

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.

IPR2021-00858
Patent 8,425,497 B2

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

SNEDDEN, *Administrative Patent Judge*.

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

I. INTRODUCTION

We have jurisdiction under 35 U.S.C. § 6. We issue this Final Written Decision pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73 in an *inter partes* review involving Alcon Inc., Alcon LenSx, Inc., Alcon Vision, LLC, Alcon Laboratories, Inc., and Alcon Research, LLC (“Petitioner”) and AMO Development, LLC (“Patent Owner”). Based on the record before us, we conclude that Petitioner has not demonstrated, by a preponderance of the evidence, that claims 1–19 of U.S. Patent No. 8,425,497 (“the ’497 patent,” Ex. 1009) are unpatentable.

A. Background and Summary

Petitioner filed a Petition requesting an *inter partes* review of claims 1–19 of the ’497 patent. Paper 1 (“Pet.”). Patent Owner filed a Preliminary Response to the Petition. Paper 10. We determined, based on the information presented in the Petition and Preliminary Response, that there was a reasonable likelihood that Petitioner would prevail in showing that at least one of the challenged claims was unpatentable over the cited art. Pursuant to 35 U.S.C. § 314, the Board instituted trial on December 14, 2021. Paper 12.

Following institution, Patent Owner filed a Response to the Petition (Paper 21, “PO Resp.”), Petitioner filed a Reply to Patent Owner’s Response (Paper 29, “Reply”), and Patent Owner filed a Sur-Reply (Paper 35, “Sur-Reply”).

Petitioner filed a Motion to Exclude (Paper 38, “Mot.”), Patent Owner filed an Opposition to Petitioner’s Motion to Exclude (Paper 39, “Opp.”), and Petitioner filed a Reply to Patent Owner’s Opposition (Paper 44, “Mot. Reply”).

On September 8, 2022, the parties presented arguments at an oral hearing. The transcript of the hearing has been entered into the record. Paper 47.

B. Real Parties in Interest

Petitioner states that “[a]fter filing [the] Petition, Alcon LenSx, Inc. merged into Alcon Research, LLC, with Alcon Research, LLC the surviving entity,” and 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, Johnson & Johnson Surgical Vision, Inc., AMO Manufacturing USA, LLC, and AMO Sales and Services, Inc. as the real parties in interest. Paper 5, 1.

C. Related Matters

Petitioner has filed petitions for *inter partes* review of eleven other related patents in the same family as the ’497 patent, including: IPR2021-00817 for U.S. Patent No. 8,394,084; IPR2021-00823 for U.S. Patent No. 8,403,921; IPR2021-00824 for U.S. Patent No. 9,693,903; IPR2021-00856 for U.S. Patent No. 8,500,724; IPR2021-00862 for U.S. Patent No. 8,709,001; IPR2021-00835 for U.S. Patent No. 9,095,415; IPR2021-00839 for U.S. Patent No. 9,101,448; IPR2021-00840 for U.S. Patent No. 9,107,732; IPR2021-00853 for U.S. Patent No. 9,125,725; IPR2021-00841 for U.S. Patent No. 9,474,648; and IPR2021-00825 for U.S. Patent No. 9,693,904. Pet. 2–3; Paper 3, 1.

The parties indicate that the ’497 patent and its related patents have been asserted against Petitioner in Civil Action No. 1:20-cv-00842-CFC in the District of Delaware. Pet. 2–3; Paper 5, 1.

D. The '497 patent (Ex. 1009)

The '497 patent is directed to a system and method for making incisions in eye tissue at different depths. Ex. 1009, Abstr. The '497 patent notes that previous methods of perforating the anterior lens capsule used a technique called “can-opener capsulotomy” in which a surgeon uses a sharp needle to perforate the anterior lens capsule in a circular fashion. *Id.* at 1:39–45. The '497 patent reports that problems with this technique included the

inability of the surgeon to adequately visualize the capsule due to lack of red reflex, to grasp it with sufficient security, to tear a smooth circular opening of the appropriate size without radial rips and extensions, or technical difficulties related to maintenance of the anterior chamber depth after initial opening.

Id. at 2:5–2:10.

The '497 patent discloses a technique and system for creating “rapid and precise openings in the lens capsule and fragmentation of the lens nucleus and cortex” using “3-dimensional patterned laser cutting.” *Id.* at 3:11–14. Figure 1 of the '497 patent is reproduced below:

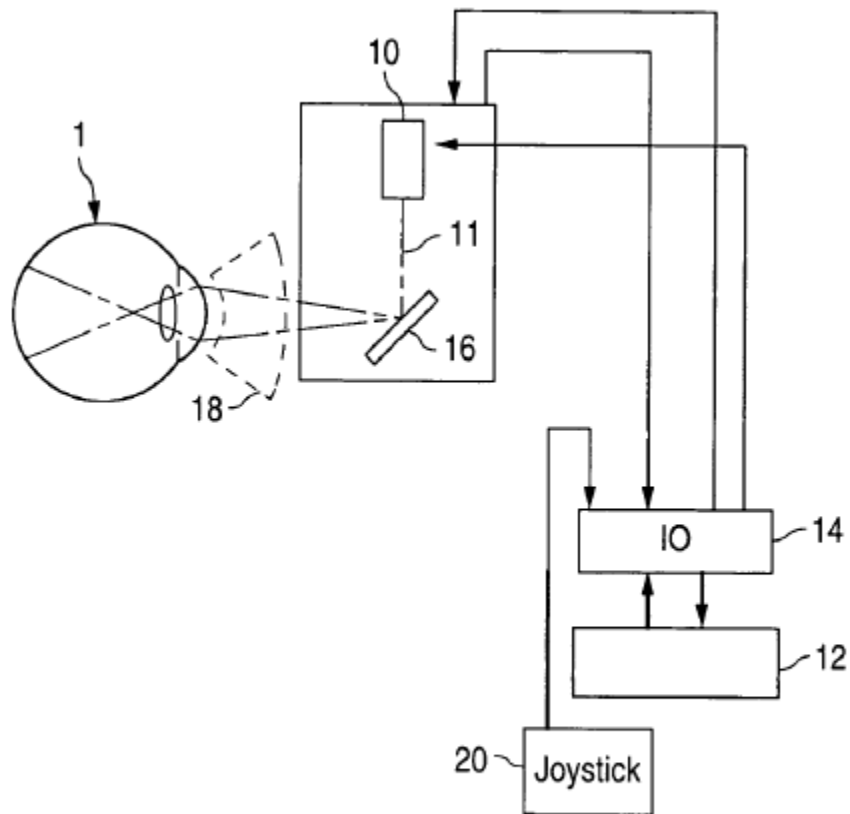


FIG. 1

Figure 1 is a plan diagram of a system that projects or scans an optical beam into a patient's eye. *Id.* at 5:18–19. The system of Figure 1 includes “a light source **10** (e.g., laser, laser diode, etc.), which may be controlled by control electronics **12**, via an input and output device **14**, to create optical beam **11**.” *Id.* at 6:18–21. Mirror **16** is used to scan the eye and may be controlled via input and output device **14**. *Id.* at 6:17–22. Optional ophthalmic lens **18** is used to focus optical beam **11** into the patient's eye **1**. *Id.* at 6:22–24.

The '497 patent explains that “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.” *Id.* at 7:49–51. In one embodiment, optical coherence tomography (“OCT”) may be used to

provide information about “the axial location of the anterior and posterior lens capsule, the boundaries of the cataract nucleus, as well as the depth of the anterior chamber.” *Id.* at 7:66–8–3. “This information may then be loaded into the laser 3-D scanning system, and used to program and control the subsequent laser assisted surgical procedure.” *Id.* at 8:3–4.

Laser cutting of the lens capsule is performed using short pulsed laser light focused into the eye tissue, which causes dielectric breakdown at the focal point and ruptures the tissue in the vicinity of the photo-induced plasma. *Id.* at 6:46–48. This creates a plasma-induced “crater” at the focal point and, by linking individual craters, a continuous cutting is provided in the eye tissue. *Id.* at 6:46–58.

