Trials@uspto.gov
571-272-7822

Paper 17
Date: December 6, 2021

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ALCON INC., ALCON LENSX, INC., ALCON VISION, LLC, ALCON LABORATORIES, INC., and ALCON RESEARCH, LLC.,
Petitioner,

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.*

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314

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. Paper 10 ("Prelim. Resp."). With authorization, Petitioner subsequently filed a Reply (Paper 12, "Reply") and Patent Owner filed a Sur-Reply (Paper 15, "Sur-Reply").

Subsequent to the filing of the Petition, Patent Owner "disclaimed independent claim 13, and its dependent claims 14–15, 17–19, and 21–24." Prelim. Resp. 1 n.1 (citing Ex. 2013 (disclaiming claims 13–24 of the '356 patent)). As such, we do not address the grounds and arguments set forth in the Petition with respect to these claims and we consider the challenged claims to be 1–12 of the '356 patent. *See* 37 C.F.R. § 42.107(e) ("No inter partes review will be instituted based on disclaimed claims.").

We have authority to determine whether to institute an *inter partes* review. 35 U.S.C. § 314; 37 C.F.R. § 42.4(a). The standard for institution is set forth in 35 U.S.C. § 314(a), which provides that an *inter partes* review may not be instituted "unless the Director determines . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition."

After considering the parties' arguments and evidence, and for the reasons set forth below, we determine that Petitioner has demonstrated a reasonable likelihood of prevailing with respect to at least one challenged claim of the '356 patent. Accordingly, we institute an *inter partes* review of

claims 1–12 of the '356 patent. *See SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1359–60 (2018).

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 '356 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; Paper 5, 1. *Inter Partes* review petitions were also filed by Petitioner against related patents in IPR2021-00843, -00845, and -00849. Paper 3, 1; Pet. 3. Patent Owner identifies the same related district court litigation. Paper 5, 1.

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 relaxation incisions in the cornea of an eye. Ex. 1010, Abstr.

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 3:1–4.

Figure 1 of the ’356 patent is reproduced below:

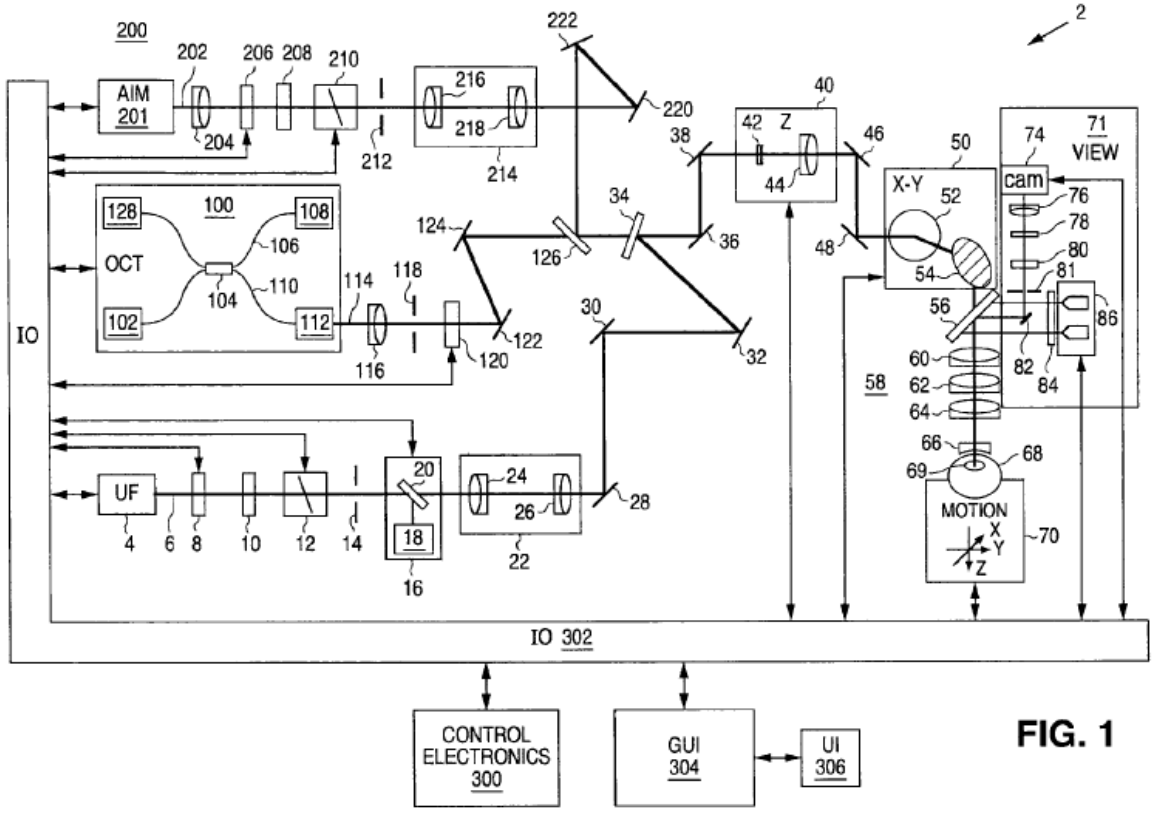

FIG. 1

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 beamcombiner 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 7:41–47.

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.

E. Illustrative Claims

Petitioner challenges claims 1–12 of the '356 patent, i.e., the remaining, challenged, but not-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 would have been 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]

In support of its grounds for unpatentability, Petitioner relies upon the declaration of Holger Lubatschowski, Ph.D. (Ex. 1001). In support of its positions, Patent Owner relies on the declarations of Jin U. Kang, Ph.D. (Ex. 2002) and Kathryn M. Hatch, M.D. (Ex. 2004).

