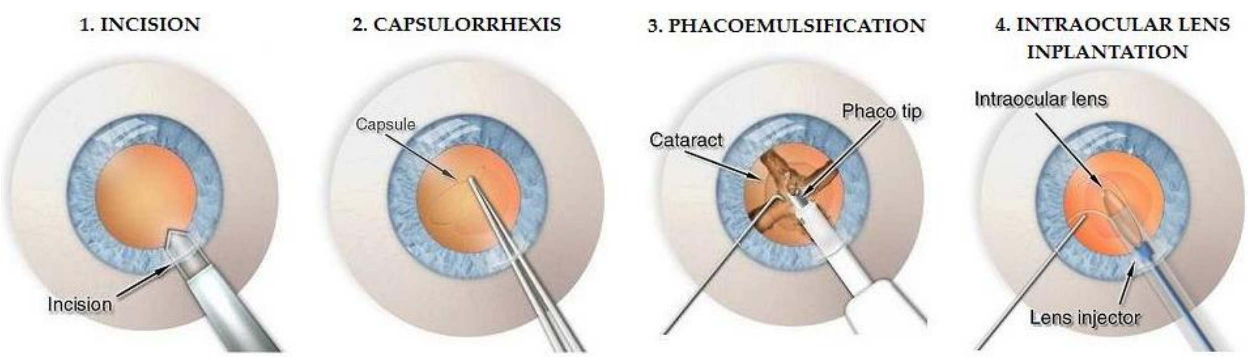
VII. BACKGROUND OF THE TECHNOLOGY

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 date 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 '024

The '024 issued from the '103 application, which was filed on August 7, 2012, is a division of the '186 application, and claims priority to Provisional Application No. 60/906,944, filed on March 13, 2007. Ex.1007. Because the '103 application was filed before March 16, 2013, its 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).

A. Alleged Problem

In order to access the cataractous lens, the ’024 explains that a complete cut of the cornea, limbus, or the sclera (referred to as a “cataract incision” in the ’024 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.” *Id*. at 10:19–34. The ’024 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 10:38–42.

In addition to describing purported challenges associated with making a cataract incision, the ’024 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 1:57–60. In particular, the ’024 explains that standard cataract incisions typically induce from 0 to 1.0 D of astigmatism, on average. *Id*. at 10:66–11:2.

B. Alleged Invention

The ’024 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.*, Ex.1007 at 3:45–4:9, 5:11–34; Fig. 1.

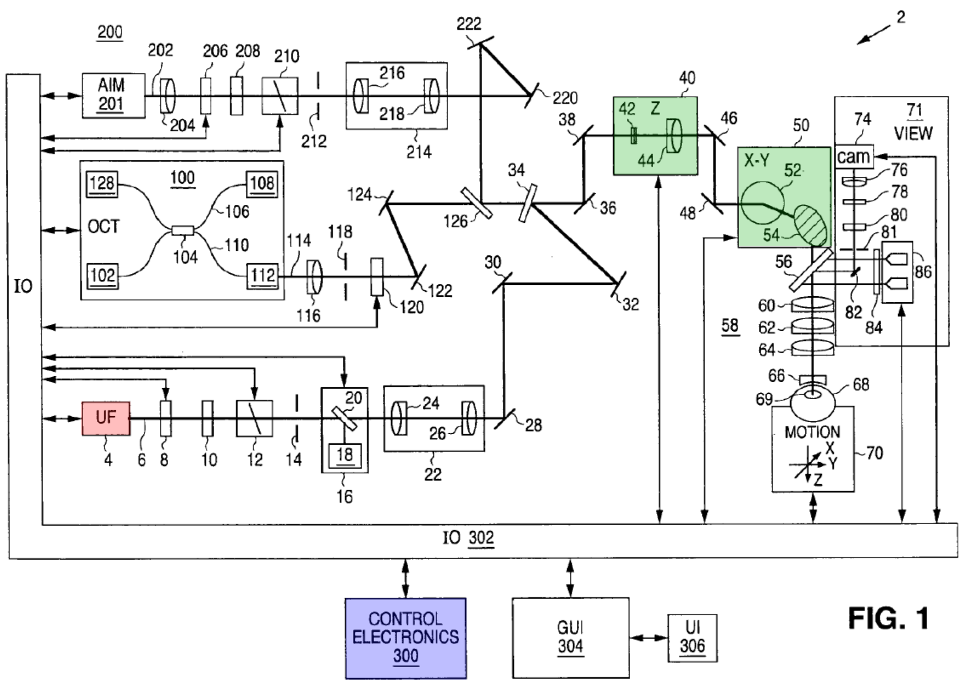


FIG. 1

The ’024 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 ’024 laser surgical system creates a relaxing incision (420) in the cornea (406). *Id*. at 11:3–21. The ’024 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 13:23–29.

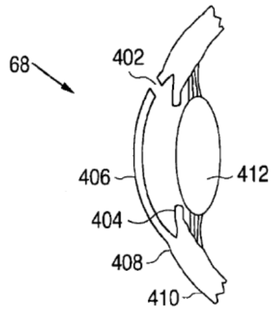


FIG. 5B

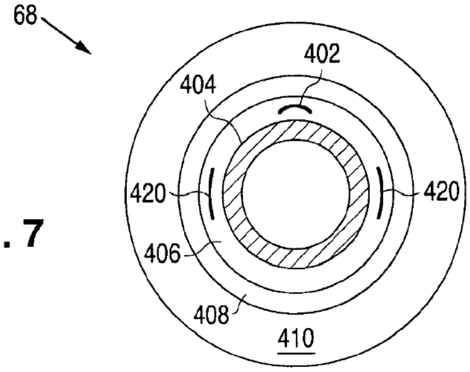


FIG. 7

C. Prosecution History

The Examiner committed two critical errors during prosecution of the ’024: (1) amending the preamble of the claims and giving it patentable weight to distinguish prior-art ophthalmic-surgery methods, while inexplicably failing to recognize that the very same prior art disclosed a process to perform cataract surgery; and (2) finding delivery of partial incisions was a point of novelty.

The original application was filed on August 7, 2012. Ex.1009 at 968. The Examiner initially rejected the claims under 102(e) as anticipated by Blumenkranz (US 2006/0195076) (noting one common inventor, Dan E. Andersen, with the ’024) and under 102(b) as anticipated by Knopp (U.S. 6,099,552). *Id.* at 863–70. The Examiner also included several non-statutory obviousness-type double-patenting rejections over co-pending applications 12/861798 (U.S. Application 2011/0184392), 12/703689 (U.S. Application 2010/0137982), and 12/702242 (U.S. Application 2010/2010/0137850) in view of Knopp. *Id.* at 855–63. PO traversed by stating that both Blumenkranz and Knopp failed to explicitly disclose “delivering the second treatment pattern to the target tissue to form a relaxation incision along or near limbus tissue or along corneal tissue anterior to the limbus tissue of the patient's eye to reduce astigmatism thereof." *Id.* at 843–44.

