Filed on behalf of: AMO Development, LLC

Entered: March 14, 2022

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ALCON INC., ALCON VISION, LLC, ALCON LABORATORIES, INC., AND ALCON RESEARCH, LLC,
Petitioner,

v.

AMO DEVELOPMENT, LLC,
Patent Owner.

Case IPR2021-00849
Patent 10,709,548

PATENT OWNER'S RESPONSE

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

CASES

STATUTES

REGULATIONS

OTHER AUTHORITIES

Exhibit List

Ex.	Description
2001	Declaration of Roger J. Chin in Support of Patent Owner's Unopposed Motion for *Pro Hac Vice* Admission Under 37 C.F.R. § 42.10(c)
2002	Declaration of Jin U. Kang, Ph.D.
2003	Curriculum Vitae of Jin U. Kang, Ph.D.
2004	Declaration of Dr. Kathryn Hatch
2005	Curriculum Vitae of Dr. Kathryn Hatch
2006	U.S. Patent No. 8,506,559 B2 ("Raksi")
2007	U.S. Patent No. 9,456,925 B2 ("Goldstein")
2008	U.S. Patent No. 8,679,100 B2 ("Buck")
2009	Holger Lubatschowski, Update on the Femtosecond Laser Technologies in Ophthalmology, 230 MONTHLY CLINICAL OPHTHALMOLOGY GAZETTE 1207-12 (2013) (German & English Translation)
2010	Tibor Juhasz, Challenges of Femtosecond Laser Technologies for Cataract Surgery in TEXTBOOK OF REFRACTIVE LASER ASSISTED CATARACT SURGERY (RELACS) 39 (Ronald R. Krueger et al. eds. 2013) (excerpt)
2011	RESERVED
2012	U.S. Patent Application Publication No. 2008/0082086 A1, dated April 3, 2008
2013	RESERVED
2014	Amended Complaint, *AMO Dev., LLC v. Alcon Lensx, Inc.*, No. 1:20-cv-00842-CFC (Sept. 28, 2020), ECF No. 16

2015	Plaintiffs' First Supplemental Response to Defendants' Interrogatory No. 21, *AMO Dev., LLC v. Alcon Vision, LLC*, No. 1:20-cv-00842-CFC (D. Del. Aug. 31, 2021) (excerpts)
2016 - 2019	RESERVED
2020	Declaration of Allison Harms In Response to Petitioner's Objections to Patent Owner's Exhibits [*served, not filed*]
2021	Declaration of Allison Harms in Support of Patent Owner's Unopposed Motion for *Pro Hac Vice* Admission Under 37 C.F.R. § 42.10(c)
2022	Uday Devgan, *Effect of Incision Size in Cataract Surgery Must Be Considered*, HEALIO (Oct. 25, 2008), https://www.healio.com/news/ophthalmology/20120331/effect-of-incision-size-in-cataract-surgery-must-be-considered#:~:text=So%20the%20ideal%20incision%20size,leakage%20or%20tear%20film%20contamination
2023	Howard Larkin, *FS Cataract Surgery – Why Lasers Designed for Corneal Flaps Don't Cut It for Cataracts*, EUROTIMES, Apr. 2012, at 24
2024	I. Howard Fine, *Clear Corneal Cataract Incisions,* 8 OPHTHALMOLOGY CLINICS N. AM. 547 (1995)
2025	Christophe Nguyen et al., *Case Report: External Cystic Epithelial Ingrowth*, CATARACT & REFRACTIVE SURGERY TODAY EUR., Apr. 2010, at 31
2026	W.N. Charman, *Optics of the Eye*, in 1 HANDBOOK OF OPTICS 24.3 (Michael Bass et al. eds., 2d ed. 1995)
2027	V.K. Pustovalov & B. Jean, *Theoretical Investigations of the Processes of Selective Laser Interaction with Melanin Granules in Pigmented Tissues for Laser Applications in Medicine*, 16 LASER PHYSICS 1011 (2006)
2028	W.M. Bourne, *Biology of the Corneal Endothelium in Health and Disease*, 17 EYE 912 (2003)

2029	LinkedIn Curriculum Vitae of Casimir A. Swinger, M.D.
2030	Holger Lubatschowki et al., *Femtosecond Laser Fundamentals*, in TEXTBOOK OF REFRACTIVE LASER ASSISTED CATARACT SURGERY (RELACS) 17 (Ronald R. Krueger et al. eds. 2013)
2031	Katrina Bell Sheehy & Jonathan H. Talamo, *The Patient Interface: Setting the Stage for Treatment*, in TEXTBOOK OF REFRACTIVE LASER ASSISTED CATARACT SURGERY (RELACS) 59 (Ronald R. Krueger et al. eds. 2013)
2032	RESERVED
2033	Uday Devgan, *Surgeons Must Manage Astigmatism During Refractive Cataract Surgery*, HEALIO (July 1, 2008), https://www.healio.com/news/ophthalmology/20120325/surgeons-must-manage-astigmatism-during-refractive-cataract-surgery
2034	*Astigmatism Correction with the Femtosecond Laser*, EYEWORLD USA, May 2012, at 59
2035	Shanhui Fan et al., *Dual Band Focus Optical Coherence Tomography for Imaging the Whole Eye Segment*, 6 BIOMEDICAL OPTICS EXPRESS 2481 (2015)
2036	RESERVED
2037	Erin L. Boyle, *Foldable IOLs Ushered in New Cataract and Refractive Paradigm*, HEALIO (June 1, 2007), https://www.healio.com/news/ophthalmology/20120331/foldable-iols-ushered-in-new-cataract-and-refractive-paradigm#:~:text=Foldable%20IOLs%20have%20helped%20alter,the%20span%20of%202%20decades.
2038	Tatsuo Yamaguchi et al., *Bullous Keratopathy After Anterior-Posterior Radial Keratotomy for Myopia and Myopic Astigmatism*, 93 AM. J. OPHTHALMOLOGY 600 (1982)

2039	RESERVED
2040	*Laser*, BRITANNICA ONLINE ENCYCLOPEDIA (Feb. 7, 2022), https://www.britannica.com/technology/laser
2041	Deposition of Holger Lubatschowski, Ph.D., Case Nos. IPR2021-00843, IPR2021-00845, IPR2021-00846, and IPR2021-00849 (Jan. 21, 2022)
2042	LinkedIn Curriculum Vitae of Mark Blumenkranz, M.D.
2043	RESERVED
2044	*Profile of Mitchell P. Weikert M.D., M.S.*, BAYLOR COLLEGE OF MEDICINE, https://www.bcm.edu/people-search/mitchell-weikert-32841 (last visited Mar. 6, 2022)
2045	G. Molesini, *Geometrical Optics*, IN ENCYCLOPEDIA OF CONDENSED MATTER PHYSICS 257 (Franco Bassani et al. eds. 2005)
2046	RESERVED
2047	Gerhard K. Lang, OPHTHALMOLOGY: A POCKET TEXTBOOK ATLAS (2d ed., rev. and enlarged 2006) (Excerpts)
2048	RESERVED
2049	Daniel Palanker, *Basic Laser Properties*, COMPREHENSIVE OPHTHALMOLOGY (2013), https://www.aao.org/munnerlyn-laser-surgery-center/basic-laser-properties
2050	*Profile of Dr. Ronald Kurtz, M.D.*, DOXIMITY, https://www.doximity.com/pub/ronald-kurtz-md (last visited Jan. 26, 2022)
2051	Luigina Sorbara et al., *Use of the Visante™ OCT to Measure the Sagittal Depth and Scleral Shape of Keratoconus Compared to Normal Corneae: Pilot Study*, 6 J. OPTOMETRY 141 (2013)

2052	Zoltan Z. Nagy, *New Technology Update: Femtosecond Laser in Cataract Surgery*, 8 CLINICAL OPHTHALMOLOGY 1157 (2014)
2053	Tyler S. Ralston et al., *Inverse Scattering for Optical Coherence Tomography*, 23 J. OPTICAL SOC'Y AM. 1027 (2006)
2054	RESERVED
2055	*2018 Lifetime Achievement Award: Dr. William Culbertson*, INT'L SOC'Y OF REFRACTIVE SURGERY, https://www.isrs.org/about-isrs/2018-lifetime-achivement-award (last visited Mar. 6, 2022)
2056	LinkedIn Curriculum Vitae of David Angeley
2057	LinkedIn Curriculum Vitae of George Marcellino
2058	RESERVED
2059	Max J. Riedl, OPTICAL DESIGN FUNDAMENTALS FOR INFRARED SYSTEMS (2d. ed. 2001) (Excerpts)
2060	Rüdiger Paschotta, FIELD GUIDE TO LASER PULSE GENERATION 1 (John E. Greivenkamp ed. 2008)
2061	Ana P. Canto et al., *Relaxing Incisions for Astigmatism Correction in ReLACS*, in TEXTBOOK OF REFRACTIVE LASER ASSISTED CATARACT SURGERY (RELACS) 125 (Ronald R. Krueger et al. eds. 2013)
2062	Declaration of Jin U. Kang, Ph.D. in Support of Patent Owner's Response ("Kang")
2063	Declaration of Dr. Kathryn Hatch in Support of Patent Owner's Response ("Hatch")

I. Introduction

The invention disclosed and claimed in U.S. Patent No. 10,709,548 ("the '548 patent") is all about using a cataract laser surgery system as never before. Previously, such systems could only cut the cloudy lens itself, deep below the eye's surface. But cataract surgery often also requires certain precise cuts in the *surface* of the eye (the cornea or limbus): "cataract incisions" to allow instruments to access the cataract and "relaxing incisions" to correct astigmatism. Prior cataract laser surgery systems could not make those crucial cuts. The patented invention discloses a system that can. This invention substantially improved laser cataract surgery, enabling surgeons to cut the lens and make corneal incisions with a single system. And it made those incisions more efficiently, precisely, and safely than ever before.

AMO's invention is undisputedly novel, and Alcon makes no anticipation arguments. Alcon argues, however, that AMO's invention would have been obvious, based on combinations of three or more references, pieced together using the claims as a roadmap. None of these grounds teaches or renders obvious the claimed invention.

First, in Ground 1, Alcon combines (1) a laser ***cataract*** system (Blumenkranz) that never mentions or suggests making cataract or relaxing incisions with (2) ***manual*** incisions touted by an article (Weikert), and (3) a ***corneal*** transplant incision method (Kurtz) that leaves "uncut gaps" in its incision pattern. This argument crumbles under the weight of the evidence.

While Alcon now alleges that it would have been obvious to use lens cataract surgery systems on the cornea, both Alcon and its expert said the ***exact opposite*** in their patents and peer-reviewed publications, insisting that doing so posed "considerable design challenges" with "divergent clinical objectives." Ex. 2006 (Raksi), 25:30-31; Ex. 2008 (Buck), 24:25-38; Ex. 2023, 004; Ex. 2010, 010. And although Alcon argues it would have been obvious to perform cataract and relaxation incisions with a laser, its own expert said something entirely different on cross-examination. He admitted that the precision of lasers compared to long-standing manual blade methods "depends on the situation" and that he didn't want to "make any judgment calls here" as a "non-ophthalmologist." Ex. 2041, 107:8-108:7. When pressed, he couldn't come up with a ***single reason*** a skilled artisan would have been motivated to switch from a diamond scalpel—which Alcon's lead reference touts for its "predictable and reproducible incision profiles"—to a laser during cataract surgery. *Id.*, 108:16-109:18.

***Second*,** the claims require a laser system programmed to form a fully-penetrating cataract incision that: (1) has a bevel shape comprised of two intersecting segments and (2) is positioned entirely in the cornea. None of the references Alcon proposes to combine—Blumenkranz, Weikert, Kurtz, and

Benedikt (Grounds 1-2) or Swinger, Weikert, Benedikt, Kurtz, L'Esperance, and Huber (Grounds 3-5)—teaches such an incision. Instead, Alcon relies on hand waving by its expert, Dr. Lubatschowski, to fill the gap. But on cross-examination, Dr. Lubatschowski admitted he was unqualified to opine on such matters: he is "not an ophthalmologist," has "no experience in wound healing," and could not say why an ophthalmologist would pick one incision type over another. Ex. 2041, 33:5-34:7. Nor did Dr. Lubatschowski speak with any ophthalmologist to inform his opinion. *Id.*, 15:18-16:13.

In fact, the references cited by Dr. Lubatschowski undermine Alcon's purported motivation to combine. For example, Kurtz warns that a laser incision *must not* completely cut through the cornea in order to protect the eye from environmental contaminants. Ex. 1018, [0014]. Kurtz thus teaches away from the claimed fully penetrating cataract incision, (i.e., the cataract incision "intersecting both an anterior surface and a posterior surface of the cornea").

Third, in Ground 3, Alcon replaces Blumenkranz's laser system with Swinger's. But Swinger discloses a manually-positioned laser system that does not use the claimed optical coherence tomography (OCT) imaging device (independent claim 1) or profilometer (claim 3) to determine treatment patterns. To make up for that shortcoming, Alcon adds a fourth reference, Benedikt, and argues it would have been obvious to add Benedikt's dual topometer/OCT imaging system to Swinger's laser surgery system. But this theory fell apart during cross-examination, when Alcon's expert admitted that laser surgery systems like Swinger's require an eye fixation device that is ***incompatible*** with Benedikt's dual topometer/OCT system. Ex. 2041, 114:1-8, 115:18-116:8, 118:1-9.

