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Paper 12
Entered: November 18, 2021

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

AMO DEVELOPMENT, LLC,
Patent Owner.

IPR2021-00841
Patent 9,474,648 B2

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

FLAX, *Administrative Patent Judge*.

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

Alcon Inc., Alcon LenSx, Inc., Alcon Vision, LLC, Alcon Laboratories, Inc., and Alcon Research, LLC (collectively "Petitioner") filed a Petition for *inter partes* review challenging claims 1–15 (all claims) of U.S. Patent 9,474,648 (Ex. 1030, "the '648 patent"). Paper 1 ("Pet."). AMO Development, LLC ("Patent Owner") filed a Preliminary Response. Paper 7 ("Prelim. Resp.").

Under 37 C.F.R. § 42.4(a), we have authority to determine whether to institute trial in an *inter partes* review. We may institute an *inter partes* review if the information presented in the petition filed under 35 U.S.C. § 311, and any preliminary response filed under § 313, shows that there is a reasonable likelihood that Petitioner would prevail with respect to at least one of the claims challenged in the petition. 35 U.S.C. § 314.

After reviewing the parties' submissions, we conclude Petitioner demonstrates a reasonable likelihood it would prevail in showing that claims of the '648 patent are unpatentable under the presented grounds. Therefore, we institute *inter partes* review of all challenged claims (1–15) under the grounds raised in the Petition, pursuant to 35 U.S.C. § 314. *See SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1359–60 (2018); *see also* Guidance on the Impact of *SAS* on AIA Trial Proceedings (April 26, 2018) (available at https://www.uspto.gov/patents-application-process/patent-trial-and-appeal-board/trials/guidance-impact-sas-aia-trial) ("Guidance").

I. INTRODUCTION

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 '648 against all Petitioners except Alcon Inc. in *AMO Development, LLC et al. v. Alcon LenSx, Inc. et al.*, No. 1:20-cv-00842-CFC (D. Del.), filed June 23, 2020 ("Delaware Litigation"). Petitioners have filed IPR petitions for eleven other patents in the same family as the '648, all of which are asserted in the Delaware Litigation: U.S. Patent Nos. 8,394,084 (IPR2021-00817); 8,403,921 (IPR2021-00823); 8,425,497 (IPR2021-00858); 8,500,724 (IPR2021-00856); 8,709,001 (IPR2021-00862); 9,095,415 (IPR2021-00835); 9,101,448 (IPR2021-00839); 9,107,732 (IPR2021-00840); 9,125,725 (IPR2021-00853); 9,693,903 (IPR2021-00824); and 9,693,904 (IPR2021-00825). This case may affect, or be affected by, the Delaware Litigation.

Paper 3, 1.

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

C. THE '648 PATENT

The '648 patent issued on October 25, 2016, from U.S. Application 14/949,645, which was filed on November 23, 2015. Ex. 1030, codes (45), (21), (22). The '648 patent ultimately claims priority to U.S. Provisional 60/643,056, filed on January 10, 2005. *Id.* at code (60), 1:7–16. At this stage of the proceeding, in the absence of any argument to the contrary, we understand that the ’648 patent is entitled to priority to this provisional application. *See, e.g.*, Pet. 1, 5 n.2.

The ’648 patent concludes with 15 claims, of which claim 1 is the sole independent claim; it is illustrative and reproduced below with added sub-numbering, as used by the parties (*see, e.g.*, Ex. 1031; Pet. 34–40; Prelim. Resp. 15, 21, 26 n.5, 28 n.6):

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

Ex. 1030, 17:30–51. Each of claims 2–15 depends, directly or indirectly, from claim 1. *Id.* at 17:52–18:61.

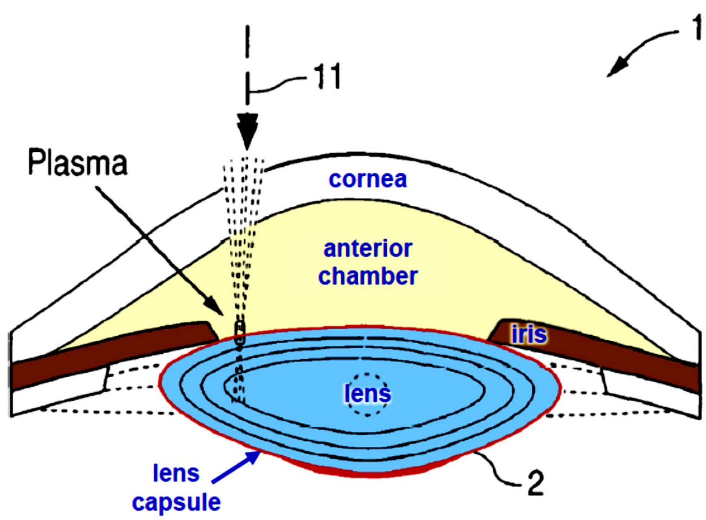
The ’648 patent’s Abstract indicates its invention is directed to a

> A system for ophthalmic surgery on an eye includes: a pulsed laser which produces a treatment beam; an OCT imaging

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

Id. at Abstract.

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



The '648 patent states that "FIG. 2 is a diagram of the anterior chamber of the eye and the laser beam producing plasma at the focal point on the lens capsule," and Dr. Walter has annotated the figure with text and coloring to identify, from most-anterior to most-posterior, the eye's cornea, anterior chamber (colored yellow), iris (colored brown), lens (colored blue), and lens capsule (colored red). *Id.* at 5:49–51; Ex. 2004 ¶ 8; *see also* Prelim. Resp. 4 (reproducing this same image). Figure 2 also shows optical beam 11 impinging upon eye tissue 2. Ex. 1030, 6:38–7:11. The ’648 patent states, “[a]s can be seen in FIG. 2, the capsule boundaries and thickness, the cortex, epinucleus and nucleus are determinable.” *Id.* at 8:50–52.

