UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

AMO DEVELOPMENT, LLC,
Patent Owner.

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IPR2021-00841
Patent 9,474,648 B2

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

FLAX, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining No Challenged Claims Unpatentable
Granting-in-Part, Dismissing-in-Part, and Denying-in-Part Petitioner's Motion to Exclude
*35 U.S.C. § 318(a); 37 C.F.R. § 42.64*

# I. INTRODUCTION

We have authority in this proceeding under 35 U.S.C. § 6. This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73.

## A. Background

AMO Development, LLC ("Patent Owner") is the owner of U.S. Patent 9,474,648 B2 (Ex. 1030, "the '648 patent"). Paper 5, 1. Alcon Inc., Alcon Vision, LLC, Alcon Laboratories, Inc., and Alcon Research, LLC (and, initially, Alcon LenSx, Inc.—*see infra* Section I.B) (collectively "Petitioner") filed a Petition for *inter partes* review challenging claims 1–15 (all claims) of the '648 patent. Paper 1 ("Pet."). We instituted trial on November 18, 2021. Paper 12 ("Institution Decision" or "DI"). Patent Owner filed a Response to the Petition (Paper 21 ("Resp."), to which Petitioner filed a Reply (Paper 30, "Reply"), to which Patent Owner filed a Sur-Reply (Paper 37, "Sur-Reply").[1]

A final hearing was conducted on September 8, 2022, where the parties presented oral argument in support of their positions in this proceeding and in the following related proceedings: IPR2021-00853 (Patent 9,125,725 B2), IPR2021-00856 (Patent 8,500,724 B2), IPR2021-00858 (Patent 8,425,497 B2), and IPR2021-00862 (Patent 8,709,001 B2). *See* Paper 51 ("Hr'g Tr.").

Petitioner bears the burden of proving unpatentability of the challenged claims, and the burden of persuasion never shifts to Patent Owner. *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375,

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[1] To the extent such is relevant, Patent Owner also initially responded to the Petition by filing a Preliminary Response (Paper 7, "Prelim. Resp.").

1378 (Fed. Cir. 2015). To prevail, Petitioner must prove unpatentability by a preponderance of the evidence. *See* 35 U.S.C. § 316(e) (2018); 37 C.F.R. § 42.1(d) (2019).

After considering the parties' arguments and supporting evidence, we conclude that Petitioner has not met its burden to prove that claims 1–15 are unpatentable over the asserted prior art. *Id.*

Petitioner also filed a Motion to Exclude certain of Patent Owner's evidence. Papers 40 and 41 (respectively, the sealed and redacted public versions; "Motion" or "Mot."). Patent Owner opposed this motion (Paper 43 ("Opposition" or "Opp.")) and Petitioner filed a Reply to Patent Owner's Opposition (Paper 48 ("Opp. Reply")). For reasons discussed herein, the Motion is *granted-in-part*, *dismissed in-part*, and *denied-in-part*.

### B. REAL PARTIES-IN-INTEREST

Petitioner states that "[a]fter filing this Petition, Alcon LenSx, Inc. merged into Alcon Research, LLC, with Alcon Research, LLC [being] the surviving entity" and identifies that "[t]he real parties-in-interest are Alcon Inc., Alcon Vision, LLC, Alcon Laboratories, Inc., and Alcon Research, LLC." Paper 3, 1. Patent Owner "identifies itself as a real party-in-interest. Patent Owner also identifies Johnson & Johnson Surgical Vision, Inc. and exclusive licensees AMO Manufacturing USA, LLC and AMO Sales and Services, Inc. as the real parties-in-interest." Paper 5, 1.

### C. RELATED MATTERS

Regarding related matters, Petitioner states:

> Patent Owner has asserted the '648 against all Petitioners except Alcon Inc. in *AMO Development, LLC et al. v. Alcon LenSx, Inc. et al.*, No. 1:20-cv-00842-CFC (D. Del.), filed June 23, 2020 ("Delaware Litigation"). Petitioners have filed IPR petitions for eleven other patents in the same family as the '648,

> all of which are asserted in the Delaware Litigation: U.S. Patent Nos. 8,394,084 (IPR2021-00817); 8,403,921 (IPR2021-00823); 8,425,497 (IPR2021-00858); 8,500,724 (IPR2021-00856); 8,709,001 (IPR2021-00862); 9,095,415 (IPR2021-00835); 9,101,448 (IPR2021-00839); 9,107,732 (IPR2021-00840); 9,125,725 (IPR2021-00853); 9,693,903 (IPR2021-00824); and 9,693,904 (IPR2021-00825). This case may affect, or be affected by, the Delaware Litigation.

Paper 3, 1. Patent Owner identifies the same litigation in the District of Delaware as related. Paper 5, 1.

D. THE ’648 PATENT

The ’648 patent issued on October 25, 2016, from U.S. Application 14/949,645, which was filed on November 23, 2015. Ex. 1030, codes (45), (21), (22). The ’648 patent indicates priority, as a continuation, to several intervening continuation applications, but ultimately claims priority to U.S. Application 11/328,970, filed January 9, 2006, and to U.S. Provisional 60/643,056, filed on January 10, 2005. *Id.* at codes (60), (63), 1:9–13. There is no dispute here that the ’648 patent is entitled to priority to this provisional application. *See, e.g.*, Pet. 1, 5 n.2.

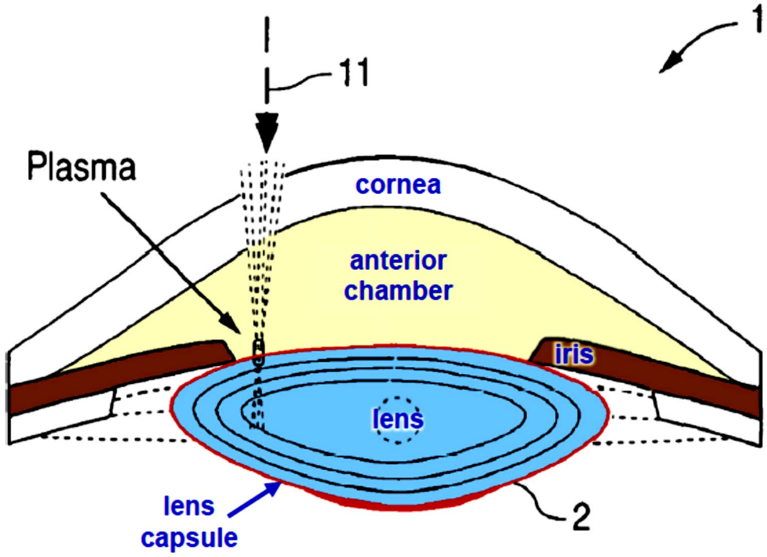
The ’648 patent’s Abstract indicates its invention is directed to

> A system for ophthalmic surgery on an eye includes: a pulsed laser which produces a treatment beam; an OCT imaging assembly capable of creating a continuous depth profile of the eye; an optical scanning system configured to position a focal zone of the treatment beam to a targeted location in three dimensions in one or more floaters in the posterior pole. The system also includes one or more controllers programmed to automatically scan tissues of the patient's eye with the imaging assembly; identify one or more boundaries of the one or more floaters based at least in part on the image data; iii. identify one or more treatment regions based upon the boundaries; and operate the optical scanning system with the pulsed laser to

> produce a treatment beam directed in a pattern based on the one or more treatment regions.

Ex. 1030, Abstract.

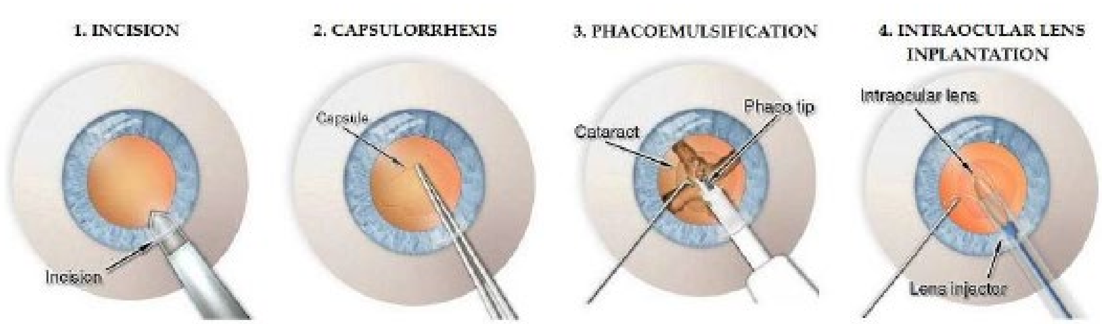
To provide context regarding the claimed cataract surgery, the ’648 patent’s Figure 2, reproduced below, illustrates a cross-section profile of the human eye being subjected to a laser beam, which Patent Owner’s witness, Dr. Keith Walter, annotates to explain the anatomy:




The ’648 patent states that “FIG. 2 is a diagram of the anterior chamber of the eye and the laser beam producing plasma at the focal point on the lens capsule,” and Dr. Walter has annotated the figure with (blue) text and coloring to identify, from most-anterior to most-posterior (top-to-bottom in the image), the eye’s cornea, anterior chamber (colored yellow), iris (colored brown), lens (colored blue), and lens capsule (colored red). *Id.* at 5:49–51; Ex. 2088 ¶ 14; *see also* Resp. 4 (reproducing this same image). Figure 2 also shows optical beam 11 impinging upon eye tissue 2. Ex. 1030, 6:38–7:11. The ’648 patent states, “[a]s can be seen in FIG. 2, the capsule boundaries and thickness, the cortex, epinucleus and nucleus are determinable." *Id.* at 8:50–52.

As background, the '648 patent describes cataract surgery as "one of the most commonly performed surgical procedures in the world," and describes the procedure as including the early and critical step of capsulorhexis or capsulotomy (the same or similar techniques), where the anterior lens capsule is perforated in a circular fashion to provide access to the underlying lens for phacoemulsification using an ultrasonic tip so the lens may be removed and replaced by an intraocular lens (IOL). *Id.* at 1:25–2:4.

Although not a part of the '648 patent, Petitioner's witness in this proceeding explained a cataract surgery procedure with reference to drawings from another reference. *See* Ex. 1001 (Dr. Izatt testimony). According to Dr. Izatt, treatment of cataracts typically involves removal of the natural lens and replacing it with an IOL. *Id.* ¶ 25; *see also* Ex. 1030, 1:40–44. Dr. Izatt provides the following figures depicting these steps (Ex. 1001 ¶ 25):




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. *Id.* Second, the capsulorhexis or anterior capsulotomy is performed in the anterior lens capsule. *Id.*; Ex. 1030, 1:33–40. Third, the eye's lens is broken apart, typically by ultrasonic phacoemulsification, and removed. Ex. 1001 ¶ 25; Ex. 1030, 1:33–36. Finally, an IOL is implanted in the lens capsule. Ex. 1001 ¶ 25; Ex. 1030, 1:42–44.

As further background, the '648 patent describes that neodymium YAG lasers have been implemented in cataract surgery to make openings centrally in a non-invasive fashion. Ex. 1030, 2:62–65. The '648 patent states that "[w]hat is needed are ophthalmic methods, techniques and apparatus to advance the standard of care of cataract and other ophthalmic pathologies." *Id.* at 3:3–5.

The '648 patent illustrates a system according to claim 1, for example, at Figure 12, which we reproduce below:

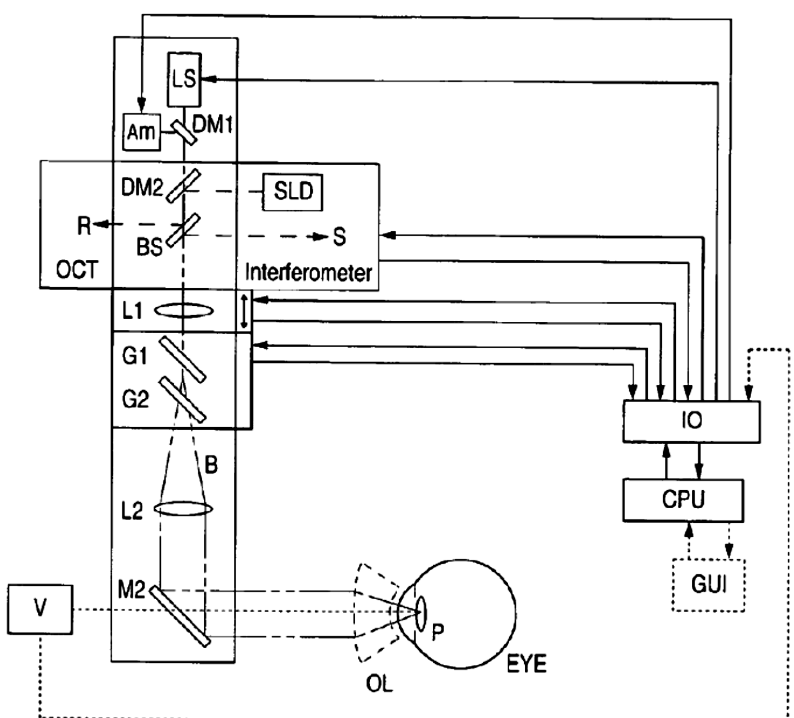



FIG. 12

Figure 12 "is a plan diagram of [a] system embodiment that projects or scans an optical beam into a patient's eye" and it shows a system including a CPU connected with an input-output device (IO) and a graphical user interface (GUI); the IO connects the CPU with laser source LS for performing cataract surgery and an OCT interferometer with imaging light source SLD (although it is also possible for the imaging and treatment to be performed using the same laser). *Id.* at 6:11–12, 11:30–13:20. These two sub-systems (treatment and imaging) of the greater system include a series of mirrors (e.g., DM1, DM2, M1, G1, G2, M2) and lenses (e.g., L1, L2, OL) for directing light to, focusing light on, and patterning light at a target point P in the eye. *Id.* at 11:30–13:20. Also shown is visualization apparatus V. *Id.* The '648 patent describes that "the entire system is controlled by the controller CPU," but that graphical user interface GUI may be used to process user input. *Id.* at 12:33–41.