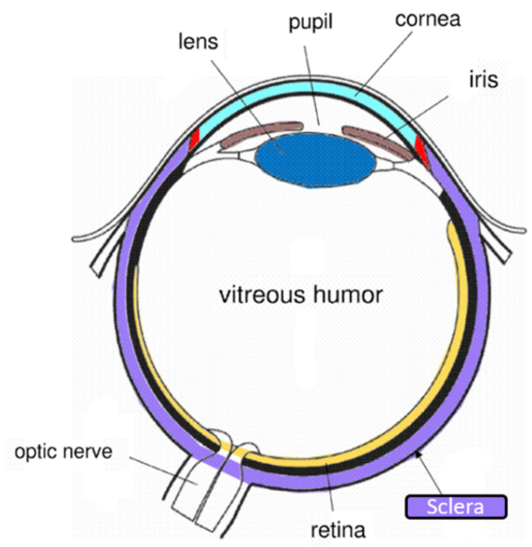
Finally, multiple dependent claims are patentable for additional reasons. For example, claims 6 and 7 require a Z-scan device. So in Ground 4, Alcon adds a *fifth* reference to its already-crowded combination, L'Esperance. But Alcon fails to provide any reason a skilled artisan would use L'Esperance's scanner when the combination's primary reference, Swinger, already includes a mechanism for scanning in the z-dimension. Similarly, claim 8 requires an ultrafast laser source with a wavelength between 1010 and 1100 nm. Alcon's cited art in Ground 3 describes wavelengths spanning an over 16-fold-larger range that fails to teach or suggest the much narrower claimed range.

Laser systems could not simply be mixed and matched, as Alcon proposes in its Petition. And as Alcon and its expert had been saying for years, even after the '548 patent was filed, using a cataract laser system for the cornea presented "considerable design challenges." AMO's invention was a major advance in eye surgery; only in hindsight can Alcon reconstruct the claimed invention.

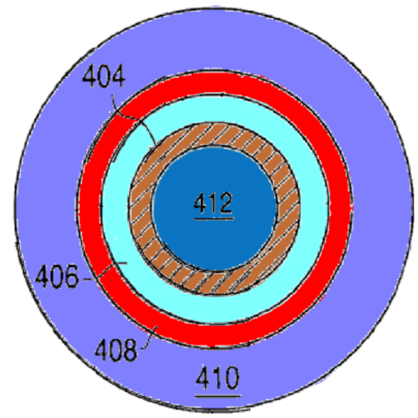
II. Background

A. The Anatomy of the Eye

The human eye is delicate and complex.



Side View



Front View

Hatch (Ex. 2063) ¶14; Kang (Ex. 2062) ¶21. The figures above show the eye in cross-section (left) and from the front (right). The clear dome-shaped structure at the front of the eye is the cornea 406 (teal). Ex. 1013, 10:34-36, 10:60-64; Hatch ¶14. The white part of the eye that provides its structural support is the sclera 410 (purple). Ex. 1013, 10:36-38; Hatch ¶14. The limbus 408 (red) is the border between the cornea 406 and the sclera 410. Ex. 1013, 10:36-38; Hatch ¶14. As shown on the left, the sclera covers most of the eye—everything but the cornea and limbus. Hatch ¶14. The iris (brown) is a ring-shaped structure that determines a person's eye color.

Hatch ¶14. The central opening in the iris is the pupil 404. Ex. 1013, 10:34-36; Hatch ¶14.

The crystalline lens 412 of the eye (dark blue) lies behind the iris in the interior of the eye, several millimeters below the cornea. Ex. 1013, 10:34-36; Hatch ¶¶14-15; Kang ¶21. The lens capsule (not shown) is a membrane-like layer of tissue that surrounds the lens (like a bag). Hatch ¶14. The front layer of the lens capsule is called the anterior capsule and the back layer is the posterior capsule. Hatch ¶14. The cornea and lens focus light on the retina (yellow) at the back of the eye, a region known as the posterior pole. Hatch ¶¶14-15.

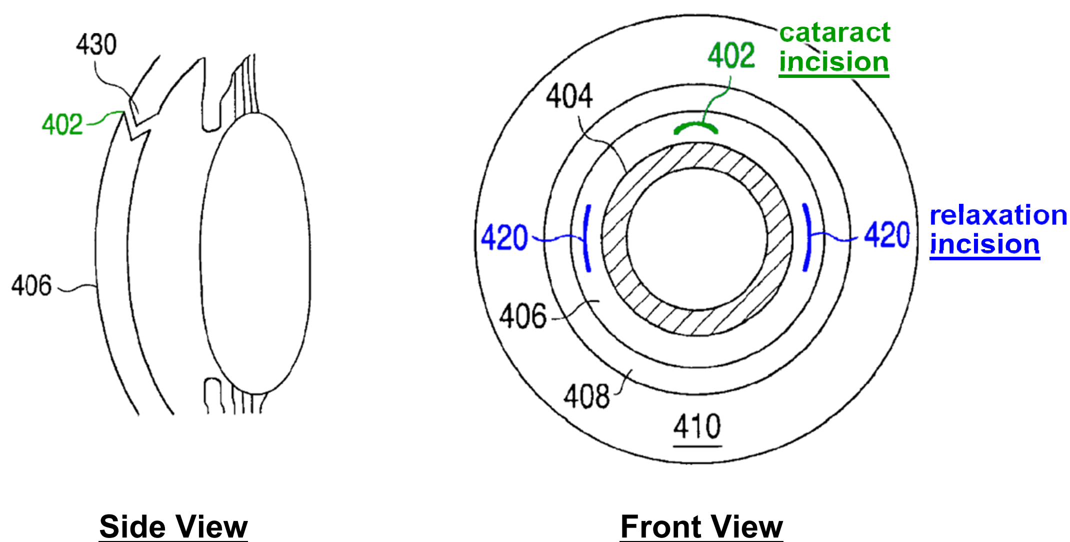
A cataract is an opacification (cloudiness) in the lens that can cause visual impairment. Hatch ¶26. In cataract surgery, a surgeon removes the clouded lens and replaces it with an artificial intraocular lens ("IOL"). Ex. 1013, 1:30-40; Hatch ¶26; Kang ¶22. The surgeon opens the capsule (i.e., performs an anterior capsulorhexis (manual) or a capsulotomy (with a laser)) then fragments or liquefies the lens for removal through an aspiration needle. Ex. 1013, 3:32-35, 3:62-66, 6:25-27, 1:30-40; Hatch ¶26; Kang ¶22.

A laser cataract surgery system facilitates removal of the cataract by focusing laser pulses deep within the eye—within the capsule (for the anterior capsulotomy) and within the lens (for lens fragmentation). Ex. 1013, 3:62-66; Kang ¶23. The laser generates a "plasma-mediated ablation process" at its focal point and is scanned in a pattern of pulses to make the desired cuts in the lens capsule and lens. Ex. 1013, 3:32-35, 3:62-66, 6:25-27; Kang ¶23.

B. The '548 Patent (Ex. 1013)

The '548 patent issued from Application No. 14/668,696, filed on March 25, 2015, and is a divisional of Application No. 13/569,103, which is a divisional of Application No. 12/048,186, filed March 13, 2008.

The inventors had the insight that a laser cataract surgery system could be adapted for two additional steps of cataract surgery: cataract incisions and relaxation incisions. This was a groundbreaking approach. As explained below, cataract and relaxation incisions are made in the *front* of the eye, typically in the cornea and limbus. At the time of the invention, conventional wisdom was that laser cataract systems designed to cut the lens *could not be used* on the front of the eye. *Infra* V.B.2. But the inventors conceived of a system to do just that.



Ex. 1013, Figs. 7, 8 (labeled, highlighted); Hatch ¶28; Kang ¶71.

Cataract incision. The cataract incision 402 (green above) is a small incision in the front of the eye—usually in the cornea 406 (or sometimes in the limbus 408, and less often, in the sclera 410). Ex. 1013, 10:32-38; Hatch ¶¶30, 32-33. The cataract incision provides access for a surgeon to insert slender instruments (e.g., an aspiration needle) to remove the clouded lens. Ex. 1013, 10:30-32; Hatch ¶30; Kang ¶72.

The claimed laser cataract incision of the '548 patent has several critical features. First, the cataract incision has an arcuate extent less than 360 degrees, as shown in the front view above (Figure 7, item 402), i.e., the cataract incision does not form a complete circle. Ex. 1013, Fig. 7; Kang ¶417. Second, the cataract incision is bevel shaped, as shown in the side view above (Figure 8, item 430), and is comprised of first and second segments that intersect each other at an angle. Ex. 1013, Fig. 8; Kang ¶418. Next, the incision intersects both the anterior and posterior surface of the cornea, i.e. it fully penetrates the cornea. Ex. 1013, Fig. 8; Kang ¶74. Finally, the cataract incision is entirely located in the cornea. Ex. 1013, 14:52-53, Fig. 7; Kang ¶74.

The claimed cataract incision is "useful for wound healing, sealing, or locking." Ex. 1013, 3:21-24, 13:60-63; Hatch ¶¶28-48. Forming such incisions with a laser proved advantageous, as the inventors observed that manual incisions are more likely to have torn edges and face significantly higher risks of endophthalmitis, which causes swelling and corneal haze. Ex. 1013, 10:50-56; Hatch ¶¶49-51.

Relaxation incision. The relaxation incision 420 (blue above) is also made in the cornea or limbus. Ex. 1013, 12:38-42, 14:46-47; Hatch ¶¶28, 39, 42. It is used to correct astigmatism, which is caused by an asymmetrically shaped cornea. Ex. 1013, 11:19-25; Hatch ¶40. The inventors figured out how to use a laser cataract surgery system to form a partially penetrating relaxation incision that allows the cornea to relax along its steep axis, thereby restoring symmetry to the cornea. Ex. 1013, 2:10-14, 11:16-37, 13:36-38; Kang ¶76.

The claimed invention further includes a controller programmed to determine the treatment pattern that forms the cataract and relaxation incisions, based on OCT imaging of the cornea and limbus. Ex. 1013, 10:45-50, 10:57-11:4 14:33-36, 14:40-42. The controller uses OCT imaging to determine the depth and placement of the incisions. *Id.*, 11:1-4. OCT imaging can also verify the surgical correction and adjust the laser during treatment. *Id.*, 3:4-7; Kang ¶77. This ensures "accurate control over the absolute and relative positioning of these incisions." Ex. 1013, 13:38-44.

C. Alcon's Proposed Person of Ordinary Skill in the Art Lacks Necessary Ophthalmic Experience

The field of the invention is "ophthalmic surgical procedures and systems." Ex. 1013, 1:15-18, 1:59-62. The team of inventors that developed the '548 patent included an ophthalmic surgeon: Dr. Culbertson, a Professor of Ophthalmology at Bascom Palmer Eye Institute. Ex. 2055.[1] And all of Alcon's key prior art was authored (or co-authored) by doctors with skill and experience in ophthalmic surgery—Blumenkranz, Kurtz, Benedikt, Weikert, and Swinger are all ophthalmologists. Exs. 1017, 1018, 1019, 1020, 1021, 2027, 2029, 2042, 2044, 2050. Thus, the correct level of ordinary skill includes meaningful experience with ophthalmic surgery—e.g., (1) an ophthalmic surgeon with experience with medical optics or lasers or (2) an engineer with a Bachelor's degree in a laser-related engineering or optics field who worked with an ophthalmic surgeon. Kang ¶80.

Alcon's proposed skilled artisan, however, has no skill or experience in ophthalmic surgery, only a "moderate understanding of ophthalmology, and refractive and cataract surgery." Pet. 26. This flaw infects Alcon's analysis, both in its analysis of the references and its hindsight-driven combinations. Indeed, Alcon's expert Dr. Lubatschowski admitted that an engineer might view aspects of the claims differently than an ophthalmologist and that he "just see[s] it in the view of a

[1] The "educational level of the inventor" is relevant in determining the level of skill in the art. *Envtl. Designs, Ltd. v. Union Oil Co. of Cal.*, 713 F.2d 693, 696 (Fed. Cir. 1983). All emphases herein are added and internal citations and quotations are omitted unless indicated.

biomechanist." Ex. 2041, 33:5-19; *see also id.* 99:18-22, 100:3-11 (distinguishing what an engineer and physician might consider a treatment pattern), 30:11-31:4 (distinguishing the formation of relaxation incisions from a "biomechanical" rather than an ophthalmological perspective).

Dr. Lubatschowski repeatedly admitted that he was not qualified to answer basic questions raised by Alcon's obviousness combination, for example, whether a skilled artisan would have replaced manual relaxation incisions with a laser:

> Q So you don't know the advantages and disadvantages, from a clinical perspective, of using a blade versus a laser for a surface cut?
>
> A Not in general.

Ex. 2041, 109:9-12; *see also id.*, 29:11-19 (unsure about the frequency at which relaxation incisions are made in the cornea versus the limbus or the sclera), 30:6-10, 31:1-4 ("I'm not ophthalmologist. I have not that training. So if I see a patient, I could not decide which kind of relaxation incisions I would do."), 33:5-34:7, 35:16-36:5, 36:8-12, 47:1-3 ("I'm not an ophthalmologist. I cannot explain you what is the reason why they do it this [incision] or that [incision]."), 107:8-22, 108:3-7.