As background, the ’648 patent describes cataract 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 1:25–2:4. As further background, the ’648 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 2:62–3:3.

The ’648 patent states that “[w]hat is needed are ophthalmic methods, techniques and apparatus to advance the standard of care of cataract and other ophthalmic pathologies.” *Id.* at 3:8–10.

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

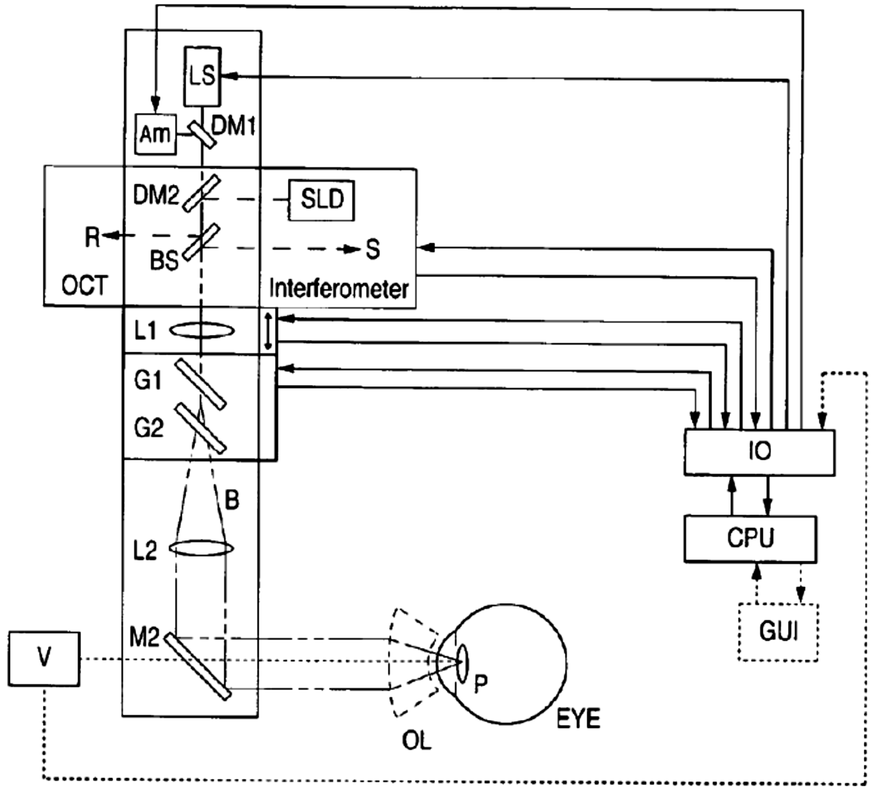


FIG. 12

Figure 12 "is a plan diagram of [a] system embodiment that projects or scans an optical beam into a patient's eye" and it shows a system including a CPU connected with an input-output device (IO) and a graphical user interface (GUI); the IO connects the CPU with laser source LS for performing cataract surgery and an OCT interferometer with imaging light source SLD (although it is also possible for the imaging and treatment to be performed using the same laser). *Id.* at 6:11–12, 11:30–13:20. These two sub-systems (treatment and imaging) of the greater system include a series of mirrors (e.g., DM1, DM2, M1, G1, G2, M2) and lenses (e.g., L1, L2, OL) for directing light to, focusing light on, and patterning light at a target point P in the eye. *Id.* Also shown is visualization apparatus V. *Id.* The '648 patent describes that "the entire system is controlled by the controller CPU," but that graphical user interface GUI may be used to process user input. *Id.* at 12:33–38.

The ’648 patent describes that “[s]hort pulsed laser light focused into eye tissue 2 will produce dielectric breakdown at the focal point, rupturing the tissue 2 in the vicinity of the photo-induced plasma.” *Id.* at 7:8–10. The ’648 patent further describes that

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

Id. at 8:10–22. The ’648 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 11:1–29.

D. SUMMARY OF PETITIONER'S ASSERTED GROUNDS FOR UNPATENTABILITY

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

Ground	Claims Challenged	35 U.S.C. §[1]	Reference(s)/Basis
1	1–5, 12–15	103	Swinger,[2] Baikoff,[3] Li[4]
2	6–9	103	Swinger, Baikoff, Li,

[1] The '648 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.

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

[3] 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").

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

Ground	Claims Challenged	35 U.S.C. §[1]	Reference(s)/Basis
			Hoppeler[5]
3	10, 11	103	Swinger, Baikoff, Li, L'Esperance[6]
4	1–5, 12–15	103	Freedman,[7] Swinger
5	6–9	103	Freedman, Swinger, Hoppeler
6	10, 11	103	Freedman, Swinger, L'Esperance

See Pet. 7.

In support of the grounds for unpatentability Petitioner submits, *inter alia*, the Declaration of Joseph A. Izatt, PhD (Ex. 1001). In support of its positions, Patent Owner submits, *inter alia*, the Declaration of Jin U. Kang, PhD (Ex. 2002) and the Declaration of Keith Walter, MD (Ex. 2004). At this stage of the proceeding, and in the absence of evidence to the contrary, we find Drs. Izatt, 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; Ex. 1002; Ex. 2002 ¶¶ 4–5, 25–28; Ex. 2003; Ex. 2004 ¶¶ 4–18; Ex. 2005.

