Filed on behalf of: AMO Development, LLC

Entered: January 27, 2023

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 IPR2021-00846
Patent 10,376,356 B2

PATENT OWNER'S NOTICE OF APPEAL

Notice is hereby given, pursuant to 37 C.F.R. § 90.2(a), that Patent Owner AMO Development, LLC ("Patent Owner") appeals to the United States Court of Appeals for the Federal Circuit from the Final Written Decision entered by the Patent Trial and Appeal Board (the "Board") on December 1, 2022 (Paper 55) (the "Final Written Decision," copy of which is attached hereto as Exhibit A).

In accordance with 37 C.F.R. § 90.2(a)(3)(ii), Patent Owner further indicates that the issues on appeal may include, without limitation:

- Whether the Board erred in determining that Petitioner has shown by a preponderance of the evidence that the challenged claims of U.S. Patent No. 10,376,356 B2 are unpatentable as obvious, along with all reasons, findings, opinions, and orders leading thereto or underlying that decision.

Pursuant to 35 U.S.C. § 142 and 37 C.F.R. § 90.2(a), this Notice is being filed with the Director of the United States Patent and Trademark Office, and a copy of this Notice is being concurrently filed with Board. In addition, a copy of the Notice of Appeal, along with the required docketing fee, is being filed with the Clerk of Court for the United States Court of Appeals for the Federal Circuit.

Respectfully submitted,

Dated: January 27, 2023

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 SERVICE

I hereby certify that, pursuant to 37 C.F.R. § 90.2(a)(1), on this 27th day of January, 2023, I electronically filed the foregoing **PATENT OWNER'S NOTICE OF APPEAL** with the Patent Trial and Appeal Board via P-TACTS, in accordance with 37 C.F.R. § 42.6(b)(1).

I also hereby certify that a true and correct paper copy of the foregoing **PATENT OWNER'S NOTICE OF APPEAL** is being filed by hand with the Director of the United States Patent and Trademark Office at the following address:

Director of the United States Patent and Trademark Office
c/o Office of the General Counsel
Madison Building East, 10B20
600 Dulany Street
Alexandria, VA 22314-5793

I also hereby certify that, pursuant to Federal Circuit Rule 52(a)(2), on the 27th day of January, 2023, a true and correct copy of the foregoing **PATENT OWNER'S NOTICE OF APPEAL** and the filing fee, were filed with the Clerk's Office of the U.S. Court of Appeals for the Federal Circuit via CM/ECF.

Pursuant to 37 C.F.R. § 42.6(e), I certify that on this 27th day of January, 2023, a true and correct copy of the foregoing **PATENT OWNER'S NOTICE OF APPEAL** was 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

Kristen P. L. Reichenbach (Reg. No. 61,162)
KIRKLAND & ELLIS LLP
555 California Street
San Francisco, CA 94104
Tel.: 415.439.1400
Fax: 415.439.1500
kristen.reichenbach@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

EXHIBIT A

Trials@uspto.gov
571-272-7822

Paper 55
Entered: December 1, 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.,
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v.

AMO DEVELOPMENT, LLC,
Patent Owner.

IPR2021-00846
Patent 10,376,356 B2

Before SHERIDAN K. SNEDDEN, JON B. TORNQUIST, and RYAN H. FLAX, *Administrative Patent Judges.*

TORNQUIST, *Administrative Patent Judge.*

JUDGMENT
Final Written Decision
Determining All Challenged Claims Unpatentable
35 U.S.C. § 318(a)

I. INTRODUCTION

A. Background and Summary

Alcon Inc., Alcon LenSx, Inc., Alcon Vision, LLC, Alcon Laboratories, Inc., and Alcon Research, LLC (collectively "Petitioner") filed a Petition (Paper 1, "Pet.") requesting an *inter partes* review of claims 1–15, 17–19, and 21–24 of U.S. Patent No. 10,376,356 B2 (Ex. 1010, "the '356 patent"). AMO Development, LLC ("Patent Owner") filed a Preliminary Response to the Petition. We authorized Petitioner to file a reply addressing the prior art status of a relied-upon reference (Paper 12, "Preliminary Reply"), to which Patent Owner filed a Sur-Reply (Paper 15). Upon review of the parties' arguments and supporting evidence, we instituted review. Paper 17 ("Decision" or "Dec.").

Patent Owner subsequently filed a Response (Paper 32, "PO Resp."), to which Petitioner filed a Reply (Paper 40, "Pet. Reply"), and Patent Owner filed a Sur-Reply (Paper 50, "Sur-Reply").

Petitioner relies, *inter alia*, upon the declaration and reply declaration of Holger Lubatschowski, Ph.D. (Exs. 1001, 1069) and the declaration of Richard Tipperman, M.D. (Ex. 1070). Patent Owner submits declarations from Jin U. Kang, Ph.D. (Exs. 2002, 2062) and Kathryn M. Hatch, M.D. (Ex. 2004, 2063).

On September 2, 2021, Patent Owner disclaimed "the entirety of claims 13–24 of U.S. Patent No. 10,376,356." Ex. 2013, 2. As such, we do not consider these claims in this proceeding, leaving claims 1–12 at issue.

An oral hearing was held on August 30, 2022, and a transcript of the hearing is included in the record (Paper 54, "Tr.").

B. Real Parties-in-Interest

Petitioner identifies Alcon Inc., Alcon Vision, LLC, Alcon Laboratories, Inc., and Alcon Research, LLC as the real parties-in-interest, noting that after the Petition was filed "Alcon LenSx, Inc. merged into Alcon Research, LLC, with Alcon Research LLC the surviving entity." Paper 3, 1; Pet. 3. Patent Owner identifies itself and Johnson & Johnson Surgical Vision, Inc., AMO Manufacturing USA, LLC, and AMO Sales and Services, Inc., as the real parties-in-interest. Paper 5, 1.

C. Related Matters

The '023 patent is asserted in *AMO Development, LLC et al. v. Alcon LenSx, Inc. et al.*, No. 1:20-cv-00842-CFC (D. Del). Pet. 2–3; Paper 5, 1. *Inter partes* review petitions were also filed by Petitioner against related patents in IPR2021-00843, 00845, and -0849. Paper 3, 1; Pet. 3.

D. The '356 Patent

The '356 patent is directed to an "optical beam scanning system for incising target tissue in a patient's eye," including forming cataract and relaxation incisions in the cornea of an eye. Ex. 1010, code (57).

The '356 patent notes that many cataract patients are astigmatic, which can occur when the cornea has a different curvature in one direction than another. *Id.* at 1:41–43. To correct such astigmatism, the '356 patent discloses applying a corneal relaxing incision using 3-dimensional patterned laser cutting, and notes that "[a] wavefront sensor, interferometer, surface profiler, or other such device may be used to yield prescriptions for correcting the astigmatism" in an eye. *Id.* at 2:55–3:4.

Figure 1 of the ’356 patent is reproduced below:

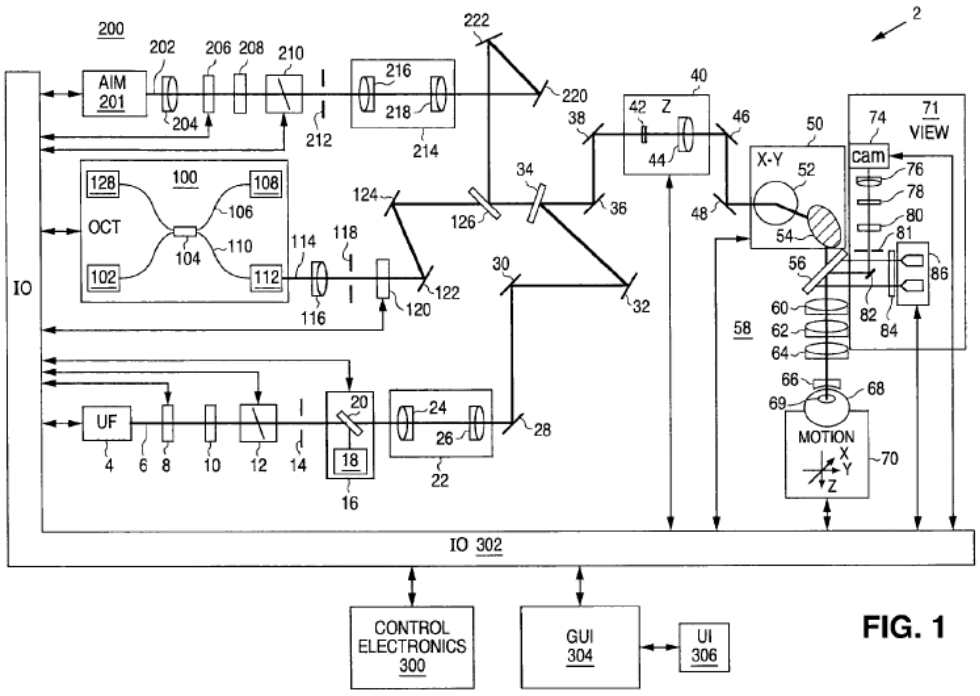

FIG. 1

Figure 1 is a schematic diagram of the optical beam scanning system of the ’356 patent. *Id.* at 2:30–31. As shown in Figure 1, control electronics 300 (or “controller 300”) control laser 4 via input/output device IO 302. *Id.* at 4:5–10. The ’356 patent explains that graphical user interface GUI 304 may be used to set operating parameters, process user input UI 306, and display gathered information such as images of ocular structures. *Id.* at 4:10–13.

