

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

AMO DEVELOPMENT, LLC,
Patent Owner.

IPR2021-00856
Patent 8,500,724 B2

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

FLAX, *Administrative Patent Judge*.

JUDGMENT

Final Written Decision

Determining Some 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

AMO Development, LLC (“Patent Owner”) is the owner of U.S. Patent 8,500,724 (Ex. 1012, “the ’724 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 and 17–23 of the ’724 patent.¹ Paper 1 (“Pet.”). We instituted trial on December 9, 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 29, “Reply”), to which Patent Owner filed a Sur-Reply (Paper 35, “Sur-Reply”).²

A final hearing was conducted on September 8, 2022, where the parties presented oral argument in support of their positions in this and the following related proceedings: IPR2021-00841 (Patent 9,474,648 B2), IPR2021-00853 (Patent 9,125,725 B2), IPR2021-00858 (Patent 8,425,497 B2), and IPR2021-00862 (Patent 8,709,001 B2). *See* Paper 47 (“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, 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).

¹ Claim 16 is not challenged in this proceeding.

² To the extent such is relevant, Patent Owner also initially responded to the Petition by filing a Preliminary Response (Paper 10, “Prelim. Resp.”).

After considering the parties' arguments and supporting evidence, we conclude that Petitioner has met its burden to prove claims 1–15 are unpatentable over the asserted prior art, but has not met its burden to prove that claims 17–23 are unpatentable over the asserted prior art. *Id.*

Petitioner also filed a Motion to Exclude certain of Patent Owner's evidence. Papers 37 and 38 (respectively, the sealed and redacted public versions; "Motion" or "Mot."). Patent Owner opposed this motion (Paper 39 ("Opposition" or "Opp.")) and Petitioner filed a Reply to Patent Owner's Opposition (Paper 44 ("Opp. Reply")). For reasons discussed herein, the Motion is *granted-in-part, dismissed in-part, and denied-in-part*.

A. 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.

B. RELATED MATTERS

Regarding related matters, Petitioner states:

Patent Owner has asserted the '724 [patent] 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 '724 [patent], 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);

8,709,001 (IPR2021-00862); 9,095,415 (IPR2021-00835);
9,101,448 (IPR2021-00839); 9,107,732 (IPR2021-00840);
9,125,725 (IPR2021-00853); 9,474,648 (IPR2021-00841);
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 a related matter. Paper 5, 1.

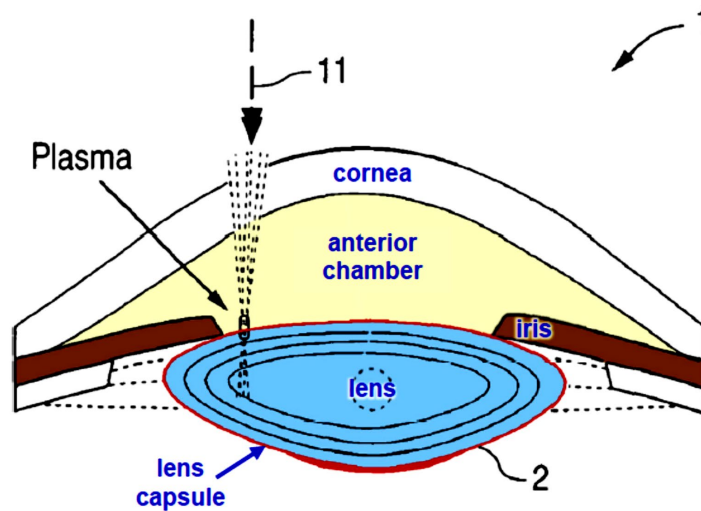
C. THE '724 PATENT

The '724 patent issued on August 6, 2013, from U.S. Application
13/072,646, which was filed on March 25, 2011. Ex. 1012, codes (45), (21),
(22). The '724 patent ultimately claims priority to U.S. Provisional
60/643,056, filed on January 10, 2005. *Id.* at code (60), 1:9–15. There is no
dispute that the '724 patent is entitled to priority to this provisional
application. *See, e.g.*, Pet. 1, 4 n.2.

The '724 patent's Abstract indicates its invention is directed to a
System and method for making incisions in eye tissue at
different depths. The system and method focuses light,
possibly in a pattern, at various focal points which are at
various depths within the eye tissue. A segmented lens can be
used to create multiple focal points simultaneously. Optimal
incisions can be achieved by sequentially or simultaneously
focusing lights at different depths, creating an expanded column
of plasma, and creating a beam with an elongated waist.

Id. at Abstract.

To provide context regarding the claimed method for cataract surgery,
the '724 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. Walter, annotates to explain the anatomy:

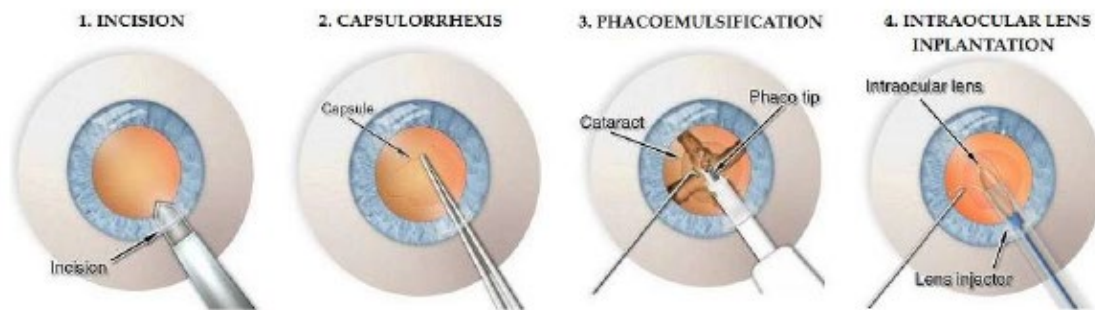


The '724 patent states that “FIG. 2 is a diagram of the anterior chamber of the eye and the laser beam producing plasma at the focal point on the lens capsule,” and Dr. Walter has annotated the figure with (blue) text and coloring to identify, from most-anterior to most-posterior (from top-to-bottom in the image), the eye’s cornea, anterior chamber (colored yellow), iris (colored brown), lens (colored blue), and lens capsule (colored red). *Id.* at 5:27–29; Ex. 2004 ¶ 8; *see also* Resp. 4 (reproducing this same image). Figure 2 also shows optical beam 11 impinging upon eye tissue 2. Ex. 1012, 6:16–60. The '724 patent states, “[a]s can be seen in FIG. 2, the capsule boundaries and thickness, the cortex, epinucleus and nucleus are determinable.” *Id.* at 8:22–24.

As background, the '724 patent describes cataract extraction surgery as “one of the most commonly performed surgical procedures in the world,” and describes the procedure as commencing with the early and critical step of capsulorhexis or capsulotomy (the same or similar techniques), where a needle perforates the anterior lens capsule 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 1:24–2:2.

Although not a part of the '724 patent, Petitioner's witness in this proceeding explains 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. 1012, 1:33–45. 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. 1012, 1:62–66. Third, the eye's lens is broken apart, typically by ultrasonic phacoemulsification, and removed. Ex. 1001 ¶ 25; Ex. 1012, 1:33–39. Finally, an IOL is implanted in the lens capsule. Ex. 1001 ¶ 25; Ex. 1012, 1:39–45.

As further background, the '724 patent describes that neodymium YAG lasers have been implemented in cataract surgery to non-invasively clear remnant epithelial cells, which were thought to cause post-surgery complications. *Id.* at 2:59–67. The '724 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 3:5–7.

The ’724 patent illustrates a system for use according to the claims, for example, at Figure 12, which we reproduce below:

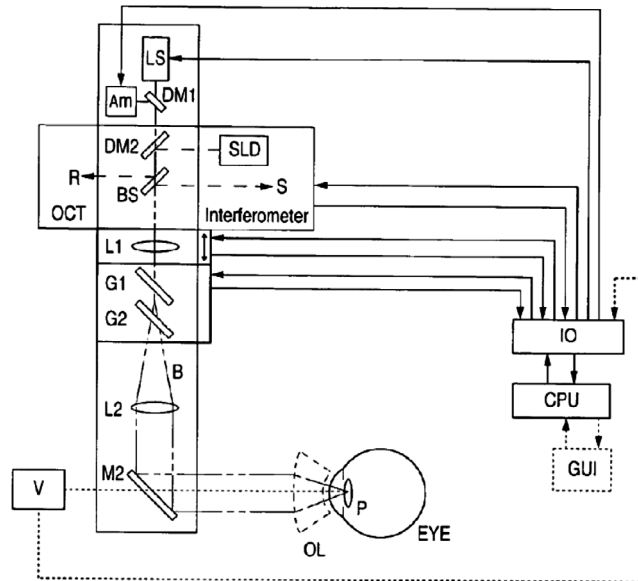


FIG. 12

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 5:56–57, 11:1–12:54. 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.* Also shown is visualization apparatus V. *Id.* The ’724 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 12:2–7.

The ’724 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 6:49–52.

The ’724 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 7:48–60. The ’724 patent 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 10:39–67.

The '724 patent describes two related embodiments illustrated by its Figures 14 and 15, which are reproduced side-by-side below:

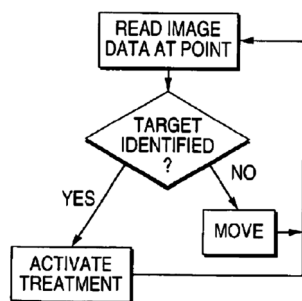


FIG. 14

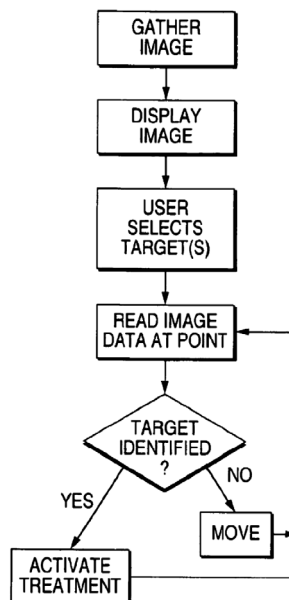


FIG. 15

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 '724 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 13:3–29. The '724 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 13:42–67. But, as noted above with reference to Figure 14, the '724 patent also

describes it to be an alternative and modified embodiment that incorporates such user input. *Id.* at 13:12–23.

The claims of the '724 patent are directed to a method for laser cataract surgery that protects the retina of the eye from laser exposure, and the '724 patent describes that this is achieved by a “bottom up,” posterior-to-anterior, treatment technique. *See id.* at 8:51–9:7. The '724 patent states:

Not only does this “bottom up” treatment technique reduce unwanted beam attenuation in tissue above the target tissue layer, but it also helps protect tissue underneath the target tissue layer. By scattering the laser radiation transmitted beyond the focal point on gas bubbles, cracks and/or tissue fragments which were produced by the previous scans, these defects help protect the underlying retina. Similarly, when segmenting a lens, the laser can be focused on the most posterior portion of the lens and then moved more anteriorly as the procedure continues.

Id. at 8:64–9:7. The '724 patent also describes controlling the radiant exposure of the eye tissue to the treatment laser, stating:

To avoid retinal damage due to explosive vaporization of melanosomes following absorption of the short laser pulse the laser radiant exposure on the RPE should not exceed 100 mJ/cm². Thus NA of the focusing optics should be adjusted such that laser radiant exposure on the retina will not exceed this safety limit. With a pulse energy of 10 μJ, the spot size on retina should be larger than 0.1 mm in diameter, and with a 1 mJ pulse it should not be smaller than 1 mm. Assuming a distance of 20 mm between lens and retina, these values correspond to minimum numerical apertures of 0.0025 and 0.025, respectively.

To avoid thermal damage to the retina due to heat accumulation during the lens fragmentation the laser irradiance on the retina should not exceed the thermal safety limit for near-IR radiation—on the order of 0.6 W/cm². With a retinal zone of about 10 mm in diameter (8 mm pattern size on a

lens+1 mm on the edges due to divergence) it corresponds to total power of 0.5 W on the retina.

Id. at 15:4–21.

The '724 patent concludes with 23 claims, of which claims 1, 16 (not challenged), 17, and 19 are independent claims. Ex. 1012, 16:47–19:16. Claims 1 and 17 are representative of the challenged claims and are reproduced below with sub-numbering, as added for convenience by Petitioner (*see, e.g.*, Ex. 1013; Pet. 37–43, 49–51):

[1P] 1. A method for laser cataract surgery that protects the retina of the eye from laser exposure, comprising:

[1.1] a. generating, using a computer, an image of at least a portion of a crystalline lens of the eye based on detecting remitted light from locations distributed throughout a volume of the crystalline lens;

[1.2] b. processing data including the image data so as to determine a targeted treatment region in the lens of the eye, wherein the targeted treatment region comprises an axially-elongated cutting zone transecting the anterior capsule and does not transect the posterior capsule of the lens;

[1.3] c. directing a laser beam, under computer guided control, in a first pattern to photodisrupt at least a portion of lens tissue of the eye to create a light scattering region; and

[1.4] d. subsequently directing the laser beam, under computer guided control, in a second pattern in lens tissue anterior to the light scattering region so as to photodisrupt at least a portion of the targeted region, thereby effecting patterned laser cutting of lens tissue for subsequent removal of pieces or segments of lens tissue.