Without experience in ophthalmic surgery, Alcon's skilled artisan would have been unable to fully evaluate key aspects of the claimed invention. Kang ¶¶81-83; Hatch ¶¶28-57; *see* Ex. 1013, 14:37-39, 14:43-56 As a result, Alcon takes a cavalier mix-and-match approach to existing surgery systems and incisions that no ophthalmic surgeon (or person consulting with an ophthalmic surgeon) would dare adopt on a complex and delicate organ such as the eye. Hatch ¶¶14, 16-25, 49-57, 59; Kang ¶¶81-83. Someone with the proper level of skill and education in ophthalmic surgery would appreciate that vital point. Alcon's proposed skilled artisan (like Alcon's expert) does not.

III. Claim Construction ("Cataract Incision")

A skilled artisan would have understood "cataract incision" in the context of the claim and the patent to mean an "incision to allow access for the lens removal instrumentation." Ex. 1013, 10:30-32.

This construction is compelled by the specification, which defines "cataract incision" in the "present invention" as "creating the *incision to allow access for the lens removal instrumentation*." Ex. 1013, 10:30-32; *see Phillips v. AWH Corp.*, 415 F.3d 1303, 1316 (Fed. Cir. 2005) (en banc) (The specification "may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess" and in those cases, "the inventor's lexicography governs"). Here, the term "cataract incision" is set off by quotation marks— a "***strong indication*** that what follows is a definition." *Sinorgchem Co., Shandong v. Int'l Trade Comm'n*, 511 F.3d 1132, 1136 (Fed. Cir. 2007). Significantly, there is no dispute that this language is definitional. Pet. 7 (the specification "defines 'cataract incision' as an 'incision to allow access for lens removal instrumentation.'"). And the remainder of the specification is in accord—consistent with this express definition, it describes the cataract incisions as "very small and geometrically precise" incisions that "provide[] access for lens removal instrumentation to a crystalline lens of the patient's eye." Ex. 1013, Abstract, 3:13-14.

Nevertheless, Alcon proposes the Board disregard the undisputed clear lexicography in the specification and construe "cataract incision" as an "incision[] that penetrates outer layers of the eye, specifically the cornea, limbus, or sclera, to permit access to the eye chamber." Pet. 8. Alcon's construction not only ignores the lexicography in the specification but also contradicts the claim language itself. The claims recite "the cataract incision being ***entirely located in the cornea***." Ex. 1013, 14:52-53. Alcon's proposed construction, which permits the incisions to be made in the "cornea, limbus, or sclera" (Pet. 8), cannot be correct.

The Board should construe "cataract incision" in accordance with the undisputed express lexicography in the specification to mean "an incision to allow access for lens removal instrumentation."

IV. Alcon Fails to Establish Weikert as Prior Art

Alcon relies on Weikert (a textbook excerpt) for all grounds and all claims. But its Petition provides no evidence of Weikert's publication date. *See* Sur-Reply 1; Reply 1. Alcon's attempts to cure via a reply brief and subsequent belated submission of the entire textbook with its Supplemental Evidence (*see* Ex. 1062) are insufficient. A petition "may be considered only if … *the petition* identifies in writing and with particularity … the evidence that supports the grounds for the challenge to each claim." 35 U.S.C. § 312(a)(3); 37 C.F.R. § 42.104(b)(5) (petition must "identify[] specific portions of the evidence that support the challenge"). The petition itself must include "the prior art relied upon and evidence that it qualifies as such." *Hulu, LLC v. Sound View Innovations, LLC*, IPR2018-01039, Paper 29 at 13 (Dec. 20, 2019) (precedential). Since Alcon failed to provide evidence *in the Petition* establishing Weikert as prior art, the Petition fails at the threshold.

V. Ground 1: Claims 1-14 Are Patentable Over Blumenkranz, Weikert, and Kurtz

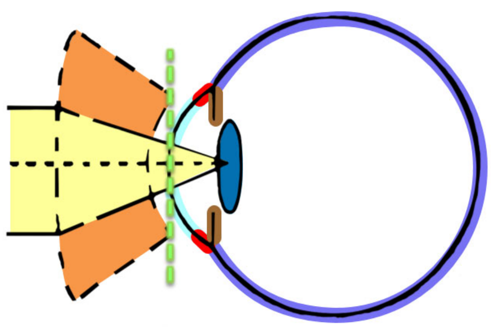
A. The Asserted References

1. Blumenkranz (Ex. 1017)

Blumenkranz discloses a laser system designed to make two specific incisions in the lens during cataract surgery: anterior capsulotomy (cutting a hole in the lens capsule through which the cataractous lens can be removed) and lens fragmentation (cutting up the lens for removal). Ex. 1017, [0009].

Alcon's Ground 1 seeks to combine Blumenkranz's laser surgery system with techniques for making incisions in the cornea, namely Weikert's manual incisions in the cornea and Kurtz's corneal transplant incisions. Pet. 29-32. But Blumenkranz never mentions *any* incision in the cornea, the eye's forwardmost surface. Kang ¶¶96-97; Ex. 2041, 59:7-10. Nor does Blumenkranz disclose cataract or relaxation incisions. *Id.*, 59:11-60:6. Rather, Blumenkranz discloses using the laser system to cut the lens and lens capsule, deep within the eye. Ex. 1017, [0009], [0069]; Kang ¶89, 96-97; Pet. 31; Ex. 1001 ¶133.

For example, as shown in Figure 11, Blumenkranz's laser uses an ophthalmic lens (orange) that contacts the patient's cornea (teal) and focuses the laser on structures well below the cornea (such as the eye lens, blue):



Ex. 1017, Fig. 11 (cropped, highlighted)[2]; Kang ¶97; *see also* Ex. 1017, [0076], [0087]. As explained in detail below, while Blumenkranz's laser delivery optics are

---

[2] In this figure, Blumenkranz depicts the eye facing the left. In Dr. Lubatschowski's testimony, the depth of structures in the eye is described relative to the front of the cornea (green dashed line) along a z-axis (horizontal axis in the figure above). Kang ¶¶87-88; Ex. 2041, 56:20-57:12, 57:21-58:14.

ideal for forming incisions in the lens, they were considered unsuitable for the cornea. *See infra* Section V.B.2.

In paragraph [0071], Blumenkranz includes a single passing reference to using the disclosed techniques for incisions in certain other parts of the eye, including the iris (brown) and sclera (purple). Ex. 1017, [0071]. But, there again, a skilled artisan would not understand this disclosure to refer to the cornea. Kang ¶¶96-97, 354. All parts of the eye mentioned in paragraph [0071]—including the iris and sclera—are millimeters *below* the cornea.[3] Ex. 1017, [0071]; Kang ¶¶96-97, 354; Hatch ¶15; Ex. 2041, 58:8-59:4, 64:17-66:4 (admitting tissues in paragraph [0071] are 3 mm or more beneath the cornea). Thus, a skilled artisan would not understand paragraph [0071] (including its generic reference to "other areas of the eye") to include the cornea. *See, e.g.*, *Int'l Bus. Machs. Corp. v. Iancu*, 759 F. App'x 1002, 1007-08 (Fed. Cir. 2019) (terms like "such as" in the context of a list "indicate that only things of a type similar to the itemized ones are covered"). Indeed, Blumenkranz's

[3] The sclera surrounds most of the eye and extends to a depth of about 24 mm behind the cornea. Ex. 2041, 64:2-65:5; Hatch ¶15. Most of the sclera lies behind the lens, where cataract and relaxation incisions are impossible. Hatch ¶¶15, 33, 42. Blumenkranz does not say where in the sclera a laser should be used or for what purpose. Ex. 1017, [0071].

conspicuous omission of the cornea—one of the most commonly discussed and targeted components of the eye—conveys just the opposite: that the system is *not* intended to be used there. *See id.*

2. Weikert (Ex. 1019)

Weikert describes manual refractive keratotomy eye surgery, which involves incisions in the cornea to reduce myopia and astigmatism. Ex. 1019, 2, 11. Weikert discloses that refractive keratotomy incisions include clear corneal cataract incision and relaxation incisions. Ex. 1019, 11. Weikert describes how a variety of scalpel blades can be used to make refractive keratotomy incisions, as shown in Figure 14.4:

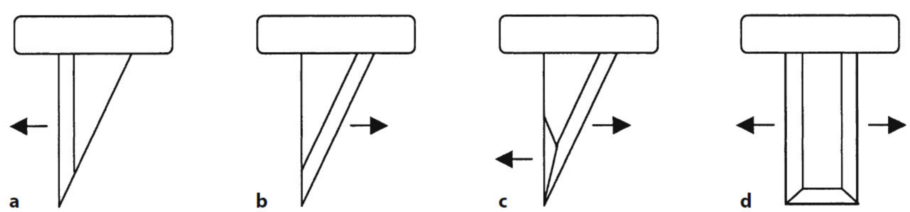


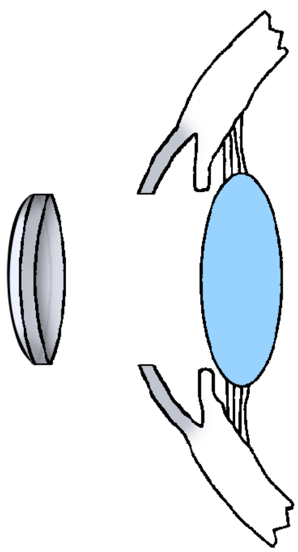
Fig. 14.4 a–d. Refractive keratotomy blade styles. **a** Russian, vertical cutting edge. **b** American, slanted cutting edge. **c** Dual pass, slanted, full cutting and partial, vertical cutting edge. **d** Arcuate blade with rectangular profile

Id., 5. Despite discussing the advantages and disadvantages of different blade types (and even acknowledging lasers available for other eye surgeries), Weikert does not contemplate making cataract or relaxing incisions with a laser. *Id.*, 4; Kang ¶¶104-107. Indeed, Weikert discloses that its manual incisions with blades "achieve predictable and reproducible incision profiles" that are "low-cost and low-risk." Ex. 1019, 4, 11; Ex. 2041, 109:19-110:4 (manual incisions are "for sure an attractive option").

3. Kurtz (Ex. 1018)

Kurtz does not disclose a cataract incision. Kang (Ex. 2062) ¶¶99, 103. Rather, Kurtz discloses a ***corneal transplant*** system. Ex. 1018, Abstract, [0002], [0013]; Ex. 2041, 86:1-6 (confirming that "Kurtz limits its discussion to corneal transplants"). The word "cataract" never even appears in Kurtz. Kang ¶103.

Kurtz uses the laser to remove the cornea so the surgeon can replace it in corneal transplant surgery. Ex. 1018, [0013] ("excise the corneal tissue … as part of a corneal transplant procedure"); Hatch ¶¶59-60; Kang ¶99. As shown on the left, a corneal transplant requires a full circular (360°) incision around the cornea that resembles a "manhole cover" in the front of the eye. Hatch ¶60; Ex. 2004 ¶23 (Kurtz "delivers 360-degree incisions to a central area of the cornea"). A skilled artisan would not make such an incision for cataract surgery. Ex. 2041, 88:3-16.



A consistent and central teaching of Kurtz is the use of "non-continuous initial incisions" leaving an "uncut gap" such that the corneal transplant incision does not fully penetrate the cornea. Ex. 1018, [54], Abstract, [0007]-[0008], [0013]-[0015]. The "uncut gap" is mentioned over 50 times in Kurtz's short, three-page specification. *Id.*

The figure below shows the side view of one such corneal transplant incision. The system leaves "uncut gaps 17" in the resection pattern 23. :

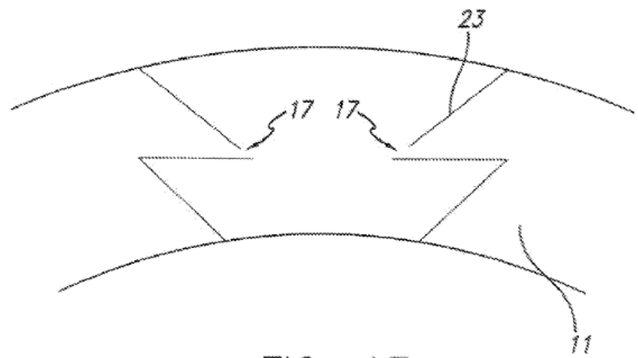


FIG. 1E

Ex. 1018, Fig. 1E; Kang ¶¶100-02; *see also* Kurtz, [0022] ("resecting corneal tissue using *non-continuous* initial incisions are disclosed").

Kurtz teaches the uncut gaps are necessary to ensure that the internal chambers of the eye remain protected from external contaminants until the corneal transplant procedure is ready to be completed. Ex. 1018, [0014], [0005]. This concern is particularly pronounced when the laser treatment is not performed in the same room as the manual steps of the corneal transplant operation. In such a case, the patient must be moved between the rooms mid-procedure, thereby increasing the risk of contamination. Ex. 1018, [0014]; [0005], [0007]-[0009], [0013], [0015], [0022]. Indeed, Kurtz warns that "[s]uch risk[s] would *always* be present if the *entire resection pattern is incised* [with the laser] in the preparation room prior to moving the patient to the operating room." Ex. 1018, [0014].