The '648 patent describes that "[s]hort pulsed laser light focused into eye tissue 2 will produce dielectric breakdown at the focal point, rupturing the tissue 2 in the vicinity of the photo-induced plasma." *Id.* at 7:8–11. The '648 patent further describes that:

> The laser 10 and controller 12 can be set to locate the surface of the capsule and ensure that the beam will be focused on the lens capsule at all points of the desired opening. Imaging modalities and techniques described herein, such as for example, Optical Coherence Tomography (OCT) or ultrasound, may be used to determine the location and measure the thickness of the lens and lens capsule to provide greater precision to the laser focusing methods, including 2D and 3D patterning. Laser focusing may also be accomplished using one or more methods including direct observation of an aiming beam, Optical Coherence Tomography (OCT), ultrasound, or

> other known ophthalmic or medical imaging modalities and combinations thereof.

*Id*. at 8:10–22. Regarding the imaging of eye anatomy, the ’648 patent further states:

> the capsule boundaries and thickness, the cortex, epinucleus and nucleus are determinable. It is believed that OCT imaging may be used to define the boundaries of the nucleus, cortex and other structures in the lens including, for example, the thickness of the lens capsule including all or a portion of the anterior or posterior capsule.

*Id.* at 8:50–56.

The ’648 patent describes an embodiment where a surgeon aligns a treatment beam pattern to the eye, adjusts the size, location, and shape of the treatment pattern, which is thereafter rapidly applied to the target tissue using a short pulsed cutting laser, but then, regarding another embodiment, explains that:

> in particular for capsulotomy and nuclear fragmentation, an automated method employing an imaging modality can be used, such as for example, electro-optical, OCT, acoustic, ultrasound or other measurement, to first ascertain the maximum and minimum depths of cutting as well as the size and optical density of the cataract nucleus. Such techniques allow the surgeon [to] account for individual differences in lens thickness and hardness, and help determine the optimal cutting contours in patients. The system for measuring dimensions of the anterior chamber using OCT along a line, and/or pattern (2D or 3D or others as described herein) can be integrally the same as the scanning system used to control the laser during the procedure. As such, the data including, for example, the upper and lower boundaries of cutting, as well as the size and location of the nucleus, can be loaded into the scanning system to automatically determine the parameters of the cutting (i.e., segmenting or fracturing) pattern. Additionally, automatic measurement (using an optical, electro-optical, acoustic, or

> OCT device, or some combination of the above) of the absolute and relative positions and/or dimensions of a structure in the eye (e.g. the anterior and posterior lens capsules, intervening nucleus and lens cortex) for precise cutting, segmenting or fracturing only the desired tissues (e.g. lens nucleus, tissue containing cataracts, etc.) while minimizing or avoiding damage to the surrounding tissue can be made for current and/or future surgical procedures. Additionally, the same ultrashort pulsed laser can be used for imaging at a low pulse energy, and then for surgery at a high pulse energy.

*Id.* at 11:1–29.

The '648 patent describes two related embodiments illustrated by its Figures 14 and 15, which are reproduced side-by-side below:

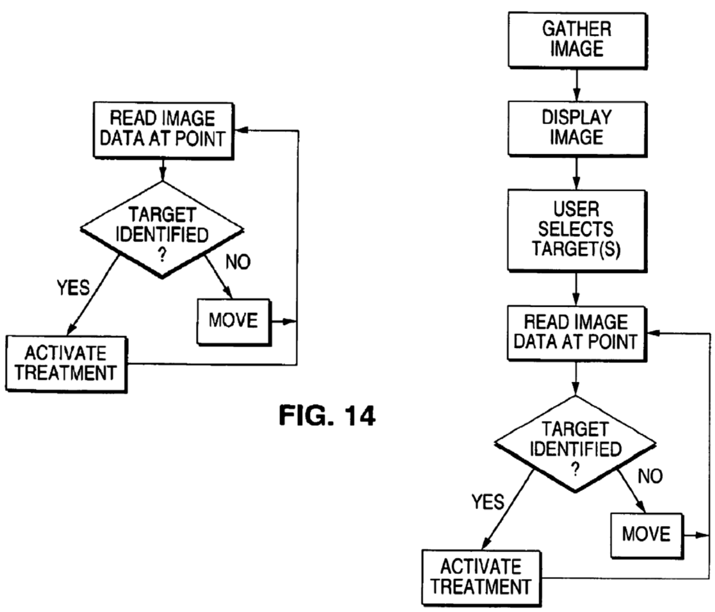



FIG. 15

Figure 14 is shown above-left and Figure 15 is shown above-right and they are flowcharts of algorithms outlining methods performed by the otherwise disclosed systems, discussed above. Regarding these figures, the '648 patent states:

> FIG. 14 is a flowchart outlining the steps utilized in a "track and treat" approach to material removal. First an image is created by scanning from point to point, and potential targets identified. When the treatment beam is disposed over a target, the system can transmit the treatment beam, and begin therapy. The system may move constantly treating as it goes, or dwell in a specific location until the target is fully treated before moving to the next point.
>
> The system operation of FIG. 14 could be modified to incorporate user input. As shown in FIG. 15, a complete image is displayed to the user, allowing them to identify the target(s). Once identified, the system can register subsequent images, thus tracking the user defined target(s). Such a registration scheme may be implemented in many different ways, such as by use of the well known and computationally efficient Sobel or Canny edge detection schemes. Alternatively, one or more readily discernable marks may be made in the target tissue using the treatment laser to create a fiduciary reference without patient risk (since the target tissue is destined for removal).
>
> In contrast to conventional laser techniques, the above techniques provide (a) application of laser energy in a pattern, (b) a high repetition rate so as to complete the pattern within the natural eye fixation time, (c) application of sub-ps pulses to reduce the threshold energy, and (d) the ability to integrate imaging and treatment for an automated procedure.

*Id.* at 13:38–64. The '648 patent describes systems where treatment laser patterns are aligned to target tissue by a surgeon, treatment laser pattern parameters are adjusted by a surgeon, and treatment is then initiated by a surgeon, where the laser system automatically calculates the number of pulses needed to produce the pattern selected by the surgeon. *Id.* at 13:65–14:36. But, as noted above with reference to Figure 14, the '648 patent also describes it to be an alternative and modified embodiment that incorporates such user input. *Id.* at 13:46–57.

The ’648 patent concludes with 15 claims, of which claim 1 is independent. Claim 1 is representative of the challenged claims and is reproduced below with added sub-numbering, as used by Petitioner:

> **[1P]** 1. A laser surgical system for making incisions in ocular tissues during a cataract surgical procedure, the system comprising:
>
> **[1.1]** a laser system comprising a scanning assembly;
>
> **[1.2]** a laser operable to generate a laser beam configured to incise ocular tissue;
>
> **[1.3]** an imaging device configured to acquire image data of at least a portion of the lens; and
>
> **[1.4]** a control system operably coupled to the laser system and configured to:
>
> > **[1.5]** operate the imaging device to generate image data for the patient’s crystalline lens;
> >
> > **[1.6]** process the image data to determine an anterior capsule incision scanning pattern for scanning a focal zone of the laser beam for performing an anterior capsule incision; and
> >
> > **[1.7]** operate the laser and the scanning assembly to scan the focal zone of the laser beam in the anterior capsule incision scanning pattern to perform the anterior capsule incision, wherein positioning of the focal zone is determined in part by the control system based on the image data.

Ex. 1030, 17:30–51; *see also* Ex. 1031. Claims 2–15 depend from claim 1. Ex. 1030, 17:52–18:61.

E. PETITIONER'S ASSERTED GROUNDS FOR UNPATENTABILITY

Petitioner asserts the following grounds for the unpatentability of claims 1–15 of the '648 patent:

| **GROUND** | **CLAIMS CHALLENGED** | **35 U.S.C. §[2]** | **REFERENCE(S)/BASIS** |
|---|---|---|---|
| **1** | 1–5, 12–15 | 103 | Swinger,[3] Baikoff,[4] Li[5] |
| **2** | 6–9 | 103 | Swinger, Baikoff, Li, Hoppeler[6] |
| **3** | 10, 11 | 103 | Swinger, Baikoff, Li, L'Esperance[7] |
| **4** | 1–5, 12–15 | 103 | Freedman,[8] Swinger |
| **5** | 6–9 | 103 | Freedman, Swinger, Hoppeler |
| **6** | 10, 11 | 103 | Freedman, Swinger, L'Esperance |

*See* Pet. 7.

[2] The '648 patent has an uncontested priority date of January 10, 2005, which is before the AIA revisions to 35 U.S.C. § 103 took effect on March 16, 2013. 35 U.S.C. § 100 (note). Therefore, pre-AIA § 103(a) applies. Our decision is not impacted by which version of the statute applies.

[3] US 6,325,792 B1, issued Dec. 4, 2001 (Ex. 1039, "Swinger").

[4] Georges Baikoff, MD, et al., *Static and dynamic analysis of the anterior segment with optical coherence tomography*, 30 J. CATARACT REFRACT SURG 1843–50 (2004) (Ex. 1041, "Baikoff").

[5] Y. Li, et al., *Automated Anterior Chamber Biometry with High-speed Optical Coherence Tomography*, ARVO Annual Meeting Abstract, 44 INVESTIGATIVE OPHTHALMOLOGY & VISUAL SCI 3604 (2003) (Ex. 1044, "Li").

[6] Thomas Hoppeler & Balder Gloor, *Preliminary clinical results with the ISL laser*, 1644 OPHTHALMIC TECH. II 96–99 (1992) (Ex. 1043, "Hoppeler").

[7] US 4,538,608, issued Sept. 3, 1985 (Ex. 1046, "L'Esperance").

[8] US 6,454,761 B1, issued Sept. 24, 2002 (Ex. 1040, "Freedman").

In support of the grounds for unpatentability Petitioner submits, *inter alia*, the Declarations of Joseph A. Izatt, PhD (Ex. 1001; Ex. 1122) and Dr. Richard Tipperman, MD (Ex. 1123). In support of its positions, Patent Owner submits, *inter alia*, the Declarations of Jin U. Kang, PhD (Ex. 2087) and Dr. Keith Walter, MD (Ex. 2088). We find Drs. Izatt, Tipperman, Kang, and Walter competent to testify as to the perspective and understanding of the person of ordinary skill in the art, as we define such herein. *See infra* Section II.A; *see also* (collectively and respectively describing these witnesses' backgrounds, qualifications, and considered materials) Ex. 1001 ¶¶ 4–15, 25–39, 45–51; Ex. 1002; Ex. 1122 ¶¶ 3, 5–7; Ex. 1123 ¶¶ 4, 6–9, 16–20; Ex. 1124; Ex. 2003; Ex. 2005; Ex. 2087 ¶¶ 5–7, 13, 29–33; Ex. 2088 ¶¶ 4–6, 44–54.

We review Petitioner's challenges and Patent Owner's arguments below.

## II. DISCUSSION[9]

### A. ORDINARY LEVEL OF 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*

[9] The claimed subject matter, arguments, and evidence of record in this proceeding are very similar to that of the above-identified related proceedings. *See supra* Section I.C (related matters). Our findings regarding certain issues, for example, level of ordinary skill, certain claim constructions, and interpretation of evidence is consistent among these proceedings.

*Accessories, Inc. v. Jeffrey-Allan Indus., Inc.*, 807 F.2d 955, 962 (Fed. Cir. 1986).

Petitioner states,

> A POSA as of January 2005 would have had a Ph.D. in Physics, Biomedical Engineering, or a related science, such as Nuclear Engineering, as well as a basic understanding of ophthalmology, or at least five years of experience in research, manufacturing, or designing medical optics or medical lasers. Additional education or experience in related fields could compensate for deficits in the above qualifications.

Pet. 25 (Petitioner cites no evidence in support of this proposed definition in the Petition, but Dr. Izatt testifies similarly at Ex. 1001 ¶ 49).[10]

Patent Owner disagrees with this proposed definition because (1) clinical experience in ophthalmology is relevant to the ordinary level of skill and is not recognized by Petitioner; and (2) PhD education is not required for ordinary skill and a Bachelor's degree will suffice for active workers in the field. Resp. 9–10. In view of these issues, Patent Owner proposes the following:

> the correct level of ordinary skill should include meaningful experience with ophthalmic surgery—e.g., (1) an ophthalmic surgeon with experience with medical optics or lasers or (2) an engineer with a Bachelor's degree in a laser-related engineering or optics field who worked with an ophthalmic surgeon. Kang [Ex. 2087] ¶¶30-32.

*Id.* at 9.

As we explained in our Institution Decision (DI 22–25), we find that the person of ordinary skill in the art (or ordinarily skilled artisan) would be inclusive of and span each party's proposed definition. The record here

[10] The parties use the acronym POSA to refer to the person of ordinary skill in the art.

includes a significant number of prior art references addressing the technological field(s) of the claimed invention that were authored by PhDs, MDs, and BSs and combinations thereof. *See, e.g.*, Ex. 1030 (we understand the challenged patent includes inventors that are PhDs and MDs); Ex. 1039 (we understand Swinger's named inventors include a PhD and MD); Ex. 1040 (we understand named inventor Freedman is a JD with a BS); Ex. 1041 (we understand Baikoff's authors include MDs and others); Ex. 1043 (we understand Hoppeler's authors are MDs); Ex. 1044 (at least one of Li's authors is a PhD); Ex. 1045 (we understand inventor is MD); *see also* Ex. 1042;Ex. 1051; Ex. 1053; Ex. 1054; Ex. 1055; Ex. 1058; Ex. 1060; Ex. 1063; Ex. 1065; Ex. 1066; Ex. 1068; Ex. 1070; Ex. 1071; Ex. 1078; Ex. 1079; Ex. 1102; Ex. 1103; Ex. 1118; Ex. 1130; Ex. 2010; Ex. 2019; Ex. 2033; Ex. 2036; Ex. 2039; Ex. 2046; Ex. 2077. This evidences that the person of ordinary skill would have been someone of similar education levels, collaborating with others of these education levels.