[1] As noted above, Patent Owner disclaimed claims 13–24 of the '356 patent. Exhibit 2013. For context, we list all the claims of the '356 patent challenged by Petitioner for each ground.
[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. Level of Ordinary Skill in the Art

In determining the level of 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 Petitioner's definition is mistaken in two respects. Prelim. Resp. 11. First, according to Patent Owner, a person of ordinary skill in the art "must include the expertise of someone with clinical experience in ophthalmology." *Id*. Second, a person of ordinary skill in the art need not have Ph.D. level training, as active workers in the field typically held Bachelor's degrees. *Id.* at 11–12. Given these modifications, Patent Owner would define the ordinarily skilled artisan as "an engineer with a Bachelor's degree in a laser-related engineering or optics field, with some experience working with medical optics or lasers" and having experience working "with a clinician having experience in the field of ophthalmic surgery." *Id.* at 11 (citing Ex. 2002 ¶¶ 30–32). Conversely, Patent Owner contends the ordinarily skilled artisan could "include an ophthalmic surgeon

with some experience working with medical optics or lasers" and experience working with an engineer or a graduate from a related field with "experience working with medical optics or lasers." *Id*.

For purposes of this Decision, we generally accept Petitioner's proposed definition of the person of ordinary skill in the art (or ordinarily skilled artisan), which appears to be consistent with the level of skill in the art reflected in the prior art of record and the disclosures of the '356 patent; however, we also agree with Patent Owner that such a definition should be flexible enough to include a person with a lesser academic degree and having experience working in the field, such as an engineer with clinical experience in ophthalmic surgery, as well as a medical doctor, such as an ophthalmic surgeon with experience working with medical optics and lasers. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (noting that the appropriate level of ordinary skill in the art may be reflected in "the prior art itself") (quoting *Litton Indus. Prods., Inc. v. Solid State Sys. Corp*., 755 F.2d 158, 163 (Fed. Cir. 1985)).

Such an expanded definition of the person of ordinary skill in the art, including aspects of both parties' definitions, is appropriate based on our review of the record, which demonstrates individuals having a broad array of scientific degrees that collaborate as a team. We note, however, that our decision to institute trial in this proceeding would not change were we to adopt Patent Owner's proposed definition.

B. 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).

Both parties provide a construction of the term "cataract incision." Pet. 7–9; Prelim. Resp. 17. Upon review of the parties' arguments and supporting evidence, we determine that no claim terms require construction for purposes of this 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.")).

C. 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. 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.

Patent Owner contends the Petition should be denied because Petitioner fails to demonstrate that Weikert was ever made publically available. Prelim. Resp. 12. According to Patent Owner, all the Petition "does is attach a few undated pages that it claims are a book chapter," but "offers no other pages from the alleged book, no declarations attesting to publication, no proof that it was publically accessible—no evidence whatsoever." *Id.*

In its Reply, Petitioner provides a copy of the front cover of Weikert, as well as pages identifying the ISBN number, Library of Congress Control Number, and a 2005 copyright date for the reference. Reply 1; Ex. 1060, 1–5.[8] Petitioner also argues that Patent Owner was in possession of the copyright page for Weikert "for the past six months," which is before it filed its Preliminary Response. Reply 1.

In its Sur-Reply, Patent Owner argues that it is the petition that must provide evidence that a reference was publically accessible before the critical date of the challenged patent, and this information may not be supplied in a reply. Sur-Reply 1 (citing *Hulu, LLC v. Sound View Innovations, LLC*, IPR2018-01039, Paper 29 at 13 (Dec. 20, 2019)) (precedential). According to Patent Owner, "[Petitioner] cites *no decisions* where the Board instituted [an] IPR based on publication information submitted after the Petition. For good reason: the statute forbids it. That ends the matter." *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*, Paper 29 at 13 (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. 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

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

CATARACT AND REFRACTIVE SURGERY as Chapter 14: *Refractive Keratotomy: Does it Have a Future Role in Refractive Surgery*? Ex. 1001 ¶ 73. Although minimal, given the type of document involved, and in the absence of any reason to question Petitioner's and Dr. Lubatschowski's assertions, Petitioner's evidence is sufficient to present a reasonable likelihood that Weikert is prior art to the '356 patent under 35 U.S.C. § 102(b).

In addition, *Hulu* contemplates additional evidence being admitted in a reply to a patent owner preliminary response, as long as that evidence is 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, 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; Ex. 1001 ¶ 73. In addition, this evidence indicates that CATARACT AND REFRACTIVE SURGERY was issued by "Springer," which is a well-known publishing company, and is the type of document that would be expected to be made publically accessible. *See* Ex. 1001 ¶ 71 (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.

In the absence of evidence or argument suggesting that Weikert was not publically available, at this stage of the proceeding, we find the information presented in the Petition, as confirmed by the Reply evidence

submitted by Petitioner, demonstrates a reasonable likelihood that Weikert is prior art to the '356 patent.

D. Claims 1–12 over Blumenkranz and Weikert

Petitioner contends the subject matter of claims 1–12 would have been obvious over the combined disclosures of Blumenkranz and Weikert. Pet. 28–45.

1. Blumenkranz

Blumenkranz is directed to a system and method for making incisions in eye tissue at different depths. Ex. 1017, Abstr. The primary disclosed use of the system of Blumenkranz is for cataract surgery, with the disclosed system providing "rapid and precise openings in the lens capsule and fragmentation of the lens nucleus and cortex . . . using 3-dimensional patterned laser cutting." *Id.* ¶¶ 3–11, 57, 69.