We review Petitioner's asserted prior art below.

E. SWINGER

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

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[5] Thomas Hoppeler & Balder Gloor, *Preliminary clinical results with the ISL laser*, 1644 OPHTHALMIC TECH. II 96–99 (1992) (Ex. 1043, "Hoppeler").
[6] US 4,538,608, issued Sept. 3, 1985 (Ex. 1046, "L'Esperance").
[7] US 6,454,761 B1, issued Sept. 24, 2002 (Ex. 1040, "Freedman").

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

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

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

Ex. 1039, Abstract.

Swinger illustrates such a system at its Figure 6, which is reproduced below:

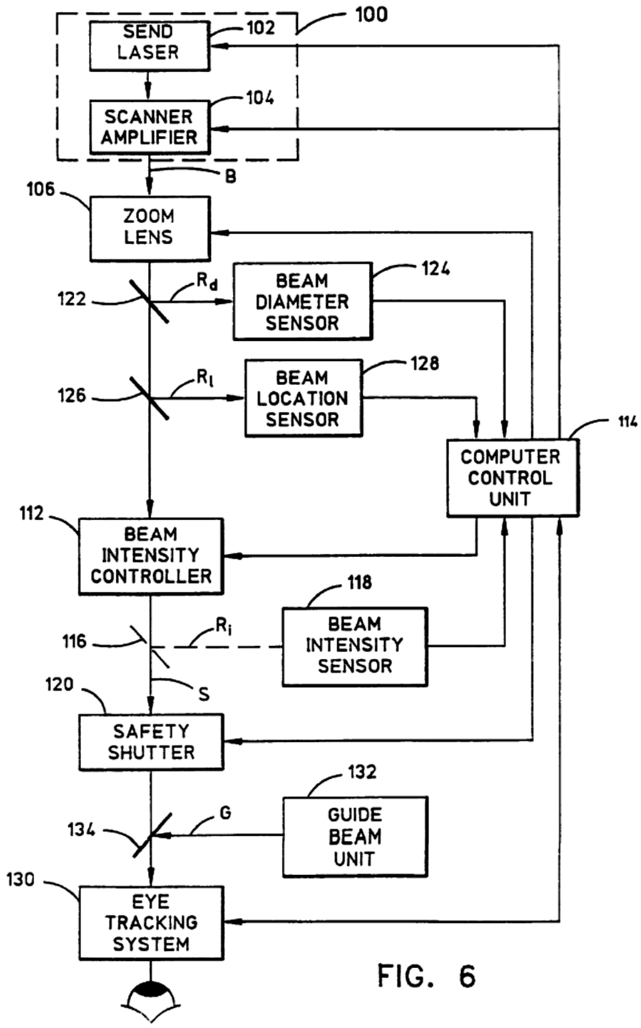

FIG. 6

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

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

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

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

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

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

F. Baikoff

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

Baikoff discloses using 1310 nm wavelength optical coherence tomography (OCT) to measure internal eye anatomy, including the horizontal diameter of the AC (anterior chamber), the anterior chamber depth (ACD), the horizontal pupil diameter, and the horizontal radius of curvature of the crystalline lens's anterior pole. Ex. 1041, 1844.[8] 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:

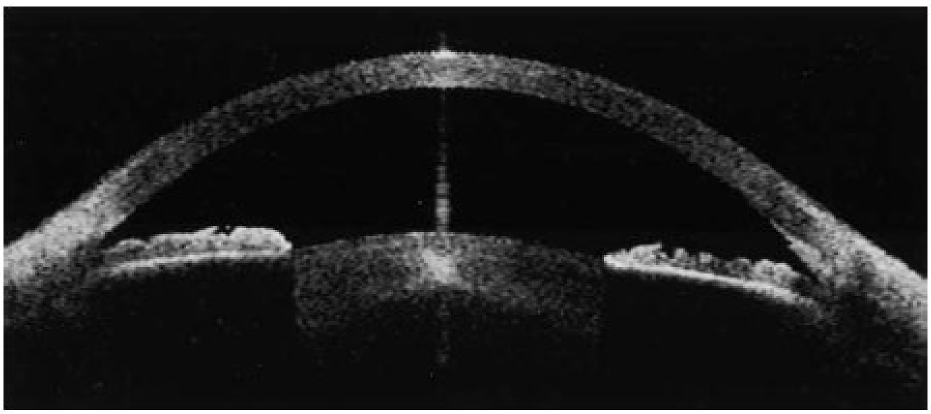

Figure 3. (Baikoff) The AC of a 55-year-old subject.

Id. at 1845.[9] 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

[8] Baikoff includes original page numbering and numbering added to its lower corner. We use the original numbering when citing to this reference.
[9] 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.

> 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,"[10] and allows "extremely precise exploration of the anterior segment." *Id.* at 1844, 1849.

G. Li

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

Li discloses that "[a]ccurate sizing of angle-supported anterior chamber intraocular lens (AC-IOL) is crucial in preventing complications," and that, "[t]o accurate[ly] measure AC width and other dimensions," the Li authors "developed a high-speed optical coherence tomography (OCT) system and automated image processing." Ex. 1044, 1. Li discloses that "[a] computer algorithm was developed to measure angle-to-angle AC width, AC depth, and lens vault,"[11] and "[t]he computer algorithm successfully measured AC diameter and AC depth from all 120 OCT images." *Id.*

Li concluded that,

> [d]ue to its longer wavelength, the OCT system was able to penetrate and image the angles. The speed was sufficient[ly] high for reproducible AC width measurement. The automated

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[10] Phakic refers IOL implantation without removing the natural lens.
[11] Lens vault refers to a measurement of the perpendicular distance between an eye's anterior lens pole and the horizontal line joining the temporal and nasal scleral spurs, i.e., an anterior dimension of the crystalline lens.