Further, the witnesses proffered by each party to testify as to the understanding of the person of ordinary skill in the art include: (1) Dr. Izatt, who asserts himself to be both a person of ordinary skill in the art and to have managed such persons, holds a PhD degree in nuclear engineering and has decades of experience in the field of the biomedical, specifically applied to eye surgery, application of lasers, optics, and imaging (Ex. 1001 ¶¶ 5, 8–15, 45–50; Ex. 1002); (2) Dr. Tipperman, who is an MD, has decades of experience and performed thousands of surgeries using laser cataract surgery and eye imaging tools like those of focus here, and asserts that he provides his understanding largely in accord with Patent Owner's above-identified definition of the ordinarily skilled artisan (Ex. 1123 ¶¶ 6–9, 16–20;

Ex. 1124); (3) Dr. Kang, who holds a PhD degree in optical science and electrical engineering, has decades of experience in the field of optical sciences and photonics (including OCT systems for ophthalmic applications), and testifies that, in his experience, teams working in the relevant field include those holding PhD, MS, and BS degrees (Ex. 2087 ¶¶ 6–7, 29–33); and (4) Dr. Walter, who is an MD, has decades of experience in ophthalmology, and has performed thousands of cataract surgeries (Ex. 2088 ¶¶ 5–6, 44–54; Ex. 2005). This also evidences that the person of ordinary skill in the art may have held either a technical degree, such as a PhD in optical science or nuclear engineering, or a medical degree specializing in ophthalmology, but that some collaboration between the two would have been customary.

Petitioner's proposed definition of the person of ordinary skill in the art appears to be consistent with the level of skill in the art reflected in the prior art of record and the disclosure of the '648 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 also including a medical doctor, such as an ophthalmic surgeon with experience working with medical optics and lasers, and that these people may collaborate. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) ("the prior art itself [may] reflect[] an appropriate level" as evidence of the ordinary level of skill in the art) (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 here, based on our review of the record. Thus, we find that the person of ordinary skill in the art would have been someone with a PhD, MS, or BS degree in physics, biomedical engineering, or a related science such as nuclear engineering, having more or less experience in research, manufacturing, or designing medical optics or medical lasers (e.g., 5 years for a PhD or more to compensate for lesser degrees), or an ophthalmic surgeon, but that such persons would have worked in collaboration with one another to fill any necessary gaps in knowledge (e.g., the engineer would consult the medical doctor on clinical issues or physiology and the medical doctor would consult the engineer on technical issues). This definition marries the two proposed by the parties and is appropriate in view of the record.

### B. CLAIM CONSTRUCTION

The Board interprets claim terms in an *inter partes* review using the same claim construction standard that is used to construe claims in a civil action in federal district court. 37 C.F.R. § 42.100(b). In construing claims, district courts and the Board here, by default, give claim terms their ordinary and customary meaning, which is "the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc).

Should claim terms require express construction, sources for claim interpretation include "the words of the claims themselves, the remainder of the specification, the prosecution history [i.e., the intrinsic evidence], and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art." *Id.* at 1314 (quoting *Innova/Pure*

*Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1116 (Fed. Cir. 2004)). "[T]he claims themselves [may] provide substantial guidance as to the meaning of particular claim terms." *Id.* However, the claims "do not stand alone," but are part of "'a fully integrated written instrument' . . . consisting principally of a specification that concludes with the claims," and, therefore, the claims are "read in view of the specification." *Id.* at 1315 (quoting *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 978–79 (Fed. Cir. 1995) (en banc)).

Any special definition for a claim term must be set forth in the specification "with reasonable clarity, deliberateness, and precision." *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994). Without such a special definition, however, limitations may not be read from the specification into the claims. *In re Van Geuns*, 988 F.2d 1181, 1184 (Fed. Cir. 1993).

"[W]e need only construe terms 'that are in controversy, and only to the extent necessary to resolve the controversy.'" *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)).

Petitioner asserts that, although dependent claim 12 is indefinite, its language, "*to determine one or more axial locations of the anterior capsule of the lens; and or more anterior capsule axial locations*," (emphasis added) should be construed to mean "to determine one or more axial locations of the anterior capsule of the lens (i.e., one or more anterior capsule axial locations)." Pet. 7–8; *see also* Ex. 1030, 18:46–50 (claim 12). Petitioner's position is that, as it reads in the '648 patent, claim 12's language is "a nonsense phrase," rendering it indefinite, but that for the purposes of this proceeding it may be understood by the definition set forth above. Pet. 7–8.

Patent Owner does not ask that any claim language be expressly construed. *See generally* Resp.

Claim 12 depends from independent claim 1 and it is not necessary for us to consider the Petition's specific challenges to claim 12 to render our decision in this proceeding in view of our determinations as to claim 1. Ex. 1030, 17:30–18:61. Therefore, we need not and do not expressly construe any claim language here. However, in our analysis below, as required for the sake of clarity, to resolve ambiguity, and for consistency with our decisions in the related proceedings addressing similar claim language and similar prior art, we address the claim language and its meaning as argued by the parties.

C. APPLICABLE LEGAL STANDARDS

"In an IPR, the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable." *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016) (citing 35 U.S.C. § 312(a)(3) (requiring *inter partes* review petitions to identify "with particularity . . . the evidence that supports the grounds for the challenge to each claim")). This burden never shifts to Patent Owner. *See Dynamic Drinkware*, 800 F.3d at 1378 (discussing the burden of proof in *inter partes* review).

Regarding obviousness, the Supreme Court in *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), reaffirmed the framework for determining obviousness set forth in *Graham v. John Deere Co.*, 383 U.S. 1 (1966). The *KSR* Court summarized the four factual inquiries set forth in

*Graham* (383 U.S. at 17–18) that are applied in determining whether a claim is unpatentable as obvious under 35 U.S.C. § 103(a) as follows:
(1) determining the scope and content of the prior art; (2) ascertaining the differences between the prior art and the claims at issue; (3) resolving the level of ordinary skill in the art;[11] and (4) considering objective evidence indicating obviousness or non-obviousness.[12] *KSR*, 550 U.S. at 406.

"The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *Id.* at 416. "[W]hen the question is whether a patent claiming the combination of elements of prior art is obvious," the answer depends on "whether the improvement is more than the predictable use of prior art elements according to their established functions." *Id.* at 417.

With these standards in mind, and in view of the definition of the ordinary skilled artisan and claim interpretation discussed above, we address Petitioner's challenges, Patent Owner's arguments thereover, and the evidence of record below.

D. REVIEW OF ASSERTED PRIOR ART

*1. Swinger*

Swinger issued on December 4, 2001, from U.S. Application 08/287,000, which was filed on August 8, 1994. Ex. 1039, codes (45), (21),

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[11] *See supra* Section II.A.

[12] Although there are disputes in this proceeding regarding the evidence of objective indicia of non-obviousness, we do not substantively address this evidence or arguments because it is not necessary to our decision, which would not change even were we to accept Patent Owner's positions thereon. *See infra* Section II.E.3.

(22). There is no dispute that Swinger is prior art to the claims of the ’648 patent. *See generally* Resp.

Swinger’s Abstract indicates its invention is directed to an apparatus and method where:

> Low energy, ultra-short (femptosecond) pulsed laser radiation is applied to the patient’s eye in one of a number of patterns such that the exposed ocular tissue is ablated or excised through the process of optical breakdown or photodisruption in a very controlled fashion. The process can be gentle enough that the invention makes possible the performance of a number of surgical procedures that in the past could not have been performed at all, such as capsulorhexis, or were performed in a fashion that provided less than an ideal result or excessive trauma to the ocular tissue. Such latter applications include the making of incisions for corneal transplantation, radial and arcuate keratotomy, and intrastromal cavitation. Using the laser inside the eye allows the surgeon to perform glaucoma operations such as trabeculoplasty and iridotomy, cataract techniques such as capsulectomy, capsulorhexis and phacoablation, and vitreoretinal surgery, such as membrane resection. The various procedures are accomplished by controlling energy flux or irradiance, geometric deposition of beam exposure and exposure time.

Ex. 1039, Abstract. Swinger illustrates such a system at its Figure 6, which is reproduced below:

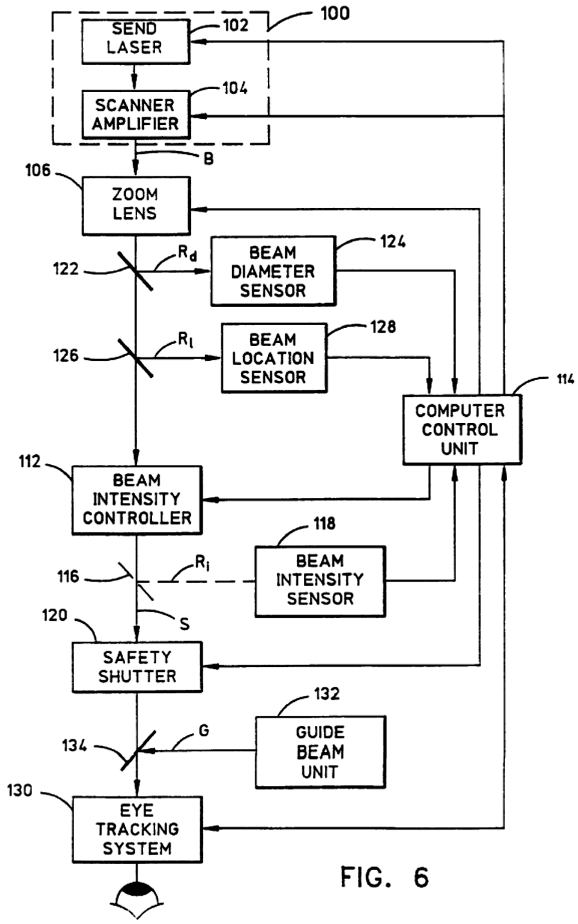


FIG. 6

Swinger states that "FIG. 6 is a block diagram of the preferred embodiment of the inventive apparatus," and further explains that Figure 6 shows laser unit 100 generating beam B, which can be computer-controlled to scan in the X and Y axes, controlled in its intensity (beam intensity controller 112) to produce surgical beam S for ablation, controlled in ablation etch depth, controlled in ablation pattern (e.g., straight lines, curved lines, any predetermined length and depth, at any location). *Id.* at 10:61–62, 17:1–62, 20:47–51. The system is also shown to have eye tracking system 130, which optically monitors the patient's eye movement and enables the system to adjust surgical laser beam S to compensate. *Id.* at 20:8–20.

Swinger discloses that a system as just described can be used for a variety of surgical procedures, including, for example, scar or infected tissue removal, cornea transplant, myopia and hyperopia correction, glaucoma surgery, lens removal (from capsule), IOL implantation, cataract surgery, keratectomy, microkeratome, photokeratectomy, cornea surfacing, *in situ* keratomileusis, astigmatism correction, iridotomy, and phacorefractive ablation. *Id.* at 21:36–36:17.

Regarding procedures on the lens and associated tissues of the eye, Swinger discloses performing anterior capsulectomy (capsulorhexis) and states that the computer-controlled laser produces a more regular-shaped and smoothly-contoured opening through the capsule, with less trauma, than accomplished under manual control. *Id.* at 34:30–36, Figs. A1–B1. Swinger discloses using ultrashort pulsed laser producing a wavelength transmitted by the cornea for this purpose. *Id.* at 34:36–37. Swinger explains that this capsulectomy "facilitate[s] the cataract surgery to follow." *Id.* at 34:40.

Swinger explains this process includes focusing the laser beam spot on the anterior lens capsule by the surgeon's direct visualization using an HeNe laser focused on the same spot as the ablating laser, which will define the diameter of the capsulorhexis. *Id.* at 34:52–57. The surgeon displaces the visual HeNe laser beam just posteriorly to the capsule, or a selected distance can be programmed into the beam control computer, and photodisruption begins. *Id.* at 34:58–61. Swinger states that "[t]he cutting process can be totally computerized once the reference point on the capsule has been fixed." *Id.* at 34:64–65. This is followed by cataract surgery. *Id.* at 34:67–35:3.

Swinger follows its discussion of cataract surgery with a disclosure of phacorefractive ablation, which is a "procedure . . . to modify the refractive power of the eye by altering the curvature, and hence refractive power, of the lens," which, again, uses a "laser source [having] an ultrashort, pulsed laser, using a wavelength transmissive to the cornea and the lens," to ablate some of the substance of the lens in a non-traumatic fashion so that lens material is removed from under the anterior lens capsule in a controlled fashion. *Id.* at 35:18–37, Figs. 15C1–D1. "The laser is focussed [*sic*] within the lens itself, scanned in a pattern appropriate for the shape of the calculated ablation, and, by photodisruption, the lens material is ablated," however, a safety zone is prescribed for the ablation of the lens to provide a computer-controlled safety distance to perform the ablation so as not to damage the capsule. *Id.* at 35:50–36:2. In such a procedure, Swinger discloses "using ultrasound measurement" to accurately measure the eye anatomy and orient the laser beam. *Id.* at 35:59–63.

*2. Baikoff*

Baikoff is a 2004 journal article and it is not disputed that it is prior art to the claims of the '648 patent. Ex. 1041; *see generally* Resp.

Baikoff discloses using 1310 nm wavelength optical coherence tomography (OCT) to measure internal eye anatomy, including the horizontal diameter of the AC (anterior chamber), the anterior chamber depth (ACD), the horizontal pupil diameter, and the horizontal radius of curvature of the crystalline lens's anterior pole. Ex. 1041, 1844.[13] Baikoff states that this OCT technique "allows rapid, noncontact examination, and

[13] Baikoff includes original page numbering and numbering added to its lower corner. We use the original numbering when citing to this reference.

the software includes a measuring system capable of calculating distance, angle, and radius of curvature." *Id.* at 1844.