In operation, UF light beam 6 passes through half-wave plate 8 and linear polarizer 10 as it proceeds towards the patient’s eye 68. *Id.* at 4:14–16. After interacting with several elements, light beam 6 reflects off fold mirrors 28, 30, and 32, which serve to align light beam 6. *Id.* at 4:53–57. Optical Coherence Tomography (OCT) beam 114 is collimated using lens 116 and is combined with UF light beam 6 at beam combiner 34. *Id.* at 6:41–65. In this way, OCT beam 114 follows the same path as UF beam 6 throughout the rest of the system and is “indicative of the location of UF

beam 6." *Id.* at 6:64–7:3. Aim beam 202 is generated by aim beam light source 201 and assists the user in directing the UF laser's focus. *Id.* at 7:40–47.

The '356 patent explains that the integrated OCT system may be used to discern the limbus and sclera relative to the cornea by virtue of the large optical scattering differences between these tissue types. *Id.* at 10:57–60. The optical scattering differences then "can be determined and used by CPU 300 . . . to guide the placement of the laser-created incisions." *Id.* at 10:60–64. According to the '356 patent, the OCT device uses wavelengths in the range of 800–1400 nm because they are less scattered in tissue and penetrate to depths of about 1 mm, "while not suffering from linear optical absorption by water or other tissue constituents that would otherwise diminish their performance." *Id.* at 11:6–11.

Figure 6 of the '356 patent is reproduced below:

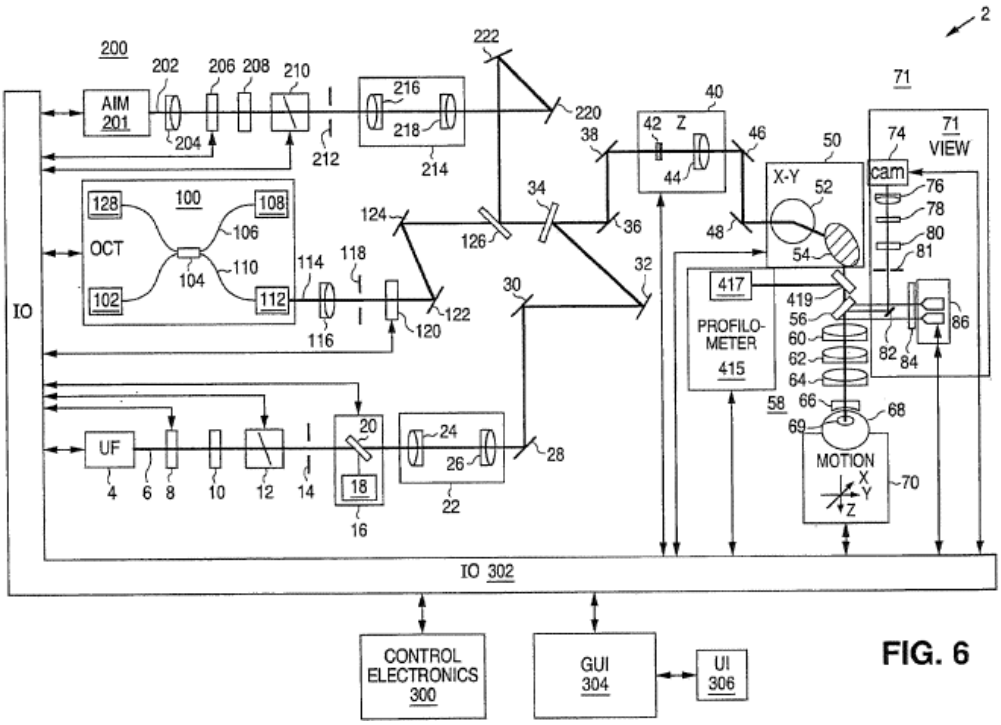

FIG. 6

Figure 6 discloses the same general apparatus as Figure 1, but includes a profilometer subsystem. *Id.* at 2:43–44. Profilometer 415 "may be a placido system, triangulation system, laser displacement sensor, interferometer, or other such device, which measures the corneal topography," and "may be used to prescribe an astigmatic keratotomy to correct the shape of a patient's cornea to diminish its astigmatism." *Id.* at 12:4–12. And, as shown in Figure 6, profilometer 415 is distal to X-Y scanner 50 "to allow for a continuous unobstructed view of the cornea of patient's eye 68." *Id.* at 11:46–48.

As shown in both Figure 1 and Figure 6, "[a]n optional contact lens 66, which can be any suitable ophthalmic lens, can be used to help further focus the optical beam 6 into the patient's eye 68 while helping to stabilize eye position." *Id.* at 5:58–65. Although contact lens 66 is shown in Figures 1 and 6, the '356 patent explains that contact lens 66 or its disposition relative to cornea 406 of eye 68 may have to be modified, compensated for, or removed to suit the profilometer's mode of operation. *Id.* at 11:52–55. "This is because profilometer 415 requires the cornea to be in its natural state, not forced into contact with a surface and possibly conforming to its shape, to accurately measure cornea 406 and provide data to system 2 for calculation . . . ." *Id.* at 11:55–67.

E. Illustrative Claim

Petitioner challenges claims 1–12 of the '356 patent, i.e., the remaining challenged, but non-disclaimed, claims. Pet. 6. Of these challenged claims, claim 1 is the only independent claim and is reproduced below:

> 1. An optical beam scanning system for incising target tissue in a patient's eye, the optical beam scanning system comprising:

a laser source configured to deliver a laser beam comprising a plurality of laser pulses, the laser beam being configured to produce optical breakdown and initiate a plasma-mediated process within the target tissue at a focal spot of the laser beam;

an Optical Coherence Tomography (OCT) imaging device configured to generate signals that can be used to create an image of eye tissue that includes the cornea of the patient's eye;

a delivery system for delivering the laser beam to the target tissue to form a cataract incision;

a scanner operable to scan the focal spot of the laser beam to different locations within the patient's eye; and

a controller operatively coupled to the laser source, the OCT imaging device and the scanner, the optical beam scanning, the controller programmed to:

scan the eye tissue with the OCT device to generate imaging data for the target tissue that includes imaging data for the cornea;

generate an incision pattern based at least in part on the imaging data, the incision pattern forming one or more relaxation incisions into the cornea, wherein each of the relaxation incision extends in an angular direction for a predetermined length less than a full circle, and wherein at least one of the one or more relaxation incisions is a partially penetrating incision that leaves an un-incised tissue thickness; and

scan the focal spot of the laser beam in the incision pattern, wherein the focal spot of the laser beam is guided based on the imaging data so that the focal spot of the laser beam is scanned from a posterior portion of the eye and proceeding anteriorly.

Ex. 1010, 14:28–62.

F. Prior Art and Asserted Grounds

Petitioner asserts that claims 1–12 are unpatentable on the following grounds (Pet. 6):

Claims Challenged[1]	35 U.S.C. §[2]	Reference(s)/Basis
1, 2, 4–14, 17–19, 21–24	103	Blumenkranz[3], Weikert[4]
2, 3, 14, 15	103	Blumenkranz, Weikert, Benedikt[5]
1–8, 14, 15, 17–19, 21	103	Swinger[6], Weikert, Benedikt
9–12, 22–24	103	Swinger, Weikert, Benedikt, L'Esperance[7]

[1] As noted above, Patent Owner disclaimed claims 13–24 of the '356 patent. Ex. 2013. For context, we list all the claims of the '356 patent challenged by Petitioner for each ground, but we will only address Petitioner's challenges to claims 1–12.

[2] The Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112-29, 125 Stat. 284, 287–88 (2011), amended 35 U.S.C. §§ 102 and 103, effective March 16, 2013. Because the '356 patent is a divisional application from US App. No. 13/569,103, filed August 7, 2012, we understand that the pre-AIA version of these statutes apply. *See* 35 U.S.C. § 100(i)(2); Ex. 1010, codes (22), (62).

[3] US Patent Publication No. 2006/0195076 A1, published August 31, 2006. Ex. 1017 ("Blumenkranz").

[4] Mitchell P. Weikert and Douglas D. Koch, *Refractive Keratotomy: Does It Have a Future Role in Refractive Surgery?*, Cataract and Refractive Surgery (2005). Ex. 1019 ("Weikert"); *see* Ex. 1001 ¶ 73.

