

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

AMO DEVELOPMENT, LLC,  
Patent Owner.

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IPR2021-00845  
Patent 9,233,024 B2

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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 1–17 and 20–26 of U.S. Patent No. 9,233,024 B2 (Ex. 1007, “the ’024 patent”). AMO Development, LLC (“Patent Owner”) filed a Preliminary Response to the Petition. Paper 7 (“Prelim. Resp.”). With authorization, Petitioner subsequently filed a Reply (Paper 11, “Reply”) and Patent Owner filed a Sur-Reply (Paper 13, “Sur-Reply”).

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 ’024 patent. Accordingly, we institute an *inter partes* review of claims 1–17 and 20–26 of the ’024 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.”

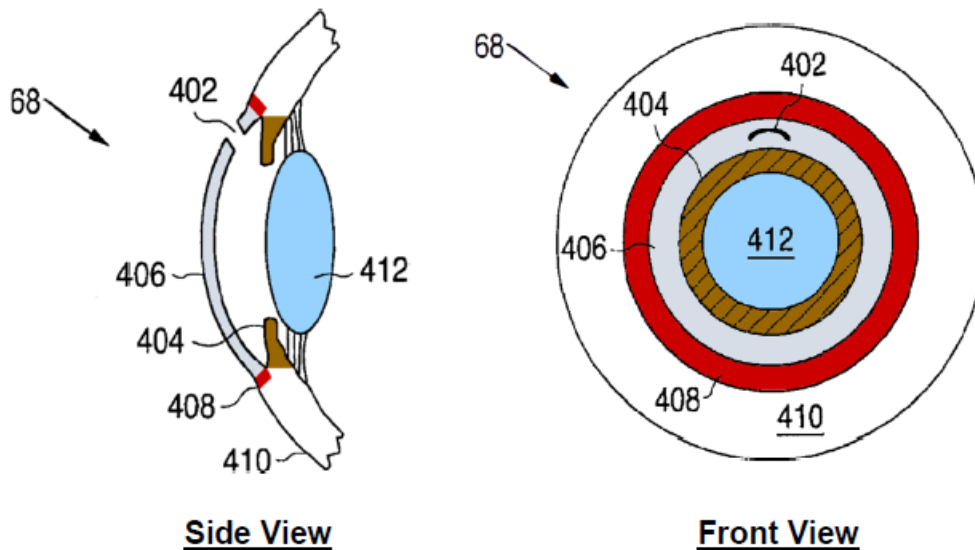
Paper 3, 1; Pet. 2. Patent Owner identifies itself and Johnson & Johnson Surgical Vision, Inc., AMO Manufacturing USA, LLC, and AMO Sales and Services, Inc., as the real parties-in-interest. Paper 5, 1.

*C. Related Matters*

The '024 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, -00846, and -00849. Paper 3, 1; Pet. 2–3.

*D. Background of Cataract Surgery*

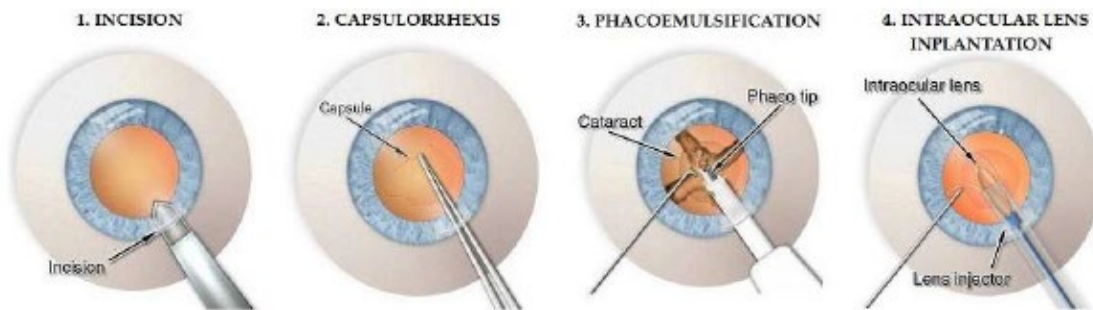
Each independent claim of the '024 patent is directed to a “cataract surgery method of treating target tissue in one or more of a cornea, limbus, or sclera of a patient’s eye.” Ex. 1007, 14:7–8, 14:49–50, 15:15–16, 16:20–21. For context, Patent Owner provides annotated figures of the '024 patent, colored to highlight anatomy, which we reproduce below:



Prelim. Resp. 5; *see also* Ex. 1007, Figs. 5A, 5B. The figures above are annotated versions of the '024 patent's Figures 5A (above-right) and 5B (above-left) and show, respectively, a front and cross-sectioned side view of the eye's anatomy, colored to highlight tissues. The annotated figures show

cornea 406 in grey, sclera 410 in white, limbus 408 in red, and iris 404 in brown; cataract incision 402 is also shown. Prelim. Resp. 5–6; Ex. 1007, 2:36–39, 10:19–27.

Cataract surgery typically involves removal of the eye's natural lens and replacing it with an intraocular lens (IOL). Ex. 1001 ¶ 23; Ex. 2004 ¶ 16. Petitioner's declarant, Dr. Lubatschowski, provides the following figures depicting these implantation steps (Ex. 1001 ¶ 23):



The figures above show four steps used in the process of implanting an IOL in a patient. *Id.* First, to access the lens, an incision must be made in the cornea or nearby tissues. *Id.* Second, in a process called capsulorhexis or anterior capsulotomy, an opening is made in the anterior lens capsule. *Id.* Third, the eye's lens is broken apart and removed, usually by ultrasonic phacoemulsification or segmenting the lens cortex and nucleus.<sup>1</sup> *Id.*; Ex. 2004 ¶ 16. Finally, an IOL is implanted in the lens capsule. Ex. 1001 ¶ 23; Ex. 2004 ¶ 16.