B. A Skilled Artisan Had No Motivation to Combine Blumenkranz With Weikert and Kurtz

Claim 1, the sole independent claim of the '548 patent, recites a "cataract incision" that is "entirely located in the cornea" and "one or more relaxation incisions in the cornea or limbus." Ex. 1013, cl. 1. Alcon relies on Blumenkranz's system to create the claimed "cataract incision" and the "one or more relaxation incisions" in Ground 1. *See* Pet. 21-22; Ex. 1001 ¶¶135, 138. Alcon's combination thus turns on whether a skilled artisan would have adapted Blumenkranz to make penetrating cataract incisions in the cornea and relaxation incisions in the cornea or limbus. As explained below, a skilled artisan would not have made that combination.

1. Blumenkranz Teaches a Cataract Laser Scanner Designed to Cut Deep Ocular Structures, Not Corneal Tissue

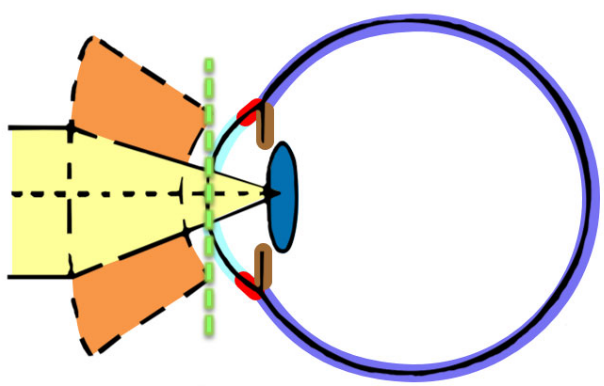
Alcon and its expert admit that "Blumenkranz does not expressly disclose using the system to deliver a cataract incision or relaxation incisions." Pet. 30; *see also* Ex. 2041, 59:7-60:14. But Alcon argues it would have been obvious to use Blumenkranz's laser system for such incisions because it is capable of delivering "incisions of different depths according to various treatment patterns." Pet. 29-31; *see also* Pet. 33, 35-36; Ex. 1001 ¶¶105-106, 108. Alcon is wrong. Blumenkranz's ability to create incisions at different depths does not indicate that it can create incisions at ***any*** depth. And Blumenkranz never suggests that its laser system can be used at the "depth[]" of the cornea (the forwardmost structure of the eye) or the limbus—it describes creating incisions only in ocular structures well behind the cornea. Kang ¶354; *see also id.* ¶¶137-142.

Blumenkranz describes a laser system that forms only two specific incisions during cataract surgery: anterior capsulotomy and lens fragmentation. Ex. 1017, [0068]-[0069], [0074]; Pet. 30; Ex. 1001 ¶133. The anterior capsulotomy creates a circular incision in the lens capsule (through which the lens can be removed) and fragmentation breaks the lens into pieces (for easier removal). Ex. 1017, [0069]; Hatch ¶¶26-27; Kang ¶¶354, 158. In other words, both incisions are made in structures (the lens capsule and lens, respectively) deep within the eye, well below the cornea (by at least 3-8 mm). Kang ¶354; *see also id.* ¶¶138, 258; Ex. 2041, 56:20-57:8. That location is important. Blumenkranz's laser system rests directly against the cornea, and focuses on structures more than 3 mm below the cornea. *Supra* V.A.1; Ex. 1017, [0076], [0087], Fig. 17. Its beam delivery system—which is comprised of movable optics such as lenses and mirrors—is designed specifically to target this tissue depth. Ex. 1017, [0075]-[0076]; Kang ¶¶354, 159. Blumenkranz's laser is not designed to be used on the cornea or limbus. Kang ¶354; *see also id.* ¶¶139-45; Hatch ¶16, 25, 51.

Despite Blumenkranz's clear purpose of performing laser surgery on the lens, deep within the eye, Alcon points to paragraph 71 to assert that Blumenkranz would have been used on the cornea or limbus, but that paragraph does not help Alcon. *See, e.g.*, Pet. 30 (citing Ex. 1017, [0071]). It states:

> The techniques described herein may be used to perform new ophthalmic procedures or improve existing procedures, including anterior and posterior *capsulotomy*, lens fragmentation and softening, dissection of tissue in the *posterior pole* (floaters, membranes, retina),
>
> as well as incisions in other areas of the eye such as, but not limited to, the *sclera and iris*.

Ex. 1017, [0071]. Every structure mentioned in this paragraph is well beneath the cornea. As depicted below, and as Alcon's expert confirmed on cross-examination, (1) the lens and lens capsule are 3-10 mm beneath the cornea; (2) the "posterior pole" (the region beneath lens near the retina at the far back surface of the sclera) is 24 mm beneath; and (3) the iris and sclera are 3-24 mm beneath.



Hatch ¶15; Ex. 2041, 64:18-66:4; Kang ¶¶354, 141; *see* Ex. 1017, [0071]; Ex. 2026, 021-22, Table 1; Ex. 2006 (Raksi), 5:30-36, 6:4-15; Ex. 2035, 011, Table 1 (retina depth 24 mm); Ex. 2051, 004-005, Fig. 1 (sclera spurs depth 3.6 mm). Blumenkranz fails to teach using the laser system on the cornea.

Blumenkranz's passing reference to cutting "other areas of the eye" does not meaningfully change its disclosure. Kang ¶354; *see also id.* ¶142; *see Bayer Schering Pharma AG v. Barr Lab'ys, Inc.*, 575 F.3d 1341, 1347 (Fed. Cir. 2009) ("[V]ague prior art does not guide an inventor toward a particular solution."). Its consistent and repeated teaching of procedures in deep ocular structures suggests that any "other areas of the eye" are likewise located deep in the eye. Kang ¶354; *see also id.* ¶¶141-45. In fact, by conspicuously omitting the cornea from the list of tissues in paragraph [0071], a skilled artisan would interpret this paragraph as teaching *not* to use the laser there. Kang ¶354; *see also id.* ¶142.

Blumenkranz thus does not disclose a scanner configured to form incisions in the cornea and limbus, as required by all challenged claims. For that reason alone, Alcon's Ground 1 fails.

2. A Skilled Artisan Would Not Have Used or Modified Blumenkranz's Laser for Incisions in the Cornea

Alcon's purported motivation fails for another reason. Blumenkranz's laser was designed for use on the lens. A skilled artisan would have understood that such a system was unsuitable, as a matter of optics and engineering, to make incisions in the cornea and limbus and would not have tried to use or modify it for that purpose.

See Sections V.B.2.a-b, *infra*. Indeed, Alcon and its expert Dr. Lubatschowski admitted as much. Section V.B.2.b, *infra*; Ex. 2006, 25:27-31.

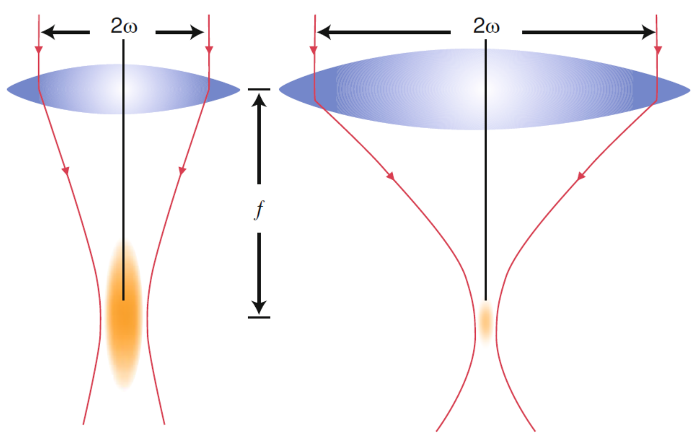
In its Institution Decision, the Board observed that this was an important factual issue to be resolved. ID 23. The record now unequivocally resolves it in AMO's favor: as explained below, attempting to modify Blumenkranz's laser for penetrating corneal cataract incisions or corneal and limbal relaxation incisions presented "considerable design challenges" (Ex. 2006, 25:27-31) that would have dissuaded a skilled artisan from making Alcon's proposed combination.

a. Blumenkranz′s Laser Would Have Been Considered Unacceptable for Incisions in the Cornea

A skilled artisan would have considered Blumenkranz's laser incompatible with making cuts in the cornea and limbus. Kang ¶355; *see also id.* ¶147. Blumenkranz uses low focusing precision and high laser energy, while corneal incisions, like the claimed cataract and relaxation incisions, require high focusing precision and low laser energy. *Id.* ¶355; *see also id.* ¶¶90-95, 149-83. Alcon's expert admitted during deposition that the claimed relaxation incisions must be precise (Ex. 2041, 38:16-39:8, 39:15-20), because an error in incision depth could overcorrect or induce more astigmatism "or even penetrate" the tissue causing a "big problem" (*id.*, 39:22-40:5). *See also id.*, 32:6-20 (describing relaxation incisions as a "refractive procedure"), 36:13-20, 38:5-15; Ex. 1019, 14; Hatch ¶48; Kang ¶¶355, 179-82. Likewise, the claimed cataract incision—a complex, bevel-shaped incision with two intersecting segments—requires a high degree of laser precision. The degree of precision and focus necessary for either claimed incision would have been difficult, if not impossible, to replicate with Blumenkranz's laser. Kang ¶¶355-56; *see also id.* ¶¶171-183, 90-95.

Blumenkranz discloses a laser for use on ocular tissues (e.g., the lens and lens capsule) well below the cornea. *Supra* Section V.B.1. To reach the necessary depth and cut through the thick, wide lens tissue, Blumenkranz focuses the laser in a tall and wide focal spot (cutting zone) that requires high pulse energy. Ex. 1017, [0050], [0054], [0060]; Ex. 2030, 31-32; Ex. 2006, 11:46-12:5, Ex. 2009, 3-4; Kang ¶¶355, 90-95, 150-54, 172-76.

As a matter of basic optics principles, Blumenkranz's approach requires a low "numerical aperture" ("NA"), as depicted on the left:



Ex. 2030, 027-028, Fig. 3.17, 29-32; Ex. 2009, 003-004; Kang ¶¶355, 147-54, 163-75.[4] Because the focal spot (yellow) is larger in such low NA systems, the laser beam energy is more spread out and higher pulse energy is typically needed to cut the tissue. Ex. 2030, Fig. 3.17, 29-32; Ex. 2009, 003-004; Kang ¶¶355, 54-55, 89, 149-52. Blumenkranz's approach differed substantially from high NA systems, depicted on the right, which create smaller focal spots and are adapted for use in shallower tissue such as the cornea. Kang ¶355; *see also id.* ¶155-62, 176-78.

Blumenkranz teaches using low NAs (0.1 or less) to create relatively large focal spots ranging from 4-15 µm in diameter and 20-240 µm in height. Ex. 1017, [0050], [0055], [0058], [0060], [0091], [0092]; Kang ¶¶355, 90-93, 172-73 (explaining calculations); Ex. 2009, 4 (Alcon's expert explaining that "requirements for a cataract [lens] laser are best met with a smaller numerical aperture"); Ex. 2030, 027-028, 36 (same); Ex. 2023, 004 (same). As a result, Blumenkranz uses a high laser pulse energy (between 3.5-10 µJ) to ensure there is sufficient energy to induce photodisruption and cut the tissue. Ex. 1017, [0054], [0089], [0092]; Kang ¶¶355, 94-95, 149-52, 172-75.

---

[4] The NA is the ratio of the laser beam's width (2ω) as it enters the focusing lens (blue) to the distance (*f*) from the focusing lens to the focal spot (yellow). Kang ¶¶45-50.

Blumenkranz teaches that its large focal spots and high pulse energies help cut the lens capsule (capsulotomy) and lens (fragmentation) efficiently. Ex. 1017, [0060], [0089]; Kang ¶¶355, 89, 175. Each laser pulse creates a large incision, allowing the system to fragment the large volume of the lens (several millimeters deep and across) using fewer laser pulses and in less time. Ex. 1017, [0060]; Kang ¶¶355, 89, 39, 152, 175. The high pulse energy also compensates for energy losses experienced by the laser beam as it passes through intervening structures—the cornea and anterior chamber—on its way to the lens. Ex. 2009, 005, Fig. 3; Ex. 2007 (Goldstein), 15:51-63; Ex. 2010, 010-011; Ex. 2030, 028; Ex. 2006, 5:55-61; Kang ¶¶355, 154.