After a Request for Continued Examination and a second Final Rejection, PO and the Examiner held two telephonic interviews. The first was initiated by PO, *id*. at 54, after which PO amended the preamble to specify that the target tissue for the incision was "one or more of the cornea, limbus or sclera," *id*. at 31. The Examiner initiated the second interview, and suggested that PO further amend the preamble of each independent claim to recite "cataract surgery method" to distinguish the claimed method from other types of treatments taught by the prior art of record, including Blumenkranz. *Id*. at 16–19. The Examiner, however, failed to appreciate that Blumenkranz expressly taught several of the steps involved in a "cataract surgery method." The Examiner subsequently issued an Examiner's Amendment on September 24, 2015 allowing all pending claims. *Id*. at 16–17. Throughout prosecution, the Examiner never cited any art that expressly taught partial cataract and relaxation incisions, despite the existence of art (cited herein) that teaches such incisions were old and well-known.

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; Figs. 1. The system then delivers a treatment light beam to create an incision in the eye tissue. *Id.* ¶50. Blumenkranz also teaches the combination of 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.* Lastly, 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. Kurtz (U.S. Application No. 2008/0058777)

Kurtz teaches a system and method "for resecting corneal tissue." Ex.1018 ¶7. The system includes a light source (31) comprising a femtosecond surgical laser, a focusing assembly (35) to focus the beam emitted by light source (31), an interface (41) that "presents the surgeon with several incision patterns from which the desired resection pattern is selected," and a controller (39) to control the location of the beam focal point and apply the selected resection pattern. *Id*. ¶19; Fig. 2. Kurtz also teaches resection patterns that comprise partial cuts, or "uncut gaps," to limit a patient's exposure to contaminants that could infect the eye, which cuts can be selectively applied using the controller (39). *Id*. ¶¶14–18; Figs. 1A–H.

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 kertotomy (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 1–17 and 20–26 Are Obvious Over Blumenkranz in View of Kurtz and Weikert

1. Motivation to Combine

Blumenkranz teaches a multifunctional laser ophthalmic surgery system fully capable of producing laser incisions of different depths along 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 fragmentation of the cataract lens, and does not provide great detail on the initial incisions in the eye tissue to reach the interior chambers. To that end, Blumenkranz does not expressly disclose using the system to deliver a partial cataract incision or relaxation incisions.

With respect to partial cataract incisions, Kurtz recognized that when corneal incisions are made in less-than-sterile environments, such as when the laser system is located in a room separate from the operating room, delivering a partial incision to the eye tissue protects the eye from environmental contaminants and infection until the surgeon is ready to complete the incision. Ex.1019 ¶14. It would have thus been obvious to a POSA to use the system and methods disclosed by Blumenkranz to deliver a cataract incision that only partially extends through the target tissue in order to protect the eye from environmental contaminants when the procedure is performed in less-than-sterile environments. Ex. 1001 ¶¶128–31, 138–39.

Additionally, 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. *Id*. ¶136. 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 Enterprises, 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.

Indeed, those in the art had already recognized that laser systems delivered more accurate and precise incisions to ocular tissue, without the risk of tearing. Ex. 1001 ¶27. 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 surgery-induced astigmatism caused by the cataract incision. Ex. 1001 ¶¶119–27, 132–37.

2. Independent Claim 1

a. **Limitation 1P**

Although the Examiner somehow missed this fact, Blumenkranz discloses a cataract surgery method that may be used for treating target tissue in one or more of the cornea, limbus, or sclera of a patient's eye.[4] Ex.1017 ¶¶8 (discussing need to advance standards of care in cataract surgeries), 11 (stating claimed techniques may be used for cataract surgery), 21 (discussing "ophthalmic surgical system for treating eye tissue"), 45 (providing structural details of system), 71 (stating system may be used to perform "incisions in other areas of the eye such as, but not limited to, the sclera"), 74 (discussing use for cataracts).

b. **Limitation 1.1**

Blumenkranz discloses generating a treatment light beam (11) using a treatment light source (10). *Id*. ¶¶45, 50; Figs. 11–12.

[4] Not only does Blumenkranz disclose that it is directed to a cataract-surgery system, but it ultimately issued as U.S. Patent No. 8,394,084, which PO is asserting against four Petitioners in the Delaware Litigation. There, PO alleges that the '084 covers PO's cataract-surgery system, Catalys, as well as Petitioners' cataract-surgery system, LenSx. Ex.1059 ¶¶87, 88, 107–29.

c. **Limitation 1.2**

Blumenkranz discloses a scanner (*e.g.*, 16) for deflecting the light beam to form treatment patterns of the treatment light beam. *Id.* ¶¶45 (scanning elements "may be controlled by control electronics 12"), 57 ("scanner [is] used to produce the patterns for cutting"), 73 ("treatment pattern can be rapidly applied to the target tissue using an automated 3 dimensional pattern generator (in the control electronics 12)").

d. **Limitations 1.3 and 1.5**

Blumenkranz discloses a method to deliver a treatment pattern to a target tissue, including the sclera of the patient's eye, to form an incision that provides access to an eye chamber of the patient's eye. *Id.* ¶¶68–71 (discussing use for anterior capsulotomies and incisions to ocular tissue), 100 (making incisions for removing lens), Fig. 3. Blumenkranz also states that incisions can be delivered to "other areas of the eye," *id.* ¶71, which a POSA would have known includes the cornea or limbus, as these are well-known incision locations for cataract surgery. Ex.1001 ¶274.

Blumenkranz also discloses delivering incisions that only partially extend through the target tissue. For example, the pulsed laser in Blumenkranz's system generates incisions that only partially extend through the target tissue. Ex.1017 ¶68 ("lens thickness is much larger than the length of the beam waist axial").

Blumenkranz states that dielectric breakdown occurs at the focal point and, to provide for continuous cutting, laser spots must be placed so that rupture zones connect. *Id.* ¶¶50–53. Because the average thickness of the cornea (*e.g.*, 550μm) is much greater than the focal spot diameter (*e.g.*, 15μm), the laser pulses would create only partial incisions. *Id*. ¶50; Ex.1001 ¶¶92, 274. A full incision requires multiple passes of the laser beam at different depths. Ex.1017 ¶¶50–53, 60–62. For instance, Blumenkranz describes using "several" "pattern scans consecutively at different depths" to produce a cut. *Id.* ¶62. Thus, when a target tissue is thicker than the focal area of the beam, the incision will be partial. The 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 ¶¶92, 274.

To the extent independent claim 1 requires the first treatment pattern produce a cataract incision for access that is only partially penetrating the target tissue, such partial incisions are taught by Kurtz. Specifically, Kurtz teaches producing incisions in a patient's eye with "uncut gaps" so that "the eye remain[s] protected and unexposed to environmental contaminants" when the procedure is conducted in less-than-sterile environments. Ex.1018 ¶14. The "uncut gaps" are later opened or incised in order to access inner compartments of the eye and allow for surgery. *Id.* at ¶¶7–8, 14–15.