* * *

[17P] 17. A method for laser cataract surgery that protects the retina of the eye from laser exposure, comprising:

[17.1] a. operating an optical coherence tomography imaging system, controlled by a computer system, so as to

acquire image data from locations distributed throughout a volume of a crystalline lens of a patient;

[17.2] b. processing data including image data, using the computer system, so as to construct a targeted treatment region of the lens of the eye, the targeted treatment region being disposed anterior to the posterior capsule of the lens; and

[17.3] c. generating a beam of light using a pulsed laser system, wherein the pulsed laser system is guided by the computer system so as to effect fragmentation of lens tissue of the targeted treatment region in a fragmentation pattern within the targeted treatment region, the fragmentation comprising:

[17.4] i. directing a laser beam in a first pattern to photodisrupt at least a portion of lens tissue of the eye to create a light scattering region; and

[17.5] ii. subsequently directing the laser beam in a second pattern in lens tissue anterior to the light scattering region so as to photodisrupt at least a portion of the targeted region and effect 3-Dimensional patterned laser cutting of the lens tissue for subsequent removal.

Ex. 1012, 16:47–67, 18:15–39. The '724 patent's claims 2–15, 18, and 20–23 depend, directly or indirectly, from independent claims 1, 17, and 19. *Id.* at 17:1–19:16.

D. ASSERTED GROUNDS FOR UNPATENTABILITY

Petitioner asserts the following grounds for the unpatentability of claims 1–15 and 17–23 of the ’724 patent:

Ground	Claims Challenged	35 U.S.C. § ³	Reference(s)/Basis
1	1–15, 17–23	103	Swinger, ⁴ Baikoff, ⁵ Hoppeler ⁶
2	1–15, 17–23	103	Freedman, ⁷ Swinger, Hoppeler

See Pet. 5.

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* (describing these witnesses’ backgrounds, qualifications, and considered materials) Ex. 1001 ¶¶ 4–15, 25–38, 45–51;

³ The ’724 patent has an uncontested January 10, 2005 priority date, 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.

⁴ US 6,325,792 B1, issued Dec. 4, 2001 (Ex. 1039, “Swinger”).

⁵ 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”).

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

⁷ US 6,454,761 B1, issued Sept. 24, 2002 (Ex. 1040, “Freedman”).

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.

II. DISCUSSION

A. LEVEL OF ORDINARY SKILL IN THE ART

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

Petitioner 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. 27 (we note, Petitioner cites no evidence in support of this proposed definition, but Dr. Izatt testifies similarly at Ex. 1001 ¶¶ 49–50).⁸

Patent Owner disagrees and asserts that “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.” Resp. 9–11 (citing Ex. 2087 ¶¶ 30–32).

⁸ The parties use “POSA” to refer to the person of ordinary skill in the art.

As we explained in our Institution Decision (DI 20–22), 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 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. 1012 (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. 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 '724 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.

To the extent the actual experience or education of witnesses in this case do not perfectly reflect the ordinary level of skill in the art, we take such into consideration when weighing their testimony, as necessary.

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)).

1. Independent claims’ preambles

Patent Owner asserts that the preambles of claims 1, 17, and 19 are limiting because they are method claims where each preamble identifies that

the method's purpose is "to 'protect[] the retina of the eye from laser exposure.'" Resp. 15. Patent Owner cites *Eli Lilly & Co. v. Teva Pharmaceuticals International GmbH*, 8 F.4th 1331, 1340–41 (Fed. Cir. 2021), as supporting that statements of intended purpose for method claims are generally construed to be limiting. *Id.* Again citing *Eli Lilly* (at 1342–43), Patent Owner also argues that "the preamble[s] [are] limiting because [each] provides the 'metric by which one practicing the claim could determine' whether the claimed 'first pattern' successfully creates a 'light scattering region.'" *Id.* at 16.

Petitioner did not initially ask that this claim language be construed. *See* Pet. 6–7. But, even in its Reply, Petitioner does not oppose Patent Owner's general position that the independent claims' preambles are limiting, and appears to accept that the preambles are limiting. Reply 3–4.

As it is uncontested, and also generally adopted by Petitioner in its Reply, we adopt as our own Patent Owner's proposed construction that the preambles of independent claims 1, 17, and 19 are limiting.

2. "light scattering region"

Patent Owner also argues that the claim term "light scattering region," which appears in claims 1–3, 16, 17, and 19, should be construed to mean "a region that scatters laser radiation that would otherwise reach the retina."

Resp. 17. Patent Owner asserts that, within the context of the '724 patent, this term refers to a feature that

interacts with excess laser radiation generated during lens fragmentation or segmentation, and absorbs and redirects it so it does not reach the retina. [Ex. 2087 ¶ 105]. The "light scattering region" must do more than just scatter light in the abstract since *all* human tissue scatters light. *Id.* Concluding

otherwise improperly renders “light scattering” superfluous and reduces the claim language to just a “region.” *See id.*

Resp. 17.

Petitioner did not initially request that this claim language be construed, but opposes Patent Owner’s proposed construction. Pet. 6–7;

Reply 3–6. Petitioner argues

the specification states that *any* “‘bottom up’ treatment technique . . . helps protect tissue underneath the target tissue layer” by “scattering the laser . . . on gas bubbles, cracks and/or tissue fragments which were produced by the previous scans, [which] help protect the underlying retina.” Ex.1012, 8:64-9:4. This includes “circular pattern[s]” like the anterior capsulotomy pattern in Figure 5. Ex.1012, 8:47-9:4.

Reply 3–4. Petitioner’s point is that the claim language “light scattering region” should not be interpreted to exclude an anterior capsulotomy scanning pattern as all the claims require is a first pattern that creates the light scattering pattern and a second pattern anterior to that first pattern to photodisrupt a portion of the targeted region. *Id.* at 4.

We generally agree with Petitioner’s position, even if not the ultimate point it attempts to make regarding anterior capsulotomies. We find the claim term “light scattering region” would have been understood from its plain language by the ordinarily skilled artisan as of the invention, particularly in view of the Specification, which clearly and succinctly describes light scattering. The ’724 patent discusses such light scattering as “attenuation” of laser beam radiation. *Id.* at 8:64–9:7. As explained in the ’724 patent itself, this disputed claim term refers to a region (as claimed) for scattering, or attenuating, the laser beam, and nothing more need be added to fully understand the language.

Therefore, we decline to read additional limitations into the claim language in the fashion proposed by Patent Owner.

3. *“wherein the targeted treatment region comprises an axially-elongated cutting zone transecting the anterior capsule”*

Petitioner asserts that the claim language “wherein the targeted treatment region comprises an axially-elongated cutting zone transecting the anterior capsule,” which is recited in claim 1, is difficult to understand because the cutting zone is defined to be at the anterior capsule, but claim 1 also defines the targeted treatment region as being in the lens of the eye.

Pet. 6. Petitioner states that “[t]o the extent ‘wherein the targeted treatment region comprises an axially-elongated cutting zone transecting the anterior capsule’ can be understood, it should be construed as requiring determination of an anterior capsulotomy cutting region.” *Id.* at 6–7.

Patent Owner does not ask that this claim language be expressly construed or contest Petitioner’s proposed interpretation. *See* Resp. 15–17.

Although uncontested, we do not adopt Petitioner’s proposed construction of “wherein the targeted treatment region comprises an axially-elongated cutting zone transecting the anterior capsule,” and instead accord this claim language its ordinary meaning as it would have been understood by the ordinarily skilled artisan as of the invention. We find this claim language would have been readily understandable on its face, particularly in view of the ’724 patent’s written description.

The portion of the contested claim language “targeted treatment region” refers to the parts of the eye to be potentially laser-cut; the entirety of the ’724 patent and the claim preambles make clear that the method is directed to cataract surgery and the claim language itself is clear that this *target treatment region is in the lens*. *See, e.g.,* Ex. 1012, Abstract, 3:12–14,

8:47–10:9, 16:17–48. The following claim language is also readily understandable and “an axially-elongated cutting zone transecting the anterior capsule” on its face, and in view of the Specification, refers to a zone for potential laser-cutting extending axially into the eye tissue that transects (cuts across) the anterior capsule, which is adjacent the lens (the claim also requires the cutting zone cannot transect the posterior lens capsule). *See id.* at 8:47–53, 9:8–13, Figs. 5, 6.

Regarding Petitioner’s proposal, which adds as a requirement for this claimed step the determining of *an anterior capsulotomy* cutting region, we find this proposal unpersuasive. Both parties’ experts agree (and the record supports) that an anterior capsulotomy is a procedure (part of cataract surgery) to cut and open the anterior lens capsule, not necessarily cutting the lens; and the anterior lens capsule is anterior to the lens itself. Ex. 1001 ¶ 25; Ex. 1123 ¶¶ 22, 24; Ex. 2088 ¶¶ 14–18, 25–28; *see also* Ex. 1012, 3:11–66, 8:20–50 (describing eye anatomy, its imaging, and anterior capsulotomy and lens fragmentation), Fig. 2; Ex. 1039, 34:30–51 (explaining anterior capsulotomy); *see also supra* Section I.C. reproducing and discussing Fig. 2. Thus, we find no reason to add such a limitation to the claim language.

Claim 1, considered as a whole, requires, *inter alia*, (1) determining a targeted treatment region *in the lens* of the eye that transects the anterior capsule; (2) laser cutting a first pattern *in the lens* of the eye to create a light scattering region; and (3) then laser cutting a second pattern *in the lens* anterior to that light scattering region created by the first pattern so lens pieces/segments can then be removed. Ex. 1012, 16:47–67 (we paraphrase the claim limitations). This claimed process is very clearly directed to laser

cutting in *the lens*, and no cutting of the lens capsule is required by the independent claims. It would make little sense for the claims to require a cutting region to be determined for an *anterior capsulotomy* procedure in the anterior lens capsule in view of the other claimed steps of laser-photodisrupting in *the lens* in a first pattern and then laser-photodisrupting in *the lens* in a second pattern *anterior to the first*, which would all be posterior to the anterior lens capsule.

Nothing in the independent claims refers to anterior capsulotomy. Only dependent claims 18 and 23 recite anterior capsulotomy. Had such been intended to be required by the independent claims, the Patent Owner clearly understood how to express it in claim language. There is a presumption that the independent claims should not be construed as requiring a limitation added by dependent claims. *Curtiss-Wright Flow Control Corp. v. Velan, Inc.*, 438 F.3d 1374, 1380 (Fed. Cir. 2006).

Even Petitioner's own argument for its proposed construction concedes that the claims "do[] not require performing an anterior capsulotomy," making construing the claims to require determining an anterior capsulotomy unreasonable. Pet. 6. We agree with this concession and, therefore, decline to read such an unrecited limitation into the claims in the fashion proposed by Petitioner.

4. "*planar pattern*" / "*planar incision pattern*"

Petitioner asserts that the similar claim terms "planar pattern" and "planar incision pattern," which appear in claims 4, 19, 20, and 21, should be construed to mean "any pattern at a single defined depth" because these various claims define such a pattern in different ways, e.g., intersecting lines

(claim 20), circular lines (claim 21), which may be at different respective depths. Pet. 7.

Patent Owner does not ask that this claim language be expressly construed or contest Petitioner's proposed interpretation. *See* Resp. 15–17.

As it is uncontested and because we find it generally supported by the intrinsic record (Ex. 1012, 5:51–53, 9:45–67, Figs. 5, 9B, 10A–10C), we adopt as our own Petitioner's proposed construction of “planar pattern” and “planar incision pattern.”

C. APPLICABLE LEGAL STANDARDS FOR PATENTABILITY

“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 of persuasion 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;⁹ and (4) considering objective evidence indicating obviousness or non-obviousness. *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 ordinarily skilled artisan, we address Petitioner’s challenges below.

D. 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), (22). There is no dispute that Swinger is prior art. *See generally* Resp.

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

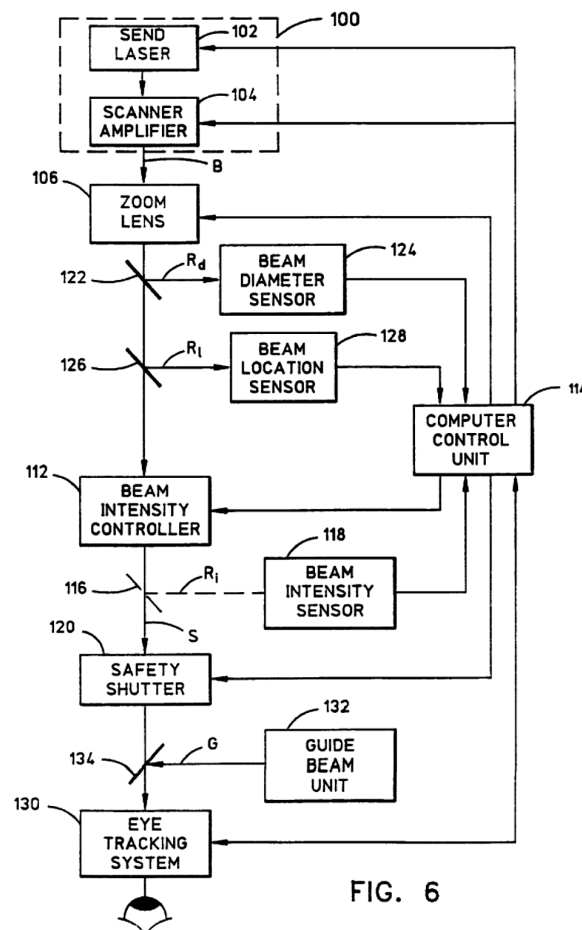
Low energy, ultra-short (femtosecond [*sic*]) pulsed laser radiation is applied to the patient’s eye in one of a number of patterns such that the exposed ocular tissue is ablated or excised through the process of optical breakdown or photodisruption in a very controlled fashion. The process can be gentle 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

⁹ *See supra* Section II.A.