#### *E. The '024 Patent*

The '024 patent is directed to cataract surgery methods for treating target tissue in one or more of the cornea, limbus, or sclera of a patient's

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<sup>1</sup> Although not shown in his figures, Dr. Lubatschowski testifies that a surgeon may also correct for astigmatism, "whether pre-existing or surgery-induced," during cataract surgery. Ex. 1001 ¶¶ 23–24.

eye. Ex. 1007, 1:15–16, 2:13–22, 14:7–8. According to the '024 patent, the techniques and systems disclosed provide for “rapid and precise openings in the cornea and/or limbus,” and the accuracy and precision by which these incisions are made is “improved over traditional methods.” *Id.* at 2:52–57.

The '024 patent states that “[m]any cataract patients are astigmatic.” *Id.* at 1:37. One use of the disclosed method is to “perform astigmatic keratotomy such as limbal and corneal relaxing incisions in conjunction with the creation of [a] surgical incision that provides the surgeon access to the anterior chamber of an eye.” *Id.* at 2:59–63. To assist in this process, a “wavefront sensor, interferometer, surface profiler, or other such device may be used to yield prescriptions for correcting the astigmatism or other visual aberrations.” *Id.* at 2:65–3:1.

Figure 1 of the '024 patent is reproduced below:

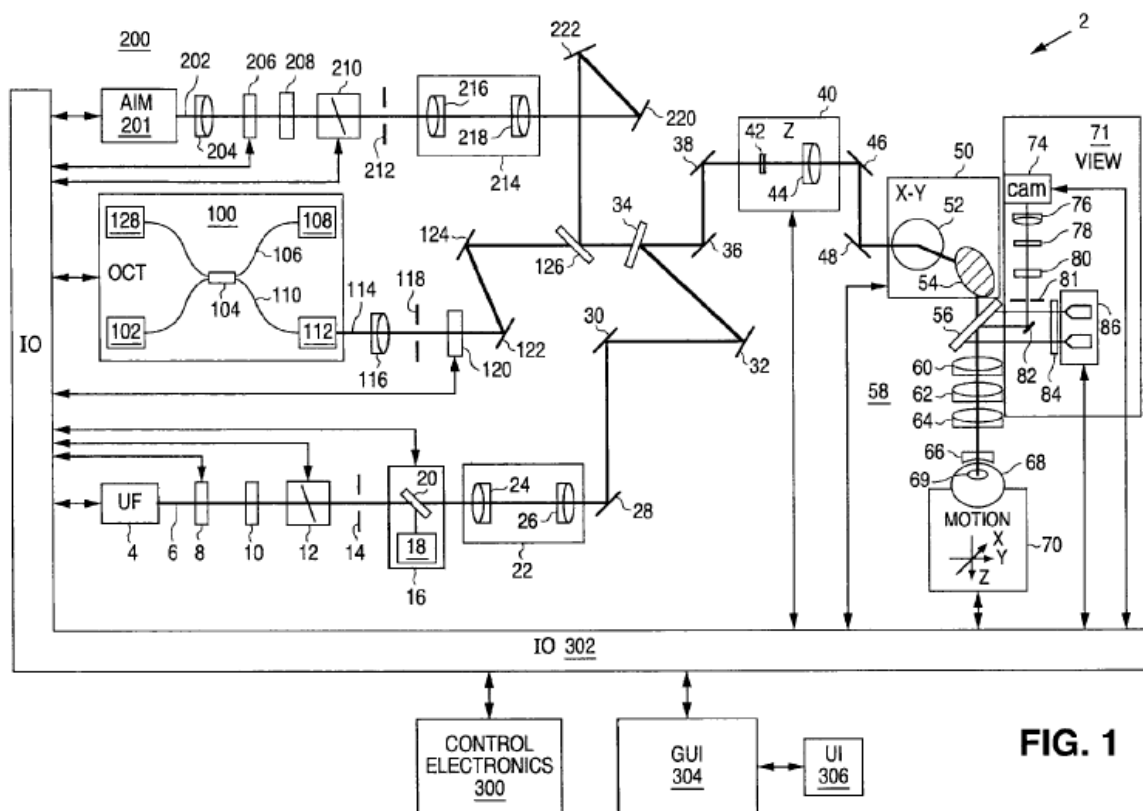


Figure 1 is a schematic diagram of the optical beam scanning system of the '024 patent. *Id.* at 2:28–29. As shown in Figure 1, control electronics 300 (or “controller 300”) control laser 4 via input/output device IO 302. *Id.* at 4:1–5. Graphical user interface GUI 304 may be used to set operating parameters, process user input UI 306, and display gathered information such as images of ocular structures. *Id.* at 4:5–9.

In operation, UF light beam 6 proceeds towards the patient’s eye 68 passing through half-wave plate 8 and linear polarizer 10. *Id.* at 4:10–12. After interacting with several elements, light beam 6 reflects off of fold mirrors 28, 30, and 32, which serve to align light beam 6. *Id.* at 4:49–51. Optical Coherence Tomography (OCT) beam 114 is collimated using lens 116 and is combined with UF light beam 6 at beamcombiner 34. *Id.* at 6:35–60. 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 6:58–61. Aim beam 202 is generated by aim beam light source 201 and is used to assist the user to direct the UF laser focus. *Id.* at 7:31–47.