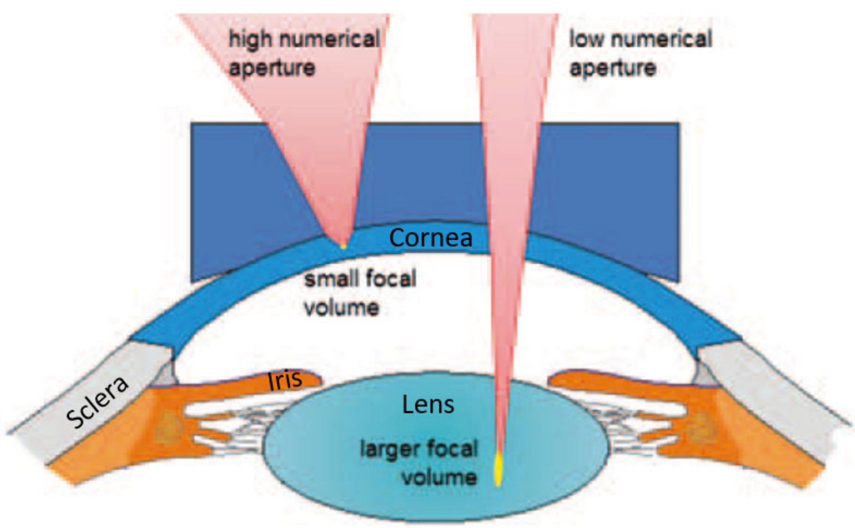
By contrast, a skilled artisan would have considered such large focal spots and high pulse energies unacceptable for *corneal* incisions, particularly the claimed relaxation incisions and bevel-shaped cataract incisions. Ex. 2030, 028, Ex. 2009, 003-005, Fig. 3; Ex. 2023, 004; Hatch ¶51; Kang ¶¶355, 171-83. The cornea, which is critical to the patient's eyesight, is only 500-600 μm thick and easily damaged. Hatch ¶¶16-21; Ex. 2026, 021, Table 1; Ex. 2047, 025; Ex. 2006, 12:6-15; Ex. 2010, 007; Kang ¶¶355, 21, 156-57. As a result, a high degree of precision and accuracy is essential for any incision in the cornea.

The claimed incisions are no exception. The claimed cataract incision requires a complex bevel-shape with two segments that intersect each other at an angle, while confined within the cornea's 500-600 μm thickness. Kang ¶356; *see also id.* ¶¶149-70. Likewise, the claimed relaxation incisions require that the laser focus be precisely controlled to correct the patient's astigmatism. Hatch ¶48; Kang ¶¶356, 178-79. As Alcon's expert testified, the "depth of the [relaxation] cut in relation to the thickness of the cornea, that's very important" (Ex. 2041, 38:20-39:8); if the depth is misplaced, the surgeon could overcorrect or "even penetrate" the tissue, which is a "big problem" (*id.*, 39:21-40:5).

To achieve the necessary precision, corneal incisions require far smaller focal spots (below 10 μm and ideally below 3 μm in diameter and height) and lower pulse energies (below 3 μJ and ideally below 1 μJ). Ex. 2010, 007, 010; Ex. 2030, 032; Ex. 2023, 04; Kang ¶¶356, 149-70. These laser properties are accomplished with a high NA (0.2-0.3). Ex. 2009, 004-005 (Alcon's expert explaining that corneal incisions are "best achieved with a high NA and low pulse energy"); Ex. 2023, 004; Ex. 2030, 027-028, 032, Fig. 3.22; Kang ¶¶356, 149-70. The smaller focal spots and lower pulse energies allow for smoother, more targeted cutting in the cornea. Kang ¶¶355-56; *see also id.* ¶177.

These design constraints are the antithesis of Blumenkranz's disclosed system. Kang ¶356; *see also id.* ¶178. A skilled artisan would have recognized that using Blumenkranz's laser system on the cornea ran the risk of imprecise incisions and inadvertent damage to the cornea. Kang ¶356; *see also id.* ¶178. For example, a single 10 µJ laser pulse of Blumenkranz's system could create a cutting zone more than 200 µm in height—nearly half the thickness of the cornea. Kang ¶356; *see also id.* ¶178; Hatch ¶17. Such a pulse is incompatible with the claimed cataract and relaxation incisions, akin to using an axe to chisel a sculpture. Blumenkranz's large cutting zone would also carry additional risks in the cornea, including inadvertently creating streaks in the cornea, producing excess pressure waves and heat that risk damaging surrounding sensitive corneal tissue, and propagating unfocused laser light through the eye and damaging the retina. Ex. 2009, 4; Ex. 1017, [0089], [0092]; Ex. 2030, 026 (low NA and 2 µJ pulse energies caused corneal streaks); Ex. 2023, 004; Ex. 2006, 13:10-33; Hatch ¶51; Kang ¶¶356, 180-82.

An article from Alcon's expert illustrates why a skilled artisan would have considered Blumenkranz's system unsuitable for corneal incisions:



Ex. 2023 (annotated to identify cornea, iris, sclera, lens), 004; Kang ¶¶355, 169-70. As Dr. Lubatschowski illustrates, a system for cutting structures behind the cornea (e.g., the lens, sclera, and iris), such as Blumenkranz's, uses a low NA (shown above right) and large focal spot (yellow) within the lens. By contrast, a system for cutting the cornea uses a high NA (shown above left) and small focal spot in the cornea at the tip of the laser beam (yellow).

In view of these differences, a skilled artisan would not have considered Blumenkranz's laser system suitable for corneal incisions. Kang ¶357; *see also id.* ¶¶147-83.

b. A Skilled Artisan Would Not Have Modified Blumenkranz′s Laser to Make Corneal Incisions

A skilled artisan would not have modified Blumenkranz's laser system to perform cataract incisions in the cornea or relaxation incisions in the cornea or limbus. Doing so would require a complex and expensive redesign. Kang ¶¶358; *see also id.* ¶¶184-85. A skilled artisan would not have been motivated to make such a modification, as it would have required a challenging, complex, and expensive optics overhaul. *Id.*

Alcon and its expert have admitted as much. In U.S. Patent No. 8,506,559 (Ex. 2006), filed after both the '548 patent and Blumenkranz, Alcon explained that "laser delivery systems … used for both corneal and lens surgeries, need to cover a broader range of apertures and corresponding [depth] ranges," which "poses ***considerable design challenges***." Ex. 2006, 25:27-31; *see id.*, 5:62-6:15, 13:19-53; *see also* Ex. 2008 (Buck), 5:3-23; 24:25-38 (another Alcon patent with similar statements); Kang ¶¶358; *see also id.* ¶186-90, 196. After the '548 patent, Alcon sought to patent its own "much-refined adaptive optics" to try to overcome the "design challenges" associated with using the laser at different depths within the eye. Ex. 2006, 6:6-15; *see id.*, 26:7-27:20 (Moveable Beam Expander block 500), 16:32-39 (Precompensator 200); Kang ¶¶358, 191-96.[5] Indeed, five years after the '548 patent, one of the founders of Alcon (Dr. Juhasz) wrote in his 2013 textbook chapter that the laser delivery system is "the ***most complex building block*** of the cataract laser" and that developing a system that can provide "variable focusing cone angle" for use on different depths "introduces considerable additional complexity for the

---

[5] The '548 patent addresses this challenge by using a "beam conditioning stage 22, in which beam parameters such as beam diameter, divergence, circularity, and astigmatism can be modified," using a "2-element beam expanding telescope." Ex. 1013, 4:35-41; *see also id.*, 4:34-51, Fig. 1. The beam conditioning stage is preferably separated from the z scanner 40 to achieve and maintain the ideal NA for a range of laser treatments. *Id.*, 6:41-51; *see also id.*, 4:43-51. Alcon's prior art does not include any such teaching. Kang ¶358; *see also id.* ¶¶203-05.

surgical beam delivery system." Ex. 2010, 010. Neither Blumenkranz nor Alcon's other art discloses any such optics. Kang ¶358; *see also id.* ¶¶195-97.

Alcon's expert made similar statements. In 2013, Dr. Lubatschowski explained that "corneal surgery with high demands for precision have a comparatively high numerical aperture (NA = 0.2-0.3)" and that "[l]aser systems for cataract surgery … in the lens of the eye … tend to have a relatively small numerical aperture (NA<0.2)." Ex. 2009, 004. As a result, "the high demands placed on focusing optics ***stand in the way*** of simply moving the work area from the cornea to the lens" or "vice versa" and that a transition could not be made "without additional corrective measures." *Id.*, 004-005. Likewise, in a 2012 interview, Dr. Lubatschowski emphasized that corneal and lens laser systems had "***divergent*** clinical objectives [that] requir[e] lasers of different power, and perhaps more important different numerical apertures." Ex. 2023, 004; *see also* Ex. 2030, 027-28, 032. In other words, even after the priority date of the '548 patent, combining corneal and cataract systems was seen as presenting a significant challenge.

The Board should credit what Alcon and its expert said in their patents and publications. A skilled artisan would not have modified Blumenkranz's laser for use on the cornea or limbus.

3. A Skilled Artisan Would Not Have Made Weikert's Manual Incisions With Blumenkranz's Laser

Alcon next turns to Weikert, arguing that it would have been obvious to make Weikert's manual incisions with Blumenkranz's laser. Pet. 30-31, 35-36. Alcon's purported motivation for doing so turns on the generalized proposition that "making centuries-old incision[s] using modern technology … would have been obvious." *See* Pet. 30-31. Alcon's appeal to this per se rule is mistaken. *See* MPEP §2144 (9th ed. Rev. June 2020) (warning "against treating any line of reasoning as a per se rule").

The clinical considerations and challenges involved in designing a laser cataract surgery system involve far more than just "using modern technology" as Alcon asserts. Kang ¶¶359-61. As described above (*see supra* Section V.B.2), the design considerations bear little resemblance to the electronic children's toys that were at issue in the decision relied upon by Alcon. *See* Pet. 30 (citing *Leapfrog Enters., Inc. v. Fisher–Price, Inc.*, 485 F.3d 1157, 1161 (Fed. Cir. 2007)).

Moreover, Alcon's sole expert, Dr. Lubatschowski, could not explain why a skilled artisan would have chosen to use a laser over manual incisions. During cross-examination, Dr. Lubatschowski admitted that he did not know "the advantages and disadvantages, from a clinical perspective, of using a blade versus a laser for a surface cut." Ex. 2041, 109:9-15. Ultimately, the precision of lasers compared to manual blade methods "depends on the situation" and Dr. Lubatschowski didn't want to "make any judgment calls here" as a "non-ophthalmologist." *Id.*, 107:8-108:7. In short, Alcon's expert was unable to articulate any concrete motivation for Alcon's proposed combination.

In fact, the skilled artisan would have had no reason to depart from Weikert's manual incision methods, which provide "predictable and reproducible incision profiles." Ex. 1019, 11; ID 16 (citing Ex. 1019, 4). These manual incisions are "effective," "low-cost and low-risk." Ex. 1019, 10-11. Even Alcon's expert Dr. Lubatschowski acknowledged that Weikert's refractive keratotomy (RK) incisions are "for sure an attractive option" (Ex. 2041, 109:19-110:4) and that blade incision may be "better sealed" (*id.*, 108:20-109:6). A skilled artisan would have had no motivation to undertake the expensive task of redesigning Blumenkranz's laser delivery optics (*supra* Section V.B.2.b), when Weikert's manual incisions already provided an effective, low-cost, and low-risk alternative. Ex. 1019, 11; Kang ¶¶358, 207-210; Hatch ¶¶52-57.

C. The Claimed Laser Cataract Incision Would Not Have Been Obvious

Independent claim 1 requires that the "cataract incision has an arcuate extent of less than 360 degrees in a top view, wherein the cataract incision includes a bevel shape in cross-sectional view, the bevel shape including a first segment and a second segment which intersect each other at an angle, the cataract incision being entirely located in the cornea and intersecting both an anterior surface and a posterior surface of the cornea." Ex. 1013, cl. 1. In other words, the claimed corneal cataract incision has four requirements. It must: (i) be less than 360 degrees, (ii) have a bevel shape with two intersecting segments, (iii) fully penetrate the cornea through both anterior and posterior surfaces, and (iv) be entirely located in the cornea. And, as properly construed, the "cataract incision" is an "incision to allow access for the lens removal instrumentation." *Id.*, 14:43-44; *see also supra* Section III.

Alcon does not argue that any of its Ground 1 references—Blumenkranz, Kurtz, Weikert—discloses cataract incisions with the claimed configuration. Pet. 31. Rather, Alcon argues that the claimed cataract incision was "a well-known, self-sealing incision shape" within the common knowledge of a skilled artisan, and that Kurtz's corneal transplant incision shows such bevel shapes could be created with a laser such as Blumenkranz's. Pet. 31. Alcon's proposed combination and motivation fail.

1. Alcon's Prior Art Does Not Disclose the Claimed Laser Cataract Incision

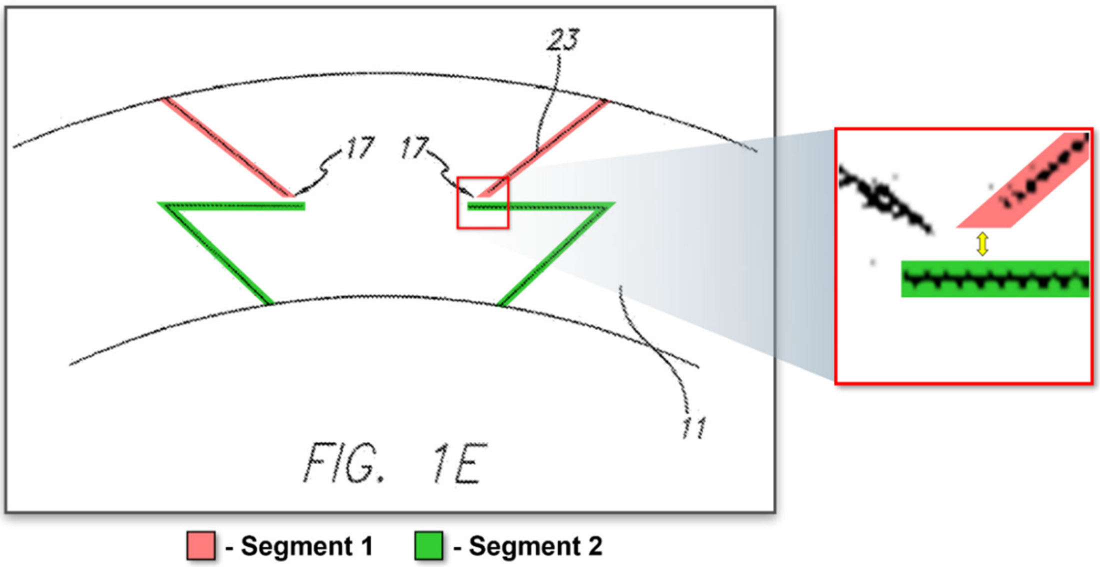
Neither Alcon nor its expert, Dr. Lubatschowski, asserts that Blumenkranz, Weikert, or Kurtz disclose the claimed cataract incision. Pet. 29-32, 35-37. Nor could they.