[5] US Patent Publication No. US 2004/0066489 A1, published April 8, 2004. Ex. 1020 ("Benedikt").

[6] US 6,325,792 B1, issued December 4, 2001. Ex. 1021 ("Swinger").

[7] US 4,538,608, issued September 3, 1985. Ex. 1022 ("L'Esperance").

II. ANALYSIS

A. Legal Standards

A patent claim is unpatentable under 35 U.S.C. § 103(a) if the differences between the claimed subject matter and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations, including (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) if in the record, objective evidence of nonobviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

B. Level of Ordinary Skill in the Art

In determining the level of ordinary skill in the art, we consider the type of problems encountered in the art, the prior art solutions to those problems, the rapidity with which innovations are made, the sophistication of the technology, and the educational level of active workers in the field. *Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc.*, 807 F.2d 955, 962 (Fed. Cir. 1986).

Petitioner contends one of ordinary skill in the art "would have had a Ph.D. in Physics, Biomedical Engineering, or a related science, such as Optical Engineering, or at least five years of experience in research, manufacturing, or designing medical optics or medical lasers." Pet. 25. According to Petitioner, "[i]n either case, a [person of ordinary skill in the art] would have also had a moderate understanding of ophthalmology, and refractive and cataract surgery." *Id.*

Patent Owner contends the field of invention is "ophthalmic surgical procedures and systems," and that the team of inventors that developed the '356 patent included Dr. Culbertson, a Professor of Ophthalmology at Bascom Palmer Eye Institute. PO Resp. 8 (citing Ex. 1010, 1:15–18, 1:59–62; Ex. 2055). Thus, according to Patent Owner, the correct level of skill in the art includes meaningful experience with ophthalmic surgery, such as an ophthalmic surgeon with experience with medical optics or lasers, or an engineer with a Bachelor's degree in a laser-related engineering or optics field who worked with an ophthalmic surgeon. *Id.* (citing Ex. 2062 ¶¶ 80, 83). Patent Owner contends this definition stands in contrast to Petitioner's proposed definition, which "has no skill or experience in ophthalmic surgery," only a "moderate understanding of ophthalmology, and refractive and cataract surgery." *Id.* at 8–9.

In its Reply, Petitioner argues that Patent Owner's definition of the ordinarily skilled artisan is belied by the fact that Patent Owner's own expert "is not a clinician and did not speak with any clinicians before rendering his opinions." Pet. Reply 4 (citing Ex. 1073, 15:17–25, 17:7–21, 18:4–8). Petitioner further argues that Dr. Lubatschowski "has ***over 20 years of experience in laser applications for ophthalmology***, working with ophthalmic surgeons," and falls squarely within Patent Owner's definition of a person of ordinary skill in the art. *Id.* (citing Ex. 1002; Ex. 2041, 17:10–12; Ex. 1069 ¶¶ 5–8).

Both parties present compelling evidence that those of skill in the art would include individuals with experience in ophthalmology, as well as in the research, manufacture, and design of medical optics or medical lasers. Pet. 25; PO Resp. 8. The evidence of record also demonstrates that few individuals actually had such experience. Rather, teams of individuals with

different expertise and various academic degrees would work together to design laser surgery systems intended to make incisions in the lens of the eye.

Accordingly, we find that the person of ordinary skill in the art would have been an ophthalmic surgeon or someone with a Ph.D., M.S., or B.S. degree in physics, biomedical engineering, or a related science such as optical engineering, with experience in researching, manufacturing, or designing medical optics or medical lasers (e.g., Ph.D. or five or more years to compensate for lesser degrees). Such individuals would have worked in collaboration with one another to fill any necessary gaps in knowledge (e.g., the engineer would consult the medical doctor on clinical issues or physiology and the medical doctor would consult the engineer on technical issues). This definition marries the two proposed by the parties.

We note that although the level of ordinary skill in the art could include individuals with varying backgrounds and experience levels, where a declarant has knowledge of ophthalmic surgery but not medical optics, or of medical optics and engineering but not ophthalmic surgery, we will take this relative lack of direct experience or knowledge into account when weighing each declarant's testimony.

C. Claim Construction

In this proceeding, the claims of the '356 patent are construed "using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. [§] 282(b)." 37 C.F.R. § 42.100(b). Under that standard, the words of a claim are generally given their "ordinary and customary meaning," which is the meaning the term would have had to a person of ordinary skill at the time of the invention, in the context of the

entire patent including the specification. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc).

Petitioner provides constructions for the terms "cataract incision" and "a delivery system for delivering the laser beam to the target tissue to form a cataract incision." Pet. 7–9. Patent Owner provides a construction for the term "cataract incision." PO Resp. 10–11.

Upon review of the parties' arguments and supporting evidence, including the fact that neither party disputes that Weikert expressly discloses cataract incisions under either parties' interpretation of that term, we determine that no claim terms require express construction for purposes of this Final Written Decision. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) ("[O]nly those terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy.")).

D. Prior Art Status of Weikert

The Petition asserts that Weikert is an article, titled *Refractive Keratotomy: Does it Have a Future Role in Refractive Surgery?*, that was published in 2005 "as Chapter 14 in CATARACT AND REFRACTIVE SURGERY" and is therefore prior art to the '356 patent under 35 U.S.C. § 102(b). Pet. 5–6, 27–28. In support of the Petition, Dr. Lubatschowski testifies that the identified chapter of Weikert was part of "the 2005 edition" of "CATARACT AND REFRACTIVE SURGERY." Ex. 1001 ¶ 73.

In its authorized Reply to the Preliminary Response, Petitioner provides a copy of the front cover of Weikert, as well as pages identifying the ISBN number, ISSN number, Library of Congress Control Number, and

a 2005 copyright date for the reference. Preliminary Reply 1; Ex. 1060, 1–5.[8]

Patent Owner contends that the Petition failed to provide evidence establishing Weikert is prior art to the '356 patent and, therefore, "the Petition fails at the threshold." PO Resp. 12. Patent Owner acknowledges that Petitioner submitted additional evidence and Reply arguments to support its assertion that Weikert is prior art to the '356 patent, but contends it is the Petition that must establish a reference is prior art, and failure to do so in this case is fatal. *Id*.

A petition must "identify *with particularity* the grounds for institution and evidence supporting such grounds," including "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 (PTAB Dec. 20, 2019) (precedential) (citing 35 U.S.C. § 312(a)). The Petition identifies the grounds for institution and the evidence supporting such grounds, and presents evidence that Weikert qualifies as prior art under 35 U.S.C. § 102(b). Pet. 5–6, 27–28. For example, Petitioner and Dr. Lubatschowski assert that CATARACT AND REFRACTIVE SURGERY "is a quarterly review series comprising chapters written by well-known specialists," and that Weikert was included in the 2005 edition of CATARACT AND REFRACTIVE SURGERY as Chapter 14: *Refractive Keratotomy: Does it Have a Future Role in Refractive Surgery?* Ex. 1001 ¶ 73; Pet. 5–6, 27–28.

In addition, *Hulu* contemplates additional evidence being admitted in a reply to a patent owner preliminary response, as long as that evidence is

[8] Here we reference the page numbers added in the bottom-right corner of the reference that were added by Petitioner.

responsive to the prior briefing. *Hulu*, Paper 29 at 14. In this case, Petitioner's evidence submitted in its Reply is responsive to arguments made in the Preliminary Response, and simply confirms what was asserted in the Petition and Dr. Lubatschowski's declaration filed therewith, i.e., that Weikert is Chapter 14 of CATARACT AND REFRACTIVE SURGERY and the document bears a copyright date of 2005 (or, as asserted by Dr. Lubatschowski, is a "2005 edition"). Ex. 1060, 5, 12; Pet. 5–6, 27–28; Ex. 1001 ¶ 73. In addition, this evidence indicates that CATARACT AND REFRACTIVE SURGERY was published by "Springer," which is a well-known publishing company, and is the type of document that would be expected to be made publicly accessible. *See* Ex. 1001 ¶ 73 (asserting that CATARACT AND REFRACTIVE SURGERY "is a quarterly review series comprising chapters written by well-known specialists"); Ex. 1019, 220, 224, 227, 228, 230, 232 (providing a "Summary for the Clinician" at the end of several sub-chapters); Ex. 1060, 4–5.

The information presented in the Petition, as confirmed by the Reply evidence submitted by Petitioner, sufficiently demonstrates that Weikert is prior art to the '356 patent.

E. Claims 1–8 over Swinger, Weikert, and Benedikt

Petitioner contends the subject matter of claims 1–8 would have been obvious over the combined disclosures of Swinger, Weikert, and Benedikt. Pet. 50–65.