Figure 11 of Blumenkranz is reproduced below:

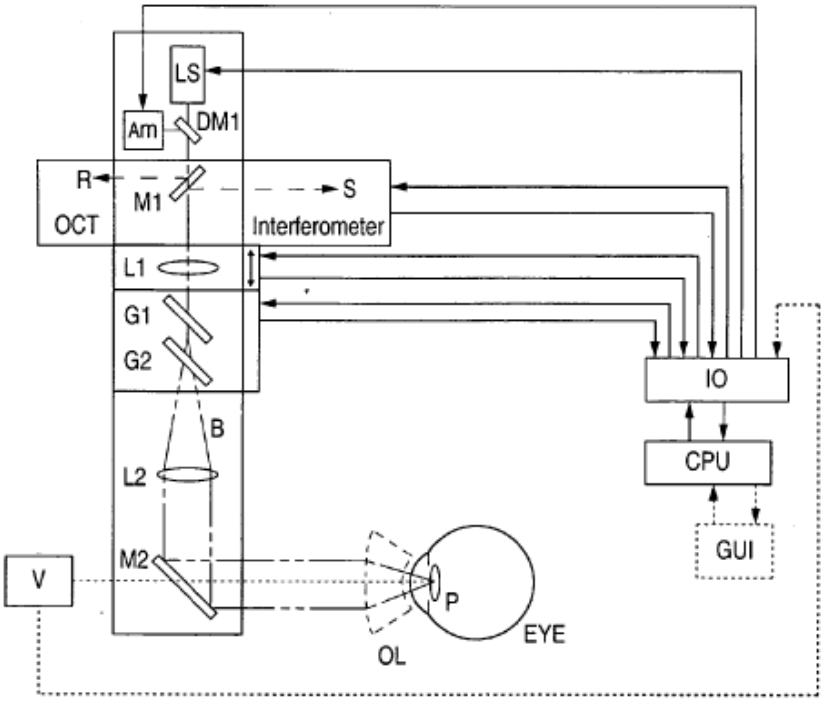

FIG. 11

Figure 11 is a plan diagram of one embodiment of Blumenkranz wherein the system projects or scans an optical beam into a patient's eye. *Id.* ¶ 34. Figure 12 shows laser source LS and aiming beam source AIM having outputs that are combined using mirror DM1. *Id.* ¶ 75. In this configuration, laser source LS may be used for both therapeutics and diagnostics. *Id.* Mirror M1 serves to provide both reference input R and sample input S to an OCT Interferometer, which provides images to graphical user interface GUI. *Id.* ¶¶ 75, 77. Cutting of ocular tissue is determined by scanning patterns that can be circular and spiral, with a vertical step similar to the length of the rupture zone. *Id.* ¶ 68.

Blumenkranz explains that although the primary discussion is of using the described system for capsulotomy and fragmenting the lens of the eye, the techniques described in the patent application "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." *Id.* ¶ 71.

2. Weikert

Weikert reviews the history, use, and potential future of refractive keratotomy, which involves making incisions in 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

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

systems "had replaced refractive keratotmy 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 explains that one method of correcting the astigmatism caused by corneal incisions for cataract surgery was to provide "a similar incision 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. Analysis: Claim 1

Petitioner provides a detailed explanation as to where it contends each limitation of claim 1 is taught or suggested in Blumenkranz and Weikert. With respect to the reason to combine these references, Petitioner contends that Blumenkranz "teaches a multifunctional laser ophthalmic surgery system fully capable of producing laser incisions of different depths according to various treatment patterns," but does not expressly disclose delivering a cataract incision or relaxation incisions. Pet. 28–29. Petitioner contends, however, that cataract incisions and partial relaxation incisions have been known for approximately 150 years, as discussed in Weikert, and "making a centuries-old type of incision using modern technology, such as a laser ophthalmic surgery system, would have been obvious." *Id.* at 29 (citing *Leapfrog Enters., Inc. v. Fisher-Price, Inc.*, 485 F.3d 1157, 1161 (Fed. Cir. 2007)).

Patent Owner asserts that claim 1 would not have been obvious over Blumenkranz and Weikert for multiple reasons, which we address below.

a) Combination of Blumenkranz's Laser Surgical System with Weikert's Manual Incisions

Patent Owner contends Petitioner's arguments fail because one of ordinary skill in the art would not have sought to use the cataract system of Blumenkranz to form Weikert's manual cataract and relaxation incisions. Prelim. Resp. 21. According to Patent Owner, Weikert actually "teaches away from *all* laser surgery" in eyes with cataracts "due to safety and efficacy concerns." *Id.* (citing Ex. 2002 ¶ 62). In support of its position, Patent Owner points to the following disclosure of Weikert:

> Since [photorefractive keratectomy (PRK)] and LASIK can treat myopic, hyperopic, and mixed astigmatism, they are typically the procedures of choice for healthy eyes, without

> contraindication, that fall within their treatment ranges. However, in eyes with cataracts, corneal transplants, or other issues that could reduce the efficacy and safety of laser treatment, refractive keratotomy can be an effective and low-cost option for surgically reducing astigmatism.

Ex. 1019, 227; Prelim. Resp. 21 (citing Ex. 1019, 227).