The system of the '024 patent may be used to create a “cataract incision,” which allows access for the lens removal instrumentation used during cataract surgery. *Id.* at 10:19–25. The '024 patent explains that a complete cataract incision is not desirable in all situations, such as when in an unsterile field where opening the eye to the environment poses further risks of endophthalmitis. *Id.* at 10:29–32. “In this case, the present invention may provide a cataract incision that only partially penetrates” the cornea, limbus, and or sclera. *Id.* at 10:32–34.

Because standard cataract incisions are known to induce some level of astigmatism, the '024 patent provides for relaxing incisions made in the

cornea along its steep axis to correct for astigmatism. *Id.* at 10:66–11:7. According to the '024 patent, these relaxing incisions may be planned and executed in conjunction with the cataract incision “to achieve a better visual correction than otherwise possible.” *Id.* at 11:18–21.

The '024 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 10:45–48. The optical scattering differences then “can be determined and used by CPU 300 . . . to guide the placement of the laser-created incisions.” *Id.* at 10:48–52. According to the '024 patent, the OCT device uses wavelengths in the range of 800-1400 nm as 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 10:61–65.

#### *F. Illustrative Claims*

Petitioner challenges claims 1–17 and 20–26 of the '024 patent. Pet. 4. Of the challenged claims, claims 1, 8, 12, and 22 are independent. Claim 1 is illustrative of the challenged claims and is reproduced below:

1. A cataract surgery method of treating target tissue in one or more of a cornea, limbus or sclera of a patient's eye, comprising:
  - generating a treatment light beam;
  - deflecting the treatment light beam using a scanner to form first and second treatment patterns;
  - delivering the first treatment pattern to a first target tissue selected from the group consisting of the cornea, limbus and sclera of the patient's eye to form a cataract incision that is sized to provide access to an eye chamber of the patient's eye for lens removal instrumentation; and

delivering the second treatment pattern to a second target tissue to form a relaxation incision along or near limbus tissue or along corneal tissue anterior to the limbus tissue of the patient's eye to reduce astigmatism thereof,

wherein the incision formed by delivering the first treatment pattern only partially extends through the target tissue.

Ex. 1007, 14:7–24.

*G. Prior Art and Asserted Grounds*

Petitioner asserts that claims 1–17 and 20–26 would have been unpatentable on the following grounds (Pet. 6):

<b>Claims Challenged</b>	<b>35 U.S.C. §<sup>2</sup></b>	<b>Reference(s)/Basis</b>
1–17, 20–26	103	Blumenkranz <sup>3</sup> , Kurtz <sup>4</sup> , Weikert <sup>5</sup>
Alternative: 16 <sup>6</sup>	103	Blumenkranz, Kurtz, Weikert, Swinger <sup>7</sup>
1–3, 6, 16, 17, 20–26	103	Kurtz, Swinger, Weikert
4, 5, 7–15	103	Kurtz, Swinger, Weikert, Benedikt <sup>8</sup>

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<sup>2</sup> 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 latest possible effective filing date of the challenged claims of the ’024 patent is before this date (August 7, 2012), the pre-AIA version of these statutes apply. *See* 35 U.S.C. § 100(i)(2); Ex. 1007, code (22).

<sup>3</sup> US Patent Publication No. 2006/0195076 A1, published August 31, 2006. Ex. 1017 (“Blumenkranz”).

<sup>4</sup> US Patent Publication No. 2008/0058777 A1. Ex. 1018 (“Kurtz”).

<sup>5</sup> 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.

<sup>6</sup> Petitioner challenges claim 16 as obvious over Blumenkranz, Kurtz, Weikert, and Swinger as an alternative ground, should the Board find that claim 16 would not have been obvious over the combination of Blumenkranz, Kurtz, and Weikert. Pet. 6, 45–46.

<sup>7</sup> US 6,325,792 B1, issued December 4, 2001. Ex. 1021 (“Swinger”).

<sup>8</sup> US Patent Publication No. US 2004/0066489 A1, published April 8, 2004. Ex. 1020 (“Benedikt”).



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).

## 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. 24–25. 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.* at 25.

Patent Owner contends Petitioner’s definition is mistaken in two respects. Prelim. Resp. 13. First, according to Patent Owner, a person of ordinary skill in the art “must include the expertise of someone with clinical experience in the field of 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 13–14. 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 ophthalmic surgery.” *Id.* at 12 (citing Ex. 2002 ¶¶ 28–29). 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.* at 12–13.

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 ’024 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 '024 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 “[a] cataract surgery method” and “the first and second treatment patterns are delivered simultaneously.” Pet. 6–10.

Patent Owner provides constructions for the terms “[a] cataract surgery method” and “cataract incision . . . only partially extends through the target tissue.” Prelim. Resp. 18–25.

We address the construction of the term a “[a] cataract surgery method” below. *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.”)).

*“A cataract surgery method”*

The preamble of independent claims 1, 8, 12, and 22 recites “[a] cataract surgery method of treating target tissue in one or more of a cornea, limbus or sclera of a patient’s eye, comprising . . . .” Ex. 1007, 14:7–9, 14:49–51, 15:15–17, 16:20–22. Petitioner contends this preamble phrase is not limiting. Pet. 6. Petitioner acknowledges that the Examiner amended

the preamble from “[a] method” to “[a] cataract surgery method” during prosecution, but contends this is an intended use that “fails to impart any patentable weight to the claimed method steps, which can be performed by multifunctional ophthalmic-surgery systems in the prior art.” *Id.* at 6–7. According to Petitioner, there is no claimed method step that is exclusive to “cataract surgery” and these steps could be performed by multifunctional systems capable of making incisions for cataract surgery as well as for other purposes. *Id.* at 7. Petitioner further contends that “‘cataract incisions’ are nothing more than incisions that penetrate outer layers of the eye . . . to permit access to the eye chamber” and could include incisions that remove a circular portion of the cornea during corneal transplant surgery. *Id.* at 7–8.