Based on these teachings, it would have been obvious to a POSA to use Blumenkranz's system to create a corneal incision that provides access for lens removal instrumentation, via a partial incision as taught by Kurtz to protect the eye from contamination until surgery commences in a sterile environment. Ex.1001 ¶274. A POSA would have known that lens removal was a known part of the cataract surgery procedure that necessitates an incision to access the lens, and it would have been obvious to make the incision with the ultrafast laser as part of a treatment pattern. Ex.1001 ¶23, 107, 274.

e. **Limitation 1.4**

Partially penetrating relaxation incisions to the cornea "to decrease astigmatism following cataract surgery" have been performed since the late 1800s. Ex.1019 at 1–2, 11–12. Specifically, Weikert teaches delivering relaxation incisions to portions of the cornea during cataract surgery. *Id.* 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).

It would have been obvious to a POSA to use Blumenkranz's system, which is capable of delivering incisions of different sizes and depths, to deliver relaxation incisions as part of a second treatment pattern to treat astigmatism, in addition to the first treatment pattern. Ex.1017 ¶¶20, 50–53, 60–62, Fig. 8; Ex.1001 ¶275. For example, Blumenkranz discloses that the system is capable of delivering more than one treatment pattern, Ex. 1017 *at* ¶¶62, 68 ("Scans can be continuous straight or curved lines, or ***one or more overlapping or spaced apart spots and/or line segments***"), 101 ("Multi-segmented lens 30 can be used to focus the beam simultaneously at multiple points not axially overlapping").

3. Dependent Claim 2

Because the cornea sits anterior to the limbus, claim 2 is directed to a second treatment pattern delivered to the cornea. Ex.1001 ¶276. Thus, Blumenkranz, Kurtz, and Weikert collectively render obvious a second treatment pattern delivered along corneal tissue anterior to the limbus tissue of the patient's eye. *See* Section XI.A.2.e; Ex.1001 ¶276.

4. Dependent Claims 3, 9, 13 and 24

Claims 3, 9, 13 and 24 have the same limitations, but depend from independent claims 1 (above), 8, 12 and 22 (below), respectively. Blumenkranz discloses delivering multiple treatment patterns simultaneously. Ex.1017 ¶101 ("Multi-segmented lens 30 can be used to focus the beam simultaneously at multiple points ***not axially overlapping***"); Ex.1001 ¶279.

Alternatively, Weikert teaches delivering cataract and relaxation incisions together, but sequentially, as part of a single procedure. *See, e.g.*, Ex.1019 at 12. A POSA would have known to apply a similar sequential delivery during a single procedure, like Weikert, using the laser system disclosed by Blumenkranz. Ex.1001 ¶280.

However, while manual blades by nature must deliver incisions sequentially, a POSA would have known that laser systems are not so limited. Ex.1001 ¶281. Instead, a POSA would have known that laser systems deliver patterns at different depths, generally beginning at a maximum depth and proceeding to lesser depths so that the laser does not traverse already-ablated tissue. *See, e.g.*, Ex.1017 ¶94 (beams have "a discrete depth of field"), 76 (planar scans at different depths), 62 (ablation proceeds in posterior-to-anterior direction), 98 (same). Based on these teachings, it also would have been obvious to a POSA to program Blumenkranz's controller to deliver combined treatment patterns on a layer-by-layer basis across different depths, moving posteriorly-to-anteriorly. Ex.1001 ¶281.

5. Dependent Claim 4

Blumenkranz discloses measuring the surface profile of a surface of the cornea of the patient's eye[5] and positioning the second treatment pattern on the

[5] The '024 discloses using a "profilometer," which "may be a placido system, triangulation system, laser displacement sensor, ***interferometer***, or other such device, which measures the corneal topography," to measure the surface profile. Ex.1007 at 11:57–62. As OCT is an interferometer that can measure corneal

patient's eye based upon the measured surface profile. Ex.1017 ¶¶56 (OCT to locate the surface of ocular tissue and create 2D and 3D patterns), 57 (OCT data used to determine location of anterior and posterior lens capsule), 59 (OCT used as "input into a laser scanning and/or pattern treatment algorithm"), 68 (OCT obtains "dimensional information" about the cornea), 73 (pattern generator in the control electronics 12), 74 ("the data [from the measurement devices] . . . can be loaded into the scanning system to automatically determine the parameters of the cutting"), 78, 85, cls. 12, 44. Moreover, it would have been further obvious to a POSA to use the surface profile to control the formation of the second treatment pattern because surface profiles can measure astigmatism, and the second treatment pattern (to form relaxation incisions) is intended to treat astigmatism. Ex.1001 ¶¶282–83.

6. Dependent Claim 5

Blumenkranz discloses measuring scattering properties from different locations on the patient's eye, and positioning at least one of the first and second treatment patterns on the patient's eye based upon the measured scattering

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topography, OCT measurements of the eye satisfy this claim. Indeed, PO has alleged infringement claiming OCT measures the surface profile of a surface of the cornea of the patient's eye. *See* Ex.1052 at 3 (identifying Petitioner's OCT system as practicing this claim).

properties. *See* Section XI.A.5; Ex.1007 at 6:58–67, 10:45–52 (OCT works by measuring "scattering" light off eye structures). Moreover, it would have been further obvious to a POSA to use the scattering properties to position the first and/or second treatment patterns because scattering properties can reveal tissue depth, which affects the positioning of the first and second treatment patterns (intended to incise at least part of that depth). Ex.1001 ¶284.

7. Dependent Claims 6, 10 and 14

Claims 6, 10 and 14 have the same limitations, but depend from independent claims 1, 8, and 12, respectively. Blumenkranz teaches generating an aiming light beam, deflecting the aiming light beam using the scanner to form an aiming pattern, and delivering the aiming pattern to the target tissue to visually indicate a position of at least one of the first and second treatment patterns. Ex.1017 ¶¶56, 75 ("aiming beam source AIM"), 77 ("aiming beam AIM may then provide the user with a view of the disposition of the treatment beam, or the location of the identified targets"), 84–85; Figs. 11–12 ("Am").

8. Dependent Claims 7, 11 and 15

Claims 7, 11 and 15 have the same limitations, but depend from independent claims 1, 8 and 12, respectively. Blumenkranz discloses capturing an image of the target tissue (*e.g.*, via a camera (V) or OCT device), displaying the captured image, and modifying a composition and location of a least one of the first and second treatment patterns on the patient's eye in response to input received from a user input device (*e.g.*, via a graphic user interface (GUI)). *Id*. ¶¶77 ("Graphical user interface GUI may be used to process user input and display the images gathered by both visualization apparatus V and the OCT interferometer"), 88 (disclosing user input may comprise identifying target tissue to track user-defined targets), Figs. 11, 12, 14.