> computer algorithm agrees well with human raters. The use of a computer measurement algorithm avoids the relatively large disagreement between human raters for AC width,

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

H. HOPPELER

Hoppeler is a journal article indicated as published in 1992. Ex. 1043, 96. At this stage of the proceeding there is no dispute that Hoppeler is prior art. *See generally* Prelim. 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, 96 (Abstract); *see also id.* at 98–99 (further describing such procedures). Hoppeler discloses that the laser is started by a surgeon by pressing a conventional foot switch. *Id.* Hoppeler discloses that the surgery is performed by using the laser to create different area patterns in/on tissue. *Id.* at 96–98.

I. L'ESPERANCE

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

L'Esperance discloses that:

> The invention involves the apparatus and the technique for non-invasive surgery to remove cataracted-lens tissue from an afflicted lens. The beam output of a laser is focused to a spot of maximum power density at the anterior surface of a cataracted

> lens and scanned over a predetermined area or areas of the cataracted lens. The beam is selective and safe since it's diffuse as it enters the eye through the cornea and is also diffuse (being divergent) in the unlikely event that the beam passes through an opening it has created in the cataracted lens. This diffusion assures against damage to either or both of the cornea and the retina. Focal power levels are used sufficient to achieve cataract material destruction thru ablative photodecomposition, thermal decomposition, photofragmentation, photoemulsification or any combination thereof. Various features are disclosed for assuring safety and uniformity in the removal of involved tissue.

Ex. 1046, Abstract.

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

FIG. 1.

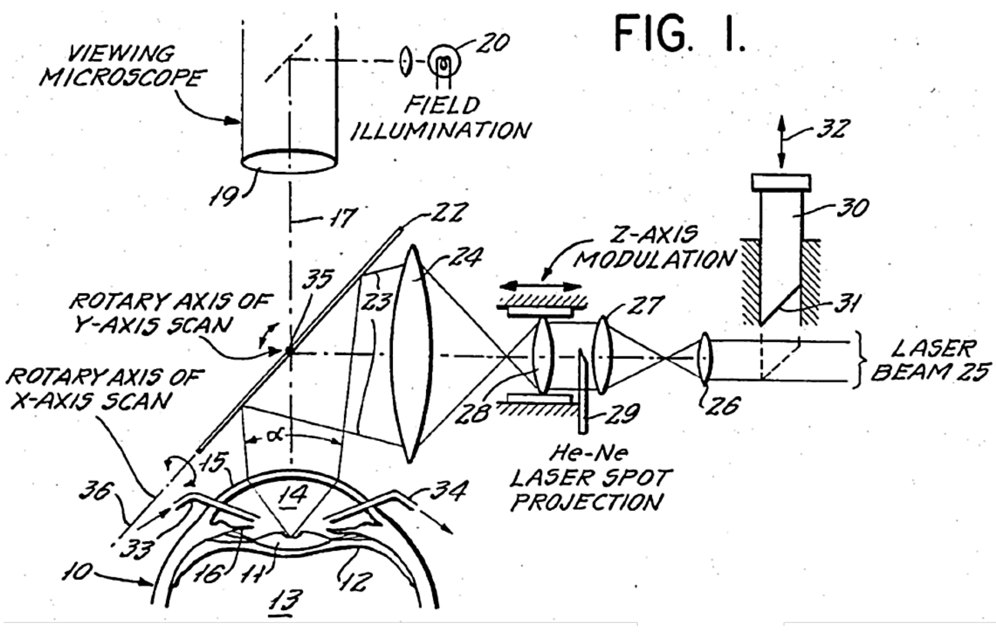

Figure 1 "is a simplified optical diagram of components of [an] apparatus of the invention, shown in application to an eye in which cataracted-lens tissue is being removed." *Id.* at 2:5–7. Figure 1 shows patient's eye 10 with cataracted natural lens 11, adjacent to an apparatus or system having a viewing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

J. 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). At this stage of the proceeding there is no dispute that Freedman is prior art. *See generally* Prelim. 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 where a treatment laser beam is controlled by interferometry, preferably by optical coherence tomography," including "controlling the laser treating of the biological tissue according to the detected surface or mass." *Id.* at 2:7–31. Freedman provides an illustration of a system for such surgery at its Figure 1, reproduced below:

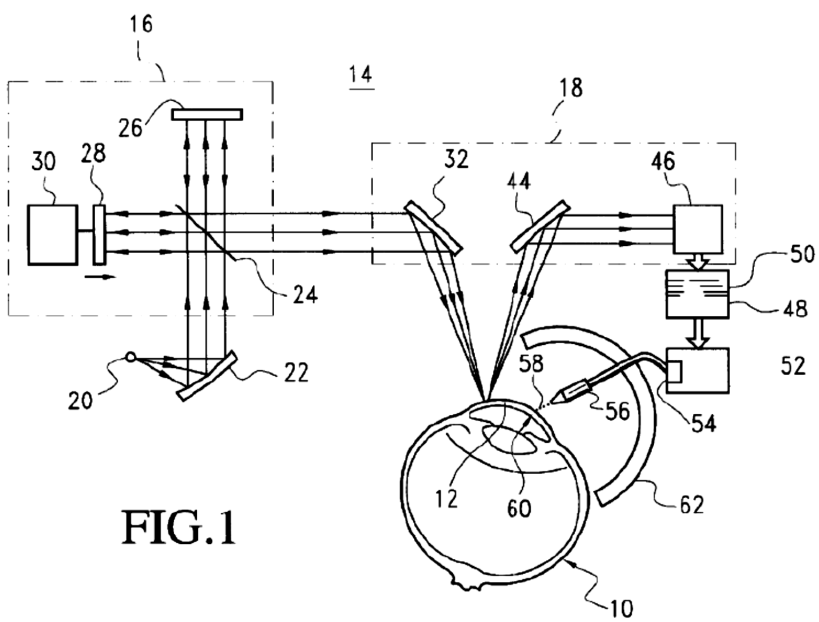

FIG.1

Freedman states that "FIG. 1 . . . [is a] schematic representation[ ] of [a] device[ ] and method[ ] for laser surgery controlled by low coherence interferometry," and the image above shows laser surgery device 14 utilizing two-wavelength interferometry to determine the characteristics of a section of optical cornea 12 tissue of patient's eye 10 for a radial keratotomy procedure. *Id.* at 4:3–5:67. 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 mutilayer thin film. The cornea can be evaluated as a mutilayer thin film to provide detailed information about cross-sectional planes of the cornea tissue or evaluated as a single layer thin film for applications requiring only gross information on the tissue structure. According to the invention, the information from the evaluation of the cornea has been found to be sufficient for processing to control the delicate ablation in a radial keratotomy and in other procedures for treating biological tissue by laser surgery.

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

As illustrated by the above-quoted and other portions of Freedman, the reference's detailed description is most focused on laser surgery on the cornea of an eye, using the "precise three-dimensional imaging capability of low coherence interferometry" to "permit[ ] precise control of ablating laser 52 in forming the incisions at the location and extent previously determined." *Id.* at 4:9–9:18. Freedman's claims, however, are not so limited and are directed to, *inter alia*, "treating biological tissue by laser surgery." *Id.* at 9:44–47. Moreover, throughout its disclosure, Freedman indicates, for example, that "[a]ccording 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," and "[a]ccording 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 4:33–35, 4:41–45; *see also id.* at 8:41–46 (discussing tumor ablation), 8:48–51 (again discussing tumor irradiation and tissue generally), 9:19–26 (discussing modifying the disclosed system to image "other optically transmissive tissue").

II. DISCUSSION

A. ORDINARY LEVEL OF SKILL IN THE ART

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

Petitioner states,

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

Pet. 25 (we note, Petitioner cites no evidence in support of this proposed definition, but Dr. Izatt testifies similarly at Ex. 1001 ¶¶ 49–50).[12]

Patent Owner disagrees with this proposed definition in two respects: (1) clinical experience in ophthalmology is relevant to the ordinary level of skill and is not recognized by Petitioner; and (2) PhD education is not required for ordinary skill and a Bachelor's degree will suffice for active workers in the field. Prelim. Resp. 8–10. In view of these issues, Patent Owner proposes the following:

> The person having ordinary skill at the time of the invention in or about January 2005 would include an engineer with a Bachelor's degree in a laser-related engineering or optics field, with some experience working with medical optics or lasers. Kang ¶ 26. The engineer would have worked with a clinician having experience with ophthalmic surgery. *Id.* Conversely, a POSA would also include an ophthalmic surgeon with some experience working with medical optics or lasers, who would have worked with an engineer or a graduate from a related field with some experience working with medical optics or lasers. *Id.*

Id. at 8.

[12] The parties use the acronym POSA to refer to the person of ordinary skill in the art. It is not preferred.

For purposes of this Decision, at this stage of the proceeding we generally accept Petitioner's proposed definition of the person of ordinary skill in the art (or ordinarily skilled artisan), which appears to be consistent with the level of skill in the art reflected in the prior art of record and the disclosure of the '648 patent; however, we also agree with Patent Owner that such a definition should be flexible enough to include a person with a lesser academic degree and having experience working in the field, such as an engineer with clinical experience in ophthalmic surgery, as well as also including a medical doctor, such as an ophthalmic surgeon with experience working with medical optics and lasers, and that these people may collaborate. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) ("the prior art itself [may] reflect[] an appropriate level" as evidence of the ordinary level of skill in the art) (quoting *Litton Indus. Prods., Inc. v. Solid State Sys. Corp*., 755 F.2d 158, 163 (Fed. Cir. 1985)).

Such an expanded definition of the person of ordinary skill in the art, including aspects of both parties' definitions, is appropriate based on our review of the record, which includes a significant number of prior art references authored by PhDs, MDs, and BSs and combinations thereof. *See, e.g.*, Ex. 1030 (we understand includes inventors that are PhDs and MDs); Ex. 1039 (we understand includes PhDs and MDs as inventors); Ex. 1040 (we understand inventor is a JD with a BS); Ex. 1041 (we understand authors are MDs); Ex. 1042 (we understand authors are PhDs, MD, and BS); Ex. 1043 (we understand authors are MDs); Ex. 1045 (we understand inventor is MD); Ex. 1046 (we understand the inventor is an MD); *see also* Ex. 1053; Ex. 1054; Ex. 1055; Ex. 2010; Ex. 2019.

If our understanding regarding the educational level of active workers in the field, such as the authors and named inventors of the afore-cited evidence, is incorrect, the parties should address the matter at trial. However, our decision to institute trial in this proceeding does not hinge on the specific definition of ordinarily skilled artisan and would not change were we to adopt Patent Owner's proposed definition.