An example of Baikoff's OCT imaging of an eye's anatomy is shown at its Figure 3, reproduced below:

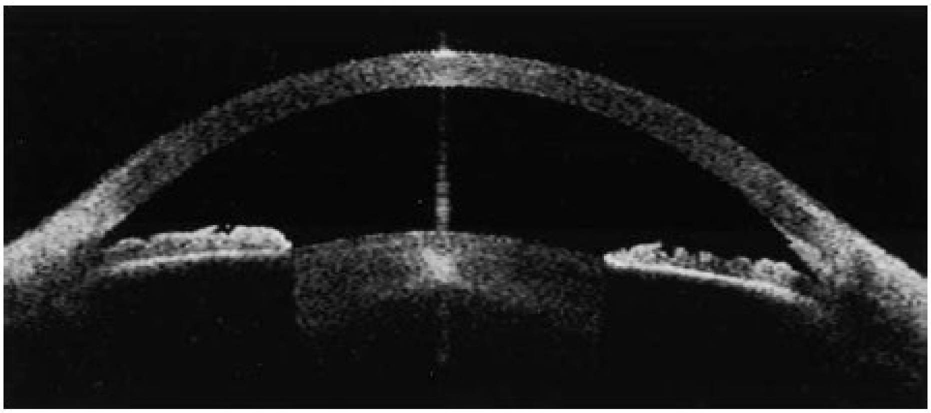

**Figure 3.** (Baikoff) The AC of a 55-year-old subject.

*Id.* at 1845.[14] Figure 3 shows a cross-section of the eye of a 55-year-old subject and the cornea, anterior chamber, iris, and at least a portion of the lens can be discerned.

Baikoff concludes that:

> The AC OCT is a user-friendly instrument for evaluating the anterior segment and examining the AC (cornea, iris, crystalline lens, and iridocorneal angle). The 1310 nm light wavelength is blocked by pigments, preventing examination behind the iris. However, the AC OCT is capable of good image quality and visualization of the anatomical relationships in the anterior segment, even behind an opaque cornea.

*Id.* at 1843 (Abstract). Baikoff states that its disclosed OCT technique offers advantages over ultrasound visualization, "will be of great value in phakic

[14] For context, compare this OCT imaging with imaging of the eye obtained via ultrasound, as shown, for example in Ex. 1070, Figures 1 and 2.

IOL implantation,"[15] and allows "extremely precise exploration of the anterior segment." *Id.* at 1844, 1849.

*3. Li*

Li is an Abstract that, on its face, indicates it is an "ARVO Annual Meeting Abstract" of "May 2003." Ex. 1044, 1. There is no dispute that Li is prior art to the claims of the '648 patent. *See generally* Resp.

Li discloses that "[a]ccurate sizing of angle-supported anterior chamber intraocular lens (AC-IOL) is crucial in preventing complications," and that, "[t]o accurate[ly] measure AC width and other dimensions," the Li authors "developed a high-speed optical coherence tomography (OCT) system and automated image processing." Ex. 1044, 1. Li discloses that "[a] computer algorithm was developed to measure angle-to-angle AC width, AC depth, and lens vault,"[16] and "[t]he computer algorithm successfully measured AC diameter and AC depth from all 120 OCT images."[17] *Id.*

Li concludes that, "[d]ue to its longer wavelength, the OCT system was able to penetrate and image the angles. The speed was sufficient[ly] high for reproducible AC width measurement. The automated computer algorithm agrees well with human raters. The use of a computer measurement algorithm avoids the relatively large disagreement between

---

[15] Phakic refers IOL implantation without removing the natural lens.

[16] Lens vault refers to a measurement of the perpendicular distance between an eye's anterior lens pole and the horizontal line joining the temporal and nasal scleral spurs, i.e., an anterior dimension of the crystalline lens. AC refers to the anterior chamber.

[17] Relevant to the subject matter of the challenged claims, we note that the tissues for which Li discloses a capability for detecting and measuring do not include the full thickness of the lens or the lens capsule.

human raters for AC width," and that "[t]he use of OCT to directly measure AC width may improve the fitting of AC-IOL and avoid complications such as IOL dislocation and pupil ovalization." *Id.* at 1–2.

*4. Hoppeler*

Hoppeler is a journal article indicated as published in 1992. Ex. 1043, 96. There is no dispute that Hoppeler is prior art. *See generally* Resp.

Hoppeler discloses an Nd:YLF pulse laser used for microsurgery of the anterior of the eye, including procedures for cataract fragmentation and iridotomy and posterior capsulotomy, under computer control. Ex. 1043, 96 (Abstract); *see also id.* at 98–99 (further describing such procedures). Hoppeler discloses that the laser is started by a surgeon by pressing a conventional foot switch. *Id.* Hoppeler discloses that the surgery is performed by using the laser to create different area patterns in/on tissue. *Id.* at 96–98.

*5. L'Esperance*

L'Esperance issued on September 3, 1985, from U.S. Application 617,931, which was filed on June 6, 1984. Ex. 1046, codes [45], [21], [22]. There is no dispute that L'Esperance is prior art. *See generally* Resp.

L'Esperance discloses that:

> The invention involves the apparatus and the technique for non-invasive surgery to remove cataracted-lens tissue from an afflicted lens. The beam output of a laser is focused to a spot of maximum power density at the anterior surface of a cataracted lens and scanned over a predetermined area or areas of the cataracted lens. The beam is selective and safe since it's diffuse as it enters the eye through the cornea and is also diffuse (being divergent) in the unlikely event that the beam passes through an opening it has created in the cataracted lens. This diffusion assures against damage to either or both of the cornea and the retina. Focal power levels are used sufficient to achieve

> cataract material destruction thru ablative photodecomposition, thermal decomposition, photofragmentation, photoemulsification or any combination thereof. Various features are disclosed for assuring safety and uniformity in the removal of involved tissue.

Ex. 1046, Abstract.

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

FIG. 1.

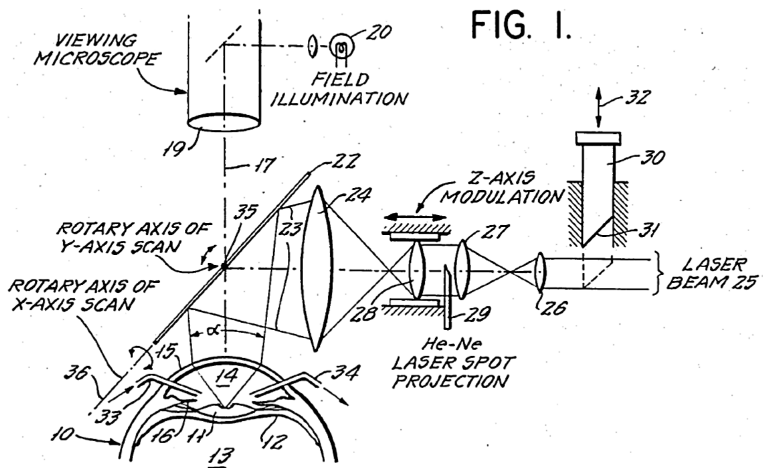


Figure 1 "is a simplified optical diagram of components of [an] apparatus of the invention, shown in application to an eye in which cataracted-lens tissue is being removed." *Id.* at 2:5–7. Figure 1 shows patient's eye 10 with cataracted natural lens 11, adjacent to an apparatus or system having a viewing microscope with objective lens 19 and a laser, producing laser beam 25, which may be a near-infrared pulsed laser of the neodymium-YAG variety (can provide energy of about 1–30 millijoules, where the convergent ray angle is about 16°–20°), or an ultraviolet laser such as an excimer laser or a frequency-quadrupled neodymium-YAG laser (can provide 1–5 joules/cm$^2$ on focal spots of 10–100 μm diameter, where the focal range is about 25°–30°). *Id.* at 2:14–3:22. The system includes partially reflecting mirror 22, which has two axes of rotation so as to direct laser light in the X and Y axes, and optical elements 26, 27, 28 for focusing laser light in a controlled manner along the Z axis. *Id.* at 2:39–55, 3:39–62.

*6. Freedman*

Freedman issued on September 24, 2002, from U.S. Application 08/380,639, which was filed on January 30, 1995. Ex. 1040, codes (45), (21), (22). There is no dispute that Freedman is prior art. *See generally* Resp. Freedman's Abstract states that its invention is related to "[l]aser surgery [that] is controlled by interferometry." Ex. 1040, Abstract.

As background, Freedman discloses that ophthalmic procedures (as well as other types of procedures) utilize laser surgery. *Id.* at 1:8–18. Freedman specifies that such biomedical applications includes, *inter alia*, clearing cataracts and that "[m]ost laser surgical methods utilize the laser heat effect" and "[i]f the wavelength of light from the laser is matched very closely with the absorption band of the target structure, the laser light will be absorbed by, and therefore damage[,] only that structure" such that "[t]he heat effect of the laser can be extremely selective and precisely controlled." *Id.* at 1:26–31; *but see id.* at 1:31–39 (explaining that is was difficult or impossible to choose an irradiating wavelength to damage target tissue without affecting surrounding tissue). Freedman also discloses pairing laser surgery with ultrasonic probes to 3D-image internal body structure for laser surgery using a computer system to control the parameters of a surgical procedure, but warns that the use of ultrasonics is limited for various reasons. *Id.* at 1:40–63.

To overcome limitations of ultrasonics, Freedman discloses "a method and device for laser surgery where a treatment laser beam is controlled by interferometry, preferably by optical coherence tomography," including "controlling the laser treating of the biological tissue according to the detected surface or mass." *Id.* at 2:7–31. Freedman provides an illustration of a system for such surgery at its Figure 1, reproduced below:

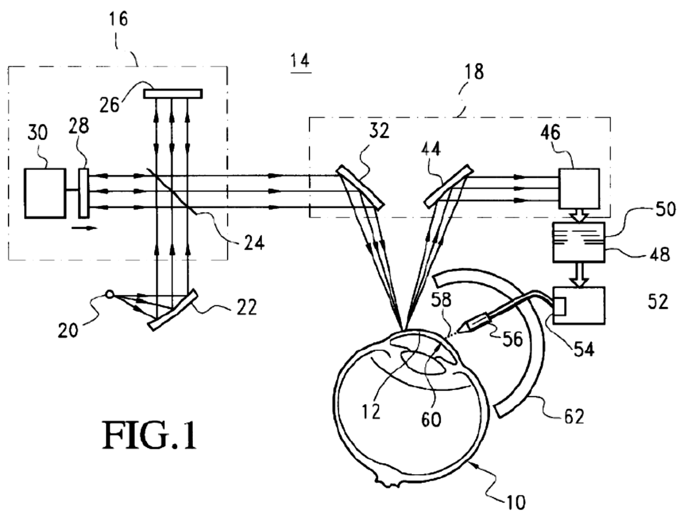

FIG.1

Freedman states that "FIG. 1 . . . [is a] schematic representation[ ] of [a] device[ ] and method[ ] for laser surgery controlled by low coherence interferometry," and the image above shows laser surgery device 14 utilizing two-wavelength interferometry to determine the characteristics of a section of optical cornea 12 tissue of patient's eye 10 for a radial keratotomy procedure. *Id.* at 4:9–5:67. Laser surgery device 14 is shown to include interferometer 16 and optical system 18 and Freedman explains that laser surgery device 14

> can control ablating of tissue to perform a radial keratotomy with high-intensity laser light by precise positioning of the laser beam and maximum absorption of the beam over a precise area and depth of incision.
>
> According to the present invention, a sequence of detection can be used to evaluate the thickness and the boundary state of each layer of the cornea or other biological

> tissue. The cornea can be considered either a single layer or mu[l]tilayer thin film. The cornea can be evaluated as a mu[l]tilayer thin film to provide detailed information about cross-sectional planes of the cornea tissue or evaluated as a single layer thin film for applications requiring only gross information on the tissue structure. According to the invention, the information from the evaluation of the cornea has been found to be sufficient for processing to control the delicate ablation in a radial keratotomy and in other procedures for treating biological tissue by laser surgery.

*Id.* at 4:28–45. Freedman discloses that the pulsed laser beam of this system, which may be "any [laser] device known in the art for conducting a radial keratotomy," is focused and patterned to ablate tissue in response to the control of processor 48 based on an ablation plan constructed based on a 3D image of the cornea achieved via the interferometer 16, and that a surgeon's input is also possible. *Id.* at 5:29–67. Such a system is used "to provide the thickness and the boundary state of a layer of [ ] biological tissue and control[ ] [the] laser treating of biological tissue according to thickness and boundary state of the layer." *Id.* at 10:33–37 (claim 10).

As illustrated by the above-quoted and other portions of Freedman, the reference's detailed description is most focused on laser surgery on the cornea of an eye, using the "precise three-dimensional imaging capability of low coherence interferometry" to "permit[ ] precise control of ablating laser 52 in forming the incisions at the location and extent previously determined." *Id.* at 4:9–9:18 (quoting *id.* at 6:5–12).

### E. PETITIONER'S PATENTABILITY CHALLENGES

As summarized above, Petitioner asserts six grounds for unpatentability of the claims of the '648 patent. *See supra* Section I.E; *see* *also* Pet. 5–7. We review Petitioner's challenges and Patent Owner's arguments below.

*1. Obviousness Based on Swinger, Baikoff, and Li (Grounds 1–3)*

Because the same facts and legal conclusions are determinative for each of Grounds 1–3, we address them as a group below and focus on Ground 1 as representative. As explained further, we find that Petitioner has not established by a preponderance of the evidence that any challenged claim would have been obvious under these grounds.

Although Petitioner's Grounds 2 and 3 add the Hoppeler and L'Esperance references to address certain challenged claims, each of Petitioner's Grounds 1–3 is foundationally based upon the combination of Swinger, Baikoff, and Li for the proposition that this prior art combination teaches and would have made obvious the core premise the invention required of all challenged claims: a ***control system configured to*** (1) operate an imaging device to generate image data of a patient's lens, (2) process that image data ***to determine an anterior capsule incision scanning pattern***, and (3) ***operate a laser to scan in the scanning pattern and perform an anterior capsule incision as determined in part by the control system based on the image data***.[18] *See* Pet. 28–55; Ex. 1030, 17:30–51 (claim 1).

*Parties' Positions and our Analysis on Grounds 1–3*

Patent Owner argues:

> the '648 patent is all about computer-controlled cataract surgery, and each claim requires that the laser surgery system be programmed to (1) process image data so as to determine an anterior capsule incision scanning pattern, and (2) perform the surgical procedure on that target tissue based on the scanning

[18] For the sake of brevity, we paraphrase the claimed steps here and below.

> pattern (i.e., operate the laser and scanning assembly to perform the anterior capsule incision).