E. Illustrative Claims

Independent claims 1, 16 and 17, reproduced below, are illustrative of the claimed subject matter of the ’497 patent.

1. A method of making an incision in eye tissue during a cataract surgical procedure, the method comprising:

operating an imaging system, coupled to *an electronics control system comprising a computer*, so as to acquire image data from locations distributed throughout a volume of a crystalline lens of a patient and construct one or more images of the patient’s eye tissues from the image data, wherein the one or more images include an image of at least a portion of the crystalline lens;

identifying, using the control system, a cutting region based on the image data, the cutting region being at least partially defined by an anterior cutting boundary and a posterior cutting boundary and including a portion of the crystalline lens;

generating a beam of light using a pulsed laser system guided by the control system so as to scan the beam in a pattern within the cutting region and segment the

crystalline lens into a plurality of pieces for subsequent removal,

the segmentation of the crystalline lens including:
focusing the beam at a first focal point located at a first depth in the eye tissue; scanning the beam on the eye while focused at the first depth so as to create an incision pattern within the cutting region at the first depth;

focusing the beam at a second focal point located at a second depth in the eye tissue different than the first depth; and

scanning the beam on the eye while focused at the second depth so as to create an incision pattern within the cutting region at the second depth.

Ex. 1009, 16:46–17:9 (emphasis added).

16. A method of making an incision in eye tissue during a cataract surgical procedure, the method comprising:

operating an optical coherence tomography imaging system, coupled to *an electronics control system comprising a computer*, so as to acquire image data from locations distributed throughout a volume of a crystalline lens of a patient and construct one or more images of at least a portion of the crystalline lens from the image data;

identifying, using the control system, a cutting region based on the image data, the cutting region being at least partially defined by an anterior cutting boundary and a posterior cutting boundary and including a portion of the crystalline lens, wherein the posterior cutting boundary is disposed anterior to the lens posterior capsule;

generating a beam of light using a pulsed laser system controlled by the control system, *wherein the pulsed laser system is guided by the control system based in part on the image data so as to scan a focal zone of the beam in a pattern in the lens for 3-dimensional patterned laser cutting and segmentation of the crystalline lens within the cutting region into a plurality of pieces for subsequent removal.*

Id. at 18:1–24 (emphasis added).

17. A method of making an incision in eye tissue during a cataract surgical procedure, the method comprising:

operating an imaging system, coupled to *an electronics control system comprising a computer*, so as to acquire image data from locations distributed throughout a volume of a crystalline lens of a patient for constructing one or more images of at least a portion of the crystalline lens from the image data;

identifying, using the control system, a cutting region based on the image data, the cutting region having an anterior cutting boundary and a posterior cutting boundary and including a portion of the crystalline lens, wherein the posterior cutting boundary is disposed anterior to the lens posterior capsule;

generating a beam of light using a pulsed laser system controlled by the control system, *wherein the pulsed laser system is guided by the control system based at least in part on the image data so as to scan a focal zone of the beam in a pattern to effect 3-dimensional patterned laser cutting of the crystalline lens within the cutting region into a plurality of segments or pieces for subsequent removal.*

Id. at 18:25–47 (emphasis added).

Claims 2–15 depend from independent claim 1. *Id.* at 18:8–34.

Claims 18 and 19 depend from independent claim 17. *Id.* at 18:48–53.

F. Information Relied Upon

Petitioner relies upon information that includes the following.

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

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

Ex. 1041, Georges Baikoff et al., *Static and Dynamic Analysis of the Anterior Segment with Optical Coherence Tomography*, 30 J. Cataract Refract. Surg. 1843 (2004) (“Baikoff”).

Ex. 1043, Thomas Hoppeler et al., *Preliminary Clinical Results with the ISL Laser*, 1644 Proc. SPIE, Ophthalmic Tech. II 96 (1992) (“Hoppeler”).

Ex. 1045, US 2004/0106929 A1, published June 3, 2004 (“Masket”).

Petitioner also relies upon the Declarations of Joseph A. Izatt, Ph.D. (Ex. 1001, “Izatt”; Ex. 1122) and Richard Tipperman, M.D. (Ex. 1123, “Tipperman”) to support its contentions.

Patent Owner relies upon, *inter alia*, the Declarations of Jin U. Kang, Ph.D. (Ex. 2087, “Kang”) of Keith A. Walter, M.D. (Ex. 2088, “Walter”) to support its contentions.

G. Asserted Grounds of Unpatentability

Petitioner asserts that claims 1–19 would have been unpatentable on the following grounds:

Ground	Claim(s) Challenged	35 U.S.C. § ¹	Reference(s)/Basis
1	1–3, 6–19	103(a)	Swinger, Baikoff, Hoppeler
2	4–5	103(a)	Swinger, Baikoff, Hoppeler, Masket
3	1–2, 6–19	103(a)	Freedman, Swinger, Hoppeler
4	3–5	103(a)	Freedman, Swinger, Hoppeler, Masket

¹ The relevant sections of the Leahy-Smith America Invents Act (“AIA”), Pub. L. No. 112–29, took effect on March 16, 2013. The application that issued as the ’903 patent was filed prior to March 16, 2013. *See* Ex. 1033, codes (22), (63). Thus, we apply the pre-AIA version of these statutes. *See* 35 U.S.C. § 100(i).

II. ANALYSIS

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 [person of ordinary skill in the art] 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. 26 (we note, Petitioner cites no evidence in support of this proposed definition, but Dr. Izatt testifies similarly at Ex. 1001 ¶ 49).

Patent Owner contends that the team that developed the '497 patent included an ophthalmic surgeon (Dr. Blumenkranz), and much of the prior art was written by doctors with skill and experience in ophthalmic surgery. PO Resp. 8–9. Thus, Patent Owner contends “the correct level of ordinary skill should include meaningful experience with ophthalmic surgery—e.g., (1) an ophthalmic surgeon with experience with medial 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.” *Id.* (citing Ex. 2087 ¶¶ 30–33). Patent Owner contends that this definition of the ordinarily

skilled artisan stands in contrast to the education and experience of Dr. Izatt who “has no skill or experience in ophthalmic surgery.” *Id.*

In Reply, Petitioner argues that Patent Owner’s definition of the ordinarily skilled artisan and contentions with respect to Dr. Izatt’s background and education are belied by the fact Patent Owner’s own Expert “is not a clinician and did not speak with any clinicians before rendering his opinions,” and by the fact that Dr. Izatt is a professor in the Department of Ophthalmology at Duke University and is “renowned for his advancements in OCT imaging of the eye.” Reply 2 (citing Ex. 1120, 15:18–20, 17:13–18:6, 30:6–11).

The parties present compelling argument and evidence that one of ordinary skill in the art would include those with experience in ophthalmology, as well as in the research, manufacture, and design of medical optics or medical lasers. Pet. 26; PO Resp. 8–9. The evidence of record also demonstrates that few individuals actually had such comprehensive experience. Rather, teams of individuals with different expertise and various academic degrees (Ph.D.s, B.S.s, and M.D.s) would work together to design laser surgery systems intended to make incisions in the lens of the eye. *See, e.g.*, Ex. 1041 (several authors are M.D.s); Ex. 1042 (the authors’ degrees include Ph.D.s, an M.D., and a B.S.); *see also* Ex. 1053; Ex. 1054; Ex. 1055; Ex. 2010; Ex. 2019.

Thus, we find that the person of ordinary skill in the art would have been either an ophthalmic surgeon or someone with a Ph.D., M.S., or B.S. degree in physics, biomedical engineering, or a related science such as nuclear engineering, having experience in researching, manufacturing, or designing medical optics or medical lasers (e.g., five years of experience for

a Ph.D. or more to compensate for lesser degrees), and 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.

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

B. Claim Construction

We interpret a claim “using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. 282(b).” 37 C.F.R. § 42.100(b) (2019). Under this standard, we construe the claim “in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent.” *Id.* Furthermore, we need only construe the claims to the extent necessary resolve the dispute between the parties. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (“[W]e need only construe terms ‘that are in controversy, and only to the extent necessary to resolve the controversy.’” (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999))).