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:



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,” and “reduces the possibilities of retinal complications.” *Id.* at 34:40–51.

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 states that “[b]y directing the laser focus at the lens of the eye, a cataractous lens can be ablated and liquefied.” *Id.* at 23:21–23.

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 the “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 35:37–39, 35:50–36:2.

Swinger also discloses “using ultrasound measurement” to accurately measure the eye anatomy and orient the laser beam. *Id.* at 35:59–63.

Finally, whether describing its anterior capsulotomy process and its lens phacorefractive ablation process, Swinger discloses that the laser

cutting progresses in a posterior-to-anterior direction in the tissue and, in the case of laser cutting within the lens, the laser cutting can take any pattern, such as cylindric, toric, aspheric, or spheric. *Id.* at 34:61–67, 36:3–5, 36:7–17, Figs. 7, 15B1.

2. *Baikoff*

Baikoff is a 2004 journal article and it is not disputed that it is prior art to the claims of the '724 patent. Ex. 1041; *see generally* Resp.

Baikoff discloses using an “image-acquisition system” with 1310 nm wavelength optical coherence tomography (OCT) to measure internal eye anatomy using software, including the horizontal diameter of the anterior chamber (AC), the anterior chamber depth (ACD), the horizontal pupil diameter, and the horizontal radius of curvature of the crystalline lens’s anterior pole. Ex. 1041, 1844.¹⁰ Baikoff states that this OCT technique “allows rapid, noncontact examination, and the software includes a measuring system capable of calculating distance, angle, and radius of curvature.” *Id.* at 1844.

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

¹⁰ Baikoff includes original page numbering and numbering added to its lower corner. We use the original numbering when citing to this reference.

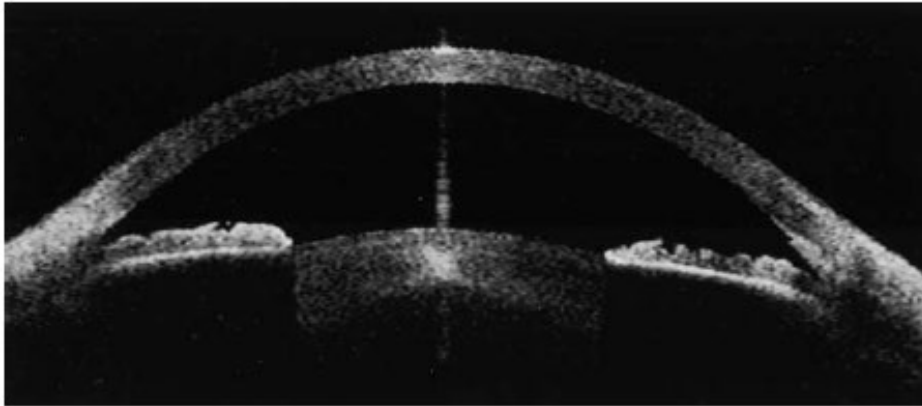


Figure 3. (Baikoff) The AC of a 55-year-old subject.

Id. at 1845.¹¹ 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 IOL implantation,”¹² and allows “extremely precise exploration of the anterior segment.” *Id.* at 1844, 1849.

¹¹ 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.

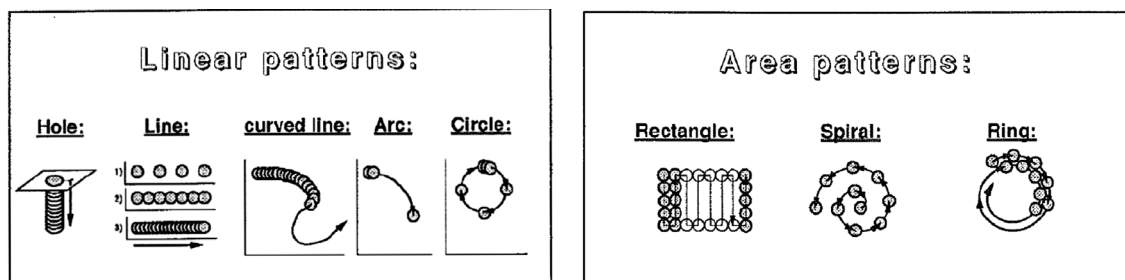
¹² Phakic refers IOL implantation without removing the natural lens.

3. *Hoppeler*

Hoppeler is a journal article indicated as published in 1992. Ex. 1043, 1.¹³ There is no dispute that Hoppeler is prior art. *See generally* Resp.

Hoppeler discloses an Nd:YLF pulsed 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, 1 (Abstract); *see also id.* at 3–4 (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 1–4.

Hoppeler discloses that “[m]ultiple [laser] patterns can be linked to cover eventually a larger area,” that “[a]ll patterns can consist of several layers and thus extend also in the z-axis,” and provides Fig. 2, reproduced below, that shows different linear patterns of lasering, and Fig. 3, also reproduced below, that shows “different area patterns like rectangle, spiral and ring.” *Id.* at 1–3.



¹³ We cite to the added pagination of Hoppeler, in the lower right corner of each page.

Fig. 2, above-left, shows several examples of laser patterned lines, indicated as formed by adjacent or overlapping laser spots, and Fig. 3, above-right, shows three examples of Hoppeler's area laser patterning, including a rectangle indicated as formed by adjacent lasered spots arranged in a rectangular, serpentine manner, a spiral laser pattern, and a ring-shaped laser pattern. *Id.*

Regarding cataract fragmentation, Hoppeler discloses:

Cataract fragmentation: The liquification or fragmentation of the cataractous lens is a procedure that benefits from the low energy and confined collateral damage of the Nd:YLF picosecond laser. The idea of cataract fragmentation is to significantly reduce phacoemulsification time in the following cataract surgery. The amount of the lens that can be fragmented is dependent on the pupillary size and the density of the nucleus itself. The application of the laser has to start in the depth of the lens, working its way anteriorly as gas bubbles form, separate the nuclear layers and prevent laser effects in the tissue behind them.

Id. at 4.

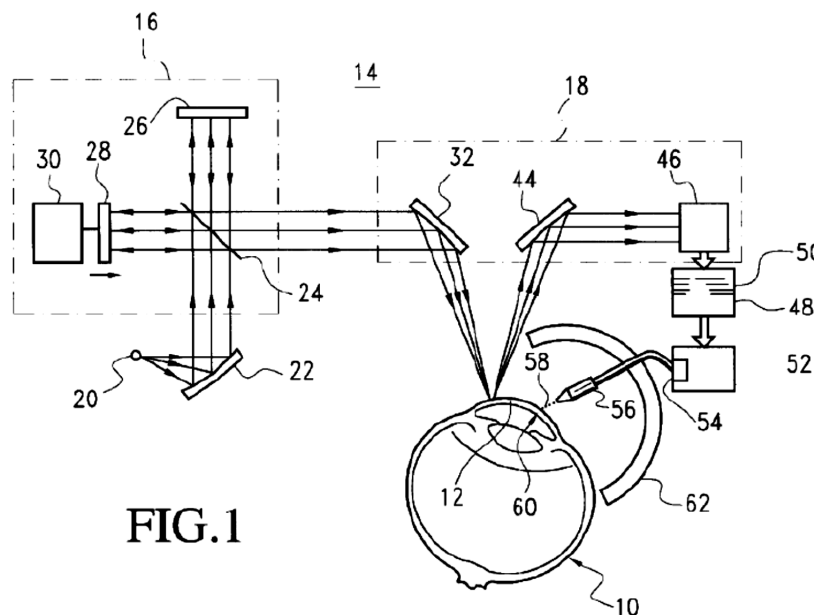
4. *Freedman*

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 include, *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 it 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 wherein 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 2:7–13. Freedman provides an illustration of a system for such surgery at its Figure 1, reproduced below:



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 4:3–5:67. 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 multilayer thin film. The cornea can be evaluated as a multilayer 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 6:9–9:18.

E. PATENTABILITY CHALLENGES

As summarized above, Petitioner asserts two grounds for unpatentability of the claims of the ’724 patent. *See supra* Section I.D; *see also* Pet. 6. We review Petitioner’s challenges and Patent Owner’s arguments below.

1. *Obviousness of Claims 1–15 over Swinger, Baikoff, and Hoppeler (Ground 1)*

Petitioner’s Ground 1 addresses claims 1–15 and 17–23, and asserts that each claim would have been obvious over the combination of Swinger, Baikoff, and Hoppeler. *See* Pet. 30, *et seq.* Unlike claims 17–23, claims 1–15 do not require that their recited step of “*processing data including the image data so as to determine a targeted treatment region in the lens of the eye, wherein the targeted treatment region comprises an axially-elongated cutting zone transecting the anterior capsule and does not transect the posterior capsule of the lens,*” be performed by a computer system. (Italics added). *Compare* Ex. 1012, 16:47–67 (claim 1) *with id.* at 18:15–39 (claim 17) and 18:45–67 (claim 19). Thus, these sets of claims are directed to significantly different inventions. The outcomes regarding these two sets of claims is also different. Therefore, we address these sets of claims

separately. As explained below, we find claims 1–15 would have been obvious over Swinger, Baikoff, and Hoppeler. We address the parties’ positions below.

*Claim 1’s Obviousness over Swinger, Baikoff, and Hoppeler*¹⁴

Petitioner’s Positions and Evidence

Petitioner asserts that the ordinarily skilled artisan would have been motivated to combine Swinger, Baikoff, and Hoppeler and modify them in view of one another because Swinger teaches laser cataract surgery and identifies the benefits of accuracy, using ultrasound imaging for example, to measure the dimensions of eye tissues to provide a safely distanced ablation region (and liquefying/fragmenting and removing the lens), because 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 because Hoppeler teaches using a computer-controlled treatment laser in various three-dimensional patterns to segment a cataractous lens into fragments as prelude to IOL placement. *Id.* at 30–37 (citing Ex. 1001 ¶¶ 145–149, 151–155, 157–159, 161, 177–180; Ex. 1012, 7:45–57, 10:39–44, 12:55–13:3, Figs. 11, 13; Ex. 1039, 15:55–63, 16:60–20:34, 23:13–25, 34:43–51, 34:61–67, 35:17–36:7, 36:61–67, Fig. 6; Ex. 1041, 1843–45, 1847, 1849, Fig. 3; Ex. 1043, 1–4, Figs. 2, 3). Petitioner’s position is that the ordinarily skilled artisan would have recognized that integrating Baikoff’s OCT imaging into Swinger’s automated cataract surgery system could replace Swinger’s direct

¹⁴ Although at times we indicate that certain of Patent Owner’s arguments are not persuasive, at no point do we shift the ultimate burden of persuasion from Petitioner to Patent Owner. Such unpersuasiveness is in the context of Petitioner’s positions and the evidence of record.

visualization HeNe beam alignment or ultrasound measurement, which would improve the precision and accuracy of such procedures. *Id.* Petitioner asserts that Swinger teaches liquefying a lens as part of cataract surgery before implanting an IOL, and also liquefying at least part of a lens in a phacorefractive ablation embodiment by patterned lasering, but that Hoppeler teaches a patterned lasering technique for lens fragmentation and removal and that it would have been obvious to use such techniques with the Swinger-Baikoff combination to reduce the time and energy of the procedure. *Id.* at 34–37 (citing Ex. 1039, 23:17–25, 35:18–42, 35:50–66, 36:15–17; Ex. 1043, 1–4; Ex. 1001 ¶¶ 145–149, 177–180).

Petitioner also asserts that the person of ordinary skill in the art would have had a reasonable expectation of success. *Id.* at 33–34, 36 (citing, *inter alia*, Ex. 1001 ¶¶ 159, 161, 180). 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 (substituting Swinger’s ultrasound with OCT imaging in a similar fashion to how the ’724 patent describes switching between ultrasound and direct visualization), and the mere programming of a control system (Swinger’s beam control computer) with known algorithms, as well as merely selecting a pattern for the treatment laser (as in Hoppeler). *Id.*

Petitioner moves on to address how each limitation of independent claim 1 is taught or suggested by Swinger, Baikoff, and Hoppeler. *Id.* at 37–43 (citing, *inter alia*, Ex. 1001 ¶¶ 279–283, 285, 288–292; Ex. 1012, 8:64–9:7; Ex. 1039, 7:50–8:1, 8:64–9:7, 9:18–21, 10:10–15, 16:60–20:34, 20:49–21:19, 23:17–25, 34:52–35:3, 35:17–36:7, 36:15–17, Figs. 6, 15A1, 15B1; Ex. 1041, 1844–45, Figs. 3, 10; Ex. 1043, 1–4, Figs. 2, 3).