We are not persuaded, on this record, that this disclosure rises to the level of a teaching away. First, Weikert does not address the specific laser system disclosed in Blumenkranz, which is already designed to successfully treat eyes with cataracts, and Patent Owner and Dr. Kang do not persuasively explain why Weikert's concerns would apply to a non-excimer laser surgery system that is already designed to treat "eyes with cataracts." *See* Ex. 1017 ¶ 8; Ex. 2002 ¶ 62; *see also* Ex. 2002 ¶ 57 (Dr. Kang asserting that the PRK and LASIK excimer laser systems disclosed in Weikert are unrelated to the claimed relaxation incision made during cataract surgery). Second, Weikert suggests that eyes with cataracts "*could* reduce the efficacy and safety of laser treatment" and that refractive keratotomy "*can be* an effective" option, but does not indicate that laser surgery is never, or is generally not, suitable for treating astigmatism in eyes with cataracts. Ex. 1019, 227 (emphasis added). As such, we are left with a disputed issue of material fact that is best resolved on a complete trial record.

Patent Owner further contends that the authors of Weikert, despite being fully aware of lasers and their use in unrelated applications, "actively promote[] making incisions by hand." Prelim. Resp. 22 (citing Ex. 1019, 220 ("Current techniques of refractive keratotomy utilize precision diamond blades to achieve predictable and reproducible incision profiles.")).

Weikert notes that manual refractive keratotomy procedures remain "a low-cost and low-risk alternative for the management of astigmatism" and

provide "predictable and reproducible incision profiles." Ex. 1019, 220, 232. Contrary to Patent Owner's arguments, however, Weikert appears to actively contemplate the replacement of manual refractive keratotomy procedures with laser-based techniques. *Id.* at 217, 232. For example, Weikert notes that as technological advances continue in the field, some have questioned whether there is any future role for manual refractive keratotomy procedures, and notes that in view of future advances "we are likely to see further decline in the use of refractive keratotomy." Ex. 1019, 217, 232. As such, on this record it does not appear that Weikert "actively promotes" using manual incisions, as opposed to noting that manual incisions retain a roll in correcting astigmatism in certain situations. *Id.* at 232.

b) Modification of Blumenkranz to Form Relaxation Incisions in the Cornea

Patent Owner contends Petitioner's arguments are insufficient to support institution because Blumenkranz is directed to a cataract surgery system that creates incisions in the lens, not the cornea, and one of ordinary skill in the art would not have thought that Blumenkranz's system was capable of "focusing and directing a laser *in the cornea*." Prelim. Resp. 24. According to Patent Owner, Blumenkranz's general discussion of creating incisions in "other areas of the eye such as, but not limited to, the sclera and iris" does not teach or suggest relaxation incisions in the cornea. *Id.* at 24–25.

Patent Owner contends Weikert does not help Petitioner's case because it teaches manually creating relaxation incisions in the cornea or limbus with a blade, and because the excimer laser surgery systems discussed in Weikert, such as Lasik and PRK, "are entirely different

procedures than the claimed relaxation incisions." *Id.* at 25 (citing Ex. 2002 ¶¶ 57–58, 68; Ex. 2004 ¶¶ 40–42). Patent Owner further contends that one of ordinary skill in the art would not have sought to modify Blumenkranz's system to create Weikert's relaxation incisions because laser surgery systems designed for surgery on the lens are not easily modified for surgery on the cornea. *Id.* at 25–26.

Patent Owner contends the difficulty in modifying lens-based systems for surgery on the cornea, or vice-versa, was "repeatedly and emphatically" stressed by Petitioner during prosecution of its own patents and by Dr. Lubatschowski in a 2013 publication. *Id.* at 26–28. For example, Patent Owner demonstrates that during prosecution of its own patents, Petitioner represented that "[t]here are crucial differences between lens surgery and cornea surgery" and that "laser systems designed for corneal procedures do not offer solutions for the considerable challenges of performing surgery on the lens of the eye." Ex. 2006, 5:33–36; Ex. 2007, 15:53–58; *see also* Ex. 2006, 25:27–31 ("Therefore, laser delivery systems which are intended to be used for both corneal and lens surgeries, need to cover a broad range of apertures and corresponding NA ranges. This requirement poses considerable design challenges.").

Likewise, in a 2013 update on femtosecond laser technologies in ophthalmology, Dr. Lubatschowski discussed the different goals and components of cataract and corneal surgery laser systems. Prelim. Resp. 27–28; Ex. 2009, 1210. In this publication, Dr. Lubatschowski notes that due to the high cost and large space requirements, "the question as to why a system designed for the cornea cannot be used for the lens and vice versa arises." Ex. 2009, 1209. Dr. Lubatschowski explains that the difficulty in adapting one type of system for use on different tissue types

arises because the laser and optics necessary for the two types of systems are different. *Id.* at 1209–10 (noting that, because of the "different refractive indices" of the cornea, aqueous water and lens, "significant aberrations of the laser beam" occur if the beam of a corneal laser surgery system is "moved deeper into the eye without additional corrections"). Providing a "look into the future," Dr. Lubatschowski speculates that gradual progress in "all-in-one systems (refractive and cataract)" can be expected, and in a different section he notes that "[t]here are now manufacturers that claim both application areas for their system," although "there are no scientific study results on this yet." *Id.* at 1209, 1211.