B. CLAIM CONSTRUCTION

"[W]e need only construe terms 'that are in controversy, and only to the extent necessary to resolve the controversy.'" *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)).

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

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

Claim 12 depends from independent claim 1 and is but one of fifteen challenged claims. Ex. 1030, 17:30–18:61. It is not necessary for us to consider the Petition's specific challenges to claim 12 to render our decision to institute trial in this proceeding. Therefore, we do not construe any claim language at this time; we accord all claim language its ordinary and customary meaning as it would have been understood by the person of ordinary skill in the art.

C. APPLICABLE LEGAL STANDARDS

"In an IPR, the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable." *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016) (citing 35 U.S.C. § 312(a)(3) (requiring *inter partes* review petitions to identify "with particularity . . . the evidence that supports the grounds for the challenge to each claim")). This burden of persuasion never shifts to Patent Owner. *See Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015) (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;[13] and (4) considering objective evidence indicating obviousness or non-obviousness.[14] *KSR*, 550 U.S. at 406.

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

[14] At this stage of the proceeding, there is no evidence pertaining to objective indicia of non-obviousness. *See* Prelim. Resp.

"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 and claim interpretation discussed above, we address Petitioner's challenges below.

D. PETITIONER'S PATENTABILITY CHALLENGES

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

1. Obviousness of Claims 1–5, 12–15 over Swinger, Baikoff, and Li (Ground 1)

Petitioner's Ground 1 addresses independent claim 1 and dependent claims 2–5 and 12–15, and asserts that each would have been obvious over the combination of Swinger, Baikoff, and Li. *See* Pet 28, *et seq.*

Petitioner begins by asserting that the ordinarily skilled artisan would have been motivated to combine these references and modify them in view of one another because Swinger teaches laser cataract surgery and identifies the benefits of accuracy, using ultrasound, for example, to measure the dimensions of eye tissues to provide a safely distanced ablation region, 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 Li teaches an OCT system like Baikoff's that replaces manual measurements of interior eye dimensions with automatic computer measurements based on imaged tissue boundaries to improve precision. *Id.* at 28–34 (citing Ex. 1001 ¶¶ 142–150, 152, 154–159; Ex. 1030, 8:13–22, 11:1–29, 13:21–37, 13:52–53, Figs. 11, 13; Ex. 1039, 16:60–20:34, 23:13–25, 34:43–51, 35:17–36:7, Fig. 6; Ex. 1041, 1843–45, 1847; Ex. 1044, 1–2). Petitioner's position is that the ordinarily skilled artisan would have recognized that further automating Swinger's cataract surgery based on Baikoff's and Li's OCT imaging would predictably automate a manual step of Swinger's procedure and improve the precision and accuracy of such procedures by replacing ultrasound imaging with OCT imaging, which was detailed, precise, accurate, and suitable for such procedures. *Id.* (citing *In re Venner*, 262 F.2d 91, 95 (CCPA 1958)).

Petitioner also asserts that the person of ordinary skill in the art would have had a reasonable expectation of success in combining and modifying this prior art. *Id.* at 31–34 (citing Ex. 1001 ¶¶ 150, 152, 154–159; Ex. 1030, 8:3–22, 11:1–29, 13:21–37, 13:52–53, Figs. 11, 13; Ex. 1039, 35:59–66; Ex. 1041, 1844; Ex. 1044, 1–2). Petitioner's position is that the prior art teaches the asserted combination and modification was not only desirable, but was a straightforward and a simple substitution of known imaging modalities (substituting Swinger's ultrasound with OCT imaging in a similar fashion to how the '648 patent describes switching between ultrasound and direct visualization), and the mere programming of a control system (Swinger's beam control computer) with known algorithms. *Id.*

Petitioner moves on to address how each limitation of the aforementioned independent claim 1 is taught or suggested by Swinger, Baikoff, and Li. *Id.* at 34–40 (citing*, inter alia*, Ex. 1001 ¶¶ 453–462;

Ex. 1024, 12:22–27, Ex. 1039, 16:60–20:34, 20:49–21:19, 34:30–35:3, 35:17–36:7, Figs. 6, 15A1, 15B1; Ex. 1041, 1844–45, Figs. 3, 10; Ex. 1044, 1–2). Petitioner asserts that all the claimed equipment, steps, and target tissue for laser cataract surgery, other than the use of an OCT imaging system and the related programmed computer-automation based thereon, is taught by Swinger. *Id.* at 34–40. For such missing steps and equipment, Petitioner asserts that Baikoff and Li provide them and would have been combined with Swinger's methods, as discussed above. *Id.* Petitioner also makes a similar showing for dependent claims 2–5 and 12–15. *Id.* at 40–46 (citing, *inter alia*, Ex. 1001 ¶¶ 463–470, 473–482; Ex. 1039, 7:51–58, 8:37–48, 16:14–16, 17:11–13, 33:36–43, 34:30–35:3; Ex. 1041, 1843–45, 1847, Fig. 10; Ex. 1044).

At this stage of the proceeding, we find Petitioner has sufficiently explained how and why the cited prior art would have been combined, why the ordinarily skilled artisan would have had a reasonable expectation of success in doing so, and that such a combination teaches or suggests the limitations or steps of claims 1–5 and 12–15. We address Patent Owner's preliminary arguments below.