Regarding the claimed “laser cataract surgery that protects the retina of the eye from laser exposure” of the preamble (limitation 1P — Ex. 1012, 16:47–48), Petitioner asserts that Swinger teaches posterior-to-anterior laser scanning to avoid absorption of the laser beam’s energy by plasma already formed, in the same manner taught in the ’724 patent itself. Pet. 37–38 (citing Ex. 1001 ¶¶ 279–280; Ex. 1012, 8:64–9:7; Ex. 1039, 7:50–8:1, 35:59–64, 35:66–36:5); *see also supra* Section II.D.1. (discussing Swinger’s disclosure, including of this lasering technique).¹⁵ Petitioner asserts that the Swinger posterior-to-anterior lasering technique protects the retina, according to the description of the ’724 patent, which at the cited portion explains

this “bottom up” treatment technique reduce[s] unwanted beam attenuation in tissue above the target tissue layer, but it also helps protect tissue underneath the target tissue layer. By scattering the laser radiation transmitted beyond the focal point on gas bubbles, cracks and/or tissue fragments which were

¹⁵ Petitioner also asserts, regarding claim 1’s limitation 1.4 relating, *inter alia*, to the same general posterior-to-anterior lasering, that “Hoppeler teaches a computer-controlled system for directing laser beams in various three-dimensional patterns, *see* [Ex. 1043] at Figs. 2, 3, in a posterior-to-anterior direction, *id.* at 4.” Pet. 42–43. As noted above at Section II.D.3., Hoppeler does teach this.¹⁶ We note also that Patent Owner has similarly asserted, for the purpose of establishing a nexus for alleged evidence of indicia of non-obviousness in several other related *inter partes* review proceedings over related patents, that the Catalys product (or aspects thereof) is covered by the claims of Patent 8,403,921 (*see* IPR2021-00823, Paper 23, 55), US Patent 9,101,448 (*see* IPR2021-00839, Paper 21, 50), US Patent 9,107,732 (*see* IPR2021-00840, Paper 23, 56), and US Patent 9,474,648 (*see* IPR2021-00841, Paper 21, 47). In the respective Patent Owner Response in each of these proceedings, Patent Owner makes the same general allegations concerning objective indicia of non-obviousness, regardless of which patent is at issue.

produced by the previous scans, these defects help protect the underlying retina.

Pet. 37–38; Ex. 1012 8:64–9:7 (cited by Petitioner).

Regarding claim 1’s limitation 1.1 (“generating, using a computer, an image of at least a portion of a crystalline lens of the eye based on detecting remitted light from locations distributed throughout a volume of the crystalline lens” — Ex. 1012, 16:49–52), Petitioner asserts that this subject matter is taught and obvious upon combining Baikoff’s OCT imaging system with Swinger’s systems to replace Swinger’s ultrasound imaging. Pet. 38–39 (citing Ex. 1001 ¶¶ 281–283; Ex. 1039, 35:17–36:7; Ex. 1042, 1044–45, Figs. 3, 10). Petitioner points to Baikoff’s Figures 3 and 10 as showing image data from locations distributed throughout a lens. *Id.*

Regarding limitation 1.2 (“processing data including the image data so as to determine a targeted treatment region in the lens of the eye, wherein the targeted treatment region comprises an axially-elongated cutting zone transecting the anterior capsule and does not transect the posterior capsule of the lens” — Ex. 1012, 16:53–58), Petitioner asserts that this step occurs in Swinger’s procedure where landmarks are identified in the eye to establish cutting boundaries for, e.g., an anterior capsulotomy where a cutting zone transects the capsule. Pet. 39–41 (citing Ex. 1039, 34:52–35:3, 35:37–36:5). Petitioner asserts it would have been obvious to apply such teachings to cataractous lens ablation, which would involve treating a larger volume of the lens than in Swinger’s partial lens ablation (Petitioner refers to the phacorefractive ablation embodiment), because Swinger cautions against damaging the posterior lens capsule during laser cataract surgery and teaches to proceed in a posterior-to-anterior lasering pattern. *Id.* at 39–40 (citing Ex. 1001 ¶¶ 285, 287; Ex. 1039, 7:50–63, 34:52–35:3, 35:37–36:5).

Petitioner's point is that merging Swinger's various examples of laser cutting a lens and anterior lens capsule and of cataract surgery (including subsequent IOL implant), as the reference is considered as a whole, renders processing of image data to determine a targeted treatment region, as claimed, obvious. Further, Petitioner asserts that Baikoff's OCT imaging coupled with Swinger's computer control unit 114 would generate the image data of the lens and that this imaging information would be used to guide Swinger's laser ablation. *Id.* at 40–41 (citing Ex. 1001 ¶¶ 287, 288; Ex. 1044, 1844, Figs. 3, 10).

Regarding the claimed “directing a laser beam, under computer guided control, in a first pattern to photodisrupt at least a portion of lens tissue of the eye to create a light scattering region” (limitation 1.3 — Ex. 1012, 16:59–61) and the claimed “subsequently directing the laser beam, under computer guided control, in a second pattern in lens tissue anterior to the light scattering region so as to photodisrupt at least a portion of the targeted region, thereby effecting patterned laser cutting of lens tissue for subsequent removal of pieces or segments of lens tissue” (limitation 1.4 — Ex. 1012, 16:62–67), Petitioner asserts that Swinger discloses the first pattern laser beam in teaching its capsulotomy or lens ablation patterning at one depth in, e.g., circles or spirals, etc., which creates a light scattering region as claimed, and asserts that Swinger also teaches the subsequent second patterned laser beam “[b]ecause Swinger's system can create a pattern of tissue breakdown in the context of other procedures, it follows that it can do so for lens fragmentation” and “Swinger discloses that ablation proceeds in a posterior-to-anterior direction for both the capsulotomy and lens ablation.” Pet. 41–42 (citing Ex. 1001 ¶¶ 289–291; Ex. 1039, 25:28–37,

34:52–35:3, 35:18–36:5, 36:15–17). Petitioner cites Hoppeler as a backup in case of “any doubt as to patterned cutting” in Swinger, asserting the Hoppeler teaches patterned laser beams to fragment cataractous crystalline lenses under computer control in a posterior-to-anterior direction. *Id.* at 42–43 (citing Ex. 1001 ¶ 292; Ex 1043, 1–4, Figs. 2, 3).

Petitioner asserts that this posterior-to-anterior laser scanning taught by Swinger and Hoppeler for anterior capsulotomies and lens fragmentation (and phacorefractive lens ablation) is the same technique described in the ’724 patent that produces a light scattering region (that protects posterior tissue like the retina and posterior lens capsule), pointing to the Specification at column 8, line 64 to column 9, line 7, which states:

Not only does this “bottom up” treatment technique reduce unwanted beam attenuation in tissue above the target tissue layer, but it also helps protect tissue underneath the target tissue layer. By scattering the laser radiation transmitted beyond the focal point on gas bubbles, cracks and/or tissue fragments which were produced by the previous scans, these defects help protect the underlying retina. Similarly, when segmenting a lens, the laser can be focused on the most posterior portion of the lens and then moved more anteriorly as the procedure continues.

Pet. 42 (citing Ex. 1012, 8:64–9:7; Ex. 1001 ¶¶ 289–290).

Having considered the record, Petitioner’s assertions, and all of Patent Owner’s arguments (which we address below), we find that Petitioner has met its burden and has shown by a preponderance of the evidence that independent claim 1 would have been obvious over Swinger, Baikoff, and Hoppeler, which combination teaches all elements of claim 1. We agree with Petitioner that these references would have been combined by the

person of ordinary skill in the art to achieve the invention with a reasonable expectation of success.

We now turn to Patent Owner's arguments.

Objective Indicia of Non-Obviousness

We first address Patent Owner's alleged evidence of objective indicia of non-obviousness. Patent Owner argues that evidence of industry praise, commercial success, failures of others, and copying supports the non-obviousness of the claims. Resp. 55–64. Patent Owner asserts that “[t]he success of the ’724 patent’s invention in the face of previous failures, coupled with garnering significant industry praise and commercial success, serves as a check against Alcon’s hindsight bias and provides real world evidence that the invention was not obvious.” *Id.* at 62. Petitioner, in turn, argues that these arguments fail because, *inter alia*, there is no nexus with the claimed invention. Reply 24–28.

Objective evidence of non-obviousness, when present, must be considered as part of an obviousness inquiry. *Transocean Offshore Deepwater Drilling, Inc. v. Maersk Drilling USA, Inc.*, 699 F.3d 1340, 1349 (Fed. Cir. 2012). Notwithstanding what the teachings of the prior art would have suggested to one of ordinary skill in the art, the totality of the evidence submitted, including objective evidence of non-obviousness, may lead to a conclusion that one or more of the challenged claims would not have been obvious to one of ordinary skill in the art. *In re Piasecki*, 745 F.2d at 1471–72.

“[F]or objective indicia of non[-]obviousness to be accorded substantial weight, its proponent must establish a nexus between the evidence and the merits of the claimed invention.” *Lectrosonics, Inc. v.*

Zaxcom, Inc., IPR2018-01129, Paper 33, 32 (PTAB Jan. 24, 2020) (precedential) (citing *ClassCo, Inc. v. Apple, Inc.*, 838 F.3d 1214, 1220 (Fed. Cir. 2016)). A patentee is entitled to a presumption of nexus “when the patentee shows that the asserted objective evidence is tied to a specific product and that product ‘embodies the claimed features, and is coextensive with them.’” *Fox Factory, Inc. v. SRAM, LLC*, 944 F.3d 1366, 1373 (Fed. Cir. 2019) (quoting *Polaris Indus., Inc. v. Arctic Cat, Inc.*, 882 F.3d 1056, 1072 (Fed. Cir. 2018) (quoting *Brown & Williamson Tobacco Corp. v. Philip Morris Inc.*, 229 F.3d 1120, 1130 (Fed. Cir. 2000))).

“Where the offered secondary consideration actually results from something other than what is both claimed and *novel* in the claim, there is no nexus to the merits of the claimed invention,” meaning that “there must be a nexus to some aspect of the claim not already in the prior art.” *In re Kao*, 639 F.3d 1057, 1068–69 (Fed. Cir. 2011); *but see WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1330 (Fed. Cir. 2016) (patent owner may show, for example, “that it is the claimed combination as a whole that serves as a nexus for the objective evidence; proof of nexus is not limited to only when objective evidence is tied to the supposedly ‘new’ feature(s).”).

Patent Owner asserts that, “[h]ere, a nexus is presumed because the objective evidence is tied to two specific products (Alcon’s [Petitioner’s] LenSx® and AMO’s [Patent Owner’s] Catalys®) and those products are ‘the invention disclosed and claimed in the patent.’” Resp. 56. As support Patent Owner asserts that its witness, Dr. Kang, explains in detail that these products practice all the limitations of the independent claims. *Id.* (citing Ex. 2087 ¶¶ 213–216).

The paragraphs of Dr. Kang’s declaration that Patent Owner cites refer to four Appendices (A–D) of that declaration that include claim charts, of which Appendix B is directed to the ’724 patent, mapping the limitations of its claims to the Catalys product. Ex. 2087 ¶ 213. Appendices A, C, and D of Dr. Kang’s declaration relate also to the Catalys product and, respectively, to U.S. Patent 9,125,725 (“the ’725 patent” (Ex. 1027), the subject of IPR2021-00853), U.S. Patent 8,425,497 (“the ’497 patent” (Ex. 1009), the subject of IPR2021-00858), and U.S. Patent 8,709,001 (“the ’001 patent (Ex.1015), the subject of IPR2021-00862). The inventions defined by the respective independent claims 1 of each of these four patents are not the same, i.e., they do not share identical limitations, and, although there is some overlap, Dr. Kang identifies different aspects of Patent Owner’s Catalys product as covered by the various limitations of these claims. *See* Ex. 2087, App’x A–D.

For example, concerning the limitations of the ’724 patent’s claim 1 (at issue in this proceeding), Dr. Kang primarily points to several user interface display screens and related functions for most of the claim limitations. *Id.* at App’x B. Concerning the limitations of claim 1 of the ’725 patent (at issue in a separate proceeding), Dr. Kang points to an “implementation overview” of a system schematic including a “Ranging OCT” system, a “cutting laser” system, and “patient interface” system (not addressed for claim 1 of the ’724 patent) as well as to some of the same, but also some different display screens as for the ’724 patent. *Id.* at App’x A. And, for the limitations of claim 1 of the ’497 patent (at issue in yet another proceeding), Dr. Kang identifies several more user interface display screens (as compared to those identified for the ’724 patent). *Id.* at App’x C.