Resp. 1, 11 (Patent Owner calling identifying the surgical target a critical step reserved for the surgeon (in Swinger)); *see also* Ex. 2088 ¶¶ 68–69 (Dr. Walter testifying that the step of identifying cutting boundaries and pattern conventionally the core responsibility of the surgeon). Likewise, Petitioner and its witness, Dr. Izatt, recognize such requirements of the claims (or at least that the Board may agree with Patent Owner on the issue), for example, Dr. Izatt states, "to the extent the claims require that a controller itself determine boundaries and treatment regions without surgeon intervention, it is my opinion that a POSA would have been motivated to program the controllers to do so." Pet. 38 n.9; Ex. 1001 ¶¶ 156, 459. Thus, the parties extensively and consistently discuss this claim language, which we address below.

"[T]he person of ordinary skill in the art is deemed to read [a] claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification. . . . To begin with, the context in which a term is used in the asserted claim can be highly instructive." *Phillips*, 415 F.3d at 1313–14. The claims recite that the "control system" is "configured to" perform the subsequently recited, above-noted steps.

As a matter of plain language, a "control system" that is configured to take certain actions is able to itself carry out the subsequently recited steps (actions or functions), which is reflected by the written description of the '648 patent. *See* Ex. 1030, 6:38–56, 8:10–22, 11:1–27, 12:15–50, 13:38–47, 14:11–36, Figs. 11–14 (describing, generally, a computer, e.g., a CPU or microcontroller, as "control electronics 12" for or capable of controlling a light source and delivery system, measuring anatomical dimensions, determining the parameters of laser cutting, and controlling the surgical laser, as well as a basic algorithm for processing image data to identify a target and manipulate a system to laser treat it). This understanding is consistent with how each party addresses this claim language and the related limitations in this proceeding (e.g., programmed computer control system, with associated imaging, processing, and treatment components, can perform claimed functions). *See* Pet. 33, 35–40, n.9; Resp. 1–3, 12–18, 23; *see also* Ex. 1001 ¶¶ 56, 60–62, 66, 71, 132, 135, 150, 156, 159, 457, 460, (Dr. Izatt discussing what programmed systems are configured to and can do); Ex. 2087 ¶¶ 57, 62–63, 86. (Dr. Kang discussing controllers configured to perform as programmed systems).

Petitioner's Ground 1 addresses independent claim 1 and dependent claims 2–5 and 12–15, and asserts they would have been obvious over the combination of Swinger, Baikoff, and Li. *See* Pet. 28, *et seq.* (citing, *inter alia*, Ex. 1001 ¶¶ 142–150, 152, 154–159, 453–463, 465–467, 470, 473–482; Ex. 1039, 7:51–58, 8:37–48, 16:14–16, 16:60–20:34, 20:49–21:19, 23:13–25, 33:36–43, 34:30–35:3, 35:17–36:7, Figs. 6, 15A1, 15B1; Ex. 1041, 1843–44, 1849, Figs. 3, 10; Ex. 1044, 1–2). Petitioner's Ground 2 addressing claims 6–9 and Ground 3 addressing claims 10 and 11 are each based upon and build from Ground 1. *Id.* at 47–55. Without a persuasive foundation under Ground 1, Petitioner fails to meet its burden of persuasion for each of Grounds 1–3. Thus, our focus here is upon Ground 1.

Petitioner asserts that the ordinarily skilled artisan would have been motivated to combine Swinger, Baikoff, and Li, and modify them in view of one another, because: Swinger teaches laser cataract surgery and identifies the benefits of accuracy, using ultrasound for example, to measure the dimensions of eye tissues to provide a safely distanced ablation region; Baikoff teaches using OCT to improve 3-dimensional imaging of eye tissue (anterior region) and indicates it would be useful for pre-surgical diagnostics and surgical planning; and Li teaches an OCT system like Baikoff's that replaces manual measurements of interior eye dimensions with automatic computer measurements based on imaged tissue boundaries to improve precision. Pet. 28–34 (citing, *inter alia*, Ex. 1001 ¶¶ 142–150, 152, 154–159).

In proposing this combination of prior art, Petitioner acknowledges that Swinger does not disclose using OCT imaging. *Id.* at 28. Further, Petitioner acknowledges that, even upon combining Swinger and Baikoff a surgeon would still have been required to make anatomy measurements manually and input them into a computer system, hence, these references do not "teach imaging systems with controllers that process image data to determine ocular structures and landmarks without manual intervention." *Id.* at 32. Finally, Petitioner expresses that even upon combining Swinger, Baikoff, and Li, the references still do not expressly teach a control system configured to image an eye's anatomy, plan a laser cutting pattern on that anatomy to perform an anterior capsule incision, and then operate the laser to perform that anterior capsule incision based at least in part on the image data, but only asserts that it would have been obvious to eliminate the surgeon from this process to allow the controller to determine the relevant scanning patterns. *Id.* at 33–34.

Petitioner's position is that the ordinarily skilled artisan would have recognized that further automating Swinger's cataract surgery based on

Baikoff's and Li's OCT imaging would predictably automate a manual step of Swinger's procedure and improve the precision and accuracy of such procedures by replacing HeNe alignment or ultrasound imaging with OCT imaging, which was detailed, precise, accurate, and suitable for such procedures. *Id.* at 28–30, 32–34 (citing *In re Venner*, 262 F.2d 91, 95 (CCPA 1958); Ex. 1001 ¶¶ 152, 154–159).

Petitioner also asserts that the person of ordinary skill in the art would have had a reasonable expectation of success in combining and modifying this prior art. *Id.* at 31–34 (citing Ex. 1001 ¶¶ 150, 152, 154–159; Ex. 1030, 8:13–22, 11:1–29, 13:21–37, 13:52–53, Figs. 11, 13; Ex. 1039, 35:59–66; Ex. 1041, 1844; Ex. 1044, 1–2). Petitioner's position is that the prior art teaches the asserted combination and modification was not only desirable, but was a *straightforward and a simple substitution* of known imaging modalities (e.g., substituting Swinger's ultrasound with OCT imaging in a similar fashion to how the '648 patent describes switching between ultrasound and direct visualization), and the *mere programming* of a control system (Swinger's beam control computer) with known algorithms. *Id.*

Petitioner moves on to address how each limitation of the aforementioned claims is taught or suggested by Swinger, Baikoff, and Li. *Id.* at 34–47 (citing for independent claim 1, *inter alia*, Ex. 1001 ¶¶ 453–462; Ex. 1030, 16:60–20:34, 20:49–21:19, 34:30–35:3, 35:17–36:7, Figs. 6, 15A1, 15B1; Ex. 1041, 1844–45, Figs. 3, 10; Ex. 1044, 1–2). Petitioner asserts that all the claimed equipment, steps, and target tissue for laser cataract surgery, other than the use of an OCT imaging system and the related control system configured to image a cataractous eye, plan a cutting pattern for capsulotomy, and implement that capsulotomy cutting pattern based on the image data, is taught by Swinger. *Id.* at 34–40.

Petitioner acknowledges that "*Swinger and Baikoff do not expressly teach imaging systems with controllers that process image data to determine ocular structures and landmarks without manual intervention*." *Id.* at 32 (emphasis added); *see also id.* at 37 (reconfirming Swinger's lack of such disclosure); Ex. 1001 ¶ 154 (Dr. Izatt testifying that, based on Baikoff's OCT imaging, "[a] ***user could*** then use the[] images and [imaged] boundaries to ***determine a treatment region***, such as an anterior capsulotomy region . . . and/or a lens fragmentation region." (emphasis added)). Petitioner asserts that Li's capability to identify certain eye tissue boundaries and make certain measurements would have led an ordinarily skilled artisan to automate in Swinger (and also in Baikoff, based on Dr. Izatt's quoted statement) what the reference teaches to be manual activity, i.e., evaluating eye anatomy, planning a cutting pattern, and implementing (having a computer-controlled laser implement) that cutting pattern. Pet. 32–34, 38–39.

In mapping the prior art's disclosures to the limitations of claim 1 (and to the respective limitations of the other independent claims), Petitioner addresses the limitations missing from Swinger and asserted to be taught by Baikoff and Li in the Petition at 35–40 and asserts that they are provided by combining Baikoff and Li with Swinger. *Id.* at 40–45. Regarding limitation 1.3 (OCT imaging device), Petitioner proposes that Baikoff's use of an OCT imager is akin to Swinger's use of ultrasound to acquire image data of the lens. *Id.* at 35 (citing Ex. 1001 ¶¶ 453–455; Ex. 1039, 35:17–36:7; Ex. 1041, 1844).

Regarding limitation 1.4 (the control system coupled to a laser and configured to perform steps), Petitioner asserts that Swinger teaches a control system coupled to a laser system and able to control it. *Id.* at 35 (citing Ex. 1039:17:41–57, 19:17–20, Fig. 6).

Regarding limitation 1.5 (the control system being configured to operate the imager to generate image data for the patient's lens), Petitioner asserts that Baikoff's system does this. *Id.* at 36–37 (citing Ex. 1001 ¶¶ 456–457; Ex. 1041, 1844, Figs. 3, 10). Petitioner asserts that Baikoff's OCT imager would be coupled to Swinger's computer control unit 114. *Id.*

Regarding limitation 1.6 (the control system also being configured to process that image data to determine an anterior capsule incision scanning pattern), Petitioner asserts that, although Swinger does not disclose using imaged landmarks to determine an anterior capsulotomy (e.g., an anterior capsule incision) scanning pattern under computer control, but rather teaches manually doing so, Li teaches that a system can use OCT imaging to identify eye anatomy landmarks and make automatic related measurements, which would lead an ordinarily skilled artisan to configure Swinger's controller to do so based on Baikoff's OCT imaging rather than require the surgeon to visually and manually identify an anatomical reference point in the eye and then estimate a starting location and depth of laser cutting. *Id*. at 37–39 (citing Ex. 1001 ¶¶ 458–460; Ex. 1039, 34:30–35:3, 35:59–66, Figs. 15A1, 15B1, Ex. 1044, 1–2).

We note that, at footnote 9 of the Petition, Petitioner proposes that "[c]laim[] 1 . . . do[es] not require the recited control system to 'determine an anterior capsule incision pattern,'" meaning, plan where to laser-cut, "but only 'process the image data' so a pattern can be determined (either by the controller or surgeon)." *Id.* at 38 n.9. As discussed above, we disagree with Petitioner's alternative argument on the requirements of the claim. Even, Petitioner itself ultimately agrees that for processing to occur, as claimed, the step is "completed by a computer." Hr'g Tr. 8:19–20. The plain language of claim 1's clause, "process the image data ***to determine an anterior capsule incision scanning pattern*** for scanning the focal zone of the laser beam ***for performing an anterior capsule incision***," refers directly to things the earlier-recited "control system" must be configured to do. Ex. 1030, 17:30–51 (emphasis added). As we discussed above, within the context of the claims and the patent's written description, this means the control system is capable of doing this act, i.e., processing image data to determine an anterior capsule incision pattern—e.g., planning the laser-cutting for a capsulotomy and then actually doing the procedure based (in part) on that processed image data.

Regarding limitation 1.7 (the control system also being configured to operate the laser to scan in the anterior capsule incision scanning pattern to perform the anterior capsule incision based in part on the image data), Petitioner asserts Swinger's laser is totally computerized and, although Swinger does not use an imaging system to determine a scanning pattern of an anterior capsulotomy (capsule incision), it would have been obvious to use Baikoff's and Li's OCT imaging technology for determining the scanning pattern and then have Swinger's system deliver the target capsule incision. Pet. 39–40 (citing Ex. 1001 ¶¶ 461–462; Ex. 1039, 17:1–10, 17:41–49, 19:44–64, 34:30–67, Figs. 6, 15A1, 15B1).

We find Petitioner's case unpersuasive based on Patent Owner's arguments and the evidence of record. We find that the evidence of record does not support that Swinger, Baikoff, and Li would have been combined by the person of ordinary skill in the art to achieve the claimed invention with a reasonable expectation of success. Specifically, we find that the claimed elements of the invention directed to ***a control system configured to*** (1) operate an imaging device to generate image data of a patient's lens, (2) process that image data ***to determine an anterior capsule incision scanning pattern***, and (3) ***operate a laser to scan in the scanning pattern and perform an anterior capsule incision as determined in part by the control system based on the image data***, are not taught by the cited prior art and would not have been obvious. Ex. 1030, 17:30–51 (claim 1). We address Patent Owner's respective arguments and our analysis below.

"The presence or absence of a reasonable expectation of success is . . . a question of fact." *Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1366 (Fed. Cir. 2016). "The reasonable expectation of success requirement refers to the likelihood of success in combining references to meet the limitations of the claimed invention." *Id.* at 1367. The evidence of record suggests that the ordinarily skilled artisan would not have had a reasonable expectation of success in achieving the claimed invention based on Swinger's, Baikoff's, and Li's teachings. Further, as our reviewing court has explained, "references to 'common sense'—" or an ordinarily skilled artisan's ordinary creativity, "whether to supply a motivation to combine or a missing limitation—cannot be used as a wholesale substitute for reasoned analysis and evidentiary support, especially when dealing with a limitation missing from the prior art references specified." *DSS Tech. Mgm't, Inc. v. Apple Inc.*, 855 F.3d 1367, 1374 (Fed. Cir. 2018) (quoting *Perfect Web Techs. Inc. v. InfoUSA, Inc.*, 587

F.3d 1324, 1326 (Fed. Cir. 2009)). Although here Petitioner has not wholly omitted any reasoned analysis or evidence regarding the claimed *computer control system programmed to automatically plan a cutting region based on image data and then perform that planned laser-cutting of the lens capsule* (and, for some claims, also the lens), this subject matter is not disclosed in any cited art and we find Petitioner's evidence and reasoning as to why it would have been obvious without such disclosure to be largely conclusory and unpersuasive.

The gap in the prior art's teaching is not minor and goes to the core of the claimed invention.

Patent Owner introduces its fundamental position as follows:

> At the time of the invention claimed in U.S. Patent No. 9,474,648 ("'648 patent") (Ex. 1030), no one had contemplated that an ophthalmologist would yield control to a computer system that uses image data to determine anterior capsulotomy scanning patterns and cutting boundaries and then operates a laser to cut those patterns.