1. Swinger

Swinger discloses the use of low energy, ultra-short (femtosecond) pulsed laser radiation to ablate ocular tissue in a controlled fashion. Ex. 1021, code (57). Swinger explains that the disclosed photodisruption process is gentle enough that it may be used for surgical procedures that

were previously impossible using laser radiation, including "radial and arcuate keratotomy," "capsulectomy, capsulorhexis, and phacoablation." *Id.*

Figure 6 of Swinger is reproduced below:

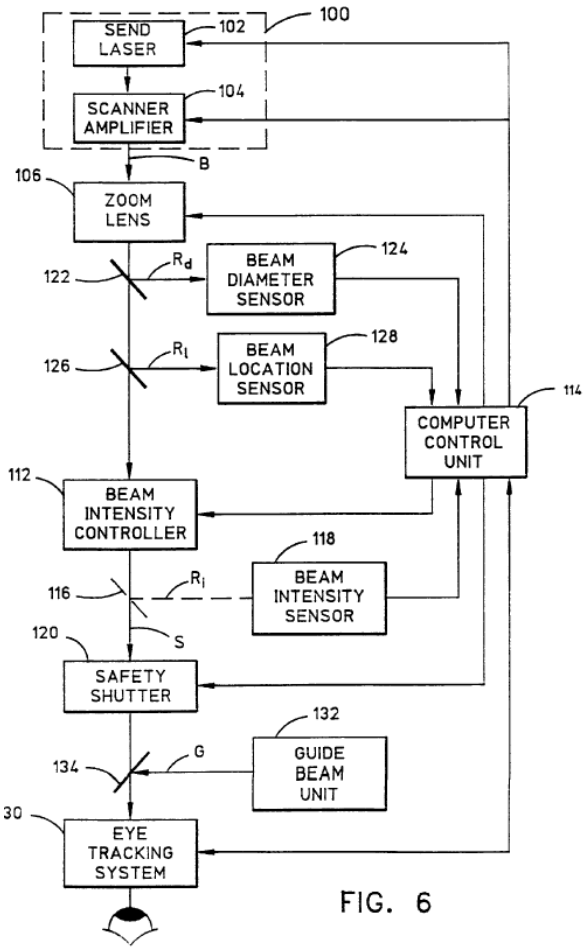

FIG. 6

Figure 6 is a block diagram of a preferred embodiment of the laser and control system of Swinger. *Id.* at 10:61–62, 17:1–30. As shown in Figure 6, laser unit 100 generates laser beam B. *Id.* at 17:1–2. Swinger explains that the preferred laser system includes a broad gain bandwidth laser using lasing ions such as titanium, chromium, or neodymium and emitting at a preferred wavelength of 400 nm to 1900 nm, "which is generally transmissive in eye tissue." *Id.* at 8:43–48.

Zoom lens 106 provides control over the diameter of laser beam B. *Id.* at 17:21–24. Beam-splitting mirrors 122 and 126 reflect part of the beam energy to beam diameter sensor 124 and beam location sensor 128, respectively. *Id.* at 18:43–45, 19:30–33. Beam intensity controller 112 is coupled to computer control unit 114, which is programmed to vary the intensity of surgical laser beam S, as necessary for a particular surgical procedure. *Id.* at 17:50–54. Safety shutter 120 is coupled to computer control unit 114 and is used to prevent unwanted or accidental laser radiation exposure of eye tissue. *Id.* at 18:10–24, 19:24–29. Guide beam unit 132 includes a low-power laser that provides a guide beam appropriate for direct viewing that is aligned with surgical laser beam S and acts as an indicator of the location of the treatment beam. *Id.* at 20:22–34.

Swinger discloses that its system "can easily create straight line and curved-line excisions, of any predetermined length and depth, at any location determined by a surgeon." *Id.* at 20:49–51. One use of this system is "for performing radial keratotomies or making T-cuts or arcuate cuts, to correct myopia, hyperopia, or astigmatism (regular or irregular)." *Id.* at 21:12–19. Swinger explains that these cuts may be made using various laser scanning patterns and that these cuts may completely penetrate the cornea or may be made within the cornea. *Id.* at 33:7–17.

Swinger also explains that the disclosed system may perform capsulorhexis surgery, as follows. *Id.* at 34:30–51. First, the focus of the laser beam spot is localized to the anterior lens capsule "by direct visualization using a visual HeNe laser beam focused to the same focal point as the ablating laser." *Id.* at 34:52–55. "Then the surgeon displaces the HeNe positioning beam just posteriorly to" the lens capsule and "photodisruption begins." *Id.* at 34:58–61. According to Swinger, "[t]he

cutting process can be totally computerized once the reference point on the capsule has been fixed, or the surgeon can terminate the process when the capsule has been visibly cut for 360 degrees." *Id.* at 34:64–67.

2. Weikert

Weikert reviews the history, use, and potential future of refractive keratotomy, which involves making incisions into the cornea of the eye, often to correct astigmatism. Ex. 1019, 217.[9] Weikert explains that the first clinical use of keratotomy to correct refractive error occurred in 1885, where a penetrating limbal incision was used to decrease astigmatism following cataract surgery. *Id.* (section 14.2). Although by the late 1990s laser-based systems "had replaced refractive keratotomy as the dominant technique for the surgical correction of refraction error," Weikert notes that "incisional corneal surgery remains a useful tool in the surgeon's repertoire of refractive procedures." *Id.* at 218.

Weikert notes that clear corneal incisions (CCIs) "made during cataract surgery have been known to induce astigmatism by flattening the meridian on which the incision is centered." *Id.* at 227 (section 14.7.1). "The amount of this surgically induced astigmatism (SIA) varies with incision length and placement." *Id.* Weikert reports that one study comparing incision sizes of 3.2 mm, 4.0 mm, and 5.2 mm, found that the mean SIA was 0.09 D, 0.26 D, and 0.54 D, respectively. *Id.* In view of the various studies on the subject, Weikert reports that "0.0–0.5 D of SIA can be expected from temporal CCIs less than or equal to 3.2 mm." *Id.* at 228.

Weikert notes that one method of correcting the astigmatism caused by corneal incisions for cataract surgery was to provide "a similar incision

[9] Our citations are to the original page numbers of the document.

placed opposite to the temporal CCI," with cataract surgery being performed only through one wound. *Id.* (section 14.7.2). Although such a procedure can reduce astigmatism, its "range is limited" and "carries [the] additional risk associated with the extra penetrating corneal wound." *Id.* To correct higher levels of astigmatism, Weikert reports that "[p]artial thickness, arcuate or transverse corneal incisions" may be used and that "[a]rcuate incision have been combined with cataract surgery to reduce pre-existing astigmatism." *Id.* at 228–229 (section 14.7.3).

In its conclusion, Weikert reports that "[a]s advances continue in the areas of intraocular lens design, crystalline lens removal and excimer laser refractive surgery, we are likely to see further decline in the use of refractive keratotomy." *Id.* at 232.

3. Benedikt

Benedikt discloses an apparatus for detecting the surface topography of a cornea of an eye. Ex. 1020, code (57). The apparatus of Benedikt includes a Placido Topometer and a CCD array. *Id.* ¶ 29. In use, light in a known pattern is projected on a cornea and the reflected light is captured as an image by the CCD array. *Id.* ¶ 31. This "allows measurement [of] the surface of the cornea within a few milliseconds by recording usually more than 8,000 measuring points." *Id.* ¶ 32. Because the recorded information "does not supply any information from deeper section of the eye," however, Benedikt discloses combining the Topometer with either a wave front analyzer or coherence tomography. *Id.* ¶¶ 15, 32.

Figure 3 of Benedikt is reproduced below:

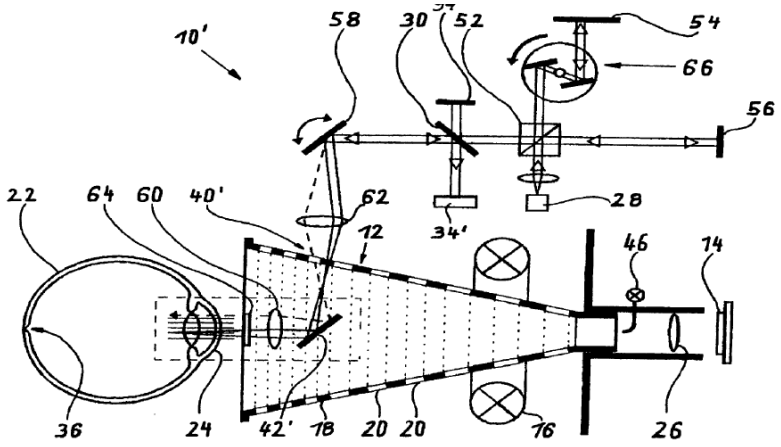

Figure 3

Figure 3 is a schematic representation "of an apparatus with a Placido Topometer and optical coherence tomography (OCT), with the optical coherence tomography being set up for acquiring tomographs from the anterior section of the eye." *Id.* ¶ 25. In Figure 3, apparatus 10' consists of "a Placido Topometer with a Placido cone 12, a cone lamp 16 and a CCD array 14, as well as an optical coherence tomography." *Id.* ¶ 41. Aperture 40' is provided on Placido cone 12, "through which the laser beam from the coherence tomography can be guided." *Id.* The OCT device detects individual boundary surfaces of the eye, including the anterior and posterior surface of the cornea, anterior and posterior surface of the lens, and fundus of the eye. *Id.* ¶ 43.