Patent Owner contends the preamble phrase is limiting because it was added by the Examiner to secure allowance of the claims. Prelim. Resp. 18–19. In particular, Patent Owner notes that an interview summary generated during prosecution states that the “Examiner suggested limiting the claimed method to cataract surgery to exclude the other types of treatments.” *Id.* at 19 (citing Ex. 1009, 14).

On this record, we agree with Patent Owner that the disputed preamble phrase is limiting. “[C]lear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art transforms the preamble into a claim limitation because such reliance indicates use of the preamble to define, in part, the claimed invention.” *Catalina Mkt’g Int’l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808–09 (Fed. Cir. 2002). Here, the Examiner expressly allowed the claims in view of the Examiner’s Amendment changing “[a] method” to “[a] cataract surgery method,” thereby transforming this portion of the preamble into a limitation. Ex. 1009, 14, 16, 19; *see Catalina Mkt’g*, 289 F.3d. at 808.

Although, as asserted by Petitioner, a multi-functional laser surgery system may be able to make additional types of incisions, we understand the current method steps to require a laser surgery system that is capable of creating the type of “cataract incision” discussed repeatedly in the ’024 patent, the Petition, the Preliminary Response, and Drs. Lubatschowski’s and Hatch’s declarations, i.e., the type of incisions traditionally used in the art when performing cataract surgery to allow for the insertion of slender surgical instruments. Ex. 1007, 3:10–13 (noting that the invention enables “the formation of very small and geometrically precise opening(s) and incision(s) in precise locations in and around the cornea and limbus”), 10:19–21, 11:7–10, Figs. 5A–B; Pet. 12 (noting that cataract incisions have been applied as part of cataract surgeries since the late 1800s), 29 (referencing the small cataract incisions discussed in Weikert); Prelim. Resp. 7–8 (asserting that a “cataract incision” is “a small incision” made in the cornea, limbus, or sclera, to provide access for “slender surgical instruments . . . to be inserted through a small opening in the cornea”); Ex. 1001 ¶¶ 23, 61 (Dr. Lubatschowski describing cataract incisions and noting that he “will apply the prior art as if the incision must be specifically for cataract surgery”); Ex. 2004 ¶¶ 16, 18 (Dr. Hatch asserting that the “cataract incisions” of the ’024 patent are small and made with the goal of minimizing refractive changes).

In view of the foregoing, for purposes of this Decision, we construe the preamble phrase “[a] cataract surgery method” recited in independent claims 1, 8, 12, and 22 to be limiting and to require, *inter alia*, a method step of creating a cataract incision of the type commonly used in cataract surgery to allow for insertion of slender surgical instruments into the eye cavity.

*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 ’024 patent under 35 U.S.C. § 102(b). Pet. 5, 26. 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. 14. According to Patent Owner, all the Petition “does is attach a few pages that it claims are a book chapter, but offers no date, no copyright notice, 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 authorized Reply, 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. Reply 1; Ex. 1060, 1–5.<sup>9</sup> Petitioner also argues that a simple internet search of the citation provided in the Petition would provide the same information. Reply 1–2.

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

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<sup>9</sup> Here we reference the page numbers added in the bottom-right corner of the reference that were added by Petitioner.

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*—and [Patent Owner] located none—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, 26–27. 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 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 ’024 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 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, 26–27; 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 publically 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.

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 '024 patent.

*D. Claims 1–17 and 20–26 as Obvious over Blumenkranz, Kurtz, and Weikert*

Petitioner contends the subject matter of claims 1–17 and 20–26 would have been obvious over the combined disclosures of Blumenkranz, Kurtz, and Weikert. Pet. 28–45.

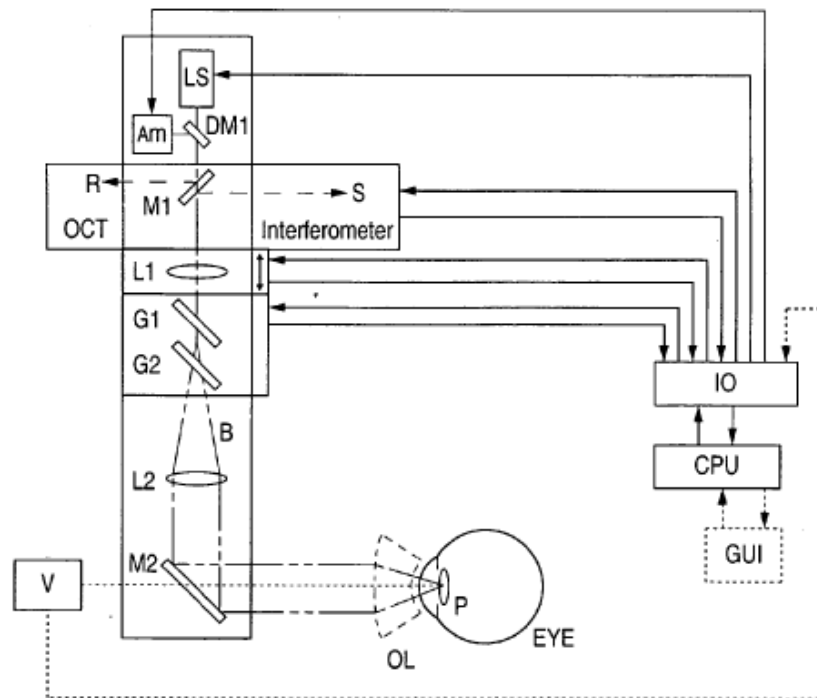
*1. Blumenkranz*

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. *Kurtz*

Kurtz discloses a system and method for resecting corneal tissue using a surgical laser. Ex. 1018, Abstr. In particular, Kurtz discloses a system and techniques for transplanting corneas. *Id.* ¶ 2.