As Alcon and its expert concede, Blumenkranz does not disclose cataract incisions in the cornea at all. Pet. 30 ("Blumenkranz does not expressly disclose using the system to deliver a cataract incision or relaxation incisions."); Ex. 2041, 59:11-60:1. And while Weikert discloses cataract incisions, those incisions are performed manually and do not have the claimed cross-sectional configuration. Ex. 1019, 227. Neither Alcon nor its expert contends otherwise. Pet. 36-37; Ex. 1001 (Lubatschowski Decl.) ¶445.

Alcon's final reference, Kurtz, also fails to disclose the claimed cataract incisions for three reasons. *First*, Kurtz does not disclose a "less than 360 degree" incision. Kurtz teaches the opposite: it discloses corneal transplant incisions that completely encircle the cornea. Kang ¶368; Hatch ¶59-62; *see* Kurtz [0001] ("techniques for transplanting corneas"), [0004], [0013]; Ex. 1001 ¶165 ("360-degree incisions to a central area of the cornea"); Ex. 2041, 86:1-6. This is a key distinction. During prosecution of the '548 patent, the prior art was overcome on precisely this basis. *See, e.g.*, Ex. 1015, 81-84, 97-101, 105-115, 127-134.

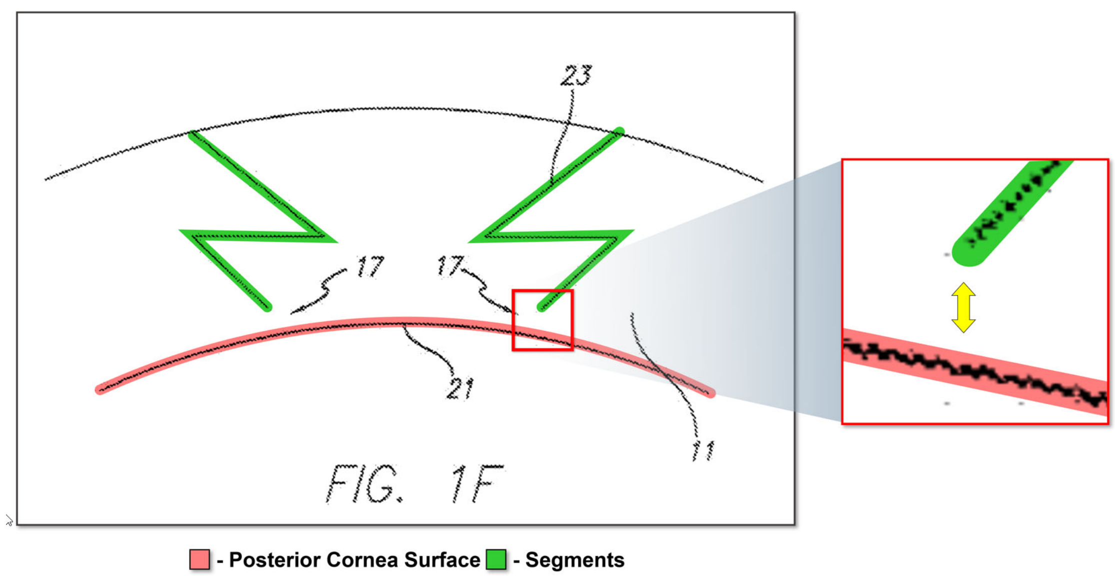
Second, the claims require an incision that fully transects the cornea, where the constituent segments "intersect each other" and together intersect "both an anterior and a posterior surface of the cornea." Ex. 1013, cl. 1. Kurtz's corneal transplant incisions, however, deliberately leave "uncut gaps" that cannot meet the claim requirement. Ex. 1018, [0013]-[0014], [0017], Abstract, [0007]-[0008]; Kang ¶¶369-71.

For example, in Figure 1E (cited by Alcon) there are uncut gaps 17 in the middle of the "zig-zag" incision:



Kurtz Fig. 1E (annotated); Kang ¶370 ; Hatch ¶61. The anterior segment (red) does not intersect the posterior segment (green), as required by the claim.

Figure 1F depicts another embodiment wherein the uncut gaps are at the posterior edge of the incision:



Kurtz Fig. 1F (annotated); Kang ¶370. In this embodiment, no segment intersects the posterior surface (red), as required by the claim. Kang ¶371.

Alcon dismisses these differences by arguing that Kurtz "deliver[s] beveled incisions that have intersecting segments (*once the incision is complete*)." Pet. 37; *see* Ex. 1001 ¶445. But that is precisely the problem with Kurtz. The laser intentionally does not "complete" the incision. Rather, a surgeon must "complete" it manually with a different surgical instrument. Ex. 1018, [0008], [0015]; Kang ¶372.

Third, Kurtz's corneal transplant incisions do not "allow access for lens removal instrumentation." Lens removal instruments are long and slender—at most a couple millimeters in diameter—to remove lens fragments and place an intraocular lens with minimum disruption to the cornea. Hatch ¶54. That is why cataract incisions are "*very small and geometrically precise opening(s)* and … *in precise locations* in and around the cornea and limbus." Ex. 1013, 3:13-16. Kurtz's incisions are completely different. To achieve their intended purpose, they require removing a large portion—if not *all*—of the cornea. Hatch ¶¶53-54. Kurtz's corneal transplant incisions would not be considered "cataract incisions" by those skilled in the art. Kang ¶373, 248-49; *see also id.* ¶¶100-02; *see* Hatch ¶¶55-57.

Alcon fails to show that any reference teaches the claimed laser cataract incision with all of its recited characteristics.

2. A Skilled Artisan Would Not Have Been Motivated to Make the Claimed Cataract Incision

Lacking prior art teaching the claimed cataract incision, Alcon turns to its expert, Dr. Lubatschowski, to argue that the incision would nonetheless have been obvious because it was allegedly a "well-known, self-sealing incision shape[]." Pet. 37 (citing Ex. 1001 (Lubatschowski Decl.) ¶445). But Dr. Lubatschowski is admittedly unqualified to opine on what types of cataract incisions were within the common knowledge of a skilled artisan. Indeed, he conceded on cross examination that he is "not an ophthalmologist" and did not speak with an ophthalmologist to inform his opinion. Ex. 2041, 33:5-19, 15:18-16:13. And despite asserting obviousness on the basis that the claimed cataract incisions were known to be "self-sealing," Dr. Lubatschowski has "no experience in wound healing." *Id.*, 34:4-5. As a result, Dr. Lubatschowski was unable to explain why one incision would be selected over another. Ex. 2041, 47:1-3 ("I cannot explain you what is the reason why they do it this [incision] or that [incision]").

Dr. Lubatschowski next turns to four additional references, Barequet (Ex. 1042), Vass (Ex. 1043), Ernest (Ex. 1044), and Rao (Ex. 1050), in an effort to support his conclusory obviousness assertion. Ex. 1001 ¶157 (cited by Ex. 1001 ¶445, referencing Section XI.A.4). These references do not support Alcon's argument: they all concern *manual* incisions and *none* so much as mentions laser surgery.[6] Indeed, the art affirmatively teaches away from the invention by touting single-plane incisions as superior to the claimed multi-plane incisions, as discussed below. Kang ¶377-89.

3. The Claimed Cataract Incisions Were Considered Inferior To Other Prior Art Incisions

In its Institution Decision, the Board encouraged the parties to fully address whether cataract incisions having the claimed configuration were "known to be advantageous, as asserted by Dr. Lubatschowski." ID 20. The record shows they were not.

Alcon and Dr. Lubatschowski argue that a skilled artisan would have been motivated to use the claimed cataract incision because it was "self-sealing" and did not require sutures. Pet. 31; Ex. 1001 ¶¶154, 157. But Alcon's own prior art shows

---

[6] The claims require that the cataract incisions have "a first segment and a second segment which intersect each other at an angle"—i.e., ***two intersecting segments*** in two planes. Ex. 1013, cl. 1; Kang ¶375-76. The so-called "beveled" embodiments of Barequet, Vass, and Ernest are single-plane cataract incisions. *See* Ex. 1044, Fig. 1 (Ernest's "beveled (paracentesis) incision" has a single plane); Ex. 1043, 2 (Vass's "beveled-incision" is stab incision having a single plane); Ex. 1042, 5 (Barequet's "corneal beveled" incision is same as Vass's single-plane "beveled-incision"); Kang ¶378-82.

that is wrong. And Dr. Lubatschowski's bald assertion to the contrary (Ex. 1001 ¶445) carries little weight, given that he admittedly has "no experience in wound healing." Ex. 2041, 34:4-5.

Alcon's prior art shows that single-plane, manual cataract incisions were believed to outperform the claimed multi-plane incisions. Kang ¶384. At the time of the claimed inventions, cataract incisions were typically 3.0 mm or smaller. Ex. 2022, 001 ("[T]he ideal incision size for cataract surgery is between 1 mm and 3 mm); Hatch ¶¶32, 35. At that range of incision sizes, Ernest teaches that its single-plane "beveled" corneal incision resisted external pressure better than a "stepped" multi-plane incision. Ex. 1044, Table 2 (2.5 and 3.0 mm), Fig. 1; Kang ¶¶385-86. Moreover, "beveled" single-planed incisions in limbus outperformed all multi-plane incision types for 2.5 mm incisions. Ex. 1044, Tables 1 and 2; Kang ¶¶385-86. A skilled artisan would not have been motivated to use multi-plane incisions that were only believed to outperform the single-plane incisions for larger incision sizes (3.5-4.5 mm) no longer in common use at the time of the invention. *See* Hatch ¶23-25.

Alcon also relies on Rao. But Rao discloses that single-plane cataract incisions exhibited "good self-sealing ability," comparable to that of multi-plane incisions, at incision angles of 30-40°. Ex. 1050, 4-5, 7-8. The multi-plane incision only exhibited an advantage if the incision angle was decreased to 20°. *Id.*, 8. But neither Rao nor Dr. Lubatschowski explains why a skilled artisan would have been motivated to use a more complex multi-plane incision at an angle of 20° instead of a simpler, single-plane incision at incision angle of 30-40°.

Indeed, Alcon's own prior art shows why one would not have done so. Vass describes both beveled (single-plane) and hinged (multi-plane) incisions as "self-sealing and sutureless." Ex. 1043, 2. But it explains that the multi-plane hinged incisions exhibited *more wound gape* and induced more astigmatism than the single-plane beveled incisions. *Id.*, 6-7, Table 5. This would have led a skilled artisan away from complex multi-plane incisions and toward the safer single-plane incisions. *See* Hatch ¶¶23-25.

Alcon fails to demonstrate that a skilled artisan would have been motivated to perform laser surgery to form the claimed cataract incision with two intersecting segments.

4. A Skilled Artisan Would Not Have Been Motivated to Form the Claimed Cataract Incision with a Laser Scanning System

As explained above, Alcon identifies no prior art that discloses the claimed laser cataract incision. Nor can Alcon demonstrate why a skilled artisan would have been motivated, even using manual techniques, to make a beveled cataract incision with two intersecting segments as claimed. Nevertheless, Alcon marries these two shortcomings by arguing that a skilled artisan would develop a laser system to make the claimed cataract incision because "the selection of a known shape is *prima facie* obvious." Pet. 31-32. Alcon's simplistic treatment of cataract surgery techniques is flawed. *See* MPEP §2144 (warning "against treating any line of reasoning as a per se rule").

For its argument of *prima facie* obviousness, Alcon's relies on the 1966 case of *In re Dailey*. Pet. 32 (citing *In re Dailey*, 357 F.2d 669 (C.C.P.A. 1966)). That case concerned a collapsible nursing container for infants where the top and bottom sections have a "generally spherical configuration." 357 F.2d at 670. The court found that claimed shape was merely "one of numerous configurations a person of skill in the art would find obvious." *Id.* at 672-73.

Alcon's shape-related obviousness argument, based on a nursing container patent, has no applicability here. "There was no evidence that the shape limitation at issue in *Dailey* had any impact on the function or operation of the device." *In re Gallant*, No. IPR2020-006725, 2021 WL 2621872, at *6 (PTAB June 23, 2021). In contrast, here the '548 patent concerns a medical intervention. Selecting the type of cataract incision involves a careful balance of minimizing tissue damage, infection control, promoting wound healing, and ensuring appropriate access for lens removal instrumentation. Hatch ¶31; *see also* Ex. 1013, 13:62-63. The design of a nursing container shares none of these considerations. And Alcon's attempt to create a per se obviousness rule based on based on the shape of a nursing container is manifestly inappropriate. The Federal Circuit has firmly rejected Alcon's approach to obviousness: "reliance on per se rules of obviousness is legally incorrect and must cease." *In re Ochiai*, 71 F.3d 1565, 1572 (Fed. Cir. 1995).