In the disclosed design, "the measurements with the Placido Topometer and the coherence tomography can be performed either simultaneously or sequentially." *Id.* ¶ 46. According to Benedikt, "the combination of Placido Topometery and coherence tomography leads to a qualitatively novel and previously unachievable quantitative description of the eye in respect of diagnostics and therapeutics."

With respect to the use of a dual imaging system, Benedikt explains that the data record may be used "to introduce the individually optimal ablation pattern for the front surface of the cornea with photo-ablative lasers," thereby detaching "the ablation process from the surgeon's manual dexterity" and providing "for the automated ablation of tissue." *Id.* ¶ 39.

4. Analysis: Claim 1

Petitioner contends the combination of Swinger, Weikert, and Benedikt teaches every limitation of independent claim 1 and renders it obvious. In particular, Petitioner contends that: (1) Swinger discloses a multi-functional ophthalmic-surgery system to make incisions during cataract surgery, including relaxation incisions (Pet. 50, 52–53 (citing Ex. 1021, 10:10–15, 16:62–20:33, 21:12–17. Fig. 6)); (2) Swinger discloses a laser source for generating a pulsed laser beam that produces a dielectric breakdown and causes plasma formation at the focal point (*id.* at 53 (citing Ex. 1021, 2:10–15, 13:10–25, 17:1–30, Figs. 4–6)); (3) Benedikt teaches an OCT device in combination with a topometer that can be used to provide topometric and OCT data to assist guided laser treatment (*id.* at 53 (citing Ex. 1020 ¶¶ 8, 10, 14–16, 19, 39, 42, 44, Figs. 3–4; Ex. 1001 ¶¶ 39, 397)); (4) Weikert teaches that cataract incisions are a well-known aspect of cataract surgery and Swinger discloses a laser delivery system for providing incisions in the cornea of a patient's eye (*id.* at 53–54 (citing Ex. 1019, 227; Ex. 1021, 8:55–67, 9:64–67, 10:10–15, 16:60–20:34, 25:61–26:33, Figs. 6, 15D)); (5) Swinger discloses a scanner for scanning the focal spot of a laser beam to different locations within a patient's eye under the control of a controller (*id.* at 54 (citing Ex. 1021, 9:1–6, 16:60–20:34, 20:49–65, 21:9–11, 25:61–26:33, Figs. 6–7, 15D)); (6) Swinger discloses operatively coupling the laser source to the scanner and Benedikt

discloses an OCT system for providing data to a controller (*id.* at 55 (citing Ex. 1021, 16:60–20:34, Fig. 6; Ex. 2020 ¶¶ 31, 36, 39, 51; Ex. 1001 ¶¶ 402–404)); (7) Benedikt discloses OCT scans that generate imaging data for target tissue, including the cornea (*id.* at 55 (citing Ex. 1020 ¶¶ 39, 43, Figs. 3–4)); (8) Benedikt discloses a detector for detecting OCT laser light and generating signals, as well as a controller to receive imaging data (*id.* at 55–56 (citing Ex. 1020 ¶¶ 31, 36, 39, 42, 51; Ex. 1001 ¶ 406)); (9) Swinger and Weikert disclose relaxation incision patterns that extend in an angular direction less than a full circle and are intended to be partially penetrating (*id.* at 56–57 (citing Ex. 1021, 21:12–24, 33:7–22, Figs. 8B, 15W; Ex. 1019, 218, 219, 228–229, 231–232)); and (10) Swinger discloses corneal incisions that are delivered in a posterior-to-anterior direction, as well as scanning the laser beam focal spot in various incision patterns on the cornea (*id.* at 58 (citing Ex. 1021, 33:7–23, 34:64–67, Fig. 15A1; Ex. 1001 ¶ 409) (Petitioner asserting that one of ordinary skill in the art would have understood that the incision patterns of Swinger are "programmed into the system to automate the delivery of the incisions").

With respect to the reason to combine Swinger and Weikert, Petitioner contends that Weikert discloses that the combined use of cataract and relaxation incisions in the cornea has been known for approximately 150 years. Pet. 50. Petitioner further contends that Swinger discloses a multi-functional ophthalmic-surgery system that expressly makes relaxation incisions and also "suggests" making cataract incisions. *Id.* Given that Swinger teaches or suggests a system that is used to make the specific incisions disclosed in Weikert, Petitioner contends that one of ordinary skill in the art would have found it obvious to use Swinger's system to make cataract and relaxation incisions in the eye of a patient. *Id.* at 50–51.

Petitioner acknowledges that neither Swinger nor Weikert expressly discloses a system with an OCT device and profilometer that can be used to determine incisions patterns, but contends one of ordinary skill in the art "would have been motivated to integrate Benedikt's imaging assembly into a system like Swinger's in order to plan and effect laser surgery with improved accuracy." *Id.* at 51–52 (citing Ex. 1001 ¶ 178). Petitioner further contends that modifying Swinger's laser system to include Benedikt's imaging assembly "merely amounts to a simple substitution (Benedikt's combined-imaging assembly in place of Swinger's direct visualization technique or ultrasound) of known imaging modalities that would obtain predictable results." *Id.* (citing Ex. 1001 ¶ 180).

Patent Owner contends Petitioner's arguments regarding the combination of Swinger, Weikert, and Benedikt fail because (1) the proposed combination does not disclose a controller programmed to use OCT signals to generate an incision pattern; and (2) Petitioner fails to establish that one of ordinary skill in the art would have combined Swinger, Weikert, and Benedikt to arrive at the subject matter of claim 1 with a reasonable expectation of success. PO Resp. 39–48. We address these arguments below.

a) Controller Programmed to use OCT Signals to Generate an Incision Pattern

Claim 1 requires a "controller programmed to . . . generate an incision pattern based on [OCT] imaging data." Ex. 1010, 14:44–46, 14:50–52. Petitioner contends that one of ordinary skill in the art "would have read Benedikt as teaching a controller programmed to generate incision patterns based on the image data," and would have operatively coupled the imaging

device of Benedikt to the controller of Swinger "in order to image the target eye tissue prior to ablation." Pet. 53, 55–56.

Patent Owner asserts that Petitioner mischaracterizes Benedikt, "conflating its imaging system with its separate photo-ablative laser system." PO Resp. 40. According to Patent Owner, Benedikt's imaging system "evaluates data from the imaging devices to measure a refractive property of the eye's optical surfaces" and provides these measurements as a "data record," but "is not coupled to any treatment laser and its evaluator unit does not determine any ablation pattern for the cornea." *Id.* (citing Ex. 1020 ¶ 39; Ex. 1062 ¶¶ 439–440).

Swinger discloses a laser system that is capable of making incision in the cornea to correct astigmatism. Ex. 1021, 33:7–23, 34:30–35. In the system of Swinger, the surgeon may position the aiming beam at the desired location, or may manually program variables into a computer, before automated laser cutting is performed by a controller. *See* Ex. 1021, 33:36–51, 34:58–65.

Benedikt discloses using a combination of a topometer and OCT device to obtain "a qualitatively novel and previously unachievable quantitative description of the eye in respect of diagnostics and therapeutics." Ex. 1020 ¶ 46. Benedikt further discloses that the highly detailed illustration of the cornea "leads to the opportunity to use the complete data record (possibly with its linkage to ray tracing programs) to introduce the individually optimal ablation pattern for the front surface of the cornea" and to automate laser surgery. *Id.* ¶ 39. As Patent Owner notes, Benedikt does not describe the laser system that obtains the "data record" and introduces the optimal ablation pattern to a patient's eye. PO Resp. 40. Benedikt also does not expressly state that a controller generates the incision

pattern, as opposed to the incision pattern being generated by a surgeon or technician. *Id.* Benedikt does state, however, that the data record, in addition to possibly a ray tracing program, could be used to "introduce the individually optimal ablation pattern for the front surface of the cornea." Ex. 1020 ¶ 39. Considering these disclosures of using programs and data to generate the optimal ablation pattern and to automate laser surgery, we credit the testimony of Dr. Lubatschowski that one of ordinary skill in the art would have understood Benedikt to teach or suggest providing its data record to a controller that is programmed to generate optimal incision patterns for the cornea of a patient's eye. Ex. 1001 ¶ 406 (citing Ex. 1020 ¶¶ 36, 39, 42); Pet. 56.