Resp. 1. Patent Owner argues that none of Swinger, Baikoff, and Li teaches a control system configured to determine the cutting region (of a lens capsule, e.g., a capsulotomy), which Dr. Izatt (Petitioner's witness) confirmed at deposition. *Id.* at 2 (citing Ex. 2057, 158:15–159:1, 204:8–10, 207:17–208:15), 19–21. Patent Owner argues that Swinger reserves the critical step of identifying the surgical target for the surgeon, that Baikoff does not suggest using OCT imaging to identify (via a controller) any cutting regions of the eye for cataract surgery or otherwise, and that Li does not suggest using any of its disclosed measurements to identify any cutting regions of the eye for cataract surgery. *Id.* at 11–15 (citing, *inter alia*, Ex. 2087 ¶¶ 37–38, 42–43, 45–46, 61, 64; Ex. 2088 ¶¶ 23, 56–59, 63; and also citing Dr. Izatt's deposition testimony cited above at Ex. 2057).

Continuing with this argument, Patent Owner makes the following points, with which we agree:

> [Li] fails to teach the claimed features, which require that the control system determine not just ***tissue*** boundaries, but rather the "anterior capsule incision scanning pattern," "anterior cutting boundary," and "posterior cutting boundary" that define the ***laser treatment***. Alcon's expert Dr. Izatt confirmed that "Li does not disclose a computer controller to determine treatment regions." Ex. 2057, 208:8-15. Li does not suggest configuring the control system to do anything at all with the measurements that it makes. Kang [Ex. 2087] ¶46. To the contrary, Li's suggestion of using measurements to "improve the fitting of AC-IOL" teaches a skilled artisan to ***manually*** use the measurement data. *Id.* Dr. Izatt testified that "in Li, the controller, so to speak, is a human." Ex. 2057, 207:17-208:7; *see also id.*, 207:20-21 (in Li, "the one who identifies the treatment region is the surgeon").

Resp. 16. Patent Owner's point is that none of the asserted prior art actually discloses a computer control system programmed to identify a cutting region for anterior capsule incision (e.g., capsulotomy), which is a limitation that "goes to the core of the invention—a sharp break from conventional wisdom and long standing techniques to control surgery," and that this missing step was not simple or straightforward so as to be simply filled-in by common sense, ordinary creativity, or general knowledge as asserted by Petitioner. *Id.* at 1, 16–17 (citing (including by cross-reference) Ex. 1001 ¶¶ 46, 63–65; Ex. 2088 ¶¶ 69–70, 82–84).

Similarly, Patent Owner also argues that the person of ordinary skill would not have been motivated to combine Swinger, Baikoff, and Li. *Id.* at 2–3, 18–28 (citing, *inter alia*, Ex. 2087 ¶¶ 54, 58–61, 63–65; Ex. 2088

¶¶ 55–59, 66, 70, 82–84; also citing Ex. 2057 (Dr. Izatt deposition as cited above)). Patent Owner argues that there is no evidence that the ordinarily skilled artisan would have wanted to replace Swinger's manual HeNe aiming system and Swinger's surgeon-identification-of-target-tissue step with an automated system reliant on OCT and computer control imaging (ceding control to the computer), as Swinger reserves this critical decision-making for the surgeon. *Id.* at 18–28; *see also* Ex. 2057, 180:6–22 (cited by Patent Owner Resp. 23—Dr. Izatt testified that he did not himself know how to define treatment regions like those claimed, but could have asked a surgeon).

Patent Owner's reasoning includes: (1) OCT was not known to be more accurate than and so improve upon Swinger's direct visualization; (2) even if the asserted prior art taught it was possible to identify eye tissue boundaries with computer imaging, it does not teach how to construct cutting regions with such information or how a computer could be programmed to do this so as to replace a surgeon's analysis or use OCT for other than diagnosis; and (3) OCT imaging was not understood to be up for the task in terms of necessary speed. *Id.* at 19–28 (citing, *inter alia*, Ex. 2006; Ex. 2057, 93:6–12 (Dr. Izatt confirming that Li does not tell whether the computer or humans are more accurate), 171:21–172:17 (confirming that defining a treatment region relative to a tissue boundary is a clinical judgment for a surgeon's "final say as to where the laser energy will be delivered"), 207:17–208:9 (confirming that in Li the "controller" is a human); Ex. 2087 ¶¶ 54, 58–61, 63–65; Ex. 2088 ¶¶ 55–59, 66, 70, 82–84).

As we explain below, we find Patent Owner's arguments persuasive, generally. "The presence or absence of a reasonable expectation of success is . . . a question of fact," and this "requirement refers to the likelihood of success in combining references to meet the limitations of the claimed invention." *Intelligent Bio-Sys.*, 821 F.3d at 1366–67. Based on the record, we conclude that, even if it would have been potentially advantageous to in some way incorporate the use of Baikoff's and Li's OCT imaging and measuring into Swinger's system and method for cataract surgery (for example, to replace the use of ultrasound imaging with OCT), we agree with Patent Owner that, other than the (ultimately) conclusory testimony of its witness Dr. Izatt (*see, e.g.*, Ex. 1001 ¶¶ 132, 135, 145, 149, 152–159, 459–462), there is no persuasive evidence that the person of ordinary skill in the art would have combined these references with the result being a control system configured to (automatically or not) *image* cataractous eye tissue, *identify* the regions thereof (capsule and lens) *to be cut* with a laser, and *then operate* that laser to actually make those cuts based is some part on that imaging. *See* Resp. 17–28.

We credit Dr. Kang's testimony that, as of the invention, the person of ordinary skill in the art would not have relieved the surgeon of responsibility for identifying cutting regions for laser capsulotomy and cataract surgery (as taught by Swinger), and relegated such task to a computer, which subsequently performs the procedure. Ex. 2087 ¶¶ 61–65. Dr. Kang takes issue with Petitioner's positions that Baikoff and Li teach or suggest such reliance on a computer because, according to Dr. Kang, neither Baikoff nor Li (and indisputably not Swinger) teaches using a computer to identify laser cutting regions or to control laser surgery, and, in fact, they suggest reliance on a surgeon to interpret their OCT images to plan a subsequent surgery. *Id.*

¶¶ 57–65; *see also id.* ¶¶ 37–38, 42, 44, 46 (addressing Swinger's, Baikoff's, and Li's shortcomings).

We further credit Dr. Kang's testimony that Petitioner fails to adequately explain, even were the ordinarily skilled artisan intent on combining Baikoff's and Li's OCT imaging systems with Swinger's cataract surgery system, how it would have been accomplished to overcome the "substantial challenges" and achieve the claimed invention. *See* Ex. 2087 ¶¶ 63–66; *see also* Resp. 17–18, 23–24 (addressing Petitioner's lack of explanation as to how to implement the combination).[19] We agree that, beyond merely suggesting plugging one system into another, Petitioner does not explain how the person of ordinary skill in the art would have programmed Swinger's computer control system to use Baikoff's and Li's OCT imaging systems and tissue recognition and measurement algorithms to determine capsulotomy cutting regions and then implement the planned

[19] We recognize Petitioner's reply argument that the '648 patent itself provides little detail on how its computer control system is programmed to use imaging data to plan and perform a cataract surgery, and argues that the prior art should not be held to a higher standard; however, whether the '648 patent's written description is satisfactory is not an issue for determination in this proceeding. Reply 6; *but see In re Epstein*, 32 F.3d 1559, 1568 (Fed. Cir. 1994) (holding "the Board's observation that appellant did not provide the type of detail in his specification that he now argues is necessary in prior art references supports the Board's finding that one skilled in the art would have known how to implement the features of the references."). On the other hand, whether the prior art sufficiently teaches or suggest the claimed subject matter is an issue for our determination and, therefore, we must analyze the prior art in view of the claimed subject matter. Under the circumstances of this case, we find Petitioner's positions require the ordinarily skilled artisan's general knowledge to fill too large a gap in the prior art and are not persuaded by Petitioner's argument.

cutting with a laser, even from a rudimentary perspective. *See* Pet. 32–33. Indeed, Petitioner concedes:

> The ultrasound and OCT imaging systems disclosed by ***Swinger and Baikoff require surgeons to make image measurements manually and input those measurements into a computer system***. *See* Ex.1039 at 35:59–66 (manual ultrasound measurements are "programmed in . . . before beginning the ablation."); Ex.1041 at 2 (discussing use of software to make measurements between ocular tissue). ***Swinger and Baikoff do not expressly teach*** imaging systems with controllers that process image data to determine ocular structures and landmarks ***without manual intervention***.

*Id.* at 32 (emphasis added).

For such, Petitioner turns to Li's disclosure of OCT-based measurement of the anterior tissues of the eye (which, we note, do not include any measurements of the lens capsule or full lens depth), but Petitioner never satisfactorily explains just how the combination would work, beyond again plugging Li's algorithms for identifying tissue boundaries into Swinger's system and proposing that surgeons knew how to plan capsulotomies and a computer control system would be programmed accordingly. *Id.* at 32–33. Petitioner asserts that "it merely requires programming the control system with algorithms that automatically evaluate the image data and identify tissue boundaries, which is within the skill of a POSA" and that such an upgrade to Swinger would be "nothing more than automating a manual activity." *Id.* at 33 (citing Ex. 1001 ¶ 159). We are unpersuaded on these issues.

We find Petitioner's foundational assertions, on balance, to be unsupported by the record. Reviewing Petitioner's witness's, Dr. Izatt's, direct testimony, we note the following (emphasis added):

- "Swinger is silent regarding OCT imaging, let alone using OCT imaging as a diagnostic tool. . . [T]he surgeon ***manually locates the center or apex*** 294 of the anterior lens capsule." Ex. 1001 ¶ 143; *see also id.* ¶ 460.
- "***[A] POSA*** would have been motivated to integrate Baikoff's OCT imaging assembly into Swinger's treatment system in order ***to plan and effect*** laser cataract surgery with improved accuracy." *Id.* ¶ 149 (emphasis added).
- "Baikoff does not explicitly describe imaging a *cataractous* lens." *Id.* ¶ 151.
- But, "Baikoff's OCT assembly could acquire image data and construct images of the cataractous lens. These images would ***enable a user to identify relevant boundaries including anterior and posterior capsules and the nucleus of the lens***. . . . ***A user could then use these images*** and boundaries ***to determine a treatment region***, such as an anterior capsulotomy region, Ex.1039 at 10:10–15, and/or a lens fragmentation region, *id*. at 23:17–25." *Id.* ¶ 154 (emphasis added).
- "Baikoff does not specify whether it is the operator or the OCT assembly itself that initially identifies these [eye anatomy] features." *Id.* ¶¶ 155–156 (from this Dr. Izatt somehow concludes that a controller is or would have been configured to process image data).
- "Li employs a computer algorithm to measure anterior chamber width, depth, and lens vault by automatically identifying boundaries of the cornea, iris, and crystalline lens." *Id.* ¶ 157. We note that Dr. Izatt correctly identifies that Li does not measure lens depth or lens capsule, yet from this, Dr. Izatt concludes that an ordinarily skilled artisan would have programmed software to measure "other [tissue] boundaries." *Id.* ¶¶ 157, 159.

However, when he testifies as to how the Swinger-Baikoff-Li combination teaches using an OCT imaging system so a control system processes acquired images to plan and then guide a laser to perform cataract surgery, Dr. Izatt merely states that the ordinarily skilled artisan would have found it obvious to allow a control system, rather than a surgeon, to do it because it would be "nothing more than moving steps previously performed manually by a surgeon to the controller." *Id.* ¶ 460.

Dr. Izatt's, and Petitioner's, position is that, although Swinger did not contemplate allowing its computer-controlled system to plan a surgery based on computer-imaged data, and then performed that surgery, "once the boundaries of the ocular tissue are identified, treatment regions and scanning patterns could readily be determined based on those boundaries" and "[o]nce the scanning pattern is determined, it naturally follows that the laser and scanning assembly would be operated to follow the scanning pattern." Pet. 39–40; Ex. 1001 ¶¶ 159, 462. Dr. Izatt takes this position in his direct testimony even though he also acknowledges that Baikoff merely "would ***enable a user to identify***" tissue boundaries and, relatedly, that "[a] ***user could then use*** the[] images and boundaries ***to determine a treatment region***," not that a computer could or would be programmed to do so. Ex. 1001 ¶ 154.

Moreover, Dr. Izatt also acknowledges, contrary to his conclusions in direct testimony, that none of Swinger, Baikoff, and Li teaches other than relying upon a *human* to evaluate what tissue will be subjected to treatment (if they address the subject at all). *See* Ex. 2057, 158:19–159:1, 204:8–10, 207:17–208:7. Dr. Izatt testifies:

- In Swinger, it's "quite clear that the human positions the cutting beam." Ex. 2057, 158:19–22.
- Q: "Baikoff does not describe a controller that identifies the treatment regions, right?" A: "No, it does not." *Id.* at 204:8–10.
- Q: "So Li does not disclose a controller that identifies a treatment region for the lens?" A: "Well, in this case, the one who identifies the treatment region is the surgeon." Q: "So in Li, the controller, so to speak, is a human?" A: "Yes." *Id.* at 207:17–208:7.

We also note Dr. Izatt's statement at paragraph 38 of his declaration: "as of the early 2000s, fully automating ophthalmic surgery based on imaging data was still in its infancy. For instance, while many in the field sought to automate aspects of surgery such as the identification of tissue boundaries utilizing various edge detection schemes, and had some successes doing so, these were rudimentary systems and ***none was robust enough to render the surgeon obsolete***." *See* Ex. 1001 ¶ 38 (emphasis added).

Then, when directly addressing the potential for adding Li's tissue-identifying and -measuring algorithm to Swinger and Baikoff to create a controller as claimed, Dr. Izatt states, "POSAs at the time [of the invention] were writing such programs and succeeding, although they were ***not nearly accurate enough to render the surgeon obsolete***. Rather, ***a surgeon would have been critical*** in ***confirming*** the accuracy of the identification s and determinations, and ***adjusting*** the cutting plan accordingly ***before executing*** the procedure." *Id.* ¶ 159 (emphasis added).

Thus, even Petitioner's own witness's statements lead us to conclude that it would have been no simple (or obvious) task to modify Swinger's control system to use an imaging system like Baikoff's or Li's to plan and then conduct incisions in the lens or lens capsule.