Alcon's obviousness argument fails for an additional reason. Alcon relies on Kurtz in each of its combinations for teaching that a laser system "can be used to deliver beveled incisions." Pet. 31, 50. But Kurtz expressly *teaches away* from using a laser to create a fully penetrating cataract incision, where the constituent segments "intersect each other" and together intersect "both an anterior and a posterior surface of the cornea." Ex. 1013, cl. 1.

Instead, Kurtz teaches it is crucial that "at least one uncut gap" must remain (Ex. 1018 [0008]), such that the segments either ***do not*** intersect each other, or ***do not*** intersect the anterior or posterior surface. *See supra* Section V.C.1. According to Kurtz, the incision should not fully penetrate the cornea, as required by claim 1, but instead should be manually opened by the surgeon in the operating room "using any appropriate surgical instrument" such as a "bladed instrument" or a "more blunt instrument." *Id.*, [0015]; *see also* Kang ¶¶390-94.

Kurtz explains that the uncut gap is necessary to: (1) ensure that "the internal chambers of the eye remain protected and unexposed to environmental contaminants" and (2) prevent the cornea tissue from becoming "dislodge[ed]" before moving to an operating room. *Id.*, [0014]. Without these uncut gaps, Kurtz explains that this risk "would *always* be present." *Id*. Far from motivating a skilled artisan to make the claimed cataract incision, Kurtz emphatically discourages it. This is a clear-cut example of teaching away. *See*, *e.g,*, *Chemours Co. FC, LLC v. Daikin Indus., Ltd*., 4 F.4th 1370, 1376 (Fed. Cir. 2021) (reversing finding of obviousness because the purported combination "alter[ed] the inventive concept" of the prior art and the prior art expressly taught away from the modification); *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994) (reference teaches away when a POSA "would be led in a direction divergent from the path that was taken by the applicant"); *see also DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1326 (Fed. Cir. 2009).

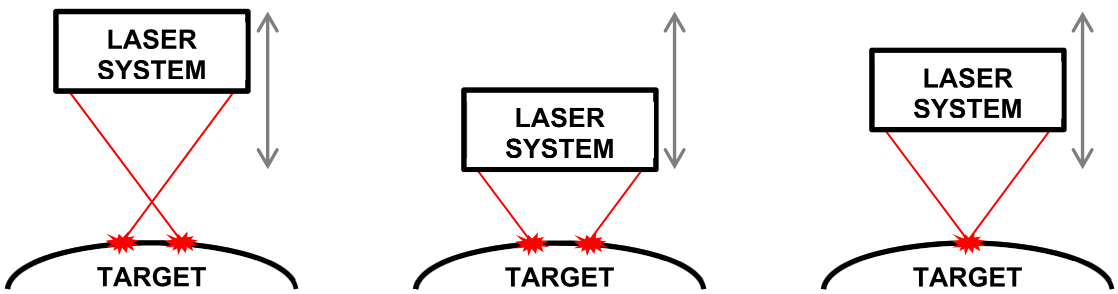
VI. Ground 3: Claims 1-5 and 8-12 Are Patentable Over Swinger, Weikert, Benedikt, and Kurtz

A. Asserted References

1. Swinger (Ex. 1021)

Swinger describes a laser surgery system that allows the surgeon to identify a treatment region using HeNe aiming beams. Ex. 1021, 33:57-61, 34:27-29, 34:52-57, 35:52-55, 36:20-23; Kang ¶¶395, 116-17. The laser system can be used for cataract surgery, such as to perform anterior capsulotomy (which it calls "anterior capsulectomy (capsulorhexis)"). Ex. 1021, 34:30-35:3. Swinger does not disclose cataract incisions. Kang ¶395; *see also id.* ¶118.

The surgeon aims the laser "by direct visualization using a visual HeNe laser beam focused to the same focal point." Ex. 1021, 34:52-55. The angled HeNe aiming beams (shown below) converge to a single point at a specific distance. Kang ¶395; *see also id.* ¶117. If the laser system is too high (shown left) or too low (shown middle), the surgeon will see multiple spots. The surgeon moves the laser system either up or down until it produces a single spot on the target (shown right):



<u>**High**</u> <u>**Low**</u> <u>**Correct**</u>

Id. Laser surgery begins after the target tissue is directly visualized and selected by the surgeon. Ex. 1021, 34:64-67; Kang ¶¶395, 117.

2. Benedikt (Ex. 1020)

Benedikt is concerned with improving a diagnostic imaging system for corneal surface topography called the "Placido" topometer or "video-keratometry." Ex. 1020, [0004]-[0006]; Kang ¶¶395, 109. A Placido topometer measures a cornea's topography by evaluating the accuracy at which the cornea, in its natural, non-deformed state, reflects a pattern projected onto its surface. Ex. 1020, [0002]-[0003]; Kang ¶¶395, 109; Ex. 2041, 113:13-114:8. According to Benedikt, the Placido topometer cannot accurately measure the topography of the central cornea or the optical properties of surfaces beneath the cornea. Ex. 1021, [0004]-[0005].

To address these issues, Benedikt discloses adding a second imaging device—either a wavefront analyzer or OCT—so that the dual-imaging system can detect the "surface topography of the cornea and at least one optical property of the layers of the eye disposed under the cornea." Ex. 1020, [0006]; *see also id.,* [0023]-[0028], [0032]-[0033], [0041], [0050], Figs. 1-6; Kang ¶¶395, 111-12. Benedikt also teaches that in addition to the OCT improving the topometer's surface topography measurements, the topometer could be used to improve the OCT results, by compensating for measurement errors caused by eye movement during data acquisition. Ex. 1020, [0015], [0017].

Benedikt is a stand-alone diagnostic system that measures the eye's optical properties. Ex. 1020, [0008], [0010], Figs. 1-6; Kang ¶¶395, 114. It is not part of any laser surgical system. While the collected data may be used in subsequent procedures with a separate "photo-ablative laser[]" system, Benedikt never suggests incorporating its imaging system into a laser system.

B. The Combination Does Not Disclose a Controller Programmed to Use OCT Signals to Determine a Treatment Pattern

Independent claim 1 requires a controller "programmed to determine a treatment pattern based upon the signals from the OCT device." Ex. 1013, 14:40-42. Alcon argues that Benedikt discloses this element because it allegedly teaches a controller, a "'PC' or 'workstation,'" that receives and uses OCT data to "'automat[e] laser surgery' by introducing 'the individually optimal ablation pattern for the front surface of the cornea with photo-ablative lasers." Pet. 52 (citing Ex. 1020, [0031], [0036], [0039]). Alcon mischaracterizes Benedikt, conflating its imaging system with its separate photo-ablative laser system.

Benedikt teaches a standalone imaging system. Ex. 1020, [0029], [0041]-[0043], Figs. 1-6. The imaging system's "evaluator unit, e.g. a PC or a workstation" (Ex. 1020, [0031]))—Alcon's alleged controller—evaluates data from the imaging devices to measure a refractive property of the eye's optical surfaces (*id.*, [0036]) and can provide a "data record" of this measurement, *id.*, [0037]. But Benedikt's imaging system is not coupled to any treatment laser, and its evaluator unit does not determine any ablation pattern for the cornea. Ex. 1020, [0039]; Kang ¶¶396-403, 114-15. This ablation is instead performed by an entirely separate photo-ablative laser system. Ex. 1020, [0039]; Kang ¶¶397, 401, 108-115. In fact, the only connection between the two systems is that the data record from Benedikt's imaging system can be used in connection with the photo-ablative laser. Ex. 1020, [0037], [0039]; Kang ¶¶397, 401, 108-115.

Nor does Benedikt suggest that the photo-ablative laser has a controller that is "programmed to determine a treatment pattern" using measurements in the data record. Benedikt is silent as to how its data record can be used in the "automated ablation of tissue," beyond mentioning that it can be used in accordance with a method known as "Assisted or Guided Topography" to "detach the ablation process from the surgeon's manual dexterity." Ex. 1020, [0039]; Kang ¶¶401-02. By contrasting it with "manual dexterity," this disclosure suggests that "automated ablation" concerns movement of the laser beam, not the determination of the treatment pattern. Kang ¶402. Benedikt does not disclose a controller that is programmed to "determine a treatment pattern."

C. Alcon Fails to Establish a Motivation to Combine

1. A Skilled Artisan Had No Motivation To Combine Swinger with Benedikt

In Ground 3, Alcon adds Benedikt for its dual topometer/OCT. Alcon relies on Benedikt (Ex. 1020) for the OCT device for creating an image of the cornea and limbus and a controller programmed to determine a treatment pattern from the OCT device. Ex. 1013, 14:33-36, 14:40-42.

A skilled artisan would have had no motivation to combine Benedikt with Swinger's laser system, which does not disclose any imaging capability at all. Combining an imaging system with a laser system is anything but trivial, and instead "represents a major challenge to optical engineers," as it would require a minimum of adjusting the delivery system's optics, and reprogramming the controller, including a calibration and registration between the treatment beam and imaging beams. Ex. 2010, 010; Ex. 2023, 004; Ex. 1007, 7:20-30; Kang (Ex. 2062) ¶¶409, 268. And as Alcon's expert admitted under cross-examination, laser treatment systems include fixation mechanisms to prevent eye movement that are incompatible with Benedikt's dual topometer/OCT system. Ex. 2041, 114:1-8, 115:18-116:8, 118:1-9.

a. Benedikt's Dual Topometer/OCT Imaging System Would Not Have Been Considered More Accurate Than Swinger's Direct Visualization

Alcon insists that a skilled artisan would have combined Swinger with Benedikt's dual topometer/OCT imaging "to plan and effect laser surgery with improved accuracy." Pet. 49. Alcon is wrong. Swinger already discloses using a HeNe beam to "accurately" create treatment patterns. Ex. 1021, 9:1-2, 35:59-63. Alcon offers no evidence that Benedikt's diagnostic imaging system would improve Swinger's accuracy or precision. Kang ¶405; *see also id.* ¶269-72.

Swinger teaches "direct visualization" with HeNe aiming beams to manually position the surgical laser for anterior capsulotomy. Ex. 1021, 34:30-57; Kang ¶¶405, 270. The HeNe aiming beams used in Swinger were the "gold standard" for precisely controlling the aim and depth of laser pulses and offered "***accurate control*** of tissue removal." Ex. 1021, 9:1-2; Hatch ¶71; Kang ¶¶405, 270. Swinger itself provides no reason to abandon its methods. Kang ¶405; *see also id.* ¶270.

b. A Skilled Artisan Would Not Use Benedikt's Imaging System With Prior Art Laser Systems

Swinger does not disclose using an imaging system. Kang ¶268. Adding Benedikt's dual imaging system, as Alcon proposes, would have presented difficult and unnecessary engineering challenges. No skilled artisan would have been motivated to make such a combination for at least three reasons.

First, the eye fixation requirement of Swinger's laser systems is incompatible with Benedikt's topometer. Benedikt's Placido topometer measures the cornea in its natural, non-deformed state. Ex. 2041, 113:13-114:8; Ex. 1020, [0032], [0002]-[0003]; Ex. 1007, 11:36-46; Kang ¶¶407, 109, 219, 273. Eye fixation devices normally are not used with Placido topometers, because they would change the natural curvature of the cornea. Ex. 2041, 116:1-8; Kang ¶¶407, 219. Swinger, on the other hand, uses an eye fixation means, called an "applanator plate," to stabilize the eye during treatment and create a point of reference for the laser scanning system. Swinger, 23:45-24:5; Kang ¶¶407, 273. This applanator plate deforms the cornea. Kang ¶407; *see also id.* ¶273.

Indeed, Alcon's expert repeatedly opined that such fixation devices are necessary for laser-based surgery. He admitted during cross-examination that, "as of 2007, [there was] a need for a fixation device" in cataract surgery. Ex. 2041, 115:18-22. He also wrote that "[a] mechanical fixation of the patient's eye using a suction ring is *essential* for laser surgery and is common practice with all providers." Ex. 2009, 005; Ex. 2023, 004. This fixation requirement of Swinger's laser systems is thus incompatible with Benedikt's topometer, which requires that the cornea be in its natural state. Ex. 1020, [0002]-[0003]; Ex. 1007, 11:33-54; Kang ¶¶407, 109, 219, 273; Ex. 2041, 113:11-114:8, 115:18-116:21.

Second, a skilled artisan would not be motivated to replace Swinger's HeNe aiming beam system, which has already been integrated with its surgical laser system. Benedikt's dual-imaging system is not incorporated into a laser system; it is a standalone device for pre-surgery imaging. Ex. 1020, [0008], [0029]-[0032], [0041]-[0043], Figs. 1-6; Kang ¶¶409, 228-44.[7]

Third, adding a dual topometer/OCT imaging system to Swinger would have presented the difficult task of modifying the system's scanning optics to account for the different types of imaging beams. Kang ¶410; *see also id.* ¶¶231, 233-37. Combining multiple imaging beams with a laser beam within a common optical path places demanding "chromatic requirements" on the system's optics because the beams tend to be different wavelengths. Kang ¶410; *see also id.* ¶¶233-37, 62-63.