In view of the foregoing, we find persuasive Petitioner's argument that the combination of Swinger, Weikert, and Benedikt teaches or suggests a controller programmed to use OCT signals (in addition to signals from a profilometer) to generate an incision pattern for the cornea of a patient's eye, as recited in independent claim 1.

b) Motivation to Combine

(1) Use of Benedikt's Imaging System in Swinger

Petitioner contends that one of ordinary skill in the art would have sought to implement Benedikt's imaging and control system in Swinger "in order to plan and effect laser surgery with improved accuracy." Pet. 52 (citing Ex. 1001 ¶ 178).

Patent Owner argues in response that one of ordinary skill in the art would not have considered Benedikt's imaging system to be more accurate than Swinger's method of direct visualization using HeNe aiming beams. PO Resp. 43. Patent Owner contends that the HeNe aiming beams of Swinger "were the gold standard for precisely controlling the aim and depth

of laser pulses and offered 'accurate control of tissue removal,'" which Swinger provides no reason to abandon. *Id.* (citing Ex. 1021, 9:1–2; Ex. 2062 ¶ 71; Ex. 2063 ¶¶ 270, 445).

Benedikt describes its combined topometer/OCT imaging device as providing a "previously unattainable comprehensive topometerical/topographical illustration of the cornea" and discloses using this comprehensive data to automate corneal laser surgery. Ex. 1020 ¶¶ 39, 46; Pet. 55–56. In contrast to the comprehensive illustration of the cornea provided by Benedikt's system, Petitioner demonstrates that HeNe beams are limited to visualizing the surface of eye tissue at a single point. Ex. 1070 ¶¶ 32–34; Pet. Reply 23; Ex. 1073, 254:2–14; Ex. 1001 ¶¶ 29–31. As Petitioner proposes to use the system of Swinger to make incisions in the cornea, which Benedikt's system can image comprehensively, we find persuasive Petitioner's argument that one of ordinary skill in the art would have found it beneficial to implement Benedikt's imaging device to aid Swinger's corneal surgery procedure(s).

(2) Challenges of Incorporating Benedikt's Imaging System in Swinger

Patent Owner contends one of ordinary skill in the art would not have combined Benedikt with Swinger because "combining an imaging system with a laser system is anything but trivial," requiring "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." PO Resp. 42 (citing Ex. 2010 ¶ 10; Ex. 2023 ¶ 4; Ex. 1007, 7:22–30; Ex. 2062 ¶¶ 268, 409, 444). Patent Owner contends the ordinarily skilled artisan would not have taken on such a difficult task because (1) Swinger's eye fixation device is incompatible with Benedikt's topometer; (2) unlike Swinger's HeNe aiming beam system, Benedikt's

dual-imaging system is not incorporated into a laser system; and (3) incorporation of Benedikt's imaging system "would have presented the difficult task of modifying the system's scanning optics to account for the different types of imaging beams." *Id.* at 44–45.

Petitioner argues in response that Swinger does not require eye fixation, and prior art laser surgical systems with integrated imaging were known in the art. Pet. Reply 19. Petitioner further argues that a person of ordinary skill in the art would have known how to adjust the delivery system's optics and reprogram the controller, "including a calibration and registration between the treatment beam and imaging beams." *Id*. Petitioner notes that the '356 patent says little about how to determine the treatment patterns, configure the controller to automate generation of an ablation pattern, "how to co-register and align beams, or address chromatic aberrations when combining multiple beams," strongly suggesting that these steps were within the skill of an ordinarily skilled artisan. *Id.* at 19–20 (citing *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1570 (Fed. Cir. 1997) ("Moreover, the '359 patent itself does not disclose the level of detail that Lockwood would have us require of the prior art.")).

In its Sur-Reply, Patent Owner argues that there is simply no reason to move away from Swinger's accurate method of using HeNe aiming beams to guide lasers in ophthalmic surgery and implement Benedikt's topometer/OCT imaging device. Sur-Reply 23. Patent Owner further argues that Swinger's eye fixation devices are incompatible with a topometer and that a topometer's measurements "would be rendered redundant by the subsequent OCT measurement." *Id.* at 24. And, given the minimal purported advantages over Swinger's HeNe aiming beam, Patent Owner contends one of ordinary skill in the art would not have sought to

overcome the considerable design challenges in aligning the imaging and treatment beams. *Id.* at 24–25.

For surgery on the cornea, Benedikt explains that a topographic scanner is particularly useful, as is a second scanner for detecting optical properties of layers of the eye disposed under the cornea. Ex. 1020 ¶¶ 3–8, 32, 39, 46. Consistent with this disclosure, and with Petitioner's arguments in general, Dr. Hatch testifies that even when OCT data is available, she finds that topometer data is very useful. Ex. 1074, 246:6–248:16 (Dr. Hatch explaining that despite having OCT images, there is "a huge benefit to topography"). As such, we find persuasive Petitioner's argument that one of ordinary skill in the art seeking to form a cataract incision and relaxing incisions in the cornea of a patient's eye would have sought to implement Benedikt's dual topometer/OCT imaging system in Swinger.

As noted by Patent Owner, use of Benedikt's topometer would require modification or removal of Swinger's eye fixation device. Petitioner persuasively demonstrates, however, that Swinger does not require eye fixation and that one of ordinary skill in the art would have found Benedikt's topometer advantageous even when the eye is not fixated, such as for pre- and -post surgical measurements. Pet. Reply 23–24 (citing Ex. 1021, 23:35–56; Ex. 1010, 11:44–12:3; Ex. 1001 ¶¶ 101–102, 146); Ex. 1069 ¶ 53. Moreover, even if modification of the eye fixation device were needed in order to appropriately image the cornea, the '356 patent merely states that "contact lens 66 or its disposition relative to cornea 406 of eye 68 may have to be modified, or compensated for, to suit the profilometer's mode of operation," without providing any particular guidance on how to do so. Ex. 1010, 11:52–66. This suggests the inventors of the '356 patent did not

consider the necessary modifications to an eye fixation device to be particularly difficult. *See* Ex. 1069 ¶¶ 53–54.

Integrating Benedikt's imaging system with a treatment laser would present technical design challenges. The evidence of record, however, including the testimony of Dr. Lubatschowski, which we credit, supports that surgical systems with integrated imaging were known and that any necessary modifications were well within the capabilities of the person of ordinary skill in the art. Pet. Reply 24–25 (citing Ex. 1069 ¶¶ 45–56; Ex. 1017 ¶ 74; Ex. 1075 ¶¶ 69–70; Ex. 2010, 10; Ex. 1072, 76:21:77–3 (Dr. Kang testifying that in 2005 a person of ordinary skill in the art knew how to develop a system which could co-register the OCT and the laser beam)).

In any event, even if difficult design challenges existed in implementing a dual topometer/OCT imaging system in Swinger, given the advantages of Benedikt's imaging system for incisions in the cornea, we find that one of ordinary skill in the art would not have foregone or avoided the use of Benedikt's imaging system in light of such design challenges.

c) Controller Programmed to Generate Incision Patterns

Petitioner contends that Swinger discloses a controller operatively coupled to a laser source and scanner, and that Benedikt discloses an imaging system comprising a profilometer and OCT device that may be used to provide a data record that can be used to automate laser surgery on the cornea of a patient's eye. Pet. 55–56. Given these complementary disclosures, Petitioner argues that one of ordinary skill in the art would have programmed the controllers of Swinger to generate incision patterns based on the image data provided in Benedikt. *Id.* at 57.

Patent Owner contends Petitioner's motivation to combine arguments fail because a person of ordinary skill in the art would not have sought to program the controllers of Swinger, Weikert, and Benedikt to generate incision patterns. PO Resp. 45–46. Patent Owner reasons that generating incision patterns is a "core competency" of surgeons and one of ordinary skill in the art would not have ceded such control based on the disclosures of Swinger and Benedikt. *Id.* at 46.

Patent Owner further argues that Benedikt merely supplies a static, diagnostic illustration of the cornea, "as opposed to a controller-generated laser incision pattern," and Petitioner fails to provide anything beyond mere conclusory assertions regarding the motivation to program Swinger's controller to generate incision patterns based on image data. *Id.* at 46 (citing Ex. 1062 ¶ 452).

Swinger discloses automating laser surgery "once the reference point on the capsule has been fixed." Ex. 1021, 34:64–67. Benedikt discloses using a profilometer/OCT imaging system to generate a data record of the cornea of a patient's eye and using this data record to "introduce the individually optimal ablation pattern for the front surface of the cornea." Ex. 1020 ¶ 39. Benedikt further discloses that this data record can be used to "detach the ablation process from the surgeon's manual dexterity" and provide "for the automated ablation of tissue." *Id.* Given these disclosures, we credit the testimony of Dr. Lubatschowski that one of ordinary skill in the art would have understood that Benedikt teaches or suggests a controller programmed to generate incision patterns for the cornea based on image data and would have sought to program the controller of Swinger to generate incisions patterns for the cornea of a patient's eye based on Benedikt's profilometer/OCT image data. Ex. 1001 ¶¶ 406–408.