Kurtz explains that traditional techniques used for performing penetrating keratoplasty involved using a full-thickness cylindrical cut in both the recipient and donor corneas to resect corneal tissue. *Id.* ¶ 4. The resected donor tissue is then grafted into the recipient cornea in the same operating room and within minutes of the resection. *Id.*

Kurtz explains that femtosecond surgical lasers were previously used to create full thickness corneal incisions, but such systems have the drawback of taking up “valuable space within the operating room.” *Id.* ¶ 5. Given this drawback, Kurtz discloses that “[a]s an alternative, the femtosecond surgical laser could be placed in a surgical preparation room.” *Id.* In that scenario, extreme care must be taken not to expose the internal tissues of the cornea to contaminants “during the process of transferring the recipient and the donor tissue to the operating room for completion of the procedure.” *Id.*

To overcome these limitations, Kurtz discloses having the pulsed laser beam skip portions of the resection pattern, thereby leaving uncut gaps in the to-be-resected cornea. *Id.* ¶ 7. Kurtz explains that by leaving uncut gaps in the resection pattern, tissue along the incision and the internal chambers of the eye remain protected and unexposed to environmental contaminants, allowing the patient to be moved between the preparation room and the operating room without exposing the patient to contamination risks. *Id.* ¶ 14. Once in the operating room, the uncut gaps may be incised by the surgeon using an alternate surgical instrument, preferably a bladed instrument. *Id.* ¶¶ 8, 15.

### 3. *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.<sup>10</sup> 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

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<sup>10</sup> Our citations are to the original page numbers of the document.

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 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.

#### 4. *Analysis: Claim 1*

Petitioner provides a detailed explanation as to where it contends each limitation of claim 1 is taught or suggested in Blumenkranz, Kurtz, 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 along various treatment patterns” and Kurtz discloses that when corneal incisions are made in less-than-sterile environments, partial incisions protect

the eye from infection until the surgeon is ready to complete the incision. Pet. 28 (citing Ex. 1017 ¶¶ 20, 62, 71, Fig. 8; Ex. 1019 ¶ 14). Given these disclosures, Petitioner contends one of ordinary skill in the art would have sought to “use the systems and methods disclosed by Blumenkranz to deliver a cataract incision that only partially extends through the target tissue,” as is disclosed in Kurtz (partial incisions). *Id.* (citing Ex. 1001 ¶¶ 128–131, 138–139).

Petitioner further contends that “combined delivery of penetrating cataract and partial relaxation incisions has been known for approximately 150 years,” as disclosed in Weikert, and, although previously implemented manually using blades, it would have been obvious to make such incisions using modern laser ophthalmic surgery systems, such as the system of Blumenkranz. *Id.* at 29 (citing *Leapfrog Enters., Inc. v. Fisher-Price, Inc.*, 485 F.3d 1157, 1161 (Fed. Cir. 2007)) (“Accommodating a prior art mechanical device that accomplishes [a desired] goal to modern electronics would have been reasonably obvious to one of ordinary skill.”).

Patent Owner asserts that claim 1 would not have been obvious over Blumenkranz, Kurtz, and Weikert for multiple reasons.<sup>11</sup>

*a) Combination of Blumenkranz and Kurtz*

Patent Owner contends Petitioner’s arguments fail because one of ordinary skill in the art would not have sought to combine the cataract system of Blumenkranz and the corneal transplant system of Kurtz. Prelim. Resp. 32–37. Patent Owner reasons that Blumenkranz is primarily directed to incisions in the lens capsule, whereas Kurtz is directed to a laser system

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<sup>11</sup> At this stage of the proceeding it is uncontested that Blumenkranz and Kurtz (as well as Swinger and Benedikt) are prior art to the challenged claims. *See* Pet. 4, n.2; *see generally* Prelim. Resp.

for corneal transplants, and contrary to Petitioner's assertions, not all laser surgical systems are interchangeable, as evidenced by Petitioner's repeated statements in its own patents and by the prior assertions of Dr. Lubatschowski. Prelim. Resp. 31–34 (citing Ex. 2006, 5:30–36, 25:27–31; Ex. 2007, 8:32–39, 15:53–58; Ex. 2008, 5:19–23; Ex. 2009, 1210).

In support of this line of argument, Patent Owner points to Petitioner's statements in its own patents, where it asserted that the difference in lasers, design, and optics between corneal and cataract laser systems posed “considerable challenges” in using one system to perform procedures intended for the other. *Id.* at 31–32 (citing Ex. 2006, 5:33–36) (“laser systems designed for corneal procedures do not offer solutions for the considerable challenges of performing surgery on the lens of the eye.”); *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.”); Ex. 2007, 15:53–58 (“There are crucial differences between lens surgery and cornea surgery . . .”).