The acknowledged criticality of a surgeon's determinations in identifying cutting regions, even in the very prior art asserted by Petitioner or based thereon, means that a controller was not understood to be suitable for the claimed steps (or functionality) directed to imaging, then processing the imaging to plan laser eye surgery, and then perform that surgery. Thus, the evidence supports that it would have been no simple or well-understood or obvious matter to make the combination of Swinger, Baikoff, and Li work like the claimed invention and this supports the non-obviousness of the challenged claims.

*Summary for Grounds 1–3*

For the reasons above, we find that the person of ordinary skill in the art would not have been motivated to combine Swinger, Baikoff, and Li in the manner proposed by Petitioner, with a reasonable expectation of success. We find that the proposed combination of prior art does not teach or suggest

> a control system operably coupled to the laser system and configured to:
>
> > operate the imaging device to generate image data for the patient's crystalline lens;
> >
> > process the image data to determine an anterior capsule incision scanning pattern for scanning a focal zone of the laser beam for performing an anterior capsule incision; and
> >
> > operate the laser and the scanning assembly to scan the focal zone of the laser beam in the anterior capsule incision scanning pattern to perform the anterior capsule incision, wherein positioning of the focal zone is determined in part by the control system based on the image data,

which is required by all claims. Ex. 1030, 17:30–18:61. The added references of Grounds 2 and 3 (Hoppeler and L'Esperance) are nether asserted to nor do we discern them to remedy the above-addressed shortcomings of the three primary references. Therefore, we conclude that no claim would have been obvious under Petitioner's Grounds 1–3. *Mylan Pharms. Inc. v. Research Corp. Techs., Inc.*, 914 F.3d 1366, 1376 (Fed. Cir. 2019) ("Dependent claims, with added limitations, are generally not obvious when their parent claims are not.").

*2. Obviousness of based on Freedman and Swinger (Grounds 4–6)*

Similar to Petitioner's Grounds 1–3, addressed above, although Grounds 5 and 6 add Hoppeler and L'Esperance to the prior art combination of Freedman and Swinger, each of Grounds 4–6 is foundationally reliant upon the combination of Freeman and Swinger as rendering obvious the basic premise of the claimed invention relating to the recited "control system" and its programmed ("configured to") functionality for laser cataract surgery planning and implementation. *See* Pet. 57–71. Here, as above, because the same facts and legal conclusions are determinative for each of Grounds 4–6, we address them as a group. As explained further, we find that Petitioner has not established by a preponderance of the evidence that any challenged claim would have been obvious under these grounds.

*Parties' Positions and our Analysis on Grounds 4–6*

Under Ground 4, Petitioner asserts that claims 1–5 and 12–15 would have been obvious over the combination of Freedman and Swinger. Pet. 56–66 (citing, *inter alia*, Ex. 1001 ¶¶ 162–164, 166–167, 493, 496–498, 500–502; Ex. 1039, 2:46–50, 7:50–8:6, 16:60–20:34, 20:49–21:19, Figs. 6, 15A1, 15B1; Ex. 1040, 1:23–25, 2:7–13, 4:46–50, 5:29–40, 5:49–52, 5:60–67, 6:12–19, 6:66–7:8, 8:30–51, 8:66–9:2, 9:21–26, Figs. 1, 3). First, Petitioner asserts that the ordinarily skilled artisan would have combined Swinger and Freedman and would have had a reasonable expectation of success in doing so. *Id.* 56–57. Then, Petitioner walks through the limitations of these claims and identifies how and where the prior art combination teaches or suggests such subject matter. *Id.* at 57–66. Grounds 5 and 6 foundationally depend on these assertions, although addressing different claims and relying on additional references. *Id.* at 66–69. Because Petitioner's basis for combining Freedman and Swinger is faulty, each of Grounds 4–6 fails.

To summarize Petitioner's position regarding combining Swinger and Freedman, Petitioner asserts that each is directed to laser eye surgery where some of the procedure is computer-controlled; Swinger to cataract (and other) surgery (including radial keratotomy) and Freedman to radial keratotomy (but mentioning other procedures). *Id.* at 56–57. Recognizing Freedman teaches a laser eye surgery system utilizing OCT imaging, but only mentioning cataract surgery as background and not discussing at all anterior capsulotomy (or incising an anterior lens capsule) or the specific parameters of such laser surgery, Petitioner asserts that the ordinarily skilled artisan would look to Swinger, which teaches laser cataract surgery and anterior capsulotomy for laser parameters. *Id*. Petitioner asserts it would amount to mere reprogramming of Freedman's system in view of Swinger's laser parameters to achieve the claimed invention and that the ordinarily skilled artisan would have had a reasonable expectation of success in doing so because the modifications were described by Swinger and predictable. *Id*.

Regarding independent claim 1, Petitioner asserts that most of the limitations, other than how to use the laser, are taught by Freedman. *Id.* at

57–61. For example, for the "laser system comprising a scanning assembly" limitation (limitation 1.1), Petitioner asserts "Freedman's system comprises a laser system (*e.g.*, 52)," which is an "'[a]blating laser . . . to form an incision')"; for the claimed "laser operable to generate a laser beam configured to incise ocular tissue" (limitation 1.2) Petitioner again asserts "Freedman comprises a laser (54) . . . configured to incise ocular tissue"; for the claim limitation requiring "imaging device configured to acquire image data of at least a portion of the lens" (limitation 1.3) Petitioner points to Freedman's imaging device 15, 18, and 66; for the claim limitation of a "control system operably coupled to the laser system and configured to," (limitation 1.4) Petitioner points to "Freedman's control system (48)"; and, finally, regarding the claimed functions for which the control system is configured (limitations 1.5–1.7), that is, operating the OCT to generate image data of a lens, process that data to determine an anterior capsulotomy scanning pattern, and operating the laser to perform that lens capsule incision (e.g., capsulotomy) in part based on the processed image data, Petitioner again points to Freedman's control system 48 and its disclosed operation taught in Freedman (perhaps using Swinger's scanning pattern laser parameters). Pet. 57–61 (citing Ex. 1001 ¶¶ 496–498, 500–502; Ex. 1040, 2:7–9, 4:46–50, 5:29–40, 5:49–52, 5:60–67, 6:12–19, 8:30–51, 8:66–9:2, 9:21–26, Figs. 1, 3); *see also id.* at 64–67 (regarding independent claims 15 and 29). (Swinger is cited only by cross-reference, where the portion of the Petition asserts Swinger teaches laser surgery parameters).

Regarding combining Swinger and Freedman, Patent Owner contends one of ordinary skill in the art would not have sought to combine these prior art references because Freedman "is far afield from the claimed invention," "has nothing to do with cataract surgery," uses "a different type of laser altogether," and "makes no reference to cataracts or the crystalline lens of the eye" (at least in relation to its described invention). Resp. 29 (citing Ex. 1040, 4:9–32, 4:33–45, 5:37–53, 7:15–51, 8:30–9:18; Ex. 2087 ¶¶ 49–52). Patent Owner further argues that "it would be ***impossible*** to perform cataract surgery with Freedman's high-powered laser" because doing so would destroy the cornea in the process. *Id.* at 29–30 (citing Ex. 2087 ¶¶ 49–51; Ex. 2010). We address these issues below.

*Use of an Ablating Laser for Cataract Surgery*

Patent Owner contends the high-energy ablating laser of Freedman (typically from an ultraviolet laser) is absorbed in a thin, superficial layer of corneal tissue, which breaks molecular bonds and ejects the decomposed material. Resp. 29–30 (citing Ex. 2087 ¶ 50). Because these "laser pulses are highly absorbed in whatever tissue they first encounter," Patent Owner contends "Freedman's corneal ablating laser . . . is incompatible with treating internal structures of the eye," as doing so "would first destroy the cornea before reaching the intended target." *Id.* (citing Ex. 2087 ¶¶ 50–51; *see also* Ex. 2087 ¶¶ 74–76 (noting that ablating laser light is absorbed in tissue within less than about ten micrometers, whereas the lens lies a "1,000 times deeper into the eye")).

Upon review of the record, we find Patent Owner's argument persuasive and credit Dr. Kang's testimony that Freedman's ablating laser is incompatible with laser surgery on the lens or lens capsule during cataract surgery. Ex. 2087 ¶¶ 49–51, 72–76. This is because the ablating laser cannot pass through the cornea to reach the lens without destroying the cornea in the process. *Id.* ¶¶ 73, 76. In contrast, lasers used to cut internal tissues of the eye use laser photodisruption. *Id.* ¶ 74. Accordingly, we find that one of ordinary skill in the art would not have used Freedman's system to perform surgery on the lens or lens capsule, as asserted by Petitioner.

Petitioner asserts in its Reply that it never suggested using Freedman's specific ablating laser to perform lens surgery, but rather proposed substituting Freedman's ablating laser with Swinger's femtosecond laser. Reply 15–16 (citing Ex. 1001 ¶ 167; Pet. 56–57). We disagree that this was Petitioner's position in the Petition.

*Inter partes* review must proceed in accordance with the Petition and the arguments set forth therein. *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1356 (2018). "It is of the utmost importance that petitioners in the IPR proceedings adhere to the requirement that the initial petition identify 'with particularity' the 'evidence that supports the ground for the challenge to each claim.'" *Intelligent Bio-Sys.*, 821 F.3d at 1369. Arguments made in a different document, such as an expert's declaration, may not be merely incorporated-by-reference in the Petition (Petitioner does not even go so far). 37 C.F.R. § 42.6(a)(3); *see also General Access Solutions, Ltd. v. Sprint Spectrum L.P.*, 811 F. App'x 654, 658 (Fed. Cir. 2020) (noting that the Board did not abuse its discretion in enforcing its rules under 37 C.F.R. § 42.6(a)(3)) (non-precedential).

The Petition asserts that "when using Freedman's system to perform an anterior capsulotomy (as taught by Swinger), a POSA would have found it obvious to use Freedman's OCT system to image at least part of the lens," that "Freedman's failure to disclose specific parameters for the surgical laser naturally would have driven a POSA to look to other prior art, such as Swinger, that teaches such parameters," and "[a] POSA would have had a reasonable expectation of success in using Swinger's laser parameters in the system disclosed by Freedman because all that is required is a particular laser source and programming to control pulse rate." Pet. 56–57 (this last quoted portion being that for which Dr. Izatt's declaration paragraph 167 is cited).

Regarding the claims' limitations directed to a laser and the control system's configuration for operating a laser to perform an anterior capsulotomy, the Petition asserts "Freedman's system comprises a laser unit (e.g., 52) for incising ocular tissue. Ex. 1040 at 5:37–40 (noting use of '[a]blating laser . . . to form an incision')," and that:

> ***Freedman comprises a laser (54)*** operable to generate a laser beam (58) configured to incise ocular tissue. Ex.1040 at 5:37–40 ("Ablating laser device 52 includes [a] laser generator . . . for applying a laser beam from the laser generator . . . to an ablating target region 60 of the cornea 12 to form an incision.").

and, further, that:

> ***Freedman discloses a control system (48) operably coupled to the laser system (52, 54, and 56)***, and programmed for automatic control of the system. Ex.1040 at Figs. 1, 3, 5:29–36 (discussing function of processor (48) operatively connected to laser and photodetector (46) to construct an image), 6:66–7:8 (same), 8:30–51 (discussing specifics of processor (48) to image target tissue).

and, finally, that:

> When ***using Freedman's system*** to perform an anterior capsulotomy and lens fragmentation, *see* Section XI.D.1, it would have been obvious to a POSA to ***use Freedman's OCT*** imaging system to image the lens. Ex.1001 ¶500. . . .
>
> When ***using Freedman's system*** to perform an anterior capsulotomy, *see* Section XI.D.1, a POSA would have known to ***configure Freedman's controller to process the image data***

> from the lens to ***determine an anterior-capsule-scanning pattern***, as taught by Swinger. Ex.1001 ¶501. [and]
>
> When ***using Freedman's system*** to perform an anterior capsulotomy and lens fragmentation, *see* Section XI.D.1, it would have been obvious to a POSA that the laser would ***scan the laser in the anterior-capsule incision-scanning pattern*** to perform an anterior capsule incision. Ex.1001 ¶502.

Pet. 58–61 (again, Section XI.D.1 of the Petition mentions using Swinger's parameters) (emphasis added). Thus, it is always Freedman's ablating laser that the Petition asserts would have been used for cataract surgery under these grounds; never Swinger's laser.

As noted by Petitioner in Reply, Dr. Izatt testifies that Swinger's laser parameters could be modified and that this would include "substitution of the laser source." *See* Reply 14–15; Ex. 1001 ¶ 167. This argument, however, was not made in the Petition, and arguments may not be incorporated from an expert's declaration wholesale into the Petition. 37 C.F.R. § 42.6(a)(3). This proposed substitution would also conflict with Petitioner's argument that Freedman's ablating laser discloses the limitations of claim 1. *See* Pet. 56–61.

In view of the foregoing, we find that (1) Petitioner's asserted prior art would not have functioned to perform cataract surgery as required by the claims and (2) Petitioner did not argue in the Petition that a person of ordinary skill in the art would have *replaced* Freedman's ablating laser with Swinger's photodisruption femtosecond laser (but only used Swinger's parameters). Petitioner's attempt to change its arguments in the Reply to assert a new combination of elements of the prior art, i.e., the use of Swinger's laser in Freedman's system, is a new argument, which we will not consider. *Intelligent Bio-Sys.*, 821 F.3d at 1369–1370.

*Modification of Freedman to Perform Surgery on the Lens*

Even were Petitioner's mere citation (at Pet. 57) without discussion to Dr. Izatt's declaration paragraph 167, which includes a statement about "simple substitution," sufficient to put Patent Owner on notice that this was Petitioner's actual argument (which we maintain it is not), the issue then presented would be whether Dr. Izatt's statement is correct. Thus, we analyze the record to determine whether one of ordinary skill in the art would have considered a "simple substitution" of Swinger's laser into Freedman's system obvious and so further modified Freedman's systems as necessary to perform the claimed cataract surgery with a reasonable expectation of success.