Patent Owner's counter-argument that a surgeon would not give up his or her "core competency" of generating incisions patterns for a patient's eye are not persuasive in this case in view of Benedikt's express disclosure of generating an "individually optimal ablation pattern" for the cornea of a patient's eye based on imaging data and of automating laser surgery. Ex. 1020 ¶¶ 39, 46; *see also* Pet. 34 (noting that Blumenkranz expressly discloses a controller programmed to generate an incision pattern based at least in part on imaging data); Ex. 1017 ¶ 73 (Blumenkranz disclosing generating and projecting an alignment pattern on a patient's eye to allow the surgeon to adjust the size, location, and shape of the treatment pattern prior to applying automated laser surgery). Moreover, there is no indication in this case that generating an incision pattern for the *cornea* of a patient's eye based on topometer/OCT data, as disclosed in Benedikt, was particularly difficult or challenging.[10]

d) Conclusion with Respect to Claim 1

For the reasons set forth above, Petitioner persuasively demonstrates that Swinger, Weikert, and Benedikt teach or suggest every limitation of independent claim 1. Petitioner also provides a reasoned explanation,

[10] In IPR2021-00817 and related cases directed to computer-controlled cataract surgeries on the lens and lens capsule, we determined that Petitioner had not demonstrated that it would have been obvious to program controllers to, among other things, automatically identify tissue boundaries, automatically identify treatment regions based on identified tissue boundaries, and then automatically scan the treatment laser in the lens or lens capsule of a patient's eye. *See Alcon, Inc., et. al. v. AMO Development, LLC*, IPR2021-00817, Paper 50 at 27 (PTAB Oct. 13, 2022). The difference in outcome in this case rests, in part, on the difference in tissues being treated and the express teaching or suggestion identified in this case of automating incisions in corneal tissue based on profilometer/OCT image data (Benedikt).

supported by record evidence, as to why one of ordinary skill in the art would have sought to combine these references to obtain the subject matter of claim 1 with a reasonable expectation of success. Accordingly, Petitioner demonstrates by a preponderance of evidence that claim 1 would have been obvious over the combined disclosures of Swinger, Weikert, and Benedikt.

5. Analysis: Claims 2–8

Petitioner identifies where Swinger, Weikert, and Benedikt teach or suggest every limitation of claims 2–8. Pet. 58–65. In particular, Petitioner demonstrates that: (1) Benedikt discloses using profilometer data to define an incision pattern and Weikert discloses using a surface profile to define the incision pattern to treat astigmatism of the eye (claim 2) (*id.* at 58–59 (citing Ex. 1020 ¶¶ 6, 13, 15, 16, 29–31, 32, 39, Figs. 3–4; Ex. 1019, 228, 230)); (2) Benedikt teaches or at least suggests disposing the profilometer distal to the scanner (claim 3) (*id.* at 59–60 (citing Ex. 1020 ¶¶ 4, 50–52, Figs. 3–4, 6; Ex. 1001 ¶ 415)); (3) Weikert teaches or suggests, when combined with the knowledge of one of skill in the art regarding depth of relaxation incisions, using OCT data to select the incision depth of one or more relaxation incisions (claims 4) (*id.* at 61 (citing Ex. 1019, 2-3; Ex. 1001 ¶ 416)); (4) Swinger and Weikert teach or suggest relaxation incisions that do not cross an anterior surface of the target tissue or a posterior surface of the target tissue (claim 5) (*id.* at 61–62 (citing Ex. 1019, 217–220, 228–229, 231–232; Ex. 1001 ¶¶ 417–419; Ex. 1021, 33:7–23)); (5) Swinger discloses one or more relaxation incisions that comprise a plurality of discrete incisions within the cornea (claim 6 and 8) (*id.* at 62 (citing Ex. 1021, 33:7–23, Fig. 5; Ex. 1019, 217–221, 228)); and (6) Swinger and Weikert teach or suggest applying a plurality of discrete incisions to form both a cataract incision and a relaxation incision (claim 7)

(*id.* at 62–63 (citing Ex. 1021, 21:12–24, 33:7–22, Figs. 8B, 15W; Ex. 1019, 228; Ex. 1001 ¶¶ 420–422)).

Patent Owner does not address Petitioner's arguments with respect to claims 2–8, beyond its arguments set forth above with respect to independent claim 1.

Upon review of the parties' arguments and supporting evidence, we determine that Petitioner demonstrates by a preponderance of the evidence that claim 2–8 would have been obvious over Swinger, Weikert, and Benedikt.

F. Claims 9–12 over Swinger, Weikert, Benedikt, and L'Esperance

Claim 9 depends from independent claim 1 and further requires, among other things, a Z-scan device operable to move the focal spot of the laser beam along a Z-axis, "wherein the laser beam propagates through the Z-scan device prior to propagating through the X-Y scan device." Ex. 1010, 15:20–27. Claims 10 and 11 depend from claim 9 and further require that the OCT beam is focused and scanned by the scanner (claim 11) and, in particular, by the Z-scan device and the X-Y scan device (claim 10). *Id.* at 15:28–33. Claim 12 depends from claim 9 and further requires that the OCT device generates signals that are used to generate three-dimensional positional data for the cornea. *Id.* at 15:34–36.

Petitioner contends the subject matter of claims 9–12 would have been obvious over the combined disclosures of Swinger, Weikert, Benedikt, and L'Esperance. Pet. 65–69.

1. L'Esperance

L'Esperance discloses that:

> The invention involves the apparatus and the technique for non-invasive surgery to remove cataracted-lens tissue from an

> afflicted lens. The beam output of a laser is focused to a spot of maximum power density at the anterior surface of a cataracted lens and scanned over a predetermined area or areas of the cataracted lens. The beam is selective and safe since it's diffuse as it enters the eye through the cornea and is also diffuse (being divergent) in the unlikely event that the beam passes through an opening it has created in the cataracted lens. This diffusion assures against damage to either or both of the cornea and the retina. Focal power levels are used sufficient to achieve cataract material destruction thru ablative photodecomposition, thermal decomposition, photofragmentation, photoemulsification or any combination thereof. Various features are disclosed for assuring safety and uniformity in the removal of involved tissue.

Ex. 1022, code (57).

L'Esperance illustrates such an apparatus at its Figure 1, reproduced below:

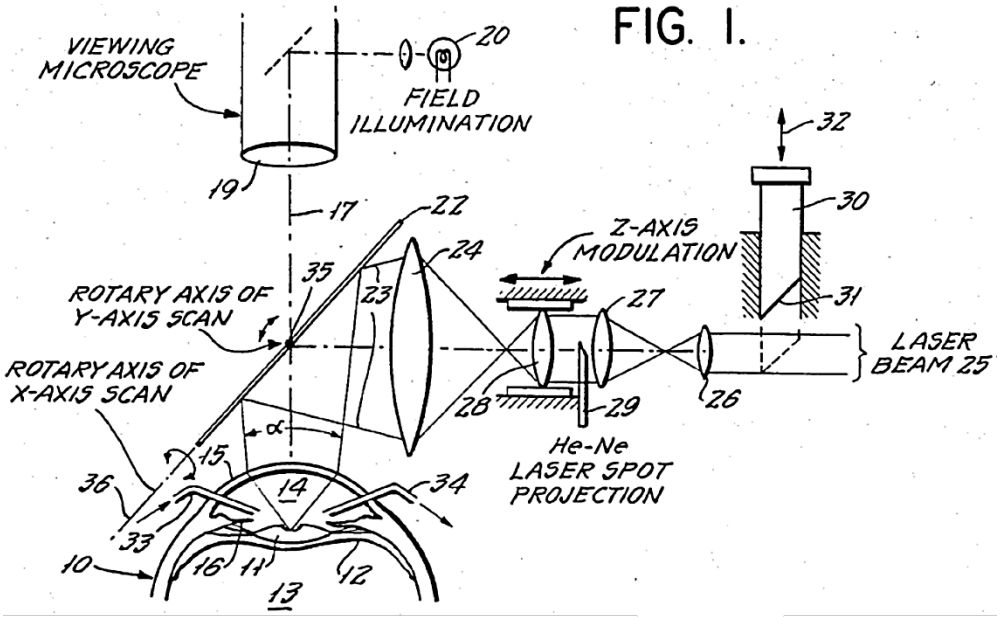

Figure 1 "is a simplified optical diagram of components of [an] apparatus of the invention, shown in application to an eye in which cataracted-lens tissue is being removed." *Id.* at 2:5–7. Figure 1 shows patient's eye 10 with cataracted natural lens 11, adjacent to an apparatus or system having a

viewing microscope with objective lens 19 and a laser, producing laser beam 25, which may be a near-infrared pulsed laser of the neodymium-YAG variety (can provide energy of about 1–30 millijoules, where the convergent ray angle is about 16°–20°), or an ultraviolet laser such as an excimer laser or a frequency-quadrupled neodymium-YAG laser (can provide 1–5 joules/cm^2 on focal spots of 10–100 μm diameter, where the focal range is about 25°–30°). *Id.* at 2:14–3:22. The system includes partially reflecting mirror 22, which has two axes of rotation so as to direct laser light in the X and Y axes, and optical elements 26, 27, 28 for focusing laser light in a controlled manner along the Z axis. *Id.* at 2:39–55, 3:39–62.