Petitioner does not assert that any claim term requires express construction. *See* Pet. 7 (stating that it “reserves the right to respond to any constructions that [Patent Owner] submits”). Patent Owner does not present any remarks regarding claim construction. *See generally* PO Resp.

On this record, we determine that no claim terms require express construction because it is not essential to our conclusions on patentability. *See Nidec Motor.*, 868 F.3d at 1017 (quoting *Vivid Techs.*, 200 F.3d at 803 (“[O]nly those terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy.”)). To the extent further discussion of the meaning of any claim term is necessary to our decision, we provide that discussion below in our analysis of the asserted grounds of unpatentability.

C. Summary of Cited Prior Art

1. Summary of Swinger (Ex. 1039)

Swinger “relates to methods of, and apparatus for, eye surgery, and more particularly to a laser-method and apparatus for corneal and intraocular surgery.” Ex. 1039, 1:15–17. Swinger describes that

an optically smooth corneal surface and a clear intraocular light path (including postoperative clarity) are all critical to successful ophthalmic surgery. The effects of eye surgery on all of the intraocular elements encountered by light traversing the optical path from the cornea to the retina must be considered. The invention was developed with a particular view to preserving these characteristics.

The preferred method of performing a surface ablation of cornea tissue or other organic materials uses a laser source which has the characteristics of providing a shallow ablation depth or region (about 0.2 μm to about 5.0 μm), a low ablation energy density threshold (about 0.2 to 5 $\mu\text{J}/(10 \mu\text{m})^2$) and extremely short laser pulses (having a duration of about 10 femtoseconds

to about 2 picoseconds per pulse) to achieve precise control of tissue removal.

Id. at 8:26–41. “The invention can be used to excise or photoablate regions within the cornea, capsule, lens, vitreoretinal membrane and other structures within the eye.” *Id.* at 8:65–67.

Figure 6 of Swinger, reproduced below, is a block diagram of a laser and control system. *Id.* at 16:66–67.

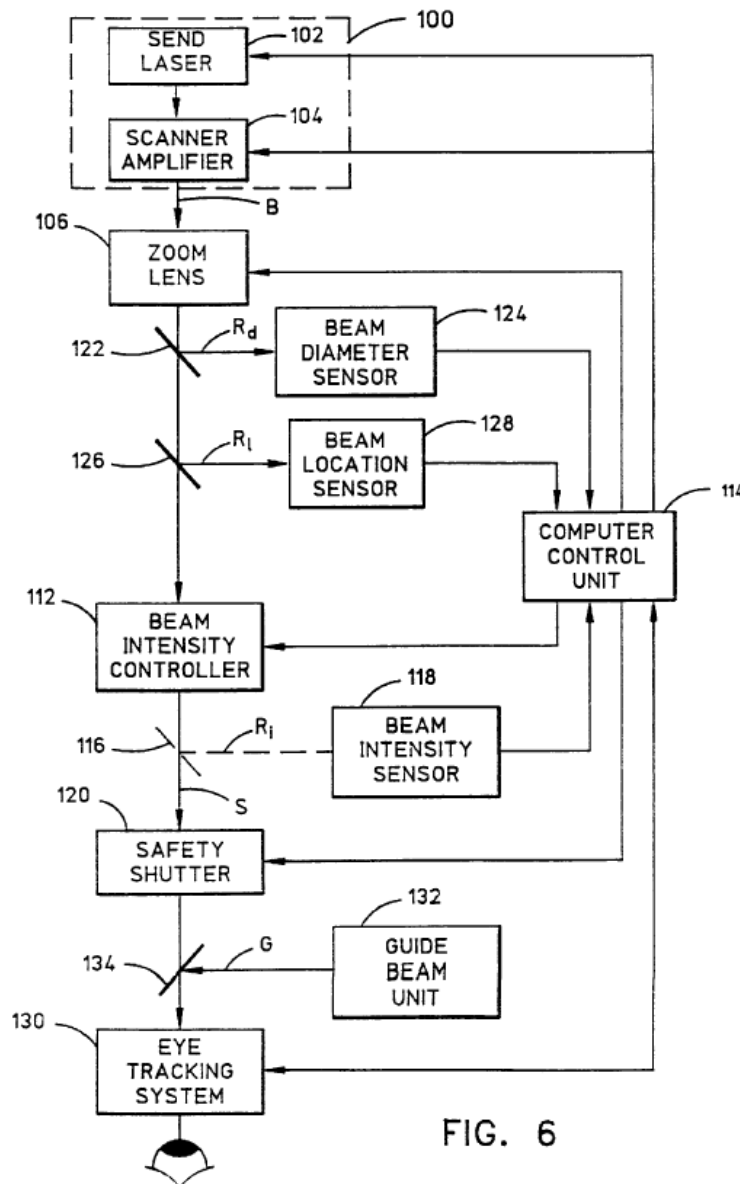


FIG. 6

Figure 6 depicts a laser and control system including laser unit 100, which generates an initial laser beam B. *Id.* at 17:1–2. “The laser unit **100** is of the type that can output a beam rapidly deflectable or scannable under electronic control in two dimensions to any location in an area defined by orthogonal X and Y axes.” *Id.* at 17:2–5. The laser beam B passes through a “beam intensity controller **112** . . . coupled to a computer control unit **114**, which is suitably programmed to vary the intensity of the output surgical laser beam S as required for a particular surgical procedure.” *Id.* at 17:50–54. Swinger describes the following:

In order to provide accurate positioning of the surgical laser beam S, an eye tracking system **130** is placed in the path of the surgical laser beam S, preferably in close proximity to a target eye. The eye tracking system **130** monitors movement of a patient’s eye and adjusts the position of the surgical laser beam S to compensate. Such tracking may be accomplished by providing fiducial marks on the eye and optically tracking movement of said fiducial marks. Deflectable mirrors may then be used to steer the surgical laser beam S.

Id. at 20:8–17. Swinger describes that, “[b]y directing the laser focus at the lens of the eye, a cataractous lens can be ablated and liquefied,” and, “[t]hus, the inventive procedure can be used prior to an IOL implant for cataract conditioning.” *Id.* at 23:21–24. Swinger explains that the preferred laser system includes a broad gain bandwidth laser using lasing ions such as titanium, chromium or neodymium and emitting at a preferred wavelength of 400 nm to 1900 nm, “which is generally transmissive in eye tissue.” *Id.* at 8:43–48.

Zoom lens 106 provides control over the diameter of laser beam B. *Id.* at 17:21–24. Beam-splitting mirrors 122 and 126 reflect part of the beam energy to beam diameter sensor 124 and beam location sensor 128,

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

Swinger explains that capsulorhexis surgery is performed using the disclosed system as follows. *Id.* at 34:30–51. First, the focus of the laser beam spot is localized to the anterior lens capsule “by direct visualization using a visual HeNe laser beam focused to the same focal point as the ablating laser.” *Id.* at 34:52–55. “Then the surgeon displaces the HeNe positioning beam just posteriorly to” the lens capsule and “photodisruption begins.” *Id.* at 34:58–61. According to Swinger, “[t]he cutting process can be totally computerized once the reference point on the capsule has been fixed, or the surgeon can terminate the process when the capsule has been visibly cut for 360 degrees.” *Id.* at 34:64–67.

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

2. Summary of Freedman (Ex. 1040)

Freedman discloses “a method and device for laser surgery wherein a treatment laser beam is controlled by interferometry, preferably by optical coherence tomography.” Ex. 1040, 2:7–9. One biomedical application for laser surgery technology includes cataract clearing. *Id.* at 1:23–25.

Figure 1 of Freedman, reproduced below, illustrates an embodiment of a laser surgery device.