Although, as noted, the evidence of nexus is not the same across these four related patents, Patent Owner asserts that the same Catalys product, or various aspects thereof, is covered by each patent.¹⁶

Dr. Kang, cites Exhibit 2056 for this evidence of alleged nexus, which is the operator manual for the Catalys product. The table of contents of the document indicates that the Catalys System includes the following sub-systems or components: (1) a touchscreen control panel GUI, (2) docking keypad, (3) Liquid Optics™ interface and (4) Liquid Optics™ circular label reader, (5) mobile patient bed or chair, (6) emergency laser stop button, (7) key switch, (8) vacuum and laser footswitches, (9) door interlock connector, (10) treatment laser, (11) OCT, (12) video subsystem, and (13) monitoring and control systems. Ex. 2065, 5. Patent Owner asserts that there is a nexus between the Catalys and the claims of the '724 patent (as well as the claims of each of the other above-identified patents, as noted), which should be presumed because the Catalys (and Alcon's LenSx®, an accused infringing product), is "the invention disclosed and claimed." Resp. 55–56. Patent Owner further argues that this is so because the product's system has

¹⁶ We note also that Patent Owner has similarly asserted, for the purpose of establishing a nexus for alleged evidence of indicia of non-obviousness in several other related *inter partes* review proceedings over related patents, that the Catalys product (or aspects thereof) is covered by the claims of Patent 8,403,921 (*see* IPR2021-00823, Paper 23, 55), US Patent 9,101,448 (*see* IPR2021-00839, Paper 21, 50), US Patent 9,107,732 (*see* IPR2021-00840, Paper 23, 56), and US Patent 9,474,648 (*see* IPR2021-00841, Paper 21, 47). In the respective Patent Owner Response in each of these proceedings, Patent Owner makes the same general allegations concerning objective indicia of non-obviousness, regardless of which patent is at issue.

a femtosecond pulsed laser, an imaging device, and a control system that can be used to (i) image the lens, (ii) identify cataractous lens tissue structure boundaries, (iii) identify cutting regions, and (iv) operate the laser to generate a treatment beam in a pattern based on the cutting regions. *Id.*; *see, e.g.*, Ex. 1012, cl 1. They both use an OCT imaging system, as recited in independent claim 17. Kang [Ex. 2087] ¶213.

Id. at 56.

Regarding a presumed nexus, Petitioner argues that Patent Owner must show that the relied upon products are “coextensive with the claims,” but that there can be no presumption of nexus “when a product embodies multiple features” and “unclaimed features” are present in the product. Reply, 24–25 (citing *SightSound Techs., LLC v. Apple Inc.*, 809 F.3d 1307, 1319 (Fed. Cir. 2015); *Fox Factory*, 944 F.3d at 1378). Petitioner argues that although

PO’s Catalys device may fall within the scope of PO’s broad claims, numerous unclaimed features distinguished Catalys. Catalys was noted for several features upon release: (1) it enabled easy, comfortable, and precise docking with a liquid interface, which was considered “critical”; (2) it could perform a range of other procedures related to cataract surgery, such as the initial corneal incision and astigmatic keratotomy; (3) it incorporated high-resolution imaging and a proprietary guidance system; all of which enabled, most importantly, (4) ***fast, high-precision*** cataract surgery on human patients sufficient to secure FDA clearance. Ex.1125, 14; Ex.1126, 1; Ex.1120, 235:15-237:9.

Id. at 25. Petitioner also identifies, as we have above, that Patent Owner has many separate patents indicated to cover the Catalys product. *Id.*

Applying *Fox Factory*, the Board uses a two-step analysis in evaluating nexus between the claimed invention and the evidence of secondary considerations. *Lectrosonics*, IPR2018-01129, Paper 33 at 33.

We first consider whether the patent owner has demonstrated “that its products are coextensive (or nearly coextensive) with the challenged claims,” resulting in a rebuttable presumption of nexus. *Id.* If not, that “does not end the inquiry into secondary considerations”; “the patent owner is still afforded an opportunity to prove nexus by showing that the evidence of secondary considerations is the ‘direct result of the unique characteristics of the claimed invention.’” *Id.* (quoting *Fox Factory*, 944 F.3d at 1373–75).

“Whether a product is coextensive with the patented invention, and therefore whether a presumption of nexus is appropriate in a given case, is a question of fact.” *Fox Factory*, 944 F.3d at 1373. “A patent claim is not coextensive with a product that includes a ‘critical’ unclaimed feature that is claimed by a different patent and that materially impacts the product’s functionality.” *Lectrosonics*, IPR2018-01129, Paper 33 at 32 (quoting *Fox Factory*, 944 F.3d at 1375). The patentee is not entitled to a presumption of nexus if the patented invention is only a component of a commercially successful machine or process. *Fox Factory*, 944 F.3d at 1373 (reaffirming the importance of the “coextensiveness” requirement). The patentee is not entitled to a presumption of nexus where the relevant product embodies at least two patented inventions, and the burden remains on Patent Owner to show that the claimed secondary considerations were due to the invention claimed in the patent at issue here. *Id.* at 1375–77 (applying precedent under *Therasense, Inc. v. Becton, Dickinson & Co.*, 593 F.3d. 1289, 1299 (Fed. Cir. 2010)).

We find that Patent Owner has not established that it is entitled to a presumption of nexus because of the presence of several critical, unclaimed features, in the identified products, and because the evidence shows that if

the claims cover the Catalys product they cover only a component (or components) thereof.

As we note above, Patent Owner has asserted that the claims of no fewer than eight separate patents cover Catalys (and by implication of Patent Owner's infringement contentions, also the LenSx product). Moreover, as we also note above, Patent Owner's evidence indicates that the Catalys product has over a dozen separate components or systems critical enough to warrant separate sub-sections in its product manual. Ex. 2056, 5, 21–30; *see also* Ex. 2087, App'x B (citing this evidence). Patent Owner has not sufficiently explained why only the claimed components of the Catalys (or LenSx) product matter while the unclaimed (or claimed by other patents) component do not regarding its objective indicia of non-obviousness. *See* Resp. 55–64; *see also* Sur-Reply 24 (discussing the same).

Furthermore, when Patent Owner argues that the Catalys product has an actual nexus with the claimed subject matter, beyond the mere presumption, Patent Owner does not specify how the specifically claimed subject matter is represented in the product, but merely generalizes that the Catalys (and LenSx) has a femtosecond laser (not claimed), an OCT imaging device (only mentioned in claims 12, 16, 17), and a control system that images, identifies tissue boundaries, identifies cutting regions, and operates the laser (generally). Resp. 56; *but see* Ex. 2087, App'x B (Dr. Kang does chart where he believes the Catalys product's features are claimed, but this is not specifically reflected in the Response).

We find Patent Owner's evidence (*see* evidence cited in Response at 55–64) of nexus fails, as to a presumption and as to actual evidence thereof, because any showing of coextensiveness between the claims at issue here

and the Catalys product (and LenSx product, for that matter) is too limited, tenuous, and vague, and there is a void of evidence establishing that any commercial success, industry praise, or failures of others can be attributed to the claimed versus unclaimed features of the Catalys (or LenSx) product, particularly in view of the many other patents identified as covering this same product and the many features of the product that are not covered by the claims at issue here. *Fox Factory*, 944 F.3d at 1373–75; *Therasense*, 593 F.3d. at 1299; *see also* Ex. 2056, 5, 21–30 (identifying the many features of the product).

Our determination on nexus is likely sufficient to dispose of Patent Owner’s evidence of objective indicia of non-obviousness. But, for the sake of completeness, we address Patent Owner’s evidence and arguments below.

One category of objective indicia of non-obviousness asserted by Patent Owner is industry praise in the form of an award by “R&D 100” and praise by “experts in the field” for a computer-guided, femtosecond, lens fragmentation laser system, called “FLACS.” Resp. 57–58 (citing Ex. 2035, 2021; Ex. 2037, 44–45; Ex. 2040; Ex. 2041, 2; Ex. 2043; Ex. 2044, 82; Ex. 2051, 1633). Petitioner argues that Patent Owner provides no evidence connecting this award to the claimed features and that general praise for the “FLACS” laser cataract surgery system does not speak to praise specifically for the invention claimed here. Reply 26. We agree with Petitioner.

As discussed more generally above, Patent Owner’s evidence is not sufficiently specific to the invention of claim 1 of the ’724 patent (or its dependent claims 2–15) to provide the requisite nexus. Patent Owner’s award exhibit is merely a list of products that won the R&D 100 award, one of which is the “Catalys Precision Laser System,” discussed above, but the

exhibit provides no context or rationale for the award and, as discussed above, the Catalys product is composed of many components and systems not specifically covered by the challenged claims. Ex. 2043, 3. Patent Owner points also to a report dated June 28, 2012, as evidencing that this award was for the specific features of the Catalys product claimed, but this evidence lacks any identification of the author and the portion identifying features of the product appears to merely be listing features thereof rather identifying than any reason for the award. Ex. 2040. Additionally, the evidence of praise cited by Patent Owner is not specific to the subject matter of claim 1 (and its dependent claims) of the '724 patent, but general praise for the FLACS system and laser-guided femtosecond laser procedures. *See* Ex. 2035; Ex. 2037; Ex. 2044; Ex. 2051. For these reasons, we are not persuaded by Patent Owner's arguments or evidence on industry praise.

Regarding Patent Owner's evidence of commercial success, because it relies on the collective sales of the Catalys (and LenSx) products, without sufficiently attributing those sales to the claimed invention specifically, we are unpersuaded. Resp. 59–60. As we noted above, the Catalys (and LenSx) product is not coextensive with the challenged claims here, but includes a variety of other features and systems that are not claimed, any one of which might be a reason for the commercial success of the product. Patent Owner argues that there is a presumed nexus, which we explained is not so. *Id.* at 59. Patent Owner also states that “the evidence shows that the “inventive combination” of features drove the commercial success, citing 2015 and 2017 reports on the cataract surgical equipment market. Ex. 2063; Ex. 2065. Patent Owner provides little detail about why these reports support its position other than that they identify virtues of image-guided femtosecond

laser technology and we do not discern that this evidence sufficiently explains why the claimed invention here is responsible for the commercial success of any product. Resp. 59–60. Moreover, we find that this evidence shows that unclaimed features were responsible for some success of the product, e.g., the unclaimed “liquid interface system” of the Catalys system. *See* Ex. 2063, 201. For these reasons, we do not find Patent Owner’s evidence on commercial success persuasive.

Regarding Patent Owner’s evidence of failures of others, Patent Owner argues that the success of the patented invention was in the context of others’ failures to develop a cataract laser surgery system for lens fragmentation. Resp. 60–62 (citing Ex. 2030, 150:2–23; Ex. 2032, 380:12–19; Ex. 2036, 605; Ex. 2057, 55:1–3, 56:20–22, 57:19–58:10, 224:3–14, 225:19–226:7, 227:18–22; Ex. 2058, 39, Ex. 2088 ¶¶ 101–107). Petitioner responds that Patent Owner’s evidence is focused on types of lasers insufficient for such procedures, which is not related to the invention claimed and, if the type of laser were a critical feature invention, then Swinger discloses using femtosecond lasers for cataract surgeries. Reply 27. We agree with Petitioner—the invention is not directed to a specific laser, but Patent Owner’s evidence of failures focuses on such as the reasons for past failures. *See* Exs. 2030 and 2032 (testimony about Er:YAG and Ne:YAG lasers failures); Ex. 2036 (discussion of various YAG laser failures); Ex. 2088 (at cited portions, Dr. Walter addressing failures of various lasers); *see also* Ex. 2057 at cited portions (testimony of Dr. Izatt summarily concluding he did not use OCT for cataract surgery); *see also* Ex. 2058 (cited portion of exhibit seems to have nothing to do with failures).

Thus, for these reasons Patent Owner's evidence of past failures of others is not persuasive.

Turning to Patent Owner's allegations of copying, Patent Owner asserts that there was unmistakable copying of the claimed patterns of dependent claims 7, 20, and 21; claim 7 is most relevant here as we are discussing claim 1 from which it depends. Resp. 62–64. Claim 7 recites selecting the laser patterning from intersecting straight lines, crosshatched intersecting lines, curved lines, a circular line, concentric circular lines or spiral shapes, and Patent Owner asserts that Alcon (1) had access to the '724 patent's Figs. 10B and 10C (showing such claimed patterns) and (2) Alcon's LenSx product features lens fragmentation patterns like those of the Figures. *Id.* at 63–64 (citing Ex. 1012, Figs. 10B, 10C; Ex. 2045, 2; Ex. 2047). Patent Owner asserts that Petitioner's access to the published application version of the '724 patent's Figs. 10B and 10C and the similarity between Petitioner's product's lasering patterns and these figures is sufficient to establish an inference of copying. *Id.* (citing *Liqwd, Inc. v. L'Oreal USA, Inc.*, 941 F.3d 1133, 1137 (Fed. Cir. 2019)).

Petitioner argues that (as opposed to the facts in *Liqwd*) there is no evidence here of any actual copying efforts. Reply, 27–28; *see Liqwd*, 941 F.3d 1138–39 (L'Oreal had access to proprietary and non-public information, upon receipt of this information L'Oreal changed business plans regarding purchasing the accessed technology, and L'Oreal used certain product components because of its access to the confidential information). We agree with Petitioner and this is likely enough to defeat Patent Owner's copying allegation.