Patent Owner addresses Petitioner's Grounds 1–3 together; each is based on a combination of Swinger, Baikoff, and Li. Prelim. Resp. 10–31 (citing, *inter alia*, Ex. 1001 (Izatt) ¶¶ 46–49, 143, 149, 159; Ex. 1030, 2:5–13, 11:19–26, 17:38–45; Ex. 1039 (Swinger), 17:50–54, 19:23–28, 23:28–31, 34:30–35:3, 35:18–36:17; Ex. 1041 (Baikoff), 1843–45, 1847, 1849, Fig. 10; Ex. 1043 (Hoppeler); Ex. 1044 (Li); Ex. 1046 (L'Esperance); Ex. 2002 (Kang) ¶¶ 32–39, 46–52, 55–57, 60; Ex. 2004 (Walter) ¶¶ 16–17;

Ex. 2006, 286, 296–98).[15] Patent Owner addresses the claims in this way as a set, presenting the same arguments for all claims, and addresses the dependent claims as not unpatentable because the additionally cited prior art (Hoppeler and L'Esperance) do not remedy the argued shortcomings regarding Swinger, Baikoff, and Li. *Id.*

Patent Owner argues that the ordinarily skilled artisan would not have combined these references because Swinger requires a surgeon's direct visualization for cataract surgery, foreclosing using OCT, and because Baikoff and Li teach that OCT is limited to the eye's anterior chamber, which makes it impossible to obtain satisfactory imaging (e.g., of lens portions behind the iris's shadow). *Id.* at 15–18. Patent Owner argues that Swinger's use of direct visualization and Baikoff's acknowledgement of an inability to OCT-image the lens where shadowed by the iris teaches away from using OCT in cataract surgery and the combination of the references. *Id.* at 15–19. Patent Owner argues that the prior art combination does not disclose a device that "generate[s] image data for the patient's crystalline lens," or "process[ing] the image data to determine an anterior capsule incision scanning pattern for scanning a focal zone of the laser beam for performing an anterior capsule incision," as recited by claim 1. *Id.* at 21–30. Patent Owner also argues that Petitioner took positions before the Office contrary to those it now asserts, specifically that in 2010 OCT imaging could

[15] Patent Owner cites this evidence by shorthand names, e.g., "Swinger" and "Kang." Although Patent Owner is free to cite evidence by any manner it desires, it is more useful to the Board if citations reference exhibit numbers, which facilitates review of the record.

not be used with ophthalmic surgery citing, for example, Exhibit 2006 at pages 286 and 296–98 (US 8,398,236 file history). Prelim. Resp. 19–20.

At this stage of the proceeding, these arguments do not dissuade us from instituting trial. Based on the record, as it now stands, Swinger, Baikoff, and Li appear to have been reasonably ripe for combination by the ordinarily skilled artisan as directed to the same general field of technology and their methods appear to be complementary. Pet. 28–34; *see also* Ex. 1001 ¶¶ 31–38, 54–72, 93–159 (discussing objectives and desires in the field and the respective teachings of the prior art). Petitioner has provided an adequate explanation as to why an ordinarily skilled artisan would have combined the references and would have had a reasonable expectation of success.

As Patent Owner argues, Swinger teaches that a surgeon uses direct visualization and manual identification of the eye to define a capsulectomy cutting region and Baikoff states that the OCT "infrared light beam is stopped by the pigments [of the iris]," and, therefore, a satisfactory view of the structures behind the epithelial pigment layer of the iris of the anterior uvea is not possible. *See* Prelim. Resp. 11–14, *et seq.* On the present record we do not find that the facts support a teaching away from either the combination of prior art or the claimed invention. Swinger does not expressly exclude techniques other than direct visualization and manual alignment of an ablation laser. In fact, its teachings appear to invite computer automation of aspects of cataract surgery, as well as the use of imaging to improve the accuracy and precision of the process. Ex. 1039, 7:50–8:6, 10:10–19, 20:8–17, 20:42–46, 34:30–35:3, 35:59–36:2, Figs. 6, 15A1, 15B1, 15D1.

Regarding Baikoff's expressed limitations of OCT imaging, were the imaging of the complete lens a requirement for cataract surgery, the inability to do so might be an impediment that would dissuade an ordinarily skilled artisan from relying solely upon such a technique; the record does not suggest such a requirement. *See generally* Ex. 2004 (discussing visualizing the lens, but not expressing it must be completely visualized); *see also* Ex. 2002 ¶ 24 (suggesting only the nucleus and cortex, and some "other structures in the lens" need be imaged). Further, Baikoff discloses actual images where OTC imaging and software renders detailed data on the thickness of the lens where it is not shadowed by the iris. Ex. 1041, 1843–45, Fig. 3. Moreover, Dr. Izatt testifies that complete imaging of the lens is neither required nor desired for cataract surgery, but explains that if the ordinarily skilled artisan wanted to mitigate the blind spots disclosed by Baikoff they would have known to adjust the spatial relationship between the system and the eye to do so. *See, e.g.*, Ex. 1001 ¶¶ 107–108, 139, 151, 154.

At this stage of the proceeding, Patent Owner's arguments regarding the claimed "generate[ing] image data for the patient's crystalline lens," and "process[ing] the image data to determine an anterior capsule incision scanning pattern for scanning a focal zone of the laser beam for performing an anterior capsule incision," do not dissuade us from instituting trial. Based on Baikoff's disclosure, it appears that the reference teaches image data from the interior portion of an eye. Ex. 1041, 1844–45. Baikoff states that "crystalline lens thickness" was measured using its OCT imaging and includes actual images of a cross-section of a lens at, for example, its Figure 3 (reproduced above). *Id.* Moreover, based upon the record at this stage of the proceeding, we understand that upon combining Swinger, Baikoff, and Li, which appears to be reasonable for the reasons we have discussed above, once Baikoff's OCT imaging and Li's automated measuring algorithms are utilized and relied upon to replace Swinger's direct visualization step (or ultrasonics), a scanning pattern and cutting region through the lens capsule to initiate a cataract surgery would automatically be determined. *See, e.g.*, Pet. 28–40; Ex. 1001 ¶¶ 452–462.