The evidence set forth by Patent Owner presents significant issues of fact to be addressed at trial. On the one hand, it is evident that modifying cataract surgical systems for use on the cornea, or providing a system that is capable of performing both corneal and lens surgery, was extremely difficult. Ex. 2006, 5:33–36, 25:27–31; Ex. 2007, 8:32–39, 15:53–58; Ex. 2009, 1209–11. On the other hand, Blumenkranz specifically asserts that its system is useful for not only cataract surgery, but also surgery on other areas of the eye, including the sclera, and Dr. Lubatschowski testifies that the system of Blumenkranz is "well-suited to perform . . . anterior incisions to permit access to the inner eye chamber." Ex. 1017 ¶ 71; Ex. 1001 ¶¶ 107–108. Such evidence facially supports Petitioner's case for obviousness. Thus, considering this evidence as a whole, we are left with a material issue of fact as to the capabilities of the Blumenkranz system that is best resolved on a complete trial record, and after reviewing the cross-examination testimony of the parties' declarants.

c) Generating Relaxation Incisions Based on OCT Imaging Data

Claim 1 requires using an OCT imaging device to generate imaging data for the cornea and using this imaging data to generate an incision pattern for forming one or more relaxation incisions in the cornea. Ex. 1010, 14:36–39, 14:47–52. Petitioner contends that Blumenkranz discloses using OCT imaging data to form incisions and that one of ordinary skill in the art would have sought to make the relaxation incisions of Weikert using Blumenkranz's imaging and laser-incision system. Pet. 34–36.

Patent Owner counters that Blumenkranz uses OCT imaging data for lens surgery, and not corneal surgery, and Weikert provides no reason to use OCT imaging for corneal surgery. Prelim. Resp. 30. Patent Owner further contends that because corneal topography measurements were well known in the art and would provide imaging data faster than OCT, one of ordinary skill in the art "would have no reason to depart from well-established cornea measurement techniques in exchange for using Blumenkranz's OCT imaging when determining relaxation incision patterns." *Id.* at 31.

Blumenkranz discloses using an OCT device to image the anterior chamber of the eye in order to determine the location and thickness of the lens and lens capsule and to "provide greater precision to the laser focusing methods, including 2D and 3D patterning." Ex. 1017 ¶ 56.
Dr. Lubatchowski testifies that the OCT images of the anterior chamber of the eye in Blumenkranz would include data regarding the cornea, limbus, and sclera. Ex. 1001 ¶ 355; Pet. 31. As such, on this record Petitioner explains sufficiently for purposes of institution why one of ordinary skill in the art would have used Blumenkranz's OCT data to plan incisions in the lens, cornea, limbus, or sclera of the eye. The question raised by Patent

Owner as to whether the relative capabilities of OCT versus corneal topography would have suggested avoiding OCT methods for corneal procedures is a question of material fact that is best resolved on a full trial record. *See* Ex. 1001 ¶ 100 (Dr. Lubatschowski testifying that it was understood that OCT could be used in combination with topometry).

d) A Controller Programmed to Form Relaxation Incisions

As noted above, claim 1 requires a controller programmed to generate one or more relaxation incisions using a laser beam, and Patent Owner contends that neither Blumenkranz nor Weikert discloses such a controller. Ex. 1010, 14:44–46, 50–63; Prelim. Resp. 32–33.

As discussed previously, Weikert discloses manually forming relaxation incisions in the cornea of an eye in order to reduce astigmatism. Ex. 1019, 228. Blumenkranz discloses using a controller programmed to make incisions in the lens and lens capsule using a laser beam, and expressly states that its system may be used on other areas of the eye including, but not limited to, the sclera. Ex. 1017 ¶¶ 19–21, 45, 71. Petitioner contends these disclosures would have led one of ordinary skill in the art to make Weikert's relaxation incisions using Blumenkranz's laser-based system. Pet. 33–34. Although Patent Owner disagrees, this is ultimately a disputed issue of material fact that is best resolved on a complete trial record.

e) Laser-Applied Cataract and Relaxation Incisions

Claim 1 requires using a laser beam to form cataract and relaxation incisions. Ex. 1010, 14:40–41, 14:50–52. Patent Owner contends that neither Blumenkranz nor Weikert disclose such laser-applied incisions. Prelim. Resp. 34–35. As noted above, Weikert discloses manually forming cataract and relaxation incisions in an eye and Blumenkranz discloses

making laser-applied incisions in various types of eye tissue, including the sclera. Ex. 1019, 228; Ex. 1017 ¶¶ 68–69, 71. The question of whether these disclosures, when considered in combination with the knowledge and skill in the art, would have led one of ordinary skill in the art to make laser-applied cataract and relaxation incisions using the system of Blumenkranz is an issue of material fact that is best resolved on a complete trial record.

f) Conclusion with Respect to Claim 1

Upon review of the parties' arguments and submitted evidence, and for the reasons set forth above, Petitioner sufficiently identifies for purposes of institution where Blumenkranz and Weikert teach or suggest every limitation of claim 1. Petitioner also provides a sufficient explanation, supported by record evidence, as to why one of ordinary skill in the art would have combined the references to arrive at the subject matter of claim 1. Accordingly, Petitioner demonstrates a reasonable likelihood that claim 1 would have been obvious over Blumenkranz and Weikert.

4. Analysis: Claims 2–12

Petitioner identifies where it contends every limitation of claims 2–12 is taught or suggested in Blumenkranz and Weikert. Pet. 37–43.

Patent Owner does not address Petitioner's arguments with respect to these claims, beyond its arguments addressing claim 1 discussed above. Prelim. Resp. 1 n.1 (noting that the Preliminary Response "only focuses on independent claim 1").

Upon review of the parties' arguments and evidence, we determine that Petitioner demonstrates a reasonable likelihood that claims 2–12 would have been obvious over Blumenkranz and Weikert.[10]

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, Abstr. 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.*

[10] Petitioner also challenges claims 2 and 3 in view of Blumenkranz, Weikert, and Benedikt. Pet. 6. Because we find that Petitioner demonstrates a reasonable likelihood that claims 2 and 3 would have been obvious over Blumenkranz and Weikert alone, we need not address this proposed combination at this time. We will, however, address this ground in the Final Written Decision if necessary.