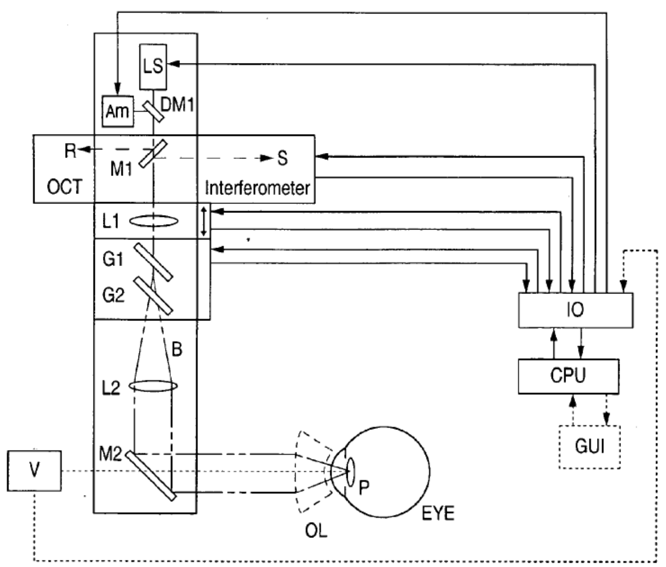

FIG. 11

9. Independent Claim 8

a. Limitations 8P, 8.1, and 8.2

Blumenkranz discloses cataract surgery methods (8P), generating a treatment light beam (8.1), and deflecting the treatment light beam using a scanner (8.2). *See* Sections XI.A.2.a, XI.A.2.b, XI.A.2.c.

b. **Limitations 8.3 and 8.6**

Blumenkranz, Kurtz, and Weikert collectively teach delivery of the claimed first treatment pattern. *See* Section XI.A.2.d.

c. **Limitation 8.4**

Blumenkranz, Kurtz, and Weikert collectively teach measuring a surface profile of a surface of the cornea of the patient's eye. *See* Section XI.A.5.

d. **Limitation 8.5**

The combination of Blumenkranz, Kurtz, and Weikert renders delivery of the claimed relaxation incision obvious. *See* Section XI.A.2.e. Moreover, Blumenkranz discloses delivery of treatment patterns to at least one target tissue based upon the measured surface profile. Ex.1017 ¶¶77 (disclosing a system for user input to define target tissues based on imaging device V), 82 (disclosing user input to control treatment); *see also* Section XI.A.5. Weikert also teaches that, when applying cataract and relaxation incisions, the relaxation incisions are delivered to a second target tissue (*e.g.*, different locations of the cornea). Ex.1019 at 1–2, 12 (teaching delivery of "[p]artial thickness, arcuate or transverse corneal incisions" to correct astigmatism from penetrating clear corneal incisions).

10. Independent Claim 12

a. Limitations 12P, 12.1, and 12.2

Blumenkranz discloses cataract surgery methods (12P), generating a treatment light beam (12.1), and deflecting the treatment light beam using a scanner (12.2). *See* Sections XI.A.2.a, XI.A.2.b, XI.A.2.c.

b. Limitations 12.3 and 12.6

The combination of Blumenkranz, Kurtz, and Weikert renders obvious measuring scattering properties from different locations on the patient's eye and positioning at least one of the first and second treatment patterns on the patient's eye based upon the measured scattering properties. *See* Section XI.A.6.

c. Limitations 12.4 and 12.7

The combination of Blumenkranz, Kurtz, and Weikert renders the claimed delivery of the first treatment pattern obvious. *See* Section XI.A.2.d.

d. Limitation 12.5

The combination of Blumenkranz, Kurtz, and Weikert renders delivery of the claimed relaxation incision obvious. *See* Section XI.A.2.e.

11. Dependent Claim 16

Blumenkranz discloses incisions formed from the inside of the target tissue towards the outside of the target tissue. Ex.1017 at ¶¶98 ("The use of a transverse line focus allows one to dissect a cataractous lens by ablating from the posterior to the anterior portion of the lens"), 62 ("the laser can be focused on the most posterior portion of the lens and then moved more anteriorly as the procedure continues"), cls. 3, 37 (claiming "focusing and scanning at the first depth … before the focusing and scanning at the second depth, and wherein the first depth is greater than the second depth"). It also would have been obvious to a POSA to form incisions in a posterior-to-anterior direction to avoid having the laser traverse already-treated tissue, which can scatter the beam and affect the treatment zone. Ex.1001 ¶¶297–98. Although Blumenkranz does not explicitly disclose posterior-to-anterior "relaxation incisions" that do not extend outside of the target tissue, it would have been further obvious to apply relaxation incisions to the posterior surface of the cornea because the same biomechanical laws apply, but posterior incisions keep the exterior surface of the cornea intact and reduce the risk of accidental tears of the partial incisions. Ex.1001 ¶298.

12. Dependent Claim 17

Weikert describes use of relaxation incisions to correct pre-existing astigmatism and/or surgically-induced astigmatism. Ex. 1019 at 1–2, 11–12. When applying the first treatment pattern (to form a cataract incision), it would have been obvious to a POSA that the incision will induce an astigmatism such that a second treatment pattern (to form relaxation incisions) would at least partially compensate for the induced astigmatism. *Id.*, Ex.1001 ¶¶118, 299.

13. Dependent Claim 20

The combination of Blumenkranz, Kurtz and Weikert renders obvious delivering incisions of the first treatment pattern formed at a limbal angle[6] of about 30 degrees as seen from directly above the eye. Blumenkranz's system is capable of creating cuts of various depths and lengths, Ex.1017 ¶¶61–62, 68–69. Kurtz likewise teaches the use of a laser system to deliver cuts of various angles. Ex.1018 Figs. 1A-1H; *see also* Ex.1052 at 7 (alleging infringement of claim 20 by system "programmed to allow for Side Cut Angles for the Primary Incision and/or Secondary Incision ***that can result*** in an incision formed at a limbal angle of about 30 degrees as seen from directly above the eye."); Ex.1001 ¶300. Indeed, the '024 states that such incision angles are "standard" in cataract surgery, and are not a new type of incision. Ex.1007 at 10:67–11:1. For these reasons, it would have been obvious to a POSA to deliver incisions at a limbal angle of about 30 degrees. Ex.1001 ¶300.

14. Dependent Claim 21

The combination of Blumenkranz, Kurtz and Weikert renders obvious delivering incisions of the first treatment pattern that are not formed at or near a

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[6] Petitioners reserve the right to challenge "limbal angle" as an indefinite. Nonetheless, Petitioners will apply the prior art as if Claim 20 is definite.

steep axis of the cornea. For example, Weikert describes a study performed with relaxing incisions (*i.e.*, "PCRI's") centered on the steep corneal meridian, and the CCI incision placed "along the horizontal meridian." Ex.1019 at 14. The study included patients with both WTR and ATR astigmatism (*i.e.*, steep axis at the vertical and horizontal, respectively). *Id.*; Ex.1001 ¶301. Thus, for patients with WTR astigmatism, the PCRI's were place on the vertical, steep meridian and the CCI was not formed at or near the steep meridian but instead along the horizontal. *Id.* It would have been obvious to perform the treatment patterns in this way as Weikert identifies favorable reduction in astigmatism for patients with WTR astigmatism after this surgery. Ex.1019 at 15; Ex.1001 ¶301.