Patent Owner also argues that 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. 33–34; 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 (one of the tissue types specifically recited in claim 1), 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 the 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.

b) *Formation of Partially Penetrating Cataract Incisions*

Claim 1 requires a cataract incision that “only partially extends through the target tissue.” Ex. 1007, 14:15–17, 14:22–24. Patent Owner argues that one of ordinary skill in the art would not have combined Blumenkranz and Kurtz to form such an incision for three reasons. First, according to Patent Owner, Kurtz’s large corneal transplant incisions would cause significant refractive changes. Prelim. Resp. 36–37. Second, one of ordinary skill in the art would not have removed the entire cornea, as disclosed in Kurtz, to allow for insertion of lens removal instrumentation. *Id.* at 37–38. Finally, one of ordinary skill in the art would have understood that cataract surgery and corneal transplant surgery are entirely different procedures, which would not work together. *Id.* at 38.

Patent Owner’s arguments do not dissuade us from instituting trial because we do not understand Petitioner’s argument to be that one of ordinary skill in the art would have used Kurtz’s corneal transplant procedure to provide access for surgical instruments during cataract surgery. Instead, Petitioner contends Kurtz’s disclosures of the risk of environmental contamination when the internal structures of the eye are exposed during laser surgery would have motivated one of ordinary skill in the art to use the system of Blumenkranz to make partial cataract incisions. Pet. 28. As such, on this record and for purposes of this Decision, Petitioner explains sufficiently why one of ordinary skill in the art would have adopted the teachings of Kurtz when operating the system of Blumenkranz.



c) *Combination of Laser Surgical Systems with Weikert's Manual Relaxation Incision*

Weikert discloses making manual relaxation incisions in the cornea to correct existing astigmatism, as well as astigmatism caused by cataract incisions. Ex. 1019, 227–228. These incisions are implemented manually using precision diamond blades, which provide “predictable and reproducible incision profiles.” *Id.* at 220. Petitioner contends one of ordinary skill in the art would have sought to make the relaxation incision of Weikert using the surgical laser of Blumenkranz because laser systems were known to provide “more accurate and precise incisions to ocular tissue” and because such a substitution represents the use of modern technology to make an incision that has been known for approximately 150 years. Pet. 29.

Patent Owner contends Weikert teaches away from using laser surgery to make relaxation incisions in eyes with cataracts. Prelim. Resp. 39–40. 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.

*Id.* at 39 (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 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 ¶¶ 64–65; *see also* Ex. 2002 ¶¶ 78, 105 (Dr. Kang asserting that the PRK and LASIK excimer laser systems disclosed in Weikert “are unrelated to the claimed relaxation incision 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 even generally not, suitable for treating astigmatism in eyes with cataracts. Ex. 1019, 227 (emphasis added). As such, we are again left with a disputed issue of material fact that is best resolved on a complete trial record.

Patent Owner further argues that “[s]ince manual relaxation incisions were known to be safe, effective, and inexpensive,” one of ordinary skill in the art “would not have chosen to undergo the difficult and expensive task of modifying Blumenkranz to apply relaxation incisions to the cornea, especially when Weikert explicitly states that laser surgery is to be avoided in cataract patients.” Prelim. Resp. 41–42 (citing Ex. 1019, 227; Ex. 2002 ¶ 67). This argument goes to the issue, discussed above, of whether Blumenkranz is capable of applying cataract incisions to the cornea or sclera and relaxation incisions to the cornea of the eye, as asserted by Petitioner. Pet. 31, 33–34 (asserting that Blumenkranz contemplates applying treatment patterns to the cornea of the eye). As such, it is part of the disputed issues of material fact that are best resolved on a full trial record.

*d) Specific Claim Limitations*

Patent Owner contends the combination of Blumenkranz, Kurtz, and Weikert fails to disclose a partially penetrating cataract incision or a laser-applied relaxation incision. Prelim. Resp. 42–49. We address these arguments in turn.

*(1) Partially Penetrating Cataract Incision*

Claim 1 recites “a cataract incision that is sized to provide access to an eye chamber of the patient’s eye for lens removal instrumentation . . . [that] only partially extends through the target tissue.” Ex. 1007, 14:15–17, 22–24. Patent Owner contends that Petitioner’s reliance on Blumenkranz and Kurtz for this claim limitation does not support institution because neither reference discloses a cataract incision. Prelim. Resp. 43–44. Patent Owner reasons that Blumenkranz discloses only generic incisions in eye tissue, not a partially penetrating cataract incision, and Kurtz discloses corneal transplant incisions that do not “allow access for lens removal instrumentation” and could not be made “without causing refractive changes” in the eye. Prelim. Resp. 44–47.

The evidence of record demonstrates that “cataract incisions” providing access for lens removal instrumentation were well known in the art. Ex. 1001 ¶ 23; Ex. 2004 ¶ 18; Ex. 1019, 227; Ex. 1007, 10:19–21. These incisions were typically made using physical instruments and fully penetrated the eye tissue. Ex. 1019, 227; Ex. 1001 ¶ 23; *see supra* Section I.D (illustrating such a process). Blumenkranz and Kurtz, however, disclose making laser incisions in the cornea or sclera of the eye and Kurtz explains that, because surgical laser systems may take up valuable floor space within an operating room, they were known to be placed in a surgical preparation room, which potentially exposes the patient’s eye to environmental contamination. Ex. 1018 ¶¶ 5, 14. To avoid exposing the interior of the eye to contamination during corneal procedures, Kurtz expressly discloses leaving the corneal tissue in place during laser surgery, with the final penetrating cuts performed within the operating room using a surgical instrument. *Id.* ¶¶ 5, 14–15. Given these disclosures, Petitioner provides a

reasoned argument as to why one of ordinary skill in the art would have sought to make partially penetrating cataract incisions within the sclera or cornea of a patient. Pet. 28–29. Petitioner also provides a reasoned argument as to why one of ordinary skill in the art would have sought to make such partially penetrating incisions using Blumenkranz’s laser surgery system. *Id.* at 29 (asserting that using modern technology to perform procedures historically performed manually would have been obvious).