Figure 6 of Swinger is reproduced below:

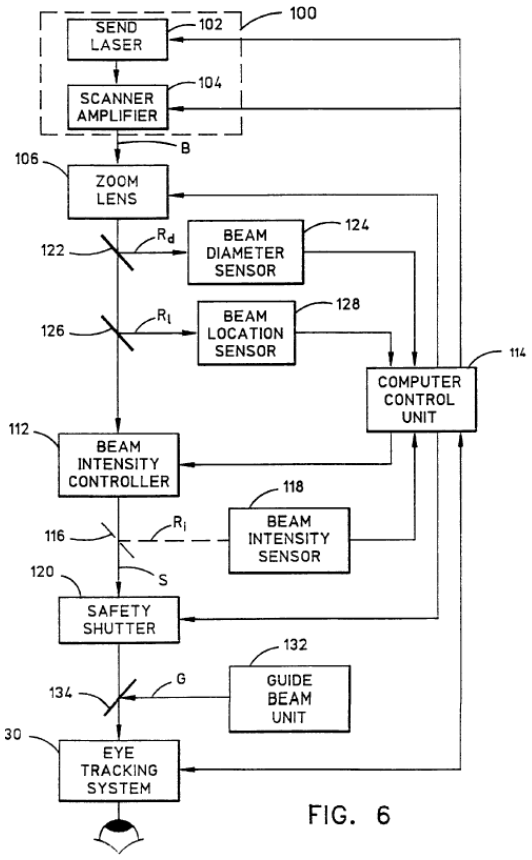

Figure 6 is a block diagram of a preferred embodiment of the laser and control system of Swinger. *Id.* at 10:61–62, 17:1–30. As shown in Figure 6, laser unit 100 generates laser beam B. *Id.* at 17:1–2. Swinger explains that the preferred laser system includes a broad gain bandwidth laser using lasing 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. Guidebeam 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 21:20–23. 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 explains that capsulorhexis surgery may also be performed using the disclosed system 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. Benedikt

Benedikt discloses an apparatus and method "for detecting the surface topometry of the cornea of the eye." Ex. 1020 ¶ 2. In one embodiment of Benedikt, both a Placido Topometer and OCT device are used to acquire images of various portions of the eye. *Id.* ¶¶ 14–15, 25. According to Benedikt, this combination "leads to qualitatively novel and previously unachievable quantitative description of the eye in respect of diagnostics and therapeutics." *Id.* ¶ 46; *see also id.* ¶ 39 ("As a result of the combination of the methods, automated laser surgery is provided with a previously unattainable comprehensive topometrical/topographical illustration of the cornea . . . .").

3. Analysis: Claim 1

Petitioner contends that Swinger discloses a laser ophthalmic-surgery system intended for various surgical procedures on the cornea or lens of the eye and that one of ordinary skill in the art would have sought to use Swinger's system to deliver the relaxation incisions and cataract incisions that are taught or suggested in both Swinger and Weikert. Pet. 50–51.

Petitioner concedes that neither Swinger nor Weikert discloses a system with an OCT device and profilometer (recited in dependent claim 2), but contends Benedikt teaches such a system and that one of ordinary skill in the art would have sought to implement Benedikt's teachings in the system of Swinger and Weikert in order to more accurately plan and effect laser surgery. *Id.* at 51–52. According to Petitioner, such a combination is merely the substitution of "known imaging modalities" to "obtain predictable results." *Id.* at 52.

Patent Owner contends the grounds based on Swinger, Weikert, and Benedikt fail because (1) the prior art teaches away from using Benedikt's

OCT system in Swinger's system; (2) a person of ordinary skill in the art would not have modified Swinger to (a) generate and scan a relaxation incision based on OCT data or (b) form laser-applied cataract incisions; and (3) none of Petitioner's references disclose a controller programmed to use OCT imaging data, much less to use such data to generate an incision pattern for forming a relaxation incision. Prelim. Resp. 46–52. We address these arguments below.

a) Teaching Away

Patent Owner contends the prior art teaches away from implementing Benedikt's OCT imaging system in Swinger. Prelim. Resp. 38–42. Patent Owner reasons that Swinger uses direct visualization using a HeNe laser beam to manually identify target tissue and generate an incision pattern, which is the "opposite of the scanning system claimed in the '356 patent, which uses an OCT device." *Id.* at 39.

As noted by Patent Owner, Swinger uses direct visualization for planning laser surgery and not OCT imaging. Ex. 1021, 34:58–61. We are directed to no teaching or suggestion in Swinger, however, to suggest that other visualization methods should be avoided or are less effective. As such, on this record, Patent Owner has not explained sufficiently why the prior art of record teaches away from using Benedikt's OCT imaging methods in the combined system of Swinger and Weikert.

Patent Owner further contends that Petitioner fails to provide evidence that OCT imaging is superior to direct visualization using Swinger's HeNe laser beams, and that paragraph 39 of Benedikt does not support Petitioner's arguments because it relates to the use of a topometer and wave front analyzer, not an OCT device. Prelim. Resp. 39–40.