15. Independent Claim 22

a. Limitations 22P, 22.1, and 22.2

The combination of Blumenkranz, Kurtz, and Weikert renders the claimed cataract surgery method (22P), generating a treatment light beam (22.1), and deflecting the treatment light beam using a scanner (22.2) obvious. *See* Sections XI.A.2.a, XI.A.2.b, XI.A.2.c.

b. Limitations 22.3 and 22.5

The combination of Blumenkranz, Kurtz, and Weikert renders delivery of the first treatment pattern obvious. *See* Section XI.A.2.d.

c. **Limitation 22.4**

The combination of Blumenkranz, Kurtz, and Weikert renders the delivery of a claimed relaxation incision obvious. *See* Section XI.A.2.e.

d. **Limitation 22.6**

Weikert teaches that relaxation incisions only partially extend through the target tissue, Ex.1019 at 1–2, 12, and Kurtz teaches how to make partial incisions using a laser ophthalmic-surgery system such as the one disclosed by Blumenkranz. Ex.1018 ¶14. 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 as part of a second treatment pattern that are partially penetrating to treat any surgery-induced astigmatism, as taught by Weikert. Ex.1001 ¶305; *see also* Section XI.A.2.e.

16. Dependent Claim 23

For the reasons discussed above, it would have been obvious to a POSA in view of Blumenkranz, Kurtz, and Weikert, that the first treatment pattern (which is intended to form a penetrating "cataract incision" for purposes of cataract surgery) would be delivered to the cornea, limbus, or sclera to provide access the cataractous lens. *See* Section XI.A.2.d.

17. Dependent Claim 25

The combination of Blumenkranz, Kurtz and Weikert renders obvious delivering relaxation incisions that leave at least 200 μm of tissue thickness. For example, Weikert teaches that the corrective effect of relaxing incisions depends on length, depth and number. Ex.1019 at 2. Thus, the depth of the incision is nothing more than a result-effective variable subject to routine optimization. *See* MPEP 2144.04. It would have been obvious to a POSA to deliver a relaxation incision that left at least 200 μm of tissue thickness when such a depth achieved the desired astigmatism correction. Ex.1001 ¶307.

18. Dependent Claim 26

Kurtz discloses incisions including a bevel feature. Ex.1018 ¶¶16 ("two sections of the resection pattern 13 … come together at an angle"), 17 ("zig-zag pattern"), Figs. 1A-1F, cl. 15. It would have been obvious to a POSA to use the system disclosed by Blumenkranz, which is capable of delivering incisions of different lengths and depths, to deliver a bevel-shaped cut, which was also a well-known, self-healing incision shape. Ex.1017 ¶99 (describing "self-sealing incisions"); Ex.1001 ¶¶308–09.

B. Ground 2: Claim 16 Is Obvious Over Blumenkranz in View of Kurtz and Weikert, and Further in View of Swinger

1. Motivation to Combine

Although it would have been obvious to a POSA to deliver posterior-surface relaxation incisions based on the teachings of Blumenkranz, Kurtz, and Weikert, Ex.1001 ¶¶150–52, no reference expressly teaches such incisions. Swinger, however, describes another multifunctional ophthalmic-surgery system, like

Blumenkranz's, and describes the use of such a system to deliver relaxation incisions on the posterior surface of the cornea, without crossing the anterior surface. Ex.1021 at 32:1–12.

When using Blumenkranz's system to deliver partial relaxation incisions, as taught by Weikert, a POSA would have known that such incisions could be applied on the posterior surface of at least the cornea. However, for further support, a POSA would have known from Swinger that posterior-surface relaxation incisions were known, which would have confirmed for a POSA that Blumenkranz's system could be used to apply such posterior-surface relaxation incisions. A POSA would have known such posterior-surface relaxation incisions would have been preferred, because the same biomechanical laws apply, but posterior-facing relaxation incisions leaves the anterior surface of the cornea completely intact, reducing the risk of any accidental tears along the relaxation incision. Ex.1001 ¶152. Thus, to the extent a POSA would not have applied posterior-surface relaxation incisions based on Blumenkranz alone, a POSA certainly would have in view of Swinger.

2. Dependent Claim 16

As discussed above, claim 1 is met by Blumenkranz in view of Kurtz and Weikert. To the extent Blumenkranz does not disclose or render obvious the incisions of claim 16, it would have been further obvious in view of Swinger, which teaches applying a relaxation incision to the posterior surface of the tissue without extending to the anterior surface. Ex.1021 at 32:1–12; *see also id.* 25:32–37 (describing generally laser system "moving from posterior to anterior"), 30:60–63 (same), 32:6–8 (same), 33:46–51 (same), 36:3–5 (same).

C. Ground 3: Claims 1–3, 6, 16–17, and 20–26 Are Obvious Over Kurtz in View of Swinger and Weikert

1. Motivation to Combine

Kurtz discloses a multifunctional ophthalmic-surgery system that can be used for corneal transplants or "[o]ther applications," Ex.1018 ¶22, but does not expressly disclose a second treatment pattern for forming a relaxation incision. Swinger, however, teaches another multifunctional ophthalmic-surgery system intended for various surgical procedures, including to reshape the cornea, perform corneal transplants, or "excise or photoablate regions within the cornea, capsule, lens, vitreoretinal membrane, and other structures within the eye." Ex.1021 at 8:34–36, 55–67. Not limited to corneal transplants, Swinger notes that such systems can be used "to open the anterior capsule of the lens of the eye in a controlled manner such that a smooth and regular opening . . . with predictable dimensions, is achievable, thereby allowing safer insertion and fixation of intraocular lenses during cataract surgery." *Id*. at 10:10–16. In other words, Swinger teaches using 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. 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 Kurtz, which is capable of making incisions of different depths, Ex.1018 ¶8; Figs. 1A–H, to deliver relaxation incisions to correct any surgery-induced astigmatism. Ex.1001 ¶162.

Based on these prior art teachings, it would have been obvious to a POSA that the multifunctional ophthalmic surgery system disclosed by Kurtz is not limited to corneal transplants. Ex.1001 ¶¶161, 163. Rather, the system could deliver numerous types of incisions on various eye tissues for several different surgery procedures, including cataract incisions to the cornea to access the eye chamber, and relaxation incisions to the cornea to correct astigmatism, as taught by Swinger and Weikert. Ex.1001 ¶¶163–65.