Patent Owner’s counter arguments relating to corneal transplant procedures and “refractive changes” do not dissuade us from instituting trial because Petitioner does not assert that one of ordinary skill would have used Kurtz’s corneal transplant incisions for cataract surgery, but rather that this ordinarily skilled artisan would have used Blumenkranz’s system to form the type of cataract incisions that were previously used in the art to access the lens during cataract surgery. Pet. 27–33; *see also* Ex. 1001 ¶ 23; Ex. 1019, 227; Ex. 1017 ¶ 3 (noting that IOLs are inserted “through a small incision” during cataract surgery); Ex. 2004 ¶ 18 (Dr. Hatch explaining that during cataract surgery a cataract incision is made which “provides access for slender surgical instruments (e.g., an aspiration needle) to be inserted through a small opening in the cornea”).

Accordingly, Petitioner explains sufficiently for purposes of institution where Blumenkranz, Kurtz, and Weikert teach or suggest using a laser surgery system to provide partially penetrating cataract incisions.

## *(2) Laser-Applied Relaxation Incision*

Claim 1 requires forming “a relaxation incision along or near limbus tissue . . . of the patient’s eye to reduce astigmatism thereof.” Ex. 1007, 14:18–21. Weikert discloses providing partial thickness, arcuate or transverse corneal incisions to correct astigmatism during cataract surgery.

Ex. 1019, 227–228. Although these incisions are made using a surgical instrument, Weikert also discloses that laser surgery has led to “a tremendous decrease” in refractive surgery performed using diamond bladed instruments. *Id.* at 217, 220–221. Moreover, Blumenkranz discloses laser scanning patterns that can be used in laser surgery and explains that its disclosed system and method can be used for other parts of the eye “such as, but not limited to, the sclera and iris.” Ex. 1017 ¶¶ 61–69, 71. The remaining question of whether one of ordinary skill in the art would have found it obvious to use Blumenkranz’s laser surgical system to perform the relaxation incisions of Weikert in limbus or corneal tissue is a disputed issue of material fact that is best resolved on a complete trial record.

*e) 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, Kurtz, 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, Kurtz, and Weikert.

*5. Analysis: Claims 2–17 and 20–26*

Petitioner identifies where it contends every limitation of claims 2–17 and 20–26 is taught or suggested in Blumenkranz, Kurtz, and Weikert. Pet. 34–45.

Patent Owner does not address Petitioner’s arguments with respect to these claims, beyond its arguments addressing claim 1 discussed above. Prelim. Resp. 49; *see id.* at 29–49 (Patent Owner presenting its arguments

with respect to Ground 1, i.e., the combination of Blumenkranz, Kurtz, and Weikert).

Upon review of the parties' arguments and evidence, we determine that Petitioner demonstrates a reasonable likelihood that claims 2–17 and 20–26 would have been obvious over Blumenkranz, Kurtz, and Weikert.

*E. Claim 16 over Blumenkranz, Kurtz, Weikert, and Swinger*

Claim 16 depends from independent claim 12 and further requires that “the relaxation incision is formed from the inside of the target tissue towards the outside of the target tissue without extending to the outside of the target tissue.” Ex. 1007, 15:50–53. To the extent that the subject matter of claim 16 would not have been obvious over Blumenkranz, Kurtz, and Weikert, Petitioner contends the subject matter of this claim would have been obvious over Blumenkranz, Kurtz, Weikert, and Swinger. Pet. 6, 45–47.

Having determined that Petitioner demonstrates a reasonable likelihood that claim 16 would have been obvious over Blumenkranz, Kurtz, and Weikert, we need not address here whether this claim would also have been obvious over Blumenkranz, Kurtz, Weikert, and Swinger. This is not an indication that this issue will not be addressed in a final decision.

*F. Claims 1–3, 6, 16, 17, and 20–26 as Obvious over Kurtz, Swinger, and Weikert*

Petitioner contends the subject matter of claims 1–3, 6, 16, 17, and 20–26 would have been obvious over the combined disclosures of Kurtz, Swinger, and Weikert. Pet. 47–57.

*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.*

Figure 6 of Swinger is reproduced below:

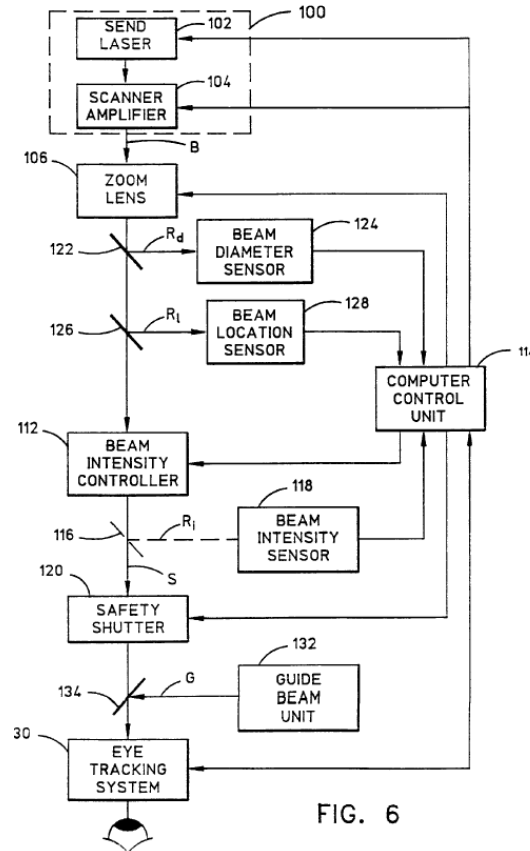


Figure 6 is a block diagram of a preferred embodiment of the laser and control system of Swinger. *Id.* at 10:61–62, 17:1–30. As shown in Figure 6, laser unit 100 generates laser beam B. *Id.* at 17:1–2. Swinger explains that the preferred laser system includes a broad gain bandwidth laser using lasing 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 21:21–23. 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. *Analysis: Claim 1*

Petitioner argues that one of ordinary skill in the art would have found it obvious to use Kurtz’s corneal laser system to create both a cataract incision and relaxation incisions, as disclosed in Weikert. Pet. 48.

Petitioner asserts that Swinger discloses a multi-functional ophthalmic-surgery system to make incisions during cataract surgery and that one of ordinary skill in the art would have used “the multifunctional ophthalmic surgery system disclosed by Kurtz” to provide both “cataract incisions to the cornea to access the eye chamber, and relaxation incisions to the cornea to correct astigmatism, as taught by Swinger and Weikert.” *Id.* (citing Ex. 1001 ¶¶ 161, 163–165). In support of the Petition, Dr. Lubatschowski testifies that one of ordinary skill in the art would have understood that Kurtz’s system is capable of making both a “cataract incision” and relaxation incisions in the cornea. Ex. 1001 ¶¶ 163–164.

As noted by Patent Owner, claim 1 of the ’024 patent requires a “cataract surgery method,” and, for the reasons set forth above, we find that this preamble phrase is limiting. Ex. 1007, 14:7; Prelim. Resp. 52–53. We understand such a “cataract surgery method” to be one or more steps in the process of treating cataracts in a patient, which requires opening the capsule of the eye for subsequent removal of the lens and placement of an intraocular lens. *See* Ex. 1001 ¶ 23 (Dr. Lubatschowski describing the steps necessary for cataract surgery); Ex. 2004 ¶¶ 16–17 (Dr. Hatch describing the steps necessary for cataract surgery). We question the sufficiency of Petitioner’s evidence with respect to its Kurtz, Swinger, and Weikert ground

because it is unclear why one of ordinary skill in the art would have considered Kurtz to be a cataract surgery system capable of opening the capsule of the eye, or why such an ordinarily skilled artisan would have modified the system of Kurtz to perform cataract surgery.<sup>12</sup>

This preliminary analysis should not be taken as an indication that this issue will not be addressed in a final decision, as no findings in this decision are final. The parties are encouraged to address this issue, as well as all other issues discussed herein or addressed in the parties' briefing, during trial.

*3. Analysis: Claims 2, 3, 6, 16, 17, and 20–26*

Claims 2, 3, 6, 16, 17, and 20–26 all depend from claim 1 or claim 22 and require a “cataract surgery method.” *See* Ex. 1007, 14:7, 16:20. Petitioner's arguments with respect to these claims do not resolve the issue noted above with respect to claim 1 and a “cataract surgery method.” Accordingly, we also question the sufficiency of Petitioner's evidence with respect to claims 2, 3, 6, 16, 17, and 20–26. However, this is not an indication of any final decision on this subject matter, which may be developed during trial.

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<sup>12</sup> The independent claims of the '024 patent only require a cataract surgery method. Thus, it is possible that the device of Kurtz could be used as simply a first step in completing cataract surgery, i.e., to provide a cataract incision and relaxation incisions, while another laser surgery system completes the remaining cataract surgery steps. Petitioner does not explain, however, why one of ordinary skill in the art would have adapted the device of Kurtz for such procedures if another device was required to subsequently complete the remaining cataract surgery steps.

*G. Claims 4, 5, and 7–15 as Obvious over Kurtz, Swinger, Weikert, and Benedikt*

Petitioner contends the subject matter of claims 4, 5, and 7–15 would have been obvious over the combined disclosures of Kurtz, Swinger, Weikert, and Benedikt. Pet. 57–65. In this ground, Petitioner relies on Benedikt for its disclosure of using multiple imaging or profiling devices for planning ophthalmic surgery. *Id.* at 58. Petitioner’s arguments for this ground, however, do not resolve the issues noted above for the combination of Kurtz, Swinger, and Weikert. Accordingly, as above, we question the sufficiency of Petitioner’s evidence with respect to its ground based on Kurtz, Swinger, Weikert, and Benedikt. We encourage the parties to address these issues at trial.

### III. CONCLUSION

For the reasons discussed above, Petitioner demonstrates a reasonable likelihood that it would prevail in showing that challenged claims 1–17 and 20–26 the ’024 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),<sup>13</sup> we institute *inter partes* review of all challenged claims (1–17 and 20–26) of the ’024 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

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

carry over to trial and any arguments not made in Patent Owner's Response may be considered waived.

#### 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 1–17 and 20–26 of the '024 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 of the '024 patent shall commence on the entry date of this Order, and notice is hereby given of the institution of trial.

IPR2021-00845  
Patent 9,233,024 B2

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