However, we also find that the claimed subject matter of which Petitioner is accused of copying was not novel or non-obvious, but was already in the prior art teachings of Swinger and Hoppeler. *See In re Kao*, 639 F.3d at 1068–69.

As identified above, Swinger, Baikoff, and Hoppeler teach all the steps of independent claim 1, and we also find that Swinger and Hoppeler also teach the claimed “*pattern . . . selected from the group consisting of: two or more intersecting straight lines, a crosshatched pattern comprising two or more sets of intersecting lines, one or more curved lines, a circular line, two or more concentric circular lines, and one or more spiral-shaped lines.*” Ex. 1012, 17:18–23 (claim 7, italics added).

For example, Swinger’s Fig. 7 illustrates several patterns of laser scanning, including straight lines, circles/spheres, squares, spirals; Swinger discloses that its “system can easily create straight line and curved-line excisions, of any predetermined length and depth, at any location determined by a surgeon,” and also “concentric circles, increasing or decreasing spirals, linear scanning” or “[a]ny pattern.” Ex. 1039, 20:49–65, 25:29–32, 36:1–17. Further, Hoppeler discloses cataract lens fragmentation with computer-controlled laser patterns such as holes, lines, curved lines, arcs, circles, rectangles, spirals, and rings. Ex. 1043, 1–4, Figs. 2, 3.

Thus, based on the teachings of the asserted prior art, at least the recited “*one or more curved lines, a circular line, two or more concentric circular lines, and one or more spiral-shaped lines*” of claim 7 was known in the prior art. The evidence shows that Petitioner copied features that appear in the prior art, if any copying occurred at all; accordingly, we do not find that Patent Owner evidence on copying is persuasive.

In view of the above, to summarize, we are not persuaded by Patent Owner's evidence and arguments over objective indicia of non-obviousness regarding claims 1–15.

The Claimed “Light Scattering Region”

Patent Owner argues that each independent claim of the '724 patent requires its method produce a “light scattering region” (limitation 1.3 of claim 1) to protect the retina from laser exposure and that Swinger fails to teach this. Resp. 14–21. Patent Owner indicates it only attacks Swinger's disclosure on this point because “[Petitioner's] sole asserted reference for this limitation is Swinger.” *Id.* at 17 (citing Pet. 41–42; Ex. 1001 ¶¶ 289–290). Patent Owner argues that Swinger's anterior capsulotomy laser cutting is not the claimed “light scattering region” because it is in front of where lens fragmentation takes place, rather than between the lens fragmentation and the retina so as to protect the retina from laser radiation during lens fragmentation. *Id.* at 18. Also, Patent Owner argues that the circular pattern of an anterior capsulotomy in Swinger cannot create the claimed “light scattering region” because it is open in the middle. Patent Owner acknowledges that Petitioner also identifies that Swinger teaches phacorefractive ablation on the lens where the laser ablation proceeds from posterior-to-anterior, but argues Swinger fails to disclose the patterns for this technique so there is no first and second pattern as claimed.

We disagree with Patent Owner's arguments for several reasons. As an initial matter, Petitioner most immediately identifies that Swinger teaches forming a light scattering region in performing “capsulotomy or lens ablation at one depth[] to photodisrupt lens tissue,” because “Swinger's delivery system may be programmed to ablate one or more additional

concentric and adjacent surfaces moving from posterior to anterior.” Pet. 41–42 (citing, *inter alia*, Ex. 1039, 25:28–37, 4:52–35:3, 35:37–36:5). But, Petitioner also asserts, regarding the following limitation of claim 1, that “Hoppeler [also] teaches a computer-controlled system for directing laser beams in various three-dimensional patterns, *see* [Ex. 1043] at Figs. 2, 3, in a posterior-to-anterior direction, *id.* at 4.” *Id.* at 42–43 (citing, *inter alia*, Ex. 1043, 1–4)); *see also* Reply 5–6. Thus, Petitioner did not point only to a capsulotomy procedure, or only to Swinger, for producing the “light scattering region” of the claim, but also identifies that Swinger and Hoppeler each teaches laser cutting the lens in a posterior-to-anterior pattern. We agree with Petitioner that this teaches the “light scattering region” claim element, as it is precisely the process described in the ’724 patent as producing such a region. *See* Ex. 1012, 8:64–9:7; *see also* Reply 3–4.

Thus, we find in agreement with Petitioner’s position that, whether following Swinger’s or Hoppeler’s teachings of posterior-to-anterior laser cutting patterns to cut a lens, the prior art teaches the claimed formation of a “light scattering region.”

Motivation to Combine the Prior Art

Patent Owner argues that there would have been no motivation to combine laser cataract surgery with OCT imaging. Resp. 25–32. Patent Owner argues that surgeons would not have “resort[ed] to a computer-controlled laser system guided by imaging such as OCT” because Swinger’s manual HeNe aiming was good enough (or even the “gold standard” for aiming lasers), OCT imaging was too slow for the job, and OCT was unable to image the lens behind the iris. *Id.* (citing Ex. 1041, 1844; Ex. 1054, 1587–88, Ex. 1056; Ex. 2006, 11, 286–87, 296–98; Ex. 2015, 12, 898;

Ex. 2087 ¶¶ 41–43, 59–60, 96–103; Ex. 2088 ¶¶ 57, 66, 72–75; Ex. 1039, 9:1–2; Ex. 2057, 85:5–14, 94:20–95:3, 99:14–17, 210:20–211:6, 212:9–19).

We are unpersuaded by Patent Owner’s arguments.

In its Reply, Petitioner points out that there is no requirement that substituting OCT imaging for direct visualization be more accurate. Reply 7–8. Petitioner also argues in response to the “too slow” argument that neither speed nor eye docking are claim requirements and that Patent Owner does not explain how long is too long or that OCT exceeds such a limit, but Petitioner identifies that OCT can image the eye in 1/8th of a second for a cross-sectional scan (4–8 scans are needed for surgery) and in only 80 seconds for a full 3D scan. *Id.* at 11–12 (citing Ex. 1120, 51:14–20, 115:2–7, 119:15–22, 122:5–123:21; Ex. 1123 ¶ 24; Ex. 1134:23:14–24:21; Ex. 1138, 225:6–20).

Critical here is that independent claim 1, as opposed to independent claims 17 and 19, does not require a method where image data produced by a computer-controlled scanning system is processed *by the computer* to plan laser-cutting of the lens and then proceed to have *that computer control* the laser-cutting of the lens. *Compare* Ex. 1012, 16:47–67 *with id.* at 18:15–39 and 18:45–67. Rather, claim 1 requires the computer to generate the image data and ultimately control the laser-cutting, but leaves open what or who processes the image data to determine a targeted treatment region in the lens for cutting. *Id.* at 16:47–67. Furthermore, none of claims 2–15 that depend from claim 1 add such a computer-processing requirement. *Id.* at 17:1–57. This makes claim 1 (and its dependent claims) significantly different from the other independent claims (and their dependent claims). Thus, as explained further below, Patent Owner’s arguments that the surgeon would

not have ceded control of surgery planning to a computer are not persuasive when considered for claim 1.

Considering the record and Petitioner's positions on the reasons for combining Swinger, Baikoff, and Hoppeler, we agree with Petitioner that the person of ordinary skill in the art would have had reasons to make that combination. *See* Pet. 30–37. It is Petitioner's position that using OCT imaging, which Baikoff evidences is a user-friendly, effective, computer-controlled technique for acquiring accurate pre-surgery images of the anterior portion of the eye, and as far posterior as a significant portion of the lens, would be a replacement for Swinger's direct visualization or ultrasound imaging in planning cataract surgery. *Id.* at 30–33 (citing, *inter alia*, Ex. 1041, 1843, 1849). One of Swinger's pre-surgical imaging techniques includes ultrasound imaging, which the record shows to be similar, but in some ways inferior to OCT imaging. *Id.* at 30–34; *see* Ex. 1039, 35:59–63 (using ultrasound to plan laser lens surgery); *see* Ex. 1041, 1844, 1849 (explaining advantages of OCT over ultrasound relating to IOL implantation); *see also* Ex. 1070, Figs. 1, 2 (illustrating ultrasound eye imaging capabilities).

Baikoff explains that OCT is faster and clearer than ultrasound. Ex. 1041, 1843–44; *see also* Ex. 1070, 300 (identifying ultrasound's resolution to be 35 μm , which is inferior to the 10 μm resolution of Baikoff); *see also* Ex. 1001 ¶ 157. We find the evidence supports that Petitioner is correct that Baikoff's OCT imaging would be an advantageous replacement for Swinger's ultrasound imaging because it offers undistorted, more comfortable, quicker, and higher resolution imaging than ultrasound. Thus, we agree with Petitioner that, as to claim 1, there would have been ample

motivation for the ordinarily skilled artisan to combine Swinger and Baikoff towards achieving the claimed invention.

The Claimed “Locations Distributed Throughout a Volume of a Crystalline Lens”

Patent Owner argues that the asserted prior art does not teach acquiring image data from “locations distributed throughout a volume of a crystalline lens,” as claimed. Resp. 32–34 (citing Ex. 1012 (claims 1 and 17); Ex. 2087 ¶¶ 119–121; Ex. 2088 ¶ 87). Patent Owner argues Swinger’s disclosed ultrasound is limited to measurements in the anterior chamber, and that Baikoff’s OCT can only obtain “clear visualization” in an albino subject and shows images only of an anterior chamber not a lens. *Id.*

We are unpersuaded by Patent Owner’s arguments, which we have considered, but we find ignore the clear evidence of record. Even looking at no more than Baikoff’s Figure 3, it is apparent that its OCT imaging is capable of acquiring image data from “locations distributed through a volume of a crystalline lens,” as claimed. Ex. 1042, 1845; *see also* Ex. 1001 ¶¶ 157–159, 282, 286–288. There is no specific claim requirement as to what the claimed lens “volume” must be or how many “locations” must be imaged or where those “locations” must be “distributed,” or, for that matter, that the lens cannot be that of an albino subject (per one of Patent Owner’s arguments). *See* Ex. 1012, 16:47–67. We find Baikoff’s Figure 3 shows a high-resolution, cross-section image of a substantial portion of a lens acquired via OCT imaging, which includes many, many imaged locations distributed in the volume of the lens. We find nothing more is required by the claim.

The Claimed Lens Fragmentation or Segmentation

Patent Owner argues that the claims require lens segmentation or fragmentation and Swinger and Hoppeler do not disclose this element. Resp. 35–42. Patent Owner devotes a significant portion of its briefing to this argument, which we have considered, but it is readily apparent from the record that this argument is incorrect.

Swinger discloses computer-controlled laser cataract surgery, anterior capsulotomy as a part of such cataract surgery, IOL implantation as a part of cataract surgery, laser ablation of the lens, and laser sectioning of tissue within the eye. Ex. 1039, 7:50–58, 8:65–67, 10:10–19, 10:31–34, 34:30–35:3, 35:18–36:17; *see* Pet. 30–43; *see also* Ex. 1001 ¶¶ 63, 133–135, 145–149, 178 (discussing Swinger). For example, Swinger discloses,

Lasers have also been used in cataract surgery for some time. This includes both for excising the posterior lens capsule, when opacified, and for delivering energy to the lens itself for ablating its interior substance, both to create an opening at the visual axis or to shorten the time of secondary phacoemulsification surgery by first liquefying the interior lens substance, which uses ultrasonic energy to remove the lens material and which is traumatic to the posterior lens capsule and intraocular structures.

Ex. 1039, 7:50–58. Swinger discloses its laser has the control and gentleness to be used to photoablate regions within the capsule and lens and teaches using that laser under computer control to scan (any) cutting patterns in the lens. *Id.* at 8:2–3, 8:65–67; *see also* Ex. 1001 ¶¶ 133, 145.

Hoppeler is similarly directed to computer-controlled laser cataract surgery where the laser is used “like a surgical knife” for “lens fragmentation.” Ex. 1043, 1; *see* Pet. 35–37; *see also* Ex. 1001 ¶¶ 78, 180, 182 (discussing Hoppeler). Hoppeler teaches that such lens fragmentation is

accomplished by applying different patterns of laser scanning to the tissue.

Ex. 1043, 2–3. Hoppeler includes the following disclosure:

Cataract fragmentation: The liquification or ***fragmentation of the cataractous lens*** is a procedure that benefits from the low energy and confined collateral damage of the Nd:YLF picosecond laser. The idea of ***cataract fragmentation*** is to significantly reduce phacoemulsification time in the following cataract surgery. The amount of ***the lens that can be fragmented*** is dependent on the pupillary size and the density of the nucleus itself. The ***application of the laser has to start in the depth of the lens, working its way anteriorly*** as gas bubbles form, separate the nuclear layers and ***prevent laser effects in the tissue behind them***.

Id. at 4 (emphasis added); *see* Pet. 35–36.