2. Independent Claim 1

a. **Limitation 1P**

Kurtz discloses a system for resecting corneal tissue of a patient's eye (using femtosecond surgical lasers). Ex.1018 ¶7. While Kurtz does not expressly disclose the system is specifically intended for cataract surgery, Kurtz discloses opening of the corneal tissue that creates access to inner compartments of the eye, which allows for cataract surgery, *id*., and that the procedure disclosed can be adapted for other ophthalmic procedures, *id*. ¶22. Swinger also teaches that laser systems like those disclosed by Kurtz are suitable for not only corneal ablation and transplanting, but also cataract surgery. Ex.1021 at 8:55–67; 10:10–15. Thus, it would have been obvious to a POSA to use the Kurtz system for cataract surgery. Ex.1001 ¶313.

b. Limitation 1.1

Kurtz discloses generating a treatment light beam (33) using a treatment light source (31). Ex.1018 ¶¶19–20. Swinger also discloses generating a pulsed laser beam (B) using a laser source (102). Ex.1021 at 17:1–30; Fig. 6.

c. Limitation 1.2

Kurtz discloses deflecting the light beam using a scanner (35) to form treatment patterns. Ex.1018 ¶19 ("focusing assembly 35, which in turn focuses the pulsed beam 33 into the cornea 37"). Swinger also discloses deflecting the light beam using a scanner (35) to form treatment patterns. 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; Figs. 6–7.

d. Limitations 1.3 and 1.5

Kurtz discloses two types of cataract incisions in the cornea to provide access. The first is when "the cornea 11 is incised with the full resection pattern 13, without any uncut gaps," (*i.e.*, the incision is fully penetrating the tissue). Ex. 1018 ¶13. The second is when "uncut gaps" in the corneal tissue are later opened in order to access inner compartments of the eye and allow for cataract surgery. Id. ¶¶7–8, 14–15. Swinger also teaches incisions in the cornea that allow access to regions of the eye below the cornea. Ex.1021 at Figs. 8B, 15W, 21:12–24, 33:7–22. For example, Figure 15W illustrates both "penetrating" (solid line) and non-penetrating (dashed line), or partial, cuts. *Id.* 33:7–22. It would have been obvious to incise partial incisions taught Swinger to provide access to the eye chamber as taught by Kurtz, *e.g.*, when the laser procedure is conducted in less-than-sterile environments. Ex.1018 ¶¶7, 14, 19; Figs. 1A–H; Ex.1001 ¶¶92, 315.

It would have been obvious to a POSA to deliver a cataract incision that provides access to an eye chamber of the patient's eye for lens removal instrumentation and that is also a partially penetrating cut, based on the teachings of Swinger and Kurtz. For example, lens removal was a known part of the cataract surgery procedure, and it would have been obvious to make the incision with the ultrafast laser as part of the treatment pattern. Ex.1021 at 7:50–8:6, 9:18–21 (use for cataract surgery), 35:31–35; Ex.1001 ¶¶92, 315.

e. **Limitation 1.4**

As explained above, *see* Section XI.C.2.d, both Kurtz and Swinger teach using a femtosecond laser to produce partial incisions in a patient's cornea. Ex.1018 ¶¶7, 14, 19; Figs. 1A–H; Ex.1021 at Figs. 8B, 15W; 21:12–24, 33:7–22. To the extent Kurtz does not disclose delivering a "relaxation incision" as part of a second treatment pattern, Swinger teaches delivering arcuate and transverse cuts in the cornea to treat astigmatism. Ex.1021 at Figs. 8B, 15W; 21:12–24, 33:7–22. Moreover, Weikert teaches that such relaxation incisions have been in use since the late 1800s, and can be used "to decrease astigmatism following cataract surgery." Ex.1019 at 1; *see id*. at 1–2, 11–12 (discussing the development of relaxation incisions over the previous century). Weikert also teaches delivering relaxation incisions to portions of the cornea during 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). As such, it would have been obvious to a POSA that the system disclosed by Kurtz could be used not only to deliver cataract incisions for corneal transplants, but also for cataract surgery, as taught by Swinger, including delivering both cataract and relaxation incisions (to treat astigmatism) as taught by Weikert. Ex.1001 ¶316.

3. Dependent Claim 2

Because the cornea sits anterior to the limbus, claim 2 is directed to a second treatment pattern delivered to the cornea. Ex.1001 ¶317. Thus, Kurtz, Swinger, and Weikert collectively render obvious a second treatment pattern delivered along corneal tissue anterior to the limbus tissue of the patient's eye. *See* Section XI.C.2.e; Ex.1001 ¶317.

4. Dependent Claims 3 and 24

Kurtz discloses a plurality of incisions being applied at the same time, with "at least one uncut gap being left in the incised resection pattern." Ex.1018 ¶8. Alternatively, Weikert teaches delivering cataract and relaxation incisions together, but sequentially, as part of a single procedure. Ex.1019 at 13, 15–16. A POSA would have known to apply a similar sequential delivery during a single procedure, like Weikert, using the laser system disclosed by Kurtz. Ex.1001 ¶320.

However, while manual blades by nature must deliver incisions sequentially, a POSA would have known that laser systems are not so limited. Ex.1001 ¶321. Instead, a POSA would have known that laser systems deliver patterns at different depths, generally beginning at a maximum depth and proceeding to lesser depths so that the laser does not traverse already-ablated tissue. *See, e.g.*, Ex.1021 at 34:61–64 (incision formed "beginning posteriorly and translating anteriorly"), 36:3–5 (same, "to avoid absorption of the beam energy by the plasma already formed."). Based on these teachings, it would have been obvious to a POSA to program Kurtz's controller to deliver combined treatment patterns on a layer-by-layer basis across different depths, moving posteriorly-to-anteriorly. Ex.1001 ¶321.

5. Dependent Claim 6

Swinger teaches generating an aiming light beam, deflecting the aiming light beam using the scanner to form an aiming pattern, and delivering the aiming pattern to the target tissue to visually indicate a position of at least one of the first and second treatment patterns. Ex.1021 at 33:58–62 ("The laser has a HeNe focusing beam 270 coaxial with the ablating beam 272, and the surgeon focuses the beams at the Surface of the iris 274 of the eye."), Fig. 15Y, 34:27–28, 34:52–35:3, 35:50–57; 36:20–31.

6. Dependent Claim 16

Swinger discloses incisions formed from the inside of the target tissue towards the outside of the target tissue, without extending outside the target tissue. Ex.1021 at 32:1–12; *see also id.* 25:32–37 (describing generally laser system "moving from posterior to anterior"), 30:60–63 (same), 32:6–8 (same), 33:46–51 (same), 36:3–5 (same). Kurtz also shows that its system can deliver partial incisions starting on the posterior surface, but not penetrating to the anterior surface, Ex.1018 at Figs. 1A, 1B, 1D, 1E, 1H, but does not describe these incisions as relaxation incisions. However, it would have been obvious, whether in view of Kurtz or Swinger, to apply relaxations to the posterior surface of the target tissue, as the same biomechanical laws apply, but it leaves the anterior surface of the cornea completely intact, reducing the risk of any accidental tears along the relaxation incision. Ex.1001 ¶323.