Benedikt discloses the use of a topometer and wave front analyzer to provide a "novel and previously unachievable quantitative description of the eye in respect of diagnostics and therapeutics" and notes that "[a]s a result of the combination of methods, *automated laser surgery* is provided with a previously unattainable comprehensive topometrical/topographical illustration of the cornea." Ex. 1020 ¶¶ 32–33, 38–39 (emphasis added). With respect to the combination of a topometer and OCT, Benedikt states that "[a]s has already been explained above, the combination of Placido Topometry and coherence tomography leads to a qualitatively novel and previously unachievable quantitative description of the eye in respect of diagnostics and therapeutics." *Id.* ¶ 46. Given the disclosures of Benedikt as a whole, including the disclosed ability of a topometer and OCT device to in combination provide a "previously unachievable quantitative description of the eye," we determine that Petitioner explains sufficiently for purposes of institution why one of ordinary skill in the art would have sought to replace Swinger's direct visualization method with the topometer and OCT device of Benedikt.[11]

[11] As noted by Patent Owner, Petitioner relies in-part on the disclosures of paragraph 39 of Benedikt, which appear to focus on the benefits of using a topometer in combination with a wave front analyzer, and not an OCT device. Prelim. Resp. 40. Petitioner relies, however, on the disclosures of Benedikt as a whole, which on this record sufficiently suggest the use of a topometer and either a wave front analyzer or OCT device to automate laser surgery. *See, e.g.*, Ex. 1020 ¶¶ 39, 46 (Benedikt explaining that the combination of "Placido Topometry and coherence tomography leads to a qualitatively novel and previously unachievable quantitative description of the eye in respect of diagnostic and therapeutics").

b) Modifying Swinger to Generate and Scan a Relaxation Incision Based on OCT Data

Patent Owner contends that the combined disclosures of Swinger, Weikert, and Benedikt would not have motivated one of ordinary skill in the art to program a controller to generate and scan a relaxation incision based on OCT data because Swinger does not use a controller to generate an incision pattern, and instead relies on manual control of the laser through direct visualization. Prelim. Resp. 42–43 ("But Swinger is notably silent about the computer generating an incision pattern for laser surgery."). Patent Owner further contends that a person of ordinary skill in the art would have understood that it would take "substantially longer" for Benedikt's OCT to acquire a corneal surface profile than a corneal topography measurement tool, which is why Benedikt uses "a corneal topography measurement *in addition to*, not in substitution of, an OCT device." *Id.* at 43–44.

On this record, Petitioner explains sufficiently for purposes of institution why one of ordinary skill in the art would have understood that Swinger has a controller that can automate the laser surgery process once target tissue is identified, and why this ordinarily skilled artisan would have programmed the controller of Swinger to use the data from Benedikt's imaging system to form a relaxation incision (as disclosed in Weikert). Ex. 1021, 34:64–65; Pet. 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). Moreover, contrary to Patent Owner's arguments, we understand Petitioner's position to be that one of ordinary skill in the art would have used both Benedikt's topometer and OCT device in combination with Swinger's device, not simply an OCT

device in isolation.[12] As such, Patent Owner's arguments do not dissuade us from instituting trial.

Patent Owner also argues that Benedikt's ablation pattern is different than an incision pattern. Prelim. Resp. 41. In particular, Patent Owner contends that ablation patterns remove tissue, whereas incisions patterns cut tissue. *Id.*

Although Benedikt produces an ablation pattern, Swinger provides both ablation and incision patterns and Petitioner explains sufficiently for purposes of institution why one of ordinary skill in the art would have sought to use Swinger's laser surgical system to make the cataract incisions of Weikert. Ex. 1020 ¶ 39; Pet. 56 (discussing the incision patterns of Swinger and Weikert); Prelim. Resp. 43–44. As such, Petitioner explains sufficiently for purposes of institution why one of ordinary skill in the art would have used Benedikt's OCT data in Swinger to generate and scan a relaxation incision.

c) Modification of Swinger to Form Laser-Applied Cataract Incisions

Patent Owner contends Petitioner's arguments are insufficient to support institution because Swinger does not mention cataract incisions, focusing instead on a capsulorhexis incision, and no disclosure in Weikert teaches or suggests re-designing a laser surgical system to make a cataract incision. Prelim. Resp. 44–45.

[12] We are directed to no limitation in claim 1 that would preclude the use of both a topometer and OCT device to provide image data. Ex. 1010, 14:28–62. Indeed, dependent claim 2 appears to require such a combination. *Id.* at 14:64–67.

Petitioner presents evidence that Swinger's laser surgery system is designed for cataract surgery, as well as for making incisions in the cornea of the eye. Pet. 54 (citing Ex. 1021, 8:55–67, 9:64–67, 10:10–15). Weikert expressly discloses making manual cataract incision in an eye and notes that such procedures have been performed since at least 1885. Ex. 1019, 217. The question of whether one of ordinary skill in the art would have sought to successfully use Swinger's system to create a cataract incision (as disclosed in Weikert) is a disputed issue of material fact that is best resolved on a full trial record.

d) Individual Elements of Claim 1

(1) Controller Programmed to use OCT Imaging Data

Patent Owner contends Petitioner errs in relying on paragraph 39 of Benedikt for teaching or suggesting a controller programmed to use imaging data because this paragraph relates to use of a topometer and wave front analyzer, not the combination of a topometer and OCT device. Prelim. Resp. 47–48. As noted above, Benedikt discloses the use of a topometer in combination with either a wave front analyzer or an OCT device to provide qualitative and quantitative descriptions of an eye, including the anterior and posterior surface of the cornea. Ex. 1020 ¶¶ 38–39, 42, 46. Benedikt also discloses that comprehensive illustrations of the cornea allow for the creation of an "optimal ablation pattern for the front surface of the cornea" and detachment of "the ablation process from the surgeon's manual dexterity." *Id.* ¶ 39. Given these disclosures, Petitioner sufficiently explains for purposes of institution where Benedikt teaches or suggests a controller programmed to use OCT imaging data (in combination with topometer data), as recited in independent claim 1. *Id.* ¶¶ 39, 43–44, 46; Pet. 51–53, 55–57.