All this is noted in the Petition and Petitioner’s testimonial evidence. *See* Pet. 30, 34–43; *see* Ex. 1001 ¶¶ 63, 78, 133–135, 145–149, 178, 180, 182, 285, 289–292 (addressing these issues). In particular, when asserting that the prior art teaches fragmenting a cataractous lens, as claimed, Petitioner specifically points to Swinger’s lens ablation discussed at its columns 35 and 36 and Hoppeler’s lens fragmentation for removal discussed at its page 4. Pet. 42–43 (citing Ex. 1039, 35:18–42, 36:3–6; Ex. 1043:1–4). None of Patent Owner’s arguments persuades us Petitioner’s position is wrong.

Thus, we find that the prior art asserted by Petitioner teaches the claimed feature of “effecting patterned laser cutting of lens tissue for subsequent removal of pieces or segments of lens tissue.”

Dependent Claims 2–15’s Obviousness over Swinger, Baikoff, and Hoppeler

Petitioner makes a similar showing for dependent claims 2–15 as made for independent claim 1. *Id.* at 43–49 (citing, *inter alia*, Ex. 1001

¶¶ 293–311; Ex. 1012, 6:49–51; Ex. 1039, 2:54–61, 5:52–53, 7:50–63, 13:10–13, 20:8–13, 20:52–65, 23:13–24, 25:28–37, 34:30–37, 34:52–35:3, 35:17–36:7, Figs. 6, 7, 15B1; Ex. 1041, 1843–45, 1847, Fig. 10; Ex. 1043, 2–4, Figs. 2, 3). Petitioner applies the same reasons for combining Swinger, Baikoff, and Hoppeler for these dependent claims as for claim 1, and Petitioner has mapped the claim limitations to the prior art combination’s disclosures similar to its mapping for claim 1. *Id.*

In particular, Petitioner demonstrates that: (for claim 2) Swinger’s disclosed ablation forms gas (cavitation) bubbles and tissue ruptures (Pet. 43 (citing Ex. 10901 ¶ 293, Ex. 1012, 6:49–51; Ex. 1039, 2:54–61, 13:10–13)); (for claim 3) Swinger teaches ablating tissue in a posterior-to-anterior direction within the tissue, in a variety of patterns and that Hoppeler also teaches the same (*id.* at 43–44 (citing Ex. 1039, 25:28–37, 34:52–3, 35:18–42, 35:37–36:5; Ex. 1043, 4, Figs. 2, 3)); (for claims 4 and 5) Swinger teaches that a first area is scanned and then a second area is scanned and that this progresses in a posterior-to-anterior direction, and that Hoppeler teaches the same in the z-axis (*id.* at 44 (citing Ex. 1001 ¶ 296; Ex. 1039, 25:32–37, 34:52–35:2, 35:37–36:5; Ex. 1043, 4, Figs. 2, 3)); (for claim 6) Swinger’s scanning pattern can be helical or stacked, concentric circles forming a cylinder, or any known pattern, which teaches 3D patterns, and that Hoppeler also teaches patterns extended in the z-axis, which are also 3D patterns (*id.* at 44–45 (citing Ex. 1001 ¶ 297; Ex. 1039, 34:52–35:3, 35:37–36:5; Ex. 1043, Fig. 3)); (for claim 7) Swinger discloses a variety of laser patterns, including curved lines, intersecting lines, circular lines, and spiral lines, and Hoppeler also teaches planar, radial, spiral, circular, and overlapping laser patterns to fragment a lens (*id.* at 45–46 (citing Ex. 1039,

20:52–65, 35:66–36:2, Fig. 7; Ex. 1043, 3–4, Figs. 2, 3)); (for claim 8) generally the same as for claim 7, but also that Swinger discloses performing anterior capsulotomy with such circular or spiral laser cuts, and that Hoppeler also disclose laser cuts “within the lens capsule of the eye” (*id.* at 46 (further citing Ex. 1043, 4, Figs. 2, 3)); (for claim 9) Swinger discloses ablating the lens to reduce phacoemulsification time by pre-fragmenting the lens for subsequent phacoemulsification, and that Hoppeler teaches the same (*id.* at 47 (citing Ex. 1001 ¶¶ 302–303; Ex. 1039, 7:50–63; Ex. 1043, 4)); (for claim 10) Swinger and Hoppeler teach ablating a lens to reduce phacoemulsification time, the purpose of which is to break the lens into pieces for removal by aspiration probe, which is often part of the same device used for phacoemulsification (*id.* at 47 (citing Ex. 1001 ¶¶ 304–306; Ex. 1039, 7:50–63; Ex. 1043, 4)); (for claim 11) Swinger teaches targeting tissues such as the cornea, iris, lens capsule, and lens (*id.* at 48 (citing Ex. 1039, 5:52–53, 23:13–17, 34:30–32, 7:50–60)); (for claim 12) Swinger teaches using ultrasound imaging and Baikoff teaches using OCT imaging (*id.* (citing Ex. 1001 ¶ 308; Ex. 1039, 35:17–36:7; Ex. 1041, 1844–45, Fig. 10)); (for claim 13) Swinger teaches it was known to phacoemulsify the lens and lens capsule interior, and that Hoppeler teaches the same (*id.* (citing Ex. 1001 ¶ 309; Ex. 1039, 7:55–60; Ex. 1043, 4)); (for claim 14) Swinger teaches control and safety systems such as a computer control unit, safety shutter, and eye-tracking system and that the laser is adjusted based on the patent’s eye movements, which is dynamic adjustment (*id.* (citing Ex. 1039, 20:8–13, 34:64–67, Fig. 6)); and (for claim 15) Swinger teaches ablating tissue in a posterior-to-anterior direction, which creates a light scattering region, and that Hoppeler teaches the same (*id.* at 49 (citing Ex. 1039,

25:28–37; Ex. 1043, 4)). *See also* Ex. 1001 ¶¶ 293–311 (Dr. Izatt addressing these dependent claims).

Other than its assertions regarding claim 7 and copying, and its arguments set forth above with respect to independent claim 1, addressed above, Patent Owner does not contest Petitioner’s arguments with respect to claims 2–15.

Upon review of the parties’ arguments and supporting evidence, we determine that Petitioner demonstrates by a preponderance of the evidence that claims 2–15 would have been obvious over Swinger, Baikoff, and Hoppeler.

Summary for Obviousness of Claims 1–15 over Swinger, Baikoff, and Hoppeler

In summary of our findings above, Petitioner has established by a preponderance of the evidence that claims 1–15 would have been obvious over Swinger, Baikoff, and Hoppeler. No argument by Patent Owner persuades us otherwise.

2. *Obviousness of Claims 17–23 over Swinger, Baikoff, and Hoppeler (Ground 1)*

Because the same facts and legal conclusions are determinative for claims 17–23 under Ground 1, we address them below as a group. As explained further, we find that Petitioner has not established by a preponderance of the evidence that any of these claims would have been obvious under Ground 1.

Parties’ Positions and our Analysis

Regarding independent claims 17 and 19, under Ground 1 Petitioner makes a similar showing as for claim 1 and, where the recited limitations are the same or similar, cites to the same evidence. Pet. 49–53 (additionally

citing, *inter alia*, Ex. 1001 ¶¶ 316, 326). As Petitioner’s asserted positions and cited evidence are substantially the same, we will not review them again here. *See supra* Section II.E.1; *see* Pet. 49 (regarding limitation 17.2), 52 (regarding limitation 19.2).

However, as we noted above, claims 17 and 19 are significantly different from claim 1 because they each require that every recited step of the claimed laser cataract surgery method be accomplished by a computer system, i.e., as summarized: (1) a computer operates an imager and acquires image data of a lens; (2) the computer processes the image data to construct a target treatment region of the lens; and (3) the computer then guides a laser to fragment the lens via a first pattern creating a light scattering region and then in a second pattern anterior to the first.¹⁷ *Compare* Ex. 1012, 16:47–67 (claim 1) *with id.* at 18:15–39 (claim 17) and 18:45–67 (claim 19).

Patent Owner argues, “[i]n [prior art] procedures, the treatment region was identified manually. Walter ¶37. Regardless of the tool, the surgeon manually identified the treatment region and operated the instruments under direct visualization. *Id.*” Resp. 6. Addressing the asserted prior art in view of the claimed methods, Patent Owner argues, *inter alia*, that:

[alt]hough Swinger contemplates that a computer may control the laser while cutting, Swinger expressly reserves the critical step of identifying the surgical target for the surgeon—in line with conventional wisdom at the time. *Id.*, 34:64-67 (“cutting process can be totally computerized ***once the reference point on the capsule has been fixed***”); Walter ¶¶56-59. In the words of Alcon’s expert, Swinger is “quite clear that the human positions the cutting beam.” Ex. 2057, 158:19-159:1.

¹⁷ For brevity, we paraphrase the common limitations of claims 17 and 19, recognizing that more specific limitations are required.

Id. at 11; *see also id.* at 11–13 (further discussing this issue). Regarding Baikoff, Patent Owner argues “Baikoff does not mention laser surgery, it does not disclose using a laser to create a ‘light scattering region.’ *Id.* ¶¶41–43.” Resp. 13. Regarding Hoppeler, Patent Owner argues that “Hoppeler also does not disclose an imaging system, much less using an imaging system for cataract fragmentation. Ex. 1043; Kang ¶53.” Resp. 14. Patent Owner’s point is that before the invention the standard way of planning a cataract surgery’s laser cutting was in the surgeon’s mind and judgment rather than tasking a computer with such responsibility.

Under the heading of no “motivation to combine laser cataract surgery with OCT imaging,” and mingled with arguments that Baikoff’s OCT would not have been used with Swinger’s system (an argument with which we do not agree, as discussed above), Patent Owner also argues that “[Petitioner] fails to offer any reason why ophthalmic surgeons would resort to a computer-controlled laser system guided by imaging such as OCT.” *Id.* at 25. Patent Owner argues that “Swinger nowhere discusses using an imaging system to position or control the laser and instead teaches that the ophthalmic surgeon is responsible for manually identifying the surgical target. Ex. 1001 ¶ 152.” Resp. 27–28 (citing Ex. 1087 ¶ 97).

Under the heading directed to the prior art combination failing to teach acquiring image data from “locations distributed throughout a volume of a crystalline lens,” Patent Owner argues,

Independent claim 17 requires “operating an optical coherence tomography imaging system, controlled by a computer system, so as to acquire image data from locations distributed throughout a volume of a crystalline lens of a patient.” *Id.*, cl. 17. [Petitioner] relies on Swinger and Baikoff for these limitations. Pet. 38–39, 49. Neither disclose such imaging.

Resp. 33 (citing Pet. 38–39, 49; Ex. 2087 ¶¶ 199–121).

Throughout the Response Patent Owner makes several other arguments with which we do not necessarily agree and need not discuss here, but we do agree with Patent Owner’s arguments noted above and we agree that the prior art combination of Swinger, Baikoff, and Hoppeler does not teach or render obvious a method as required by independent claims 17 and 19 where (1) a ***computer operates an imager*** and acquires image data of a lens; (2) the ***computer processes the image data to construct a target treatment region*** of the lens; and (3) the ***computer then guides a laser to fragment the lens*** via a first pattern creating a light scattering region and then in a second pattern anterior to the first.¹⁸ See Ex. 1012, 18:15–19:16.

“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 Hoppeler’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

¹⁸ This conclusion is consistent with the similar conclusions by the Panel over similar claims, and the same prior art, at issue in related proceedings. See *supra* Section I.B and the final decisions in the identified, related *inter partes* reviews, where entered.

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.*, 885 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 *processing data including image data, using the computer system, so as to construct a targeted treatment region of the lens of the eye, the targeted treatment region being disposed anterior to the posterior capsule of the lens*, this subject matter is not disclosed in any cited art, certainly not paired with the other computer-controlled steps of the claimed method based on this step, 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 (this is exemplified in the different outcomes here for claims 1, 17, and 19 over the same prior art combination). We note several statements by Petitioner and points of evidence that support Patent Owner’s arguments for the patentability of claims 17–23 over Swinger, Baikoff, and Hoppeler.

For example, Petitioner states:

Swinger’s pre-surgical analysis for directing the treatment beam instead employs manual estimation or the use of ultrasound to image ocular tissue. *Id.* at 35:17–36:7 (teaching ultrasound to measure distance between cornea and anterior lens capsule to identify a safe distance to begin phacorefractive ablation of lens); see Ex.1001 ¶¶151–53.

Pet. 30. Petitioner is clear throughout that Swinger does not have a computer that determines a target cutting region for a laser, it is a human surgeon that performs this task, whether using an HeNe orienting beam or an ultrasound image. *See generally id.*

It is similarly clear from the record that Baikoff also does not teach a computer that determines a target cutting region for laser cataract surgery. For example, Petitioner's witness Dr. Izatt states, "Baikoff does not specify whether it is the operator or the OCT assembly itself that initially identifies these features." Ex. 1001 ¶ 164. Petitioner and Dr. Izatt rely on the combination of Swinger and Baikoff to disclose the claim requirement that a computer processes image data to determine a target treatment region for laser cutting. Pet. 49; Ex. 1001 ¶¶ 162–168. However, Dr. Izatt testifies that, based on combining Baikoff's OCT imaging with Swinger's system, "[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." Ex. 1001 ¶ 163 (emphasis added)).