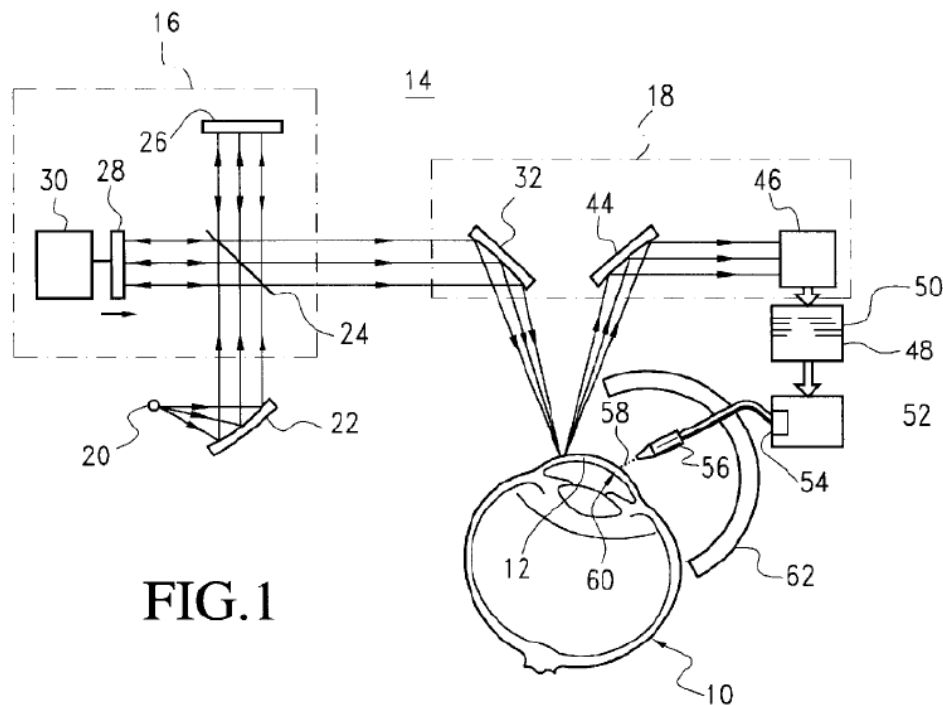


FIG. 1

Figure 1 depicts laser surgery device 14 including interferometer 16 and optical system 18, which are emitter/receptor elements that can be used to create a spatialgram. *Id.* at 4:46–51. A light beam is emitted from light source 20 and is transformed into a parallel light beam by an aspherical mirror 22. *Id.* at 4:58–61. Interferometer 16 includes beam splitter 24 for splitting the parallel light beam into two beams: a transmitted beam and a reflected beam. *Id.* at 4:62–63. Using fixed mirror 26 and mobile mirror 28, the light beams are reflected back to the beam splitter 24, where they are synthesized by beam splitter 24 and emitted towards optical system 18. *Id.* at 4:63–5:9.

At optical system 18, aspherical mirror 32 projects [an] interference light beam onto the surface 34 of cornea 12 at an incident angle. As shown schematically in FIG. 2, cornea 12 has surfaces 34 and 36. The interference light beam is designated

incident light beam **38**. Reflected light from front surface **34** is designated **40** and reflected light from back surface **36** is designated **42**. Reflected light components **40** and **42** generate phase differences due to their respective different optical path lengths. The reflected beams **40** and **42** are converged through an aspherical mirror **44** onto the light-receiving surface of photodetector **46**. The light receiving surface of photodetector **46** detects the reflected beams and measures an interferogram from the converged interference light beam. Processor **48** detects a signal from photodetector **46** that represents the interferogram. Processor **48** can be a computer. Processor **48** can include a Fourier transformer **50** as shown. Fourier transformer **52** transforms the interferogram, filters the resulting reflection spectrum and subjects the filtered reflection spectrum to reverse transforming to provide a spatialgram.

Processor **48** compares spatialgram data to data representing a standard of improved visual acuity to construct an ablating plan. Processor **48** can construct a virtual or real time display three dimensional image of the cornea film from the spatialgram and construct an ablating plan by comparing the constructed image to a representation of a standard of improved acuity. Processor **48** controls ablating laser **52** in accordance with the ablating plan.

Id. at 5:10–36. Control of ablating laser **52** may include

the processor **48** detecting a signal from the photodetector **46** and comparing the signal to a standard of improved acuity. The standard may be a shaped cornea that is has increased focal length and relaxed radius of curvature that is characterized by improved acuity compared to the target cornea **12** of eye **10**. From the comparison, the processor **48** constructs an ablating plan for ablating incisions into the target cornea **12** or the processor **48** can construct a plan by accepting real time input, for example from a surgeon responding to a signal in the form of an image visually displayed on the screen of a computer.

Id. at 5:55–65. According to Freedman, the disclosed “invention encompasses the use of low-coherence interferometry in several optical

coherence tomography sequences to three dimensionally image a target cornea and to precisely incise the cornea with a laser.” *Id.* at 7:15–18.

3. *Summary of Baikoff (Ex. 1041)*

Baikoff discloses a study using optical coherence tomography (OCT) to evaluate biometry of the anterior chamber (AC) of the eye for anterior segment surgery, such as refractive lens implantation. Ex. 1041, 1844.² In particular, “[t]he horizontal diameter of the AC, the anterior chamber depth (ACD), the horizontal pupil diameter, and the horizontal radius of curvature of the crystalline lens’ anterior pole were measured in the unaccommodated state and after stimulating accommodation.” *Id.* Based on the results of the study, Baikoff concludes that AC OCT is easy to use, “it is possible to explore the iris and anterior surface of the crystalline lens behind a totally opaque cornea and indicate before surgery the presence and location of anterior or posterior synechias,” and “[s]urgery can then be based on objective documents.” *Id.* at 1849.

Baikoff notes that AC OCT using 820 nm wavelength light was well known in the art for imaging the posterior segment of the eye and, in 1994, it was suggested for use in imaging the anterior segment. *Id.* at 1844. Baikoff further notes that in 2001 high-speed AC OCT was developed using 1320 nm wavelength light, resulting in “good-quality, easy-to-interpret” images. *Id.*

In Baikoff’s study, AC OCT was used to acquire video images of the examined zone at rate of 8 frames per second. *Id.* “At the end of the examination, the images [were] reviewed by the examiner and the best shots retained.” *Id.* The images were then reconstructed using software and all

² Our citations are to the original page numbers of the Exhibit.

required AC measurement made, including “AC diameter, anterior chamber depth (ACD), corneal pachymetry, radius of curvature of the crystalline lens, crystalline lens thickness, and iridocorneal angle opening.” *Id.* Baikoff notes that because the infrared beam used for imaging is blocked by “the epithelial pigment layer of the iris” and the “anterior uvea,” clear visualization of the entire crystalline lens is not possible using its AC OCT system. *Id.*

4. Summary of Hoppeler (Ex. 1043)

Hoppeler discloses using a Nd:YLF picosecond pulse laser to perform computer-controlled microsurgery of the anterior segment of the eye, including cataract fragmentation, iridotomy, and posterior capsulotomy. Ex. 1043, 1. A built-in computer system controls the laser to produce different 3-dimensional patterns, such as line, arc, and circle patterns. *Id.* at 1–2. According to Hoppeler, it is beneficial to use the Nd:YLF picosecond pulse laser to perform cataract fragmentation surgery due to the laser’s low energy and the confined collateral damage produced. *Id.* at 4.

5. Summary of Masket (Ex. 1045)

Masket discloses

[m]ethods and devices of performing an improved anterior capsulorhexis, wherein the capsulorhexis is more precisely sized, shaped and positioned on the eye lens capsule are described. A capsulorhexis, also referred to as a capsulotomy, is a procedure for creating an aperture in a lens capsule by making an incision. The incision should be of a certain size and shape and be positioned on the capsule as determined by the surgeon. An image projection device is used to project a visible target image on the anterior or posterior of the lens capsule as a guide or trackable image for the surgeon. Before a procedure begins, a target image is configured by a surgeon to have a desired size and shape. During the procedure, target image is projected onto

a desired location on the surface of lens capsule. In another preferred embodiment, a template is configured to a desired shape and size by a surgeon to correspond to the appropriate capsulorhexis. Once configured, the template is inserted into the anterior chamber, using an appropriate delivery mechanism if necessary. The template is used to make a physical impression or mark on the lens capsule wherein the mark closely corresponds to the intended incision.