(2) Controller Programmed to Generate an Incision Pattern

Petitioner contends that one of ordinary skill in the art would have understood Benedikt to disclose a controller programmed to generate incision patterns based on imaging data. Pet. 55–56. Petitioner further contends that Swinger and Weikert both disclose relaxation incision patterns. *Id.* at 56. In view of these disclosures, Petitioner asserts that one of ordinary skill in the art would have found it obvious to use the imaging data of Benedikt in the controller of Swinger to generate incision patterns. *Id.* at 57.

Patent Owner contends Petitioner's arguments are insufficient to support institution because Benedikt discloses ablation patterns, and not incision patterns. Prelim. Resp. 48. According to Patent Owner, an incision pattern cuts or slices tissue but leaves the tissue intact, whereas an ablation pattern removes portions of the targeted tissue to reshape that tissue. *Id.*

On this record, Petitioner present a facially reasonable explanation as to where Swinger discloses a controller programmed to generate an *incision* pattern and explains why one of ordinary skill in the art would have used Benedikt's imaging system to program the controller of Swinger to generate the incision patterns disclosed in Weikert. Pet. 54–57 (citing Ex. 1019, 227 (Weikert discussing "cataract *incisions*" and "relaxing *incisions*") (emphasis added); Ex. 1021, 16:60–20:34; Ex. 1020 ¶¶ 31, 36, 39, 42, 51; Ex. 1001 ¶ 406). Thus, Patent Owner's arguments do not dissuade us from instituting trial.

(3) Controller Programmed to Scan the Laser Beam . . . Guided by OCT Imaging Data

Petitioner contends that once the incision pattern in Swinger is generated based on Benedikt's imaging data, delivery of the laser pattern would also be based on the same imaging data. Pet. 58. Patent Owner contends Petitioner's evidence is insufficient to support institution because the generation of an incision pattern does not address the further requirement of scanning the laser in the incision pattern based on OCT image data. Prelim. Resp. 50.

Petitioner sufficiently explains for purposes of institution why Benedikt teaches or suggests using OCT imaging data in combination with topographical data to form an ablation pattern, as well as automating the ablation of tissue in order to detach "the ablation process from the surgeon's manual dexterity." Ex. 1020 ¶¶ 39, 46. We understand that this would require both scanning and guiding the laser beam in the ablation pattern, which is delivered based in part on OCT imaging data. In view of these disclosures, Petitioner explains sufficiently for purposes of institution why the proposed system of Swinger, Weikert, and Benedikt would have a controller programmed to (1) generate an incision pattern based on OCT data, and (2) scan a laser beam along the incision pattern (derived based on OCT data) to generate an incision. Pet. 53–58; Ex. 1021, 34:58–65 (Swinger disclosing scanning a laser beam in a specified pattern to create an incision).

e) Conclusions with Respect to Claim 1

Upon review of the parties' arguments and supporting evidence, we determine that Petitioner demonstrates a reasonable likelihood that claim 1

would have been obvious over the combined disclosures of Swinger, Weikert, and Benedikt.

4. Analysis: Claims 2–8

Claims 2–8 each depend from claim 1. Petitioner provides a detailed explanation as to why it contends these claims would have been obvious over Swinger, Weikert, and Benedikt. Pet. 58–63. Patent Owner does not address Petitioner's arguments with respect to claims 2–8, apart from its arguments directed to claim 1.

Upon review of the parties' arguments, we determine that Petitioner demonstrates a reasonable likelihood that claims 2–8 would have been obvious over Swinger, Weikert, and Benedikt.

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

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. In support of this ground, Petitioner identifies where it contends each limitation of these claims can be found in the recited references. *Id.*

Patent Owner does not address Petitioner's arguments with respect to claims 9–12, apart from its arguments addressing claim 1.

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

III. CONCLUSION

For the reasons discussed above, Petitioner demonstrates a reasonable likelihood that it would prevail in showing that challenged claims 1–12 of the '356 patent are unpatentable. Our decision at this stage derives from our

review of the preliminary record before us and the parties are encouraged to further develop the record as to all arguments and positions discussed herein.

In accordance with the Court's decision in *SAS*, 138 S. Ct. at 1359–60, and Guidance on the Impact of *SAS* on AIA Trial Proceedings (April 26, 2018),[13] we institute *inter partes* review of all challenged claims (1–12) of the '356 patent on all grounds asserted in the Petition.

This decision does not reflect a final determination on the patentability of the claims. No arguments from the Preliminary Response carry over to trial and any arguments not made in Patent Owner's Response may be considered waived. *In re Nuvasive, Inc*., 842 F.3d 1376, 1380–81 (Fed. Cir. 2016) (holding Patent Owner waived an argument addressed in the Preliminary Response by not raising the same argument in the Patent Owner Response).

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that, pursuant to 35 U.S.C. § 314(a), an *inter partes* review of claims 1–12 of the '356 patent is instituted with respect to all grounds set forth in the Petition; and

FURTHER ORDERED that, pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4(b), an *inter parties* review shall commence on the entry date of this Order, and notice is hereby given of the institution of trial.

[13] Available at https://www.uspto.gov/patents-application-process/patent-trial-and-appeal-board/trials/guidance-impact-sas-aia-trial.

FOR PETITIONER:

Gregg F. LoCascio
W. Todd Baker
Noah S. Frank
KIRKLAND & ELLIS LLP
gregg.locascio@kirkland.com
todd.baker@kirkland.com
noah.frank@kirkland.com

FOR PATENT OWNER:

Michael A. Morin
Jonathan M. Strang
S. Giri Pathmanaban
Susan Y. Tull
LATHAM &WATKINS LLP
michael.morin@lw.com
jonathan.strang@lw.com
giri.pathmanaban@lw.com
susan.tull@lw.com