Dr. Izatt conclusively opines that it would be simply obvious to program a controller to use Baikoff's OCT image data to determine the boundaries of tissue and determine a treatment region without surgeon intervention. *See id.* ¶¶ 165, 168 (without citation to any evidence). However, Dr. Izatt concedes at the same portion of his testimony that

POSAs at the time 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 identifications and determinations, and adjusting the cutting plan accordingly before executing the procedure.

Id. ¶ 168 (emphasis added). This reflects Dr. Izatt's earlier testimony that

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). We also note that Dr. Izatt testifies on cross-examination that in Swinger it's "quite clear that the human positions the cutting beam," and in response to the question "Baikoff does not describe a controller that identifies the treatment regions, right?" answers "No, it does not." Ex. 2057, 158:19–22; 204:8–10.

Thus, even Petitioner's own points and its 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, and then to allow a computer to generate and use image data to plan and then conduct incisions in the lens or lens capsule. Petitioner does not assert Hoppeler remedies Swinger's and Baikoff's shortcomings in this regard. See *generally* Pet.; Ex. 1001.

We also credit Dr. Kang's and Dr. Walter's testimony on the issue, including 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 cataract surgery on the lens or lens capsule, and relegated such task to a computer, which subsequently performs the procedure. Ex. 2087 ¶¶ 37–39, 42, 97; *see also id.* ¶¶ 63–65 (addressing similar claim limitations of a related patent and Swinger and Baikoff's shortcomings); *see also* Ex. 2088 ¶¶ 40, 59, 68–71 (Dr. Walter testifying similarly). These witnesses take issue with Petitioner's and Dr. Izatt's positions that the

Swinger-Baikoff combination teaches or suggests such reliance on a computer, and we agree.

The acknowledged criticality (as of the invention) of a surgeon's determinations in identifying cutting regions, even by Petitioner, means that a computer was not understood to be a suitable replacement for the human for all of the claimed steps directed to imaging, then processing the image data to plan laser eye surgery for the lens or lens capsule, 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 Hoppeler work like the claimed invention of claims 17 and 19 and this supports the non-obviousness of the challenged claims.

Summary for Ground 1 and Obviousness of Claims 17–23 over Swinger, Baikoff, and Hoppeler

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 Hoppeler in the manner proposed by Petitioner, with a reasonable expectation of success to achieve the invention of claims 17–23. We find that the proposed combination of prior art does not teach or suggest methods including:

- a. operating an optical coherence tomography imaging system, controlled by a computer system, so as to acquire image data from locations distributed throughout a volume of a crystalline lens of a patient;
- b. processing data including image data, using the computer system, so as to construct a targeted treatment region of the lens of the eye, the targeted treatment region being disposed anterior to the posterior capsule of the lens; and
- c. generating a beam of light using a pulsed laser system, wherein the pulsed laser system is guided by the computer

system so as to effect fragmentation of lens tissue of the targeted treatment region in a fragmentation pattern within the targeted treatment region, the fragmentation comprising:

- i. directing a laser beam in a first pattern to photodisrupt at least a portion of lens tissue of the eye to create a light scattering region; and
- ii. subsequently directing the laser beam in a second pattern in lens tissue anterior to the light scattering region so as to photodisrupt at least a portion of the targeted region and effect 3-Dimensional patterned laser cutting of the lens tissue for subsequent removal,

required by claims 17 and 18, or

- a. operating an imaging system, controlled by a computer system, so as to acquire image data from a crystalline lens of a patient;

- b. processing data including the image data, using the computer system, so as to generate a targeted treatment region in the lens of the eye, wherein the targeted treatment region is anterior to the posterior capsule of the lens; and

- c. generating a beam of light using a pulsed laser system so as to effect cutting of lens tissue of the targeted treatment region, the cutting comprising:

- i. directing a laser beam, under computer-guided control, in a first pattern to photodisrupt at least a portion of lens tissue to create a light scattering region; and

- ii. subsequently directing the laser beam, under computer-guided control, in a second pattern in lens tissue anterior to the light scattering region, the second pattern comprising a plurality of intersecting planar incision patterns, so as to effect cutting of lens tissue into a plurality of segments or fragments for subsequent removal,

required by claims 19–23.

Therefore, we conclude that none of claims 17–23 would have been obvious under Petitioner’s Ground 1. *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.”).

3. *Obviousness of Claims 1–15 and 17–23 over Freedman, Swinger, and Hoppeler (Ground 2)*

Under Ground 2, Petitioner asserts that claims 1–15 and 17–23 would have been obvious over the combination of Freedman, Swinger, and Hoppeler. Pet. 54–69 (citing, *inter alia*, Ex. 1001 ¶¶ 169–176, 181–182, 332–358, 361–363, 367, 375–383; Ex. 1012, 6:49–51, 8:64–9:7; Ex. 1039, 7:50–63, 13:10–13, 16:60–20:34, 20:49–21:19, 23:17–25, 25:28–37, 34:30–37, 34:52–35:3, 35:18–36:5, 36:15–17, Figs. 6, 7, 15A1, 15B1; Ex. 1040, 1:23–26, 2:3–4, 2:7–13, 4:9–14, 4:33–35, 4:46–5:45, 5:54–67, 6:12–52, 7:15–60, 8:31–34, 9:12–19, Figs. 1–3; Ex. 1043, 1–4, Figs. 2, 3). First, Petitioner asserts that the ordinarily skilled artisan would have been motivated to combine Swinger, Freedman, and Hoppeler (we do not discern that Petitioner expressly asserts that the ordinarily skilled artisan would have had a reasonable expectation of success). *Id.* at 54–56. Then, Petitioner walks through the limitations of the claims and identifies how and where the prior art combination teaches or suggests their subject matter. *Id.* at 56–69.

To summarize, regarding combining Swinger, Freedman, and Hoppeler, 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), Freedman to radial keratotomy (but mentioning other procedures), and Hoppeler to the use of a computer-controlled surgical laser for cataract fragmentation. *Id.* at 54–56 (citing,

inter alia, Ex. 1001 ¶¶ 169–176, 181–182). Petitioner asserts that the ordinarily skilled artisan would have been motivated to use Freedman’s computer-controlled OCT imaging and laser surgical system for Swinger’s computer-controlled cataract surgery, using Hoppeler’s technique for patterned laser segmentation of the lens tissue for removal. *Id.*

Regarding independent claim 1, Petitioner asserts that most of the limitations, other than how to use the laser, are taught by Freedman, most importantly, what laser is used. *Id.* at 56–61. For example, for the general concept of the laser cataract surgery (limitation 1P), Petitioner identifies that “Freedman teaches a laser surgical method . . . but provides details only regarding corneal procedures” and “Swinger discloses another laser surgical system, like Freedman’s, for making incisions in ocular tissue during a cataract procedure,” and concludes, “[t]hus, it would have been obvious to a POSA to use Freedman’s multifunctional ophthalmic-surgery system to perform a cataract surgery method.” *Id.* at 56 (citing, *inter alia*, Ex. 1001 ¶¶ 332–333). Regarding the limitation regarding computer-controlled imaging (limitation 1.1) and the limitation regarding computer processing to determine a target treatment region, Petitioner points to Freedman’s OCT imaging and control system and asserts it is not disclosed for the use, but could be used on the lens and that an ordinarily skilled artisan would know what tissues needed treatment for cataract surgery. *Id.* at 57–58 (citing, *inter alia*, Ex. 1001 ¶¶ 334–338). Finally, regarding the computer-guided laser cutting limitations (limitations 1.3 and 1.4), Petitioner points to using Freedman’s “‘pulsed laser beam’ controlled by a processor ‘in accordance with [an] ablating plan’” using laser patterning as taught in Swinger (on the lens, posterior-to-anterior). *Id.* at 59–60 (citing, *inter alia*, Ex. 1001 ¶¶ 339–

342; Ex. 1040, 5:35–36, 5:45; Ex. 1039, 35:37–36:5 (Swinger’s phacorefractive ablation embodiment), 34:61–64 (capsulotomy), 36:3–5 (lens ablation); Ex. 1043, 1–4 (Hoppeler’s lens fragmentation)).

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. 43–44 (citing Ex. 1001 ¶¶ 136, 170; Ex. 1040, 4:9–32, 4:33–45, 5:37–53, 7:15–51, 8:30–9:18; Ex. 2087 ¶¶ 48–52, 78–80). 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.* (citing, *inter alia*, 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. 43–44 (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 ¶¶ 79–82 (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, 79–82. This is because the ablating laser cannot pass through the cornea to reach the lens without destroying the cornea in the process. *Id.* ¶¶ 79, 82. In contrast, lasers used to cut internal tissues of the eye use laser photodisruption. *Id.* ¶ 80. 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 20–21 (citing Ex. 1001 ¶ 176; Pet. 54–56). 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 grounds 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, “[a]lthough Freedman’s exemplary procedure focuses on corneal incisions, it would have been obvious to a POSA that applying Freedman’s system to other target tissue, such as the lens as part of cataract surgery, the system would be used to segment the lens, as taught by Swinger.” Pet. 55. We note, Dr. Izatt’s declaration paragraph 176 cited in Petitioner’s Reply at 20 for the proposition that Swinger’s laser might be substituted for Freedman’s, is cited in the Petition for the propositions that “Freedman’s OCT imaging system is fully capable of imaging any target tissue” and 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 a part of the lens.” Pet. 55 (substituting Swinger’s laser for Freedman’s is never mentioned in the Petition).

As noted, Petitioner in its Reply argues that Dr. Izatt testifies that Swinger’s laser parameters could be modified and that this would include “substitution of the laser source.” See Reply 20; Ex. 1001 ¶ 176. This argument, however, was not expressly made or even hinted at 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 use of its ablating laser and laser system 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. 55), without discussion, to Dr. Izatt's declaration paragraph 176, 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. 54–60 (as Petitioner acknowledges, "Freedman does not disclose using the system to perform lens fragmentation."); *see also* Resp. 45 (identifying this concession). Petitioner argues, however, that it would have been obvious to use Freedman's system for cataract surgery on the lens, to use Freedman's system to perform anterior capsulotomy (as taught by Swinger), to use Freedman's system to segment the leans, as taught by

Swinger or Hoppeler, and to use ablating plans as disclosed by Swinger or Hoppeler. Pet. 54–69 (citing, *inter alia*, Ex. 1001 ¶¶ 169–176, 181–182, 332–358, 361–363, 367, 375–383; Ex. 1039, 7:50–63, 13:10–13, 16:60–20:34, 20:49–21:19, 23:17–25, 25:28–37, 34:30–37, 34:52–35:3, 35:18–36:5, 36:15–17, Figs. 6, 7, 15A1, 15B1; Ex. 1040, 1:23–26, 2:3–4, 2:7–13, 4:9–14, 4:33–35, 4:46–5:45, 5:54–67, 6:12–52, 7:15–60, 8:31–34, 9:12–19, Figs. 1–3).

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. 45–50.

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. 49–50. 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. 49. 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. 29–30, 53. 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.¹⁹ Indeed, Petitioner’s above-noted statements demonstrate that the

¹⁹ 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 20–21. 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

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 cataract laser surgical systems"); Ex. 2014, 15:53–58 ("There are crucial differences between lens surgery and corneal surgery"); *see also* Sur-Reply 11, 21–22 (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.²⁰ Ex. 2014, 16:13–18; Ex. 2015, 898 ("Increasing a

particular claim language distinguishes a prior art reference, but that a court would later hold the patentee to the distinction he pressed during prosecution").

²⁰ Petitioner asserts that Swinger discloses a system for cataract surgery (on the lens capsule and lens). Pet. 43–54. Petitioner does not assert, however, that Swinger explains how to modify an existing corneal surgery system to

system's performance by an order of magnitude cannot be regarded as obvious.”).

Summary for Ground 2

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 (with or without Hoppeler) to achieve the claimed invention with a reasonable expectation of success. Thus, Petitioner fails to demonstrate by a preponderance of the evidence that any of the claims challenged under Ground 2 would have been obvious over Freedman and Swinger whether or not also combining Hoppeler with these references.

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.*

also perform surgery on the lens. *Id.* Nor does the Petition assert under Ground 2 that Swinger would have been used by the ordinarily skilled artisan to perform the claimed optical scanning and laser procedure. *Id.* 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).

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. Walter 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 establishes by a preponderance of the evidence that claims 1–15 of the '724 patent are unpatentable as obvious over Swinger, Baikoff, and Hoppeler. Petitioner does not establish by a preponderance of the evidence that claims 17–23 of the '724 patent are unpatentable as obvious over the asserted prior art.

Our final decision is summarized as follows:

Claims	35 U.S.C. §	References/ Basis	Claims Shown Unpatentable	Claims Not Shown Unpatentable
1–15, 17–23	103	Swinger, Baikoff, Hoppeler	1–15	17–23
1–15, 17–23	103	Freedman, Swinger, Hoppeler		1–15, 17–23
Overall Outcome			1–15	17–23

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 proved by a preponderance of the evidence that claims 1–15 of the ’724 patent are unpatentable;

FURTHER ORDERED that Petitioner has not proved by a preponderance of the evidence that claims 17–23 of the ’724 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

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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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