Ex. 1045, Abstract; *see also id.* ¶¶ 5–7, 15, 19 (further describing this image projection of a guide for laser eye surgery).

D. Petitioner's Asserted Grounds of Patentability

1. Ground 1: Obviousness of Claims 1–3 and 6–19 over the Combination of Swinger, Baikoff, and Hoppeler

Petitioner contends that claims 1–3 and 6–19 would have been obvious over the combination of Swinger, Baikoff, and Hoppeler. Pet. 6, 29–50. In support of its contention, Petitioner provides a detailed discussion explaining how each claim limitation is disclosed in the combination of Swinger, Baikoff, and Hoppeler. *Id.* Petitioner also provides a detailed discussion explaining why a person of ordinary skill in the art would have been motivated to combine the teachings of Swinger, Baikoff, and Hoppeler to arrive at the subject matter of the claims. *Id.* at 29–36. In summary, Petitioner relies on Swinger for its disclosure of a computer-controlled laser-surgery system configured to perform anterior-capsulotomy and lens-fragmentation procedures of cataract surgery. *Id.* at 29 (citing Ex. 1039, Fig. 6, 16:60–20:34, 23:13–25). Petitioner acknowledges that Swinger does not utilize OCT imaging as a diagnostic tool, but contends that the claimed concept of a cataract surgery system that combines a laser with an OCT aiming system would have been achieved by a person of ordinary skill in the art by taking a laser cataract surgery system of Swinger and adding an OCT

imaging system such as the one disclosed by Baikoff. *Id.* at 31. According to Petitioner, a “[person of ordinary skill in the art] would have been motivated to integrate an OCT assembly like Baikoff’s into Swinger’s system to plan and effect laser cataract surgery with improved accuracy, as taught by Baikoff.” *Id.* at 31 (citing Ex. 1001 ¶ 158).

To that point, Petitioner contends that “Baikoff teaches an OCT assembly configured to provide high-resolution images of the cornea, iris, and crystalline lens to help plan ophthalmic surgical procedures,” and that is “especially useful for pre-surgical anterior segment diagnostics.” *Id.* at 30–31 (citing Ex. 1041, 1843, 1849). Petitioner contends that one of ordinary skill in the art would have sought to implement Baikoff’s OCT imaging in Swinger’s system in order “to plan and effect laser cataract surgery with improved accuracy, as taught by Baikoff.” *Id.* at 31 (citing Ex. 1001 ¶ 158). According to Petitioner, “accurate incisions,” including those for anterior capsulorhexis, “are only beneficial to the extent they derive from an accurate understanding of the target anatomy” and “Baikoff’s OCT assembly represents a sophisticated imaging technique available at the time for obtaining precise measurements of the anterior segment in a fast and user-friendly manner.” *Id.* at 30–31 (citing Ex. 1001 ¶¶ 154–156; Ex. 1041, 1843). Petitioner contends that a “[person of ordinary skill in the art] would have endeavored to improve the accuracy of laser cataract surgeries by looking at the best available imaging techniques to help generate ideal ablation patterns.” *Id.* (citing Ex. 1001 ¶ 158); *see also id.* at 38 (“the benefit of adding an OCT imaging system to Swinger lies in the ability to guide laser ablation based on imaging information”).

Additionally, Petitioner contends that, beyond the need for improved accuracy, the use of Baikoff's OCT assembly in place of Swinger's direct visualization method would have been obvious because it constitutes the mere substitution of one known imaging modality for another, and because there were "a finite number of identified and predictable imaging modalities" known in the art. *Id.* at 32 (citing Ex. 1001 ¶ 161).

Petitioner also asserts that the person of ordinary skill in the art would have had a reasonable expectation of success in combining and modifying Swinger with Baikoff to achieve the subject matter of the challenged claims. *Id.* at 32–33. Petitioner's position is that the combined 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 '497 patent describes switching between ultrasound and direct visualization). *Id.* (citing Ex. 1001 ¶¶ 159–161).

Petitioner also contends that, "to the extent Swinger cannot be read as disclosing fragmenting the lens into segments, doing so would have been obvious" in view of Hoppeler, which discloses "a computer-controlled system for directing laser beams in various three-dimensional patterns." *Id.* at 34 (citing Ex. 1001 ¶ 177–180; Ex. 1043, 1–4). More specifically, Petitioner contends that Hoppeler discloses using specific treatment patterns to segment a cataractous lens into discrete segments in preparation for IOL placement. *Id.* at 47 (citing Ex. 1043, 1–4). Petitioner further contends that one of ordinary skill in the art would have adopted Hoppeler's laser fragmentation methods in a method and system of the Swinger and Baikoff, combination because Hoppeler teaches that its system improves patient

outcomes by significantly reducing phacoemulsification time during cataract surgery. *Id.* at 48 (citing Ex. 1043, 4; Ex. 1001 ¶ 180).

Patent Owner contends that none of the cited prior art teaches or suggests the claim requirements for using a control system 1) to identify a lens fragmentation treatment region and corresponding lens fragmentation scanning pattern based on image data of the crystalline lens of the eye and 2) to operate a laser beam to create an incision pattern on the crystalline lens of the eye based on that scanning pattern. PO Resp. 11–15; Sur-Reply 3–10.

We address the parties’ contentions below.

a. Analysis

“A claimed invention may be obvious even when the prior art does not teach each claim limitation, so long as the record contains some reason why one of skill in the art would modify the prior art to obtain the claimed invention.” *Nike, Inc. v. Adidas AG*, 812 F.3d 1326, 1335 (Fed. Cir. 2016) (overruled on other grounds by *Aqua Prods., Inc. v. Matal*, 872 F.3d 1290, 1358–1359 (Fed. Cir. 2017) (addressing the burden of persuasion with respect to amended claims)). In addressing motivation to modify the prior art in a way that is not disclosed in the art, we are cognizant that an ordinarily skilled artisan’s ordinary creativity, “whether to supply a motivation to combine or a missing limitation—cannot be used as a wholesale substitute for reasoned analysis and evidentiary support, especially when dealing with a limitation missing from the prior art references specified.” *DSS Tech. Mgm’t, Inc. v. Apple Inc.*, 885 F.3d 1367, 1374 (Fed. Cir. 2018) (*quoting Perfect Web Techs. Inc. v. InfoUSA, Inc.*, 587 F.3d 1324, 1328 (Fed. Cir. 2009)).

Having considered the parties' positions and evidence of record, summarized above, we find that the evidence of record does not support a conclusion that it would have been simple, straightforward, or otherwise routine to convert Swinger's manual HeNe aiming system and Swinger's surgeon-identification-of-target-tissue step to a computer-controlled, OCT-guided laser system. Even assuming that a person of ordinary skill in the art would have combined the teachings of Swinger and Baikoff to achieve a laser surgical system incorporating an OCT imaging system, that combination still would not have achieved the required "control system" of the claims and all of its programmed surgical functionality. Petitioner relies on the ability of a person of ordinary skill in the art to configure Swinger's computer control unit with the missing functionality, thus necessitating an electronic conversion of the steps performed by a surgeon using Swinger's direct visualization method using a HeNe aiming beam to manually identify a surgical treatment region for laser surgery. Ex. 1039, 34:52–57; Ex. 2088 ¶¶ 55–59, 66. That conversion, however, involves the incorporation of OCT imaging technology as the basis for a computer-controlled system to plan and then implement the planned cataract surgery, two technological leaps that the record fails to show were known or suggested. In particular, the evidence of record does not support a conclusion that OCT was a well-known system used routinely, if at all, in the identification of treatment regions in the lens or lens capsule for cataract surgery, and further does not support a conclusion that a computer-controlled system to plan and to implement a planned cataract surgery in the lens was commonplace or even considered before the invention.