7. Dependent Claim 17

Weikert describes use of relaxation incisions to correct pre-existing astigmatism and/or surgically-induced astigmatism. Ex.1019 at 1–2, 11–12. When applying the first treatment pattern (to form a cataract incision), it would have been obvious to a POSA that the incision will induce an astigmatism such that a second treatment pattern (to form relaxation incisions) would at least partially compensate for the induced astigmatism. *Id.* at 1–2, 11–12, Ex.1001 ¶118, 324.

8. Dependent Claim 20

The combination of Kurtz, Swinger and Weikert renders obvious delivering incisions of the first treatment pattern formed at a limbal angle of about 30 degrees as seen from directly above the eye. Swinger's system is capable of delivering incisions of any shape (including angle). *See, e.g.*, Ex.1021 at 32:30–34 (walls of corneal incision can be at any angle), 32:60–63 (walls of incision can be "any shape" and "at any desired angle"). Kurtz likewise teaches the use of a laser system to deliver cuts of various angles. Ex.1018 Figs. 1A-1H; *see also* Ex1052 at 7 (alleging infringement of claim 20 by system "programmed to allow for Side Cut Angles for the Primary Incision and/or Secondary Incision ***that can result*** in an incision formed at a limbal angle of about 30 degrees as seen from directly above the eye."); Ex.1001 ¶325. Indeed, the '024 states that such incision angles are "standard" in cataract surgery, and are not a new type of incision. Ex.1007 at 10:66–11:1. For these reasons, it would have been obvious to a POSA to deliver incisions at a limbal angle of about 30 degrees. Ex.1001 ¶325.

9. Dependent Claim 21

Weikert renders this limitation obvious, for the reasons discussed above. *See* Section XI.A.14.

10. Independent Claim 22

a. Limitation 22P, 22.1, and 22.2

The combination of Kurtz, Swinger, and Weikert renders the claimed cataract surgery method (22P), generating a treatment light beam (22.1), and deflecting the treatment light beam using a scanner (22.2) obvious. *See* Sections XI.C.2.a, XI.C.2.b, XI.C.2.c.

b. Limitations 22.3 and 22.5

The combination of Kurtz, Swinger, and Weikert renders delivery of the first treatment pattern obvious. *See* Section XI.C.2.d.

c. Limitation 22.4

The combination of Kurtz, Swinger, and Weikert renders the delivery of a claimed relaxation incision obvious. *See* Section XI.C.2.e.

d. Limitation 22.6

Weikert teaches that relaxation incisions only partially extend through the target tissue, and that there is a long history of "non-penetrating" relaxation incisions dating back to the late 1800s. Ex.1019 at 1–2, 11–12. Kurtz teaches how to make partial incisions using laser ophthalmic surgery systems such as those disclosed by Kurtz. Ex.1018 ¶14. Specifically, Kurtz discloses a treatment pattern that leaves "uncut gaps 17 in the resection pattern 13" such that "tissue along the incision and the internal chambers of the eye remain protected and unexposed to environmental contaminants so long as the corneal tissue 15 remains in place." *Id.* Moreover, Swinger teaches partially and fully penetrating arcuate and transverse in the cornea to treat astigmatism, and that the depth of the T-cuts or arcuate cuts could be varied over the length of the predetermined excision. Ex.1021 at 21:4–24, 33:7–22.

It would have been obvious to a POSA to use the system disclosed by Swinger or Kurtz, which is capable of delivering incisions of different depths, to deliver relaxation incisions as part of a second treatment pattern that are partially penetrating, *e.g.*, to treat any surgery-induced astigmatism, as taught by Weikert. Ex.1001 ¶330. *See* Section XI.C.2.e.

11. Dependent Claim 23

Kurtz and Swinger disclose treating target tissue in one or more of the cornea, limbus or sclera of a patient's eye. *See* Section XI.C.2.d.

12. Dependent Claim 25

The combination of Kurtz, Swinger and Weikert renders obvious delivering incisions of the second treatment pattern that leave at least 200 μm of tissue thickness. For example, Weikert teaches that the corrective effect of relaxing incisions depends on length, depth and number. Ex.1019 at 2. Thus, the depth of the incision is nothing more than a result-effective variable subject to routine optimization. *See* MPEP 2144.04. It would have been obvious to a POSA to deliver a relaxation incision that left at least 200 μm of tissue thickness when such a depth achieved the desired astigmatism correction. Ex.1001 ¶332.

13. Dependent Claim 26

Kurtz discloses incisions including a bevel feature. Ex.1018 ¶¶16 ("two sections of the resection pattern 13 … come together at an angle"), 17 ("zig-zag pattern"), Figs. 1A-1F; cl. 15. Swinger also teaches that the "walls" of the incision "can take any shape," including conical at "any desired angle." *Id.* at 32:60–63, 25:44–49 (describing "bevel" or flange shaped cuts). It would have been obvious to a POSA to use the Swinger system to deliver a bevel-shaped cut, because this is a well-known, self-healing incision shape. Ex.1001 ¶¶333–34.

D. Ground 4: Claims 4–5 and 7–15 Are Obvious Over Kurtz in View of Swinger and Weikert, and Further in View of Benedikt

1. Motivation to Combine

As discussed above, Kurtz, Swinger, and Weikert collectively teach a surgery scanning system for treating target tissue, including cataracts, in a patient's eye by delivering partial or complete incisions in a given eye tissue to gain access to interior chambers. But Kurtz, Swinger, and Weikert do not expressly disclose a system with multiple detecting, imaging, and profiling subsystems, such as a detector and/or profilometer that can influence one or more treatment patterns. Rather, Swinger's pre-surgical analysis for directing the treatment beam entails manual estimation or ultrasound. *See* Ex.1021 at 34:52–57 (direct visualization), 35:59–63 (ultrasound); Ex.1001 ¶167. And Kurtz informs that the size and location of treatment patterns are left to the discretion of the surgeon. *See* Ex.1020 ¶13; Ex.1001 ¶167. Although Swinger and Kurtz use a manual diagnostic approach, Swinger itself recognized the virtue 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 and Kurtz 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 (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 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 laser treatment system such as described by Kurtz and Swinger in order to plan and effect laser surgery with improved accuracy. Ex.1001 ¶¶169–70.

Indeed, a skilled artisan would have had a reasonable expectation of success integrating Benedikt's imaging assembly into a laser treatment system. Ex.1001 ¶173. 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 treatment system to include Benedikt's imaging assembly since doing so merely amounts to a simple substitution (Benedikt's imaging assembly in place of Swinger's/Kurtz's direct visualization technique) of known imaging modalities that would obtain predictable results. Ex.1001 ¶171.