---

[7] Benedikt mentions that it may be used with a treatment laser in paragraph [0039]. But, as discussed in *supra* Section VI.B, in that case, a "data record" from the dual-imaging system may be used by *separate* "photo-ablative lasers" in a method known as "Assisted or Guided Topography." Ex. 1020, [0039]; Kang ¶¶406, 229; *see also supra* Section VI.B.

"Chromatic requirements" relates to how the laser delivery system's optics focus light beams with different wavelengths differently. Ex. 2059, 61; Kang ¶¶410, 233.

Alcon's own patents and papers recognize this challenge. One Alcon patent (Raksi) explains that "surgical and imaging functions of the system … generally all operate in different spectral bands." Ex. 2006, 7:21-34. "Combining beam paths in common, or shared, optical components *places demanding chromatic requirements* on the optics of the laser surgical system." *Id.*; *see also* Ex. 2010, 010. Alcon's prior art fails to acknowledge or address this challenge, and fails to explain how a skilled artisan would resolve it. Kang ¶¶234-44. These drawbacks must be considered together with any alleged reasons to combine the prior art. *See Arctic Cat Inc. v. Polaris Indus., Inc.*, 795 F. App'x 827, 833 (Fed. Cir. 2019) ("The Board must weigh the benefits and drawbacks of the modification against each other, to determine whether there would be a motivation to combine."). Alcon's proposed combination fails because adding Benedikt's imaging system to Swinger's laser would serve no purpose and, at the same time, present considerable design difficulties.

2. A Skilled Artisan Would Not Have Developed Controllers Programmed to Determine Treatment Patterns

Alcon's motivation theory fails for another reason. Alcon fails to demonstrate that a skilled artisan would combine Swinger and Benedikt to obtain a controller "programmed to determine a treatment pattern," as required by independent claim 1. Benedikt focuses on diagnosis, not controlling any laser system to cut treatment regions. Kang ¶¶412, 396-403; *see also supra* Section **Error! Reference source not found.**. Alcon points to Benedikt's statement that the data obtained from its imaging system "can be used to detach the ablation process from the surgeon's manual dexterity and to provide it as a data record for the automated ablation of tissue in the laser." Pet. 52-53 (quoting Ex. 1020, [0039]). But a skilled artisan would understand the "data record" to be simply the static, diagnostic "illustrations of the cornea" in preparation for a surgery, as opposed to a controller-determined laser treatment pattern. Kang ¶¶401-402, 412.

Dr. Lubatschowski's declaration confirms the lack of motivation. There, he asserts that a skilled artisan "would have known, upon integrating an imaging system like Benedikt's with the ophthalmic-surgery system disclosed by Swinger, to program Swinger's controller to generate incisions patterns based on the image data." Ex. 1001 ¶473. But this conclusory assertion cannot support a motivation to combine. *See TQ Delta, LLC v. CISCO Sys., Inc.*, 942 F.3d 1352, 1360 (Fed. Cir. 2019) ("conclusory statement is not sufficient and is fraught with hindsight bias"). Dr. Lubatschowski provides no explanation why surgeons ***would*** have ceded control of their core competency—determining a treatment pattern—simply because an imaging system was incorporated into the laser system. *See, e.g.*, Hatch ¶68.

In fact, there would have been substantial challenges to using Benedikt's dual topometer/OCT system with Swinger's controller to determine a laser treatment pattern. Kang ¶¶230-37, 409-412. Benedikt's imaging system is not integrated with a surgical laser, and, as a result, its imaging coordinate system is not aligned to that of any laser. *See* Section *supra* **Error! Reference source not found.**; Kang ¶¶409, 413, 421. Alcon fails to address how a skilled artisan would align Benedikt's imaging coordinate system with Swinger's laser coordinate system or whether they would be motivated to undertake such a significant effort. Kang ¶¶231, 412-14. This failure is significant because Alcon proposes to replace a robust, commercially-available HeNe aiming system integrated with the surgical laser with an OCT system that is not. *Id*.

Alcon also argues that "automating a [] manual activity" cannot be patentable. Pet. 53. That sweeping rule is incorrect. *See* MPEP §2144 (warning "against treating any line of reasoning as a per se rule"). The clinical considerations—and intricate challenges—of determining laser treatment patterns for cataract surgery are different from contexts in which the courts have found automation obvious (such as for the industrial equipment in the 1958 decision that Alcon relies upon). *See* Pet. 53 (citing *In re Venner*, 262 F.2d 91, 95 (C.C.P.A. 1958)). For example, although Swinger describes some computer-controlled steps of laser surgery, Swinger expressly leaves determination of the treatment pattern solely to the surgeon.

Ex. 1021, 33:39-46 ("The surgeon [] selects the pattern or shape of the incision"); Kang ¶414. In ophthalmic surgery, surgeons retained manual control for centuries—for good and long-standing reasons. Hatch ¶¶49-51. Alcon identifies nothing motivating a skilled artisan to discard that approach.

3. A Skilled Artisan Would Not Have Been Motivated to Form the Claimed Cataract Incision With a Laser Scanning System

Alcon asserts that Swinger discloses the claimed cataract incisions and points to a variety of incisions shown in Swinger to support its argument. Pet. 47-48. But not one of those incisions bears the characteristics of the claimed cataract incision: none is a bevel shape incision with two intersecting segments designed to allow access for the lens removal instrumentation. Kang ¶415.

So for Ground 3, Alcon again relies on common knowledge, Kurtz, and its shape-related argument to argue obviousness. Pet. 55-56. But, as discussed above, far from demonstrating obviousness, the prior art teaches away from the invention. *See supra* Section V.C; Kang ¶¶416-19.

VII. Dependent Claims Are Further Patentable Over the Prior Art

A. A Skilled Artisan Would Not Have Used a "Z-Scan Device" (Claim 6 and 7)

Claim 6 requires a "z-scan device operable to move a focus position of the laser beam along a z-axis and a X-Y scan device operable to move the focus position of the laser beam laterally relative to the z-axis." Ex. 1013, 15:9-10. In Ground 4, Alcon contends that a skilled artisan would have further combined Swinger, Kurtz, Weikert, and Benedikt with L'Esperance because "Swinger does not specify how its scanning assembly effects scans in the z-dimension." Pet. 61. Not so. Swinger scans in the z-dimension by moving the entire system up and down. Kang ¶¶420-21; Ex. 1001 (Lubatschowski Decl.) ¶184 (Swinger "appears to move the entire system along the z axis").[8]

Alcon admits that there are "numerous ways to achieve three-dimensional scanning." Pet. 61. Alcon nevertheless contends that "a POSA would have preferred utilizing optical components to control the focal spot because their small size is suitable for ***precise control***." *Id.* Alcon is wrong. Swinger's system already discloses "precise control of tissue removal" and explains that the "etch depth of each pulse may be precisely controlled." Ex. 1021, 8:41, 17:43-45. The system "ablat[es] tissue at any desired location with predetermined ablation depth." *Id.*, 9:1-4. Because Swinger already had "precise control," a skilled artisan would not have been motivated to look to other references such as L'Esperance to implement a different way to scan in the z-dimension.

---

[8] Alcon relies on L'Esperance for a scanning assembly, which does not cure the deficiencies of Ground 3. Thus, claims 6-7 are also nonobvious for the reasons already articulated above for Ground 3.

Alcon's expert, Dr. Lubatschowski, alleges that Swinger would nevertheless be combined with L'Esperance because "actuating a different lens [] along the beam path [as L'Esperance does] would enable more precise control of the axial depth of the focal zone than moving the entire laser system, as Swinger apparently suggests." Ex. 1001 ¶186. Dr. Lubatschowski provides no further explanation and does not address the existing "precise control" provided by Swinger. The conclusory assertion of "more precise control" fails to provide any articulated reasoning or rational underpinning to combine. *TQ Delta*, 942 F.3d at 1360. It should be rejected.

B. A Skilled Artisan Would Not Have Found It Obvious to Select a Laser Beam Having a Wavelength Between 1010 nm to 1100 nm (Claim 8)

Claim 8 requires that "the ultrafast laser source is configured to deliver a laser beam having a wavelength between 1010 nm to 1100 nm." Ex. 1013, 15:17-19. In Ground 3, Alcon contends that Swinger's disclosure of a laser system with a "wavelength of about 400 nm and about 1900 nm" teaches this limitation. Pet. 59. But Swinger's disclosure of this broad range does not render obvious the much narrower claimed range of 1010 to 1100 nm.

"[W]here the disclosed range is so broad as to encompass a very large number of possible distinct compositions," the narrower claimed range is nonobvious. *See Genetics Inst., LLC v. Novartis Vaccines & Diagnostics, Inc.*, 655 F.3d 1291, 1306 (Fed. Cir. 2011). Swinger's laser wavelength range spans over 1500 nanometers—

covering the entire visible spectrum (about 400 to 700 nm) and extending well into the infrared. Kang ¶423. Swinger's wavelength range is more than 16-fold broader than the claimed range, and includes a wide array of distinct laser types. *Id.* Different lasers at different wavelengths have their own unique characteristics, advantages, and disadvantages. *Id.* Neither Alcon nor its expert explains why a skilled artisan would have been motivated to select the narrower 1010 to 1100 nm wavelength range, which only spans 90 nm, out of the large breadth of possible wavelengths (and lasers) proposed by Swinger. *Id.*

Alcon's expert argues that two lasers, titanium-doped sapphire and Nd:YLF, have wavelengths that fall within the claimed range. Ex. 1001 ¶484 (citing Ex. 1047, Ex. 1048). But Alcon offers no explanation or evidence that a skilled artisan would have selected those two lasers, with the claimed wavelengths, out of the many options offered by Swinger to use in the claimed invention. Kang ¶424. In fact, Swinger criticizes the Nd:YLF laser as having "a considerable acoustic shock component" and lacking "control or gentleness of beam that allows a smooth and regular" incision. Ex. 1021, 7:60-63, 8:2-3; *see also* Kang ¶424. As for the titanium-doped sapphire laser, Alcon's own reference teaches that the "optimum operating range" is near "780-nm wavelength range," far outside the claimed 1010-1100 nm range. Ex. 1047, 1; Kang ¶424. If anything, by suggesting an "optimum" wavelength of 780 nm, the prior art teaches away. Kang ¶424.

VIII. Conclusion

For the reasons set forth above, the Board should deny the Petition for Inter Partes Review.

Respectfully submitted,

Dated: March 14, 2022

By: / Michael A. Morin /

Michael A. Morin (Reg. No. 40,734)
michael.morin@lw.com
Latham & Watkins LLP
555 Eleventh Street, NW, Ste. 1000
Washington, D.C. 20004-1304
Telephone: 202.637.2200
Fax: 202.637.2201

Counsel for Patent Owner
AMO Development, LLC

CERTIFICATE OF COMPLIANCE WITH 37 C.F.R. § 42.24

I hereby certify that this Patent Owner's Response complies with the word count limitation of 37 C.F.R. § 42.24(b)(2) because the Patent Owner's Response contains 12,712 words using Microsoft Word's counting feature, plus 103 words hand-counted in the imaged text, for a total of 12,815 words, excluding the cover page, signature block, and the parts of the Patent Owner's Response exempted by 37 C.F.R. § 42.24(b)(2).

By: / Michael A. Morin /

Michael A. Morin (Reg. No. 40,734)
michael.morin@lw.com
Latham & Watkins LLP
555 Eleventh Street, NW, Ste. 1000
Washington, DC 20004
Telephone: 202.637.2200
Fax: 202.637.2201

Counsel for Patent Owner
AMO Development, LLC

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), I certify that on this 14th day of March, 2022, a true and correct copy of the foregoing **Patent Owner's Response and all Exhibits** were served by electronic mail on Petitioner's lead and backup counsel at the following email addresses:

Gregg F. LoCascio, P.C. (Reg. No. 55,396)
W. Todd Baker (Reg. No. 45,265)
Noah S. Frank (Reg. No. 67,279)
KIRKLAND & ELLIS LLP
1301 Pennsylvania Ave., N.W.
Washington, D.C. 20004
Tel.: 202.389.5000
Fax: 202.389.5200
gregg.locascio@kirkland.com
todd.baker@kirkland.com
noah.frank@kirkland.com
Alcon_IPR@kirkland.com

Jeanne M. Heffernan (*pro hac vice*)
KIRKLAND & ELLIS LLP
401 Congress Avenue
Austin, TX 78701
Tel.: 512.678.9100
Fax: 512.678.9101
jheffernan@kirkland.com

Matthew A. Lembo (Reg. No. 75,633)
KIRKLAND & ELLIS LLP
601 Lexington Ave.
New York, NY 10022
Tel.: 212.446.4800
Fax: 212.446.4900
matthew.lembo@kirkland.com

By: / Michael A. Morin /

Michael A. Morin (Reg. No. 40,734)
michael.morin@lw.com
Latham & Watkins LLP
555 Eleventh Street, NW, Ste. 1000
Washington, DC 20004
Telephone: 202.637.2200
Fax: 202.637.2201

Counsel for Patent Owner
AMO Development, LLC