We recognize that Petitioner directs us to the testimony of Dr. Izatt who opines that a person of ordinary skill in the art would have found it obvious to, for example, use a controller to determine the claimed scanning pattern. Ex. 1001 ¶ 159; Pet. 32–33; Reply 3–5; *see also* Ex. 1123 ¶ 31 (“Once the anterior capsule is identified, it is a relatively simple process to determine the location to place the capsulotomy.”). Here, however, we agree with Patent Owner that the Petition and supporting testimony fails to provide the requisite reasoned analysis with sufficient evidence to support Petitioner’s position on obviousness. In particular, absent some evidentiary support beyond Dr. Izatt’s and Dr. Tipperman’s bare opinions that it would have been obvious to program a controller to bridge the gap between the functionality disclosed in Swinger and the required functionality of the challenged claims, we are unwilling to accept this line of reasoning. PO Resp. 27; Sur-Reply 4–7; Ex. 1001 ¶ 159; *see also* DSS, 885 F.3d at 1374 (Fed. Cir. 2018) (A skilled artisan’s “common sense” or “common knowledge” can potentially “fill in a missing limitation only when ‘the limitation in question was unusually simple and the technology particularly straightforward.’” (emphasis omitted)).

Moreover, the evidence of record supports that the required conversion would have not been as routine or straightforward as proposed by Petitioner. Pet. 30. Swinger explains that capsulorhexis (or similar, capsulotomy) surgery is performed using the disclosed system as follows. Ex. 1039, 34:30–67. First, the focus of the laser beam spot is localized to the anterior lens capsule “by direct visualization using a visual HeNe laser beam focused to the same focal point as the ablating laser.” *Id.* at 34:52–55. “Then the surgeon displaces the HeNe positioning beam just posteriorly to”

the lens capsule and “photodisruption begins.” *Id.* at 34:58–61. According to Swinger, “[t]he cutting process can be totally computerized once the reference point on the capsule has been fixed, or the surgeon can terminate the process when the capsule has been visibly cut for 360 degrees.” *Id.* at 34:64–67.

Swinger, however, nowhere discusses using an imaging system to position or control the laser, or allow a computer to do so based on imaging, and instead teaches that the ophthalmic surgeon is responsible for identifying the surgical target using HeNe aiming beams. Ex. 2088 ¶ 66; Ex. 1001 ¶ 143 (“Swinger is silent regarding OCT imaging”); Ex. 2087 ¶ 162. That is, we agree with Patent Owner that,

Though 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***”); [Ex. 2088] ¶¶ 56–59. In the words of [Petitioner]’s expert, Swinger is “quite clear that the human positions the cutting beam.” Ex. 2057, 158:19–159:1.

PO Resp. 14–15.

Nor does Baikoff suggest that OCT would improve on Swinger’s manual method, or allow a computer to plan and implement a cataract surgery, as Baikoff focuses on diagnosis, not controlling any laser system to plan and then cut treatment regions. Ex. 2087 ¶ 65. The OCT imaging systems in Baikoff are not integrated with a surgical laser. *Id.* ¶ 66. Moreover, Petitioner’s evidence about OCT’s purported accuracy concerns identifying boundaries and does not inform a person of ordinary skill in the art about the subsequent identification and cutting of the treatment regions in the lens or lens capsule. *See* Pet. 31 (“Baikoff’s OCT assembly represents a

sophisticated imaging technique available at the time for obtaining precise measurements of the anterior segment in a fast and user-friendly manner”).

We also appreciate Patent Owner’s argument that there is insufficient evidence that the ordinarily skilled artisan would have wanted to replace Swinger’s manual HeNe aiming system and Swinger’s surgeon-identification-of-target-tissue step with an automated system reliant on OCT imaging (ceding control to the computer) and computer control, as Swinger reserves this critical decision-making for the surgeon. PO Resp. 1, 10, 14–15; Ex. 2087 ¶¶ 56–59, 66; Ex. 2088 ¶¶ 66, 69, 72–73; Ex. 1039, 34:64–67 (“cutting process can be totally computerized once the reference point on the capsule has been fixed”). Here, we credit Dr. Kang’s testimony that, as of the invention, none of the references relied upon by Petitioner teach using a computer to identify laser cutting regions or to control laser cataract surgery. Ex. 2087 ¶¶ 96–99; *see also id.* ¶¶ 37, 42–43 (addressing Swinger’s and Baikoff’s shortcomings), ¶¶ 126–128 (addressing the claims’ computer control system programming limitations).

In contrast, beyond merely suggesting plugging one system into another, Petitioner does not explain how the person of ordinary skill in the art would have programmed Swinger’s computer control system to use Baikoff’s OCT imaging systems and tissue recognition and measurement algorithms to determine capsulotomy cutting regions and then implement the planned cutting with a laser, even from a rudimentary perspective. *See* Pet. 39–42. Petitioner merely asserts that a “[person of ordinary skill in the art] would have endeavored to improve the accuracy of laser cataract surgeries by looking at the best available imaging techniques to help generate ideal ablation patterns.” *Id.* at 31 (citing Ex. 1001 ¶ 158). We have considered

those positions, but find that the preponderance of evidence fails to support Petitioner's position that it would have been a simple or well-understood matter to make the combination of Swinger and Baikoff work like the claimed invention as proposed by Petitioner.

Moreover, we find other of Dr. Izatt's testimony to support Patent Owners position that, even if the OCT system of Baikoff was incorporated into Swinger's system in some way, the ordinarily skilled artisan would not have been motivated to use it to program a computer to identify where and how to treat cataract eye tissue (in the lens or lens capsule) with a laser and then proceed to do so. For example, Dr. Izatt states,

that Baikoff's OCT assembly could acquire image data and construct images of the cataractous lens. These images would ***enable a user to identify relevant boundaries*** including anterior and posterior capsules and the nucleus of the lens. *See, e.g.,* Ex. 1041 at 2 (obtaining lens thickness measurement, necessarily entailing identification of anterior and posterior capsule boundaries). ***A user could then use these images and boundaries to determine a treatment region***, such as an anterior capsulotomy region, Ex. 1039 at 10:10–15, and/or a lens fragmentation region, *id.* at 23:17–25. *See* [Ex. 1001] ¶ 130.

Ex. 1001 ¶ 163 (emphasis added). Dr. Izatt further states, “Baikoff's OCT ‘software includes a measuring system capable of calculating distance, angle, and radius of curvature...’” *Id.* at ¶ 164 (citing Ex. 1041, 1845).

From this, Dr. Izatt concludes,

a [person of ordinary skill in the art] would have understood this to mean that the software locates certain features of the anterior segment and lens to make these calculations. Baikoff does not specify whether it is the operator or the OCT assembly itself that initially identifies these features. However, even if the operator identifies these features, the controller is still “configured to” perform this step, since I would not interpret this phrase as precluding user input. *See, e.g.,* Ex. 1021 at cl. 18 (“wherein the

control system configures the anterior capsulotomy scanning pattern based in part on an input from a user interface.”).

Id. (citing Ex. 1041 at 1845–1846). We find Dr. Izatt’s conclusion, based on his other testimony, quoted above, to be unpersuasive, particularly because Dr. Izatt expressly stated that Baikoff’s OCT capabilities “would **enable a user to identify**” tissue boundaries and, relatedly, that “[a] **user could then use** the[] images and boundaries **to determine a treatment region**,” not that a computer could or would be programmed to do so. *Id.* at ¶ 163 (emphasis added).

We also note Dr. Izatt testifies that programming a computer system to image a cataractous eye, then plan surgery based on that image, and then perform surgery based on that plan, would have been obvious. *Id.* at ¶ 168. Dr. Izatt there concludes that “once the boundaries of the ocular tissue are identified, treatment regions and scanning patterns could readily be determined based on those boundaries,” which would have made “it obvious to program the controllers to identify the relevant boundaries and treatment regions of the crystalline lens in an automated manner.” *Id.* However, this is counter to Dr. Izatt’s other testimony that “[persons of ordinary skill in the art] at the time were writing such programs and succeeding, although they were **not nearly accurate enough to render the surgeon obsolete**,” and counter to Dr. Izatt’s deposition testimony confirming that Baikoff fails to teach a controller that identifies treatment regions, just like it is with Swinger. *Id.* at ¶ 168 (emphasis added); Ex. 2057, 158:19–22, 204:8–10, 207:17–208:7.