Freedman discloses laser surgery methods on the cornea of a patient's eye, but does not disclose a system capable of performing surgery on the lens. Pet. 56 (as Petitioner acknowledges, "Freedman does not disclose using the system to perform an anterior capsulotomy, or the specific parameters of the laser system for tissue ablation."); *see also* Resp. 30 (identifying this concession). Petitioner argues, however, that Swinger already discloses a laser surgical system that can perform numerous types of surgeries, including radial keratotomy of the cornea, and, because Freedman is silent on specific laser parameters, it would have been obvious to use Freedman's system to perform cataract surgery, but use Swinger's laser parameters. Pet. 56–57 (citing Ex. 1039, 2:46–50, 7:50–8:6; Ex. 1001 ¶¶ 162–164, 166–167).

The evidence of record demonstrates that modifying an existing corneal surgery system to image and perform surgery on the lens was not the simple task asserted by Petitioner. Multiple statements by Petitioner to the U.S. Patent and Trademark Office support this. Resp. 33–34.

For example, in a patent application filed in November 2009, Petitioner asserted that due to the different depth ranges for the laser's focus, "laser systems designed for corneal procedures do not offer solution[s] for the considerable challenges of performing surgery on the lens of the eye." Ex. 2007, 4:65–67, 5:30–36, code (22); *see* Resp. 34. Similarly, in another patent filed in December 2008, Petitioner outlined the various challenges in developing laser surgery systems for creating incisions in the lens, including the difficulty in focusing a laser beam that propagates through regions of the eye with different optical properties and different curvatures. Ex. 2014, 15:53–16:18, code (22); Resp. 33–34. This patent then states:

> Because of all the described hard challenges, corneal surgical laser systems are qualitatively simpler than lens surgical lasers. This is well supported by the fact that even though corneal surgical systems were suggested about 40 years ago, none have been adapted successfully for lens surgery to date.

Ex. 2014, 16:13–18.

During prosecution of yet another patent filed in September 2008, and in office action responses filed in 2012 and 2013, Petitioner argued that a corneal OCT system "simply will not work" on the lens and that it would not have been obvious to modify such an OCT system to image the lens. Ex. 2015, 898, 1591, 1788; Resp. 38. This was because OCT systems designed to image the lens would be required to deliver and scan an imaging beam "to a depth ten times bigger and a depth range ten times bigger" than an OCT system designed to image the cornea. Ex. 2015, 1591. According to Petitioner, "it is not obvious" to modify an OCT imaging system to achieve a depth and scanning range that is ten times larger than that disclosed in the art. *Id.* at 898 ("Increasing a system's performance by an order of magnitude cannot be regarded as obvious."), 1590–1591.

Petitioner's arguments presented in prosecuting its own patents directed to similar technology to that at issue here are probative of the difficulties in adapting the optics of a laser surgery system designed to image and create incision in the cornea to allow for imaging and incisions in the lens.[20] Indeed, Petitioner's above-noted statements demonstrate that the challenges facing the ordinarily skilled artisan in modifying Freedman's systems were "considerable," "hard," and were considered unsolved for over 40 years.

The Petition does not address the design differences between corneal and lens surgery systems, or the considerable design issues that would face one of ordinary skill in the art when seeking to modify Freedman's corneal surgery system to image and perform surgery on the lens. Ex. 2013, 43 (noting that there are "several important differences between corneal and

[20] Petitioner contends its "past prosecution statements regarding the differences between corneal and cataract lasers and the implementation challenges of adapting corneal lasers for cataract surgery . . . have no bearing" here. Reply 15. We find, however, that Petitioner's understanding of the knowledge of an ordinarily skilled artisan provided outside the context of litigation and under a duty of candor is probative, regardless of whether the Examiner required additional claim amendments before allowing the claims. *See Springs Window Fashions LP v. Novo Indus., L.P.*, 323 F.3d 989, 995 (Fed. Cir. 2003) (noting for purposes of prosecution disclaimer (not at issue here) that "it is not surprising that an examiner would not be satisfied with the applicant's insistence that particular claim language distinguishes a prior art reference, but that a court would later hold the patentee to the distinction he pressed during prosecution").

cataract laser surgical systems"); Ex. 2014, 15:53–58 ("There are crucial differences between lens surgery and corneal surgery"); *see also* Sur-Reply 14–15 (addressing this evidence). Absent some persuasive explanation in *the Petition* as to how the optics of Freedman would have been successfully modified for lens rather than corneal surgery, and how Freedman's OCT system would be modified for imaging of the lens rather than the cornea, we agree with Patent Owner that Petitioner has not explained sufficiently why one of ordinary skill in the art would go to the significant effort to modify Freedman's system for lens surgery or had a reasonable expectation of success doing so. This would constitute overcoming design limitations that Petitioner asserted in its own patents had not been successfully solved in 40 years and that Petitioner asserted would have been non-obvious.[21] Ex. 2014, 16:13–18; Ex. 2015, 898 ("Increasing a system's performance by an order of magnitude cannot be regarded as obvious.").

*Summary for Grounds 4–6*

In view of the foregoing, we determine that Petitioner fails to sufficiently explain that one of ordinary skill in the art would have combined Freedman and Swinger to achieve the claimed invention with a reasonable

[21] Petitioner asserts that Swinger discloses a system for cataract surgery (on the lens capsule and lens). Pet. 56–57. Petitioner does not assert, however, that Swinger explains how to modify an existing corneal surgery system to also perform surgery on the lens. Nor does the Petition assert under Grounds 4–6 that Swinger would have been used by the ordinarily skilled artisan to perform the claimed optical scanning and laser procedure. *Id.* at 56–61. Moreover, Swinger issued in 1994, more than 10 years before Petitioner made its assertion that for over 40 years no corneal surgical systems had been successfully adapted for surgery on the lens, meaning that Swinger was not then considered a solution to such issues. Ex. 2014, 16:13–18; Ex. 1039, code (22).

expectation of success. Thus, Petitioner fails to demonstrate by a preponderance of the evidence that any of the claims challenged under Grounds 4–6 would have been obvious over Freedman and Swinger whether or not also combining Hoppeler or L'Esperance.

## F. OBJECTIVE INDICIA OF NON-OBVIOUSNESS

Objective indicia of non-obviousness, sometimes called "secondary considerations," guard against hindsight reasoning in an obviousness analysis, and are often "the most probative and cogent evidence in the record." *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1328 (Fed. Cir. 2016) (citations omitted). As stated by our reviewing court, evidence of objective indicia of non-obviousness is to be considered when analyzing the issue of obviousness. *KSR*, 550 U.S. at 406.

Patent Owner contends that the evidence of record indicates that the claimed invention achieved substantial commercial success, received praise in the art, and succeeded in providing a laser cataract system where others had tried and failed. Resp. 46–54. According to Patent Owner, "[t]he success of the '648 patent's invention in the face of previous failures, coupled with garnering significant industry praise and commercial success, serves as a check against [Petitioner's] hindsight bias and provides real world evidence that the invention was not obvious." *Id*. at 54.

Because we determine that Petitioner has not demonstrated by a preponderance of the evidence that any challenged claim of the '648 patent would have been obvious over the recited prior art, we need not analyze Patent Owner's arguments addressing objective indicia of non-obviousness.

## III. PETITIONER'S MOTION TO EXCLUDE

Petitioner moves to exclude Exhibits 2002, 2029, 2030, 2032, 2035–2044, 2048, 2051, 2054–2056, 2058–2068, 2071–2077, 2080–2085, 2087, 2089, and 2091–2094. Mot. 1–2. Petitioner contends that these exhibits should be excluded because they are either irrelevant and unduly prejudicial, not cited in the Patent Owner's Response or Sur-Reply, or constitute unreliable validity opinions. *Id.*

### A. EVIDENCE CONCERNING OBJECTIVE INDICIA OF NON-OBVIOUSNESS

Petitioner contends that Exhibits 2029, 2030, 2032, 2035–2044, 2051, 2054, 2055, 2058, 2060–2068, 2071–2073, 2075, 2076, and 2089 should be excluded because they "are unsupported by any showing of nexus, and therefore" are irrelevant. Mot. 2–9.

As, under the circumstances, we were not required to and did not consider Patent Owner's arguments or evidence concerning objective indicia of non-obviousness in rendering our Decision on unpatentability, Petitioner's Motion to exclude these exhibits is moot and is *dismissed*.

### B. UNCITED EXHIBITS

Petitioner contends that Exhibits 2029, 2038, 2039, 2048, 2056, 2059, 2071–2077, 2080–2085, and 2091–2094 should be excluded because they are not cited in Patent Owner's Response or Sur-Reply. Mot. 9–14. In its opposition to the motion to exclude, Patent Owner has withdrawn Exhibits 2059 and 2091–2094, as these exhibits are not cited in any paper in this case. Opp. 9 n.2. Thus, as to these exhibits, Petitioner's Motion is *granted*.

With respect to Exhibits 2029, 2038, 2039, 2048, 2056, 2071–2077, and 2080–2085, Patent Owner contends that these exhibits were all cited in either Dr. Kang's (Ex. 2087) or Dr. Walter's (Ex. 2088) supplemental declarations and should not be excluded. *Id.* at 9.

Petitioner argues in its respective reply that these remaining exhibits are irrelevant because they are not cited in Patent Owner's papers. Opp. Reply 4.

Here, Dr. Kang and Dr. Walters rely on the identified exhibits to support their opinions. As such, they are relevant to understanding the weight to be given the declarants' testimony. Accordingly, we decline to exclude Exhibits 2029, 2038, 2039, 2048, 2056, 2071–2077, and 2080–2085 and respectively *deny* Petitioner's Motion.

C. DR. KANG'S TESTIMONY

Petitioner contends that Dr. Kang's testimony (Exhibits 2002 and 2087) should be excluded because he applies an incorrect standard for obviousness. Mot. 9–14. To support this argument, Petitioner points to various testimony from Dr. Kang that Petitioner asserts conflicts with Supreme Court and Federal Circuit precedent regarding the standard for obviousness. *Id.* at 10–11.

Patent Owner argues in its opposition that Petitioner's motion "does not address the substance of Dr. Kang's Declarations themselves, but instead rests on a handful of cherry-picked deposition answers from a 261-page transcript." Opp. 11. According to Patent Owner, Dr. Kang's declarations provide a detailed discussion of the legal standards that he applied, including the law related to obviousness, and he confirmed at his deposition that those were the standards that he applied in his Declarations. *Id.* (citing Ex. 2002 ¶¶ 7–18; Ex. 2087 ¶¶ 8–21; Ex. 1120, 250:12–252:21). Patent Owner further argues that Dr. Kang's declarations provide the facts necessary for the Board to make obviousness determinations and, therefore, Dr. Kang's deposition responses to questions about patent law are irrelevant. *Id.* at 13.

The vast majority of Dr. Kang's declaration testimony relates to what is or is not disclosed in the prior art, the knowledge of one of ordinary skill in the art in the relevant time period, and the challenges faced by one of ordinary skill in the art when adapting various systems for surgery on the lens of an eye. This testimony is relevant to the parties' obviousness dispute and we find it should not be excluded and respectively *deny* the motion as to these exhibits.

To the extent Dr. Kang renders any legal conclusions regarding whether a particular claim would have been obvious to one of ordinary skill in the art, we will consider the factual support provided by Dr. Kang in his declarations in view of the applicable law of obviousness. And, as there is no concern in *inter partes* review proceedings in confusing a jury, exclusion of Dr. Kang's testimony is unnecessary; the Board is capable of determining whether Dr. Kang's testimony is relevant and helpful under the applicable law of obviousness. Thus, we *deny* Petitioner's Motion as to Exhibits 2002 and 2087.

D. SUMMARY ON PETITIONER'S MOTION TO EXCLUDE

In view of the foregoing, Petitioner's Motion to Exclude is *granted* with respect to Exhibits 2059 and 2091–2094, is *dismissed* with respect to Exhibits 2029, 2030, 2032, 2035–2044, 2051, 2054, 2055, 2058, 2060–2068, 2071–2073, 2075, 2076, and 2089, and, recognizing there is some overlap among the aforementioned dismissals and certain of the following denials, is *denied* with respect to Exhibits 2002, 2029, 2038, 2039, 2048, 2056, 2071–2077, 2080–2085, and 2087.

## IV. CONCLUSION

Petitioner does not establish by a preponderance of the evidence that claims 1–15 of the ’648 patent would have been obvious over the asserted prior art, as discussed above. Therefore, we do not find any challenged claim unpatentable.

Our final decision is summarized as follows:

| Claims | 35 U.S.C. § | References/ Basis | Claims Shown Unpatentable | Claims Not Shown Unpatentable |
|---|---|---|---|---|
| 1–5, 12–15 | 103 | Swinger, Baikoff, Li | | 1–5, 12–15 |
| 6–9 | 103 | Swinger, Baikoff, Li, Hoppeler | | 6–9 |
| 10, 11 | 103 | Swinger, Baikoff, Li, L’Esperance | | 10, 11 |
| 1–5, 12–15 | 103 | Freedman, Swinger | | 1–5, 12–15 |
| 6–9 | 103 | Freedman, Swinger, Hoppeler | | 6–9 |
| 10, 11 | 103 | Freedman, Swinger, L’Esperance | | 10, 11 |
| **Overall Outcome** | | | | 1–15 |

Further, Petitioner’s Motion to Exclude is *granted* with respect to Exhibits 2059 and 2091–2094, is *dismissed* with respect to Exhibits 2029, 2030, 2032, 2035–2044, 2051, 2054, 2055, 2058, 2060–2068, 2071–2073, 2075, 2076, and 2089, and, recognizing there is some overlap with the aforementioned dismissals, is *denied* with respect to Exhibits 2002, 2029, 2038, 2039, 2048, 2056, 2071–2077, 2080–2085, and 2087.

## V. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that Petitioner has not proved by a preponderance of the evidence that claims 1–15 of the ’648 patent are unpatentable;

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

FURTHER ORDERED that Petitioner’s Motion to Exclude is *granted* with respect to Exhibits 2059 and 2091–2094, is *dismissed* with respect to Exhibits 2029, 2030, 2032, 2035–2044, 2051, 2054, 2055, 2058, 2060–2068, 2071–2073, 2075, 2076, and 2089, and is *denied* with respect to Exhibits 2002, 2029, 2038, 2039, 2048, 2056, 2071–2077, 2080–2085, and 2087.

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