2. Analysis: Motivation to Combine

Petitioner contends that Swinger discloses controlling the location of an output beam in the X and Y axes, as well as "a z-scanner to perform incisions at prescribed depths in tissue." Pet. 65 (citing Ex. 1021, 17:2–5, 25:62–67, 34:52–64). Petitioner asserts that "Swinger does not specify how its scanning assembly effects scans in the z-dimension," but Dr. Lubatschowski testifies that certain disclosures of Swinger could suggest that scanning in the z-dimension is done by moving the entire assembly. *Id.* at 66; Ex. 1001 ¶ 184. Given the potential ambiguity in how Swinger adjusts the focal spot in the z-direction, Dr. Lubatchowski testifies that one of ordinary skill in the art would have looked to other references to see how this may be accomplished. Ex. 1001 ¶ 184.

Petitioner contends various methods of adjusting a beam in the z-direction were known in the art, such as the use of motor or optical systems, and that the preferred method for adjusting a beam in the z-direction was to utilize optical components to control the focal spot "because their small size is suitable for precise control." Pet. 66

(citing Ex. 1001 ¶ 183). Petitioner contends L'Esperance teaches a laser surgical system for treating cataracts and the use of a z-axis scanning device that controls the focal spot of a laser using optical components. And, "[b]ecause Swinger implies that its system comprises a z-scanner disposed at some location along the optical path," Petitioner contends one of ordinary skill in the art "would have naturally looked" to L'Esperance when determining how to implement a z-scanner in Swinger. *Id.* at 66–67.

Patent Owner argues in response that, contrary to Petitioner's assertions, Swinger actually does specify how its scanning assembly effects scans in the z-dimension—by moving the entire system up and down. PO Resp. 48 (citing Ex. 1001 ¶ 184; Ex. 2062 ¶¶ 421, 461). Patent Owner further argues that Dr. Lubatschowski's assertion that using lens-based methods to scan in the z-direction would be preferable to moving the entire laser system is a conclusory assertion that "fails to provide any articulated reasoning or rational underpinning to combine." *Id.* at 49 (citing Ex. 1001 ¶ 186).

Patent Owner further argues that one of ordinary skill in the art would not have sought to use optical components to control the focal spot in the z-direction based on any perceived increase in precision because "Swinger's system already discloses 'precise control of tissue removal' and explains that the 'etch depth of each pulse may be precisely controlled.'" *Id.* (citing Ex. 1021, 8:41, 17:43–45). Given this ability to "precise[ly] control" tissue removal in Swinger, Patent Owner contends "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." *Id.*

Both Dr. Lubatschowski and Dr. Kang agree that Swinger "appears" to, or at least "suggests," that it adjusts the depth of its laser incisions by

moving the entire system along the z-axis. Ex. 2062 ¶¶ 421, 461; Ex. 1001 ¶ 184. Neither declarant argues, however, that Swinger provides any detailed discussion or figures of precisely how this is done. Ex. 2062 ¶ 421; Ex. 1001 ¶ 184. Accordingly, we find persuasive Petitioner's argument that one of ordinary skill in the art would have looked to known methods of controlling the focal spot of a treatment laser in the z-direction. We further credit the testimony of Dr. Lubatschowski that it was understood in the art that "actuating a different lens" along the beam path, as disclosed in L'Esperance, would enable more precise control of the axial depth of the focal zone than moving the entire laser system. Ex. 1001 ¶¶ 184, 186. Thus, Petitioner provides two cogent explanations (implementation details and improved performance) as to why one of ordinary skill in the art would have implemented L'Esperance's system in Swinger, Weikert, and Benedikt.

As noted by Patent Owner, Swinger describes its system as providing "precise control of tissue removal" and of "etch depth." Ex. 1021, 8:41, 17:43–45. That a system already provides precise control, however, does not suggest that one of ordinary skill in the art would not seek to further improve the precision of the system. On that point, neither Patent Owner nor Dr. Kang expressly contest Dr. Lubatschowski's testimony that actuating a different lens, as is expressly disclosed in L'Esperance, would enable more precise control of axial depth than moving the entire system in the z-direction. *See* Ex. 2062 ¶ 461; Ex. 1001 ¶ 186.

For the reasons set forth above, we determine that Petitioner sufficiently explains why one of ordinary skill in the art would have sought to combine the disclosures of Swinger, Weikert, Benedikt, and L'Esperance in the manner set forth in the Petition.

3. Analysis: Claims 9–12

Petitioner identifies where the subject matter of claims 9–12 is disclosed in Swinger, Weikert, Benedikt, and L'Esperance. Pet. 67–69.

Patent Owner does not address Petitioner's arguments and supporting citations regarding claims 9–12, apart from its arguments set forth above addressing the proposed combination of references. *See* PO Resp. 48–49.

Upon review of the parties' arguments and evidence, we determine that Petitioner demonstrates by a preponderance of evidence that claims 9–12 would have been obvious over Swinger, Weikert, Benedikt, and L'Esperance.

G. Blumenkranz-Based Grounds

Petitioner contends claims 1, 2, and 4–12 would have been obvious over the combined disclosures of Blumenkranz and Weikert and that claims 2 and 3 would have been obvious over the combined disclosures of Blumenkranz, Weikert, and Benedikt. Pet. 28–50. Because we have found that claims 1–12 would have been obvious in view of the Swinger-based grounds discussed above, we do not address Petitioner's Blumenkranz-based grounds. *See SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348, 1359 (2018) (holding a petitioner "is entitled to a final written decision addressing all of the claims it has challenged"); *Boston Sci. Scimed, Inc. v. Cook Grp. Inc.*, 809 F. App'x 984, 990 (Fed. Cir. Apr. 30, 2020) (non-precedential) (recognizing that the "Board need not address issues that are not necessary to the resolution of the proceeding" and, thus, agreeing that the Board has "discretion to decline to decide additional instituted grounds once the petitioner has prevailed on all its challenged claims").

III. CONCLUSION[11]

For the reasons set forth above, Petitioner demonstrates by a preponderance of evidence that claims 1–12 of the '356 are unpatentable.

In summary:

Claims[12]	35 U.S.C. §	Reference(s)/Basis	Claims Shown Unpatentable	Claims Not Shown Unpatentable
1, 2, 4–12	103(a)	Blumenkranz, Weikert[13]		
2, 3	103(a)	Blumenkranz, Weikert, and Benedikt[14]		
1–8	103(a)	Swinger, Weikert, Benedikt	1–8	
9–12	103(a)	Swinger, Weikert, Benedikt, and L'Esperance	9–12	
Overall Outcome			1–12	

[11] Should Patent Owner wish to pursue amendment of the challenged claims in a reissue or reexamination proceeding subsequent to the issuance of this decision, we draw Patent Owner's attention to the April 2019 *Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding*. *See* 84 Fed. Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. *See* 37 C.F.R. § 42.8(a)(3), (b)(2).

[12] As discussed above, the Petition originally challenged claims 1–15, 17–19, and 21–24 of the '356 patent. Patent Owner subsequently disclaimed claims 13–24 of the '356 patent. Thus, we address only the non-disclaimed claims in this Decision, i.e., claims 1–12.

[13] For the reasons set forth above, we do not address Petitioner's ground based on Blumenkranz and Weikert.

[14] For the reasons set forth above, we do not address Petitioner's ground based on Blumenkranz, Weikert, and Benedikt.

VI. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that claims 1–12 of the '356 patent are unpatentable;

FURTHER ORDERED that, because this is a Final Written Decision, parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

PETITIONER:

Gregg LoCascio
W. Todd Baker
Noah Frank
KIRLAND & ELLIS LLP
glocascio@kirkland.com
todd.baker@kirkland.com
noah.frank@kirkland.com

PATENT OWNER:

Michael Morin
Jonathan Strang
Giri Pathmanaban
Susan Tull
Inge A. Osman
Allison harms
Roger J. Chin
LATHAM & WATKINS LLP
michael.morin@lw.com
jonathan.strang@lw.com
giri.pathmanaban@lw.com
susan.tull@lw.com
inge.osman@lw.com
Allison.harms@lw.com
Roger.chin@lw.com