Finally, we have considered Petitioner’s reliance on Hoppeler with respect to this ground. Such reliance, however, does not resolve the issues discussed above with respect to the combination of Swinger and Baikoff.

b. Conclusion

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, to achieve the claimed invention with a reasonable expectation of success. Therefore, we conclude that no challenged claim 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.").

2. Ground 2: Obviousness of Claims 4 and 5 over the Combination of Swinger, Baikoff, Hoppeler, and Masket

Challenged dependent claims 4 and 5 each require, directly or indirectly, generating an image of an alignment pattern on a tissue of the patient's eye. Petitioner asserts that the combination of Swinger, Baikoff, and Hoppeler teach every limitation of the claims except the generation of an "alignment pattern" required by claims 4 and 5. For that element, Petitioner relies on Masket and contends,

Masket . . . teaches performing an anterior capsulorhexis with a laser, with an eye toward precision, and aligns the treatment in the physical context, i.e., directly on the lens capsule itself rather than indirectly through a virtual representation of the lens capsule. *Id.* at Abstract. Ex.1045 ¶¶5–7, Abstract. Specifically, Masket teaches an image projection device (220) that projects a target image (211) onto the surface of the lens capsule (202). *Id.* ¶¶ 15, 19, Fig. 1. The target image represents the surgeon's intended treatment pattern, which the surgeon can tailor to a desired size, shape, and position. *Id.* ¶¶ 15, 19. Equipped with a physical representation of the precise locations in which to target laser ablation, the surgeon can begin the procedure assured that the treatment occurs only where intended. Ex.1001 ¶¶183–85. A POSA would have been motivated to integrate Masket's

alignment and imaging technique into the system taught by Swinger and Baikoff, in order to confirm the accuracy of the virtual representation of the cutting region in the physical world. Ex.1001 ¶¶183–86. A POSA would have had a reasonable expectation of success in doing so, because the modification merely requires providing an aiming light source capable of projecting images onto the ocular surface, and coupling it to Swinger’s controller (114) to project the anticipated incisions.

Pet. 51–52

We have considered Petitioner’s arguments with respect to this ground. Those arguments, however, do not resolve the issues discussed above with respect to the combination of Swinger, Baikoff, and Hoppeler with respect to independent claim 1, from which claims 4 and 5 depend. Accordingly, Petitioner fails to demonstrate by a preponderance of the evidence that claims 4 and 5 would have been obvious over Swinger, Baikoff, Hoppeler, and Masket.

3. Grounds 3: Obviousness of Claims 1, 2, and 6–19 over the Combination of Freedman, Swinger, and Hoppeler

Petitioner contends that claims 1, 2, and 6–19 would have been obvious over the combination of Freedman, Swinger, and Hoppeler. Pet. 52–66. In support of its contentions, Petitioner provides a detailed discussion explaining how each claim limitation is disclosed in the combination of Freedman, Swinger, and Hoppeler. *Id.*

Petitioner contends that one of ordinary skill in the art would have sought to use Freedman’s corneal laser system to perform anterior capsulotomy and fragmentation, as such procedures are disclosed in Swinger, because Swinger “teaches that laser surgical systems like Freedman’s are suitable for numerous types of surgical procedures.” *Id.* at 55–56 (citing Ex. 1001 ¶ 172). According to Petitioner,

When using Freedman's system for other surgical procedures involving tissues other than the cornea, it would have been obvious to a [person of ordinary skill in the art] to use Freedman's OCT imaging system to image the target tissue. *Id.* Indeed, a [person of ordinary skill in the art] would have known that Freedman's OCT imaging system is fully capable of imaging any target tissue that other OCT systems are capable of imaging, including the cornea, anterior chamber, iris, and lens. Ex. 1001 ¶¶ 173–74. Thus, when using Freedman's system to perform an anterior capsulotomy (as taught by Swinger), a [person of ordinary skill in the art] would have found it obvious to use Freedman's OCT system to image at least a part of the lens. *Id.* *Id.* at 52–53.

Patent Owner contends one of ordinary skill in the art would not have sought to combine Freedman and Swinger because Freedman “is far afield from the claimed invention,” “has nothing to do with cataract surgery,” and uses “a different type of laser altogether.” PO Resp. 30 (citing Ex. 1040, 4:9–32, 5:37–53, 8:30–9:18; Ex. 2087 ¶ 49–51). Patent Owner further argues that “it would be *impossible* to perform cataract surgery with Freedman's high-powered laser” because doing so would destroy the cornea in the process. *Id.* at 30 (citing Ex. 2087 ¶ 51). We address both issues below.

a. 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. PO Resp. 41 (citing Ex. 2087 ¶¶ 50–51). 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); Ex. 2087 ¶ 51 (“An ablative laser would essentially have to destroy the cornea in order to reach the anterior chamber to perform the anterior capsulotomy or lens fragmentation.”); *see also* PO Resp. 33 (citing Ex. 2050,³ 1164 (“[Photoablation] can be used to treat only accessible superficial areas such as the cornea.”)); *id.* at 34 (citing Ex. 2011,⁴ 4:2–6 (“laser light radiation “is absorbed in the tissue of the cornea within less than about ten micrometers.”)); Ex. 2087 ¶ 172 (noting that ablating laser light is absorbed in tissue within less than about ten micrometers, whereas the lens lies a “thousand-fold deeper into the eye”).

Upon review of the record, we agree with Patent Owner that Freedman’s ablating laser is incompatible with laser surgery on the lens or lens capsule during cataract surgery. Ex. 2087 ¶¶ 171–172. This is because the ablating laser cannot pass through the cornea to reach the lens without destroying the cornea in the process. *Id.* ¶ 172. In contrast, lasers used to cut internal tissues of the eye use photodisruption induced by a laser. *Id.* ¶ 170. 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 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. Pet. Reply 17 (citing Ex. 1001 ¶ 176). We disagree.

³ Ex. 2050, D. O’Neill et al., *Current Uses of Ophthalmic Lasers*, 304 BRIT. MED. J. 1161 (1992).

⁴ Ex. 2011, U.S. Patent No. 4,648,400, issued March 10, 1987.

Inter partes review must proceed in accordance with the Petition and the arguments set forth therein. *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1356 (2018). “It is of the utmost importance that petitioners in the IPR proceedings adhere to the requirement that the initial petition identify ‘with particularity’ the ‘evidence that supports the ground for the challenge to each claim.’” *Intelligent Bio-Systems, Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1369 (Fed. Cir. 2016). Arguments made in a different document, such as an expert’s declaration, may not be incorporated-by-reference in the Petition. 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 one of ordinary skill in the art “would have known that Freedman’s combined OCT-and-laser-surgery system is not limited to corneal procedures, but can be used for a number of other ophthalmic-surgery procedures, including cataract surgery.” Pet. 52. In addressing claim 1 that requires a laser operable to generate a laser beam configured to incise ocular tissue, the Petition cites to *Freedman’s disclosures* and asserts that Freedman’s ablating laser beam discloses these limitations. *Id.* at 52 (a [person of ordinary skill in the art] would have known that Freedman’s combined OCT-and-laser-surgery system is not limited to corneal procedures”), 56–57 (“it would have been obvious to use Freedman’s system to perform other aspects of cataract surgery, including lens ablation”). In each of these arguments, the Petition does not sufficiently argue for the use of Swinger’s laser in Freedman’s system.

As noted by Petitioner in Reply, Dr. Izatt testifies that Swinger's laser parameters could be modified and that this would include "substitution of the laser source." Reply 17; Ex. 1001 ¶ 176. This argument, however, was not made or even alluded to in the Petition itself, and arguments may not be incorporated from an expert's declaration wholesale into the Petition. 37 C.F.R. § 42.6(a)(3). This proposed substitution would also conflict with Petitioner's argument that Freedman's ablating laser alone discloses the limitations of claim 1. Pet. 54–57.