2. Dependent Claim 4

As discussed above, claim 1 is met by Kurtz in view of Swinger and/or Weikert. Benedikt discloses measuring the surface profile of a surface of the cornea of the patient's eye and positioning the second treatment pattern on the patient's eye based upon the measured surface profile. For example, 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 ¶¶29–31, and that 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 and to provide it as a data record for the automated ablation of tissue in the laser per se." *Id*. ¶39.

It also would have been obvious to a POSA, when utilizing a profilometer in the systems disclosed by Kurtz or Swinger, to position the second treatment pattern based upon the measured surface profile because topometers measure astigmatism, and the second treatment pattern is intended to treat astigmatism, as taught by Weikert. Ex.1018 ¶19 ("The controller 39 is a programmable computer which precisely controls the location of the beam focal point within the cornea 37 according to parameters received from the surgeon interface 41."); Ex.1019 at 2; Ex.1021 at 16:60–20:34 (describing "scanner" and "computer control unit 114"), Fig. 6; Ex.1001 ¶¶336–37.

3. Dependent Claim 5

Benedikt discloses measuring scattering properties from different locations on the patient's eye, and positioning at least one of the first and second treatment patterns on the patient's eye based upon the measured scattering properties. 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

¶¶8 (allows for "determination of the optical properties of the entire eye"), 10, 14–16, 19, 42, 44 (scans provide "three-dimensional information"), Figs. 3, 4; *see also* '024 at 6:58–67, 10:45–52 (admitting OCT works by measuring "scattering" light off eye structures). 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 and to provide it as a data record for the automated ablation of tissue in the laser per se." Ex. 1020 ¶39.

4. Dependent Claims 7, 11, and 15

Claims 7, 11, and 15 have the same limitations, but depend from independent claims 1 (above), 8 and 12 (below), respectively. Benedikt discloses capturing an image of the target tissue (*e.g.*, via a CCD array 14 or an OCT device). Ex.1020 at Figs. 3, 4, ¶¶4, 31, 42. Benedikt also discloses displaying the captured image and modifying a composition and location of a least one of the first and second treatment patterns on the patient's eye in response to input received from a user input device (*e.g.*, via a workstation). *Id.* ¶¶31 (describing a "PC" or "workstation"), 36 (same), 51(same), 37 (results can be "output … on a screen"), 39 (topometric and OCT data can be used to assist or guide the laser treatment).

Moreover, Kurtz discloses the use of a "programmable computer" with an interface (41) to "present[] the surgeon with several incision patterns from which the desired resection pattern is selected," including "gap placement," and the system then applies the selected incision. Ex.1018 ¶19. Therefore, a POSA would have understood that Kurtz's "programmable computer" could be used to capture an image of the target tissue (*e.g.*, as generated by imaging systems taught by Benedikt), to display the captured image (*e.g.*, so that a surgeon could see the treatment pattern as it would be applied to the eye upon delivery), and to allow the surgeon to modify the composition and location of at least one treatment pattern on the patient's eye (*e.g.*, based on surgeon selections received through an input). Ex.1001 ¶¶340–41.

5. Independent Claim 8

a. Limitations 8P, 8.1, and 8.2

The combination of Kurtz, Swinger, and Weikert renders the claimed cataract surgery method (8P), generating a treatment light beam (8.1), and deflecting the treatment light beam using a scanner (8.2) obvious. *See* Sections XI.C.2.a, XI.C.2.b, XI.C.2.c.

b. Limitations 8.3 and 8.6

The combination of Kurtz, Swinger, and Weikert renders the claimed delivery of the first treatment pattern obvious. *See* Section XI.C.2.d.

c. **Limitation 8.4**

The combination of Kurtz, Swinger, Weikert and Benedikt renders obvious measuring a surface profile of a surface of the cornea of the patient's eye. *See* Section XI.D.2.

d. **Limitation 8.5**

The combination of Kurtz, Swinger, and Weikert renders the delivery of the claimed relaxation incision obvious. *See* Section XI.C.2.e.

Moreover, Benedikt discloses delivery of treatment patterns to at least one target tissue based upon the measured surface profile. Ex. 1020 ¶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 and to provide it as a data record for the automated ablation of tissue in the laser per se."); *see also* Section XI.D.2. Weikert also teaches that, when applying cataract and relaxation incisions, the relaxation incisions are delivered to a second target tissue (*e.g.*, different locations of the cornea). Ex.1019 at 1–2, 12 (teaching delivery of "[p]artial thickness, arcuate or transverse corneal incisions" to correct astigmatism from penetrating clear corneal incisions). Ex.1001 ¶345.

6. Dependent Claims 9 and 13

Claims 9 and 13 have the same limitations, but depend from independent claims 8 (above) and 12 (below), respectively. Kurtz discloses a plurality of incisions being applied at the same time, with "at least one uncut gap being left in the incised resection pattern." Ex.1018 ¶8. Moreover, Weikert teaches delivering cataract and relaxation incisions together. Ex.1019 at 13, 15–16. As such, it would have been obvious to a POSA that, when delivering both cataract and relaxation incisions, as taught by Weikert, the treatment patterns for these incisions can be delivered simultaneously. Ex.1001 ¶346.

7. Dependent Claims 10 and 14

Claims 10 and 14 have the same limitations, but depend from independent claims 8 (above) and 12 (below), respectively. Swinger teaches generating an aiming light beam, deflecting the aiming light beam using the scanner to form an aiming pattern, and delivering the aiming pattern to the target tissue to visually indicate a position of at least one of the first and second treatment patterns. Ex.1021 at 33:58–62 ("The laser has a HeNe focusing beam 270 coaxial with the ablating beam 272, and the surgeon focuses the beams at the Surface of the iris 274 of the eye."), Fig. 15Y, 34:27–28, 34:52–35:3, 35:50–57, 36:20–31.

8. Independent Claim 12

a. Limitations 12P, 12.1, and 12.2

The combination of Kurtz, Swinger, and Weikert renders the claimed cataract surgery method (12P), generating a treatment light beam (12.1), and deflecting the treatment light beam using a scanner (12.2) obvious. *See* Sections XI.C.2.a, XI.C.2.b, XI.C.2.c.

a. **Limitations 12.3 and 12.6**

The combination of Kurtz, Swinger, Weikert and Benedikt renders obvious measuring scattering properties from different locations on the patient's eye and positioning at least one of the first and second treatment patterns on the patient's eye based upon the measured scattering properties. *See* Section XI.D.3.

b. **Limitations 12.4 and 12.7**

The combination of Kurtz, Swinger, and Weikert renders the claimed delivery of the first treatment pattern obvious. *See* Section XI.C.2.d.

c. **Limitation 12.5**

The combination of Kurtz, Swinger, and Weikert renders delivery of the claimed relaxation incision obvious. *See* Section XI.C.2.e.

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 13,825 (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
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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")
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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
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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 ROGs

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)
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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)
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Exhibit 1051	'023 Infringement Contentions
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