In view of the foregoing, we find that Petitioner did not sufficiently argue in the Petition that a person of ordinary skill in the art would have replaced Freedman's ablating laser with Swinger's femtosecond laser. Moreover, any attempt to switch arguments in Reply to assert a new combination of elements, i.e., the use of Swinger's laser in Freedman's system, would be an improper new argument. *Intelligent Bio-Sys.*, 821 F.3d at 1369–1370. As such, Petitioner fails to demonstrate by a preponderance of the evidence that any of claims 1–6, 8–15, 17, and 18 would have been obvious over Freedman and Swinger.

b. Modification of Freedman to Perform Surgery on the Lens

If we were to consider Dr. Izatt's statement about "a simple substitution of the laser source" as sufficient to put Patent Owner on notice that it was Petitioner's actual argument that a person of ordinary skill in the art would have sought to use Swinger's laser in Freedman's system (which we maintain it is not), the issue then presented would be whether Dr. Izatt's statement is persuasive. Pet. Reply 17 (citing Ex. 1001 ¶ 176). 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. Ex. 1040, 4:10–17; Pet. 52 (“Freedman does not disclose using the system to perform lens fragmentation.”). Petitioner argues, however, that a person of ordinary skill in the art would have known that Freedman's system could have been used for a number of other ophthalmic-surgery procedures, including cataract surgery, and is not limited to corneal procedures. Pet. 52 (citing Ex. 1040, 2:7–13; Ex. 1001 ¶¶ 171–172).

The evidence of record demonstrates, however, that modifying an existing corneal surgery system to image and perform surgery on the lens was not the simple task asserted by Petitioner. 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). Similarly, in a different 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, 15:51–16:18, code(22). 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.

Id. at 16:13–18.

During prosecution of another patent filed in 2008, and in responses to office actions 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. 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. *Id.* at 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 its own patents and during their prosecution directed to similar technology, 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.⁵ *See*

⁵ Petitioner contends its arguments regarding the difficulties of adapting corneal OCT systems for use on the lens are “irrelevant to this proceeding” because the Office rejected these arguments. Pet. Reply 19. 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. *Cf. Springs Window Fashions LP v. Novo Indust., L.P.*, 323 F.3d 989, 995 (Fed. Cir. 2003) (noting for purposes of prosecution disclaimer (not at issue here) that “it is

Qualcomm Inc. v. Apple Inc., 24 F.4th 1367, 1376 (Fed. Cir. 2022) (“[A] patentee’s admissions about the scope and content of the prior art provide a factual foundation as to what a skilled artisan would have known at the time of invention.”). Indeed, Petitioner’s own arguments demonstrate that the challenges were “considerable,” “hard,” and were considered unsolved for over 40 years.

Petitioner argues in Reply that even if the challenges in adapting Freedman for surgery on the lens were significant, Patent Owner does not assert that they were beyond the level of skill in the art. Pet. Reply 18 (citing Ex. 1122 ¶¶ 23–25). Patent Owner responds that this argument “misses the point entirely,” as fundamental differences between the references may be central to a motivation to combine inquiry. Sur-Reply 18 (citing *Adidas AG v. Nike, Inc.*, 963 F.3d 1355, 1359 (Fed. Cir. 2020)).

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.”). Absent some persuasive explanation in *the Petition* as to how the optics of Freedman would be successfully modified for lens surgery, and how Freedman’s OCT system would be modified for imaging of the lens, we agree with Patent

not surprising that an examiner would not be satisfied with the applicant’s insistence that particular claim language distinguishes a prior art reference, but that a court would later hold the patentee to the distinction he pressed during prosecution”).

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. 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 (OCT).⁶ Ex. 2014, 16:13–18; Ex. 2015, 898 (“Increasing a system's performance by an order of magnitude cannot be regarded as obvious.”).

In view of the foregoing, we determine that Petitioner fails to sufficiently explain why one of ordinary skill in the art would have sought to combine Freedman and Swinger to perform surgery on the lens. Thus, Petitioner fails to demonstrate by a preponderance of the evidence that any of claims 1, 2, and 6–19 would have been obvious over Freedman, Swinger, and Hoppeler.

c. Conclusion

For the reasons set forth above, we determine that Petitioner has not sufficiently demonstrated that one of ordinary skill in the art would have combined the disclosures of Freedman, Swinger, and Hoppeler to arrive at the subject matter of any claim of the '497 patent, or that the combined

⁶ Petitioner asserts that Swinger discloses a system for surgery on the cornea and lens (anterior capsulotomy). Pet. 53. Petitioner does not assert, however, that Swinger is the result of modifying an existing corneal surgery system to also perform surgery on the lens. Nor does the Petition argue that Swinger would be used to perform the claimed incisions. *Id.* at 56–57. 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. Ex. 2014, 16:13–18; Ex. 1039, code(22).

system could successfully perform the claimed capsulotomy steps due to use of an ablating laser. Accordingly, Petitioner fails to demonstrate by preponderance of the evidence that any of 1, 2, and 6–19 would have been obvious over Freedman, Swinger, and Hoppeler.

4. Ground 4: Obviousness of Claims 3–5 over the Combination of Freedman, Swinger, Hoppeler, and Masket

Petitioner contends the subject matter of claims 3–5 would have been obvious over the combined disclosures of Freedman, Swinger, Hoppeler, and Masket. Pet. 67–68. In this ground, Petitioner adds Masket to the prior art combination for its disclosure of an image projection device that projects a target image representing a surgeon’s intended treatment pattern onto the surface of the lens capsule. *Id.* at 67 (citing Ex. 1045 ¶¶ 5–7, 15, 19).

Petitioner’s arguments with respect to this ground, however, do not resolve the issues discussed above with respect to the combination of Freedman, Swinger, and Hoppeler. Accordingly, Petitioner fails to demonstrate by a preponderance of the evidence that claims 3–5 would have been obvious over Freedman, Swinger, Hoppeler, and Masket.

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. 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.

A. Objective Indicia Evidence

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.

As we do not consider Patent Owner’s evidence regarding objective indicia of non-obviousness, having determined Petitioner’s challenges otherwise fall short, Petitioner’s motion to exclude these exhibits is moot.

B. Uncited Exhibits

Petitioner contends 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.

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, the 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 reply to Patent Owner’s opposition that the remaining exhibits are irrelevant because they are not cited in Patent Owner’s papers. Mot. Reply 4.

Here, Dr. Kang and Dr. Walters rely on the identified exhibits to support their opinions. As such, they are relevant to understanding the weight to be given the declarants’ testimony. Accordingly, we decline to

exclude Exhibits 2029, 2038, 2039, 2048, 2056, 2071–2077, and 2080–2085 and the motion is respectively denied with regard to those exhibits.

C. Dr. Kang’s Testimony

Petitioner contends Dr. Kang’s validity 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 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 ¶¶ 6–17; 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 answers 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 general 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. This testimony is relevant to the parties’ obviousness dispute and should not be excluded and we respectively deny Petitioner’s Motion.

To the extent Dr. Kang renders 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 and apply these considerations using 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. Conclusion on Petitioner's Motion

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

In summary:

Claims	35 U.S.C. §	Reference(s)/ Basis	Claims Shown Unpatentable	Claims Not Shown Unpatentable
1–3, 6–19	103(a)	Swinger, Baikoff, Hoppeler		1–3, 6–19
4–5	103(a)	Swinger, Baikoff, Li, Hoppeler		4–5

Claims	35 U.S.C. §	Reference(s)/ Basis	Claims Shown Unpatentable	Claims Not Shown Unpatentable
1–2, 6–19	103(a)	Freedman, Swinger, Hoppeler		1–2, 6–19
3–5	103(a)	Freedman, Swinger, Hoppeler, Masket		3–5
Overall Outcome				1–19

VI. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that claims 1–19 of the '497 patent are not determined to be unpatentable;

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

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.

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