We find that, based on the preliminary record, Petitioner sufficiently shows that there is a reasonable likelihood that it would prevail at trial in establishing that independent claim 1 would have been obvious over the Swinger, Baikoff, and Li combination. Petitioner makes similar showings for dependent claims 2–5 and 12–15, and Patent Owner does not, at this stage, argue separately over these dependent claims. Pet. 40–46; *see generally* Prelim. Resp.

2. *Obviousness of Claims 6–11 over the Swinger, Baikoff, Li Combination, and Adding Hoppeler or L'Esperance (Grounds 2 & 3)*

Similar to Ground 1, under Grounds 2 and 3 Petitioner asserts claims 6–11 would have been obvious over Swinger, Baikoff, and Li, also adding Hoppeler or L'Esperance. Pet. 47–55 (citing, *inter alia*, Ex. 1001 ¶¶ 138–139, 169–170, 182–184, 186, 486, 489–490; Ex. 1039, 8:34–40, 15:55–63, 17:2–5, 20:52–56, 23:17–25, 25:62–67, 34:52–67, 35:50–37:2, Fig. 7; Ex. 1041, 2; Ex. 1043, 1–4, Figs. 2, 3; Ex. 1046, 1:13–15, 2:39–61, 3:39–4:23, 6:25–49, Fig. 1).

Grounds 2 and 3 appear to stand or fall largely with Ground 1. As discussed above, Patent Owner does not separately argue over these grounds or the claims challenged therein. *See generally* Prelim. Resp. As we find that, on the preliminary record, Petitioner has shown how the claim limitations are taught or suggested by the cited prior art combinations, we will not address these grounds further herein. However, this does not signal that we will not consider these grounds at trial and in a final decision.

3. Obviousness of Claims 1–5 and 12–15 over Freedman and Swinger (Ground 4)

Under Ground 4, Petitioner asserts that claims 1–5 and 12–15 would have been obvious over the combination of Freedman and Swinger. Pet. 56–66 (citing, *inter alia*, Ex. 1001 ¶¶ 162–164, 166–167, 493, 496–498, 500–505, 509–510, 512–514, 516–517, 519; Ex. 1039, 7:50–8:6, 16:60–20:34, 20:49–21:19, 34:61–62, 36:3–5, Figs. 6, 15A1, 15B1; Ex. 1040, 1:23–25, 2:7–12, 4:33–5:40, 5:49–52, 5:60–67, 6:12–19, 6:66–7:8, 8:30–51, 8:66–9:2, 9:21–26, 9:51–53 (claim 3), 9:66–10:5 (claim 6), Figs. 1, 3). First, Petitioner asserts that the ordinarily skilled artisan would have combined Swinger and Freedman and would have had a reasonable expectation of success in doing so. *Id.* at 56–57. Then, Petitioner walks through the limitations of claims 1–5 and 12–15 and identifies how and where the prior art combination teaches or suggests the subject matter. *Id.* at 57–66.

To summarize, regarding combining Swinger and Freedman, Petitioner asserts that each is directed to laser eye surgery where some of the procedure is computer-controlled; Swinger to cataract (and other) surgery (including radial keratotomy) and Freedman to radial keratotomy (but mentioning other procedures). *Id.* at 56–57 (citing, *inter alia*, Ex. 1001 ¶¶ 162–164, 166–167). 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 Swinger's specific laser parameters for cataract surgery (anterior capsulotomy). *Id.* Petitioner asserts that the ordinarily skilled artisan "would have had a reasonable expectation of success in using Swinger's laser parameters in the system disclosed by Freedman because all that is required is a particular laser source and programming to control the pulse rate." *Id.* at 57.

On the preliminary record and our understanding of the prior art, we recognize the potential of the Freedman-Swinger combination in view of the '648 patent's claims, but question whether Petitioner has established a reasonable likelihood of prevailing at trial on this ground. Based on what we discern from the teachings of Swinger and Freedman, the necessary hardware, method steps, and programming needed to achieve the claimed invention appears to be disclosed in the prior art combination; however, the specifics of Petitioner's challenges over these references appears to combine the teachings of these references in a way that may not function properly. We address such issues and Patent Owner's arguments below.

Patent Owner addresses Petitioner's Grounds 4–6 together, arguing that Swinger and Freedman would not have been combined by the ordinarily skilled artisan, and that the prior art combination does not teach acquiring image data from locations distributed throughout the lens or a computer control system programmed to automatically use image data to define a cutting regions, as such subject matter is recited by the claims. Prelim. Resp. 31–44 (citing, *inter alia*, Ex. 1001 (Izatt) ¶¶ 143, 161; Ex. 1030, 17:38–51 (claim 1); Ex. 1039 (Swinger), 3:53–54, 34:58–61, 35:39; Ex. 1040 (Freedman), 1:23–25, 4:15–17, 4:33–50, 5:37–53, 5:55–60, 6:12–19, 7:15–51, 8:30–9:18, Figs. 1, 3; Ex. 2002 (Kang) ¶¶ 33, 41–43, 61–62, 64–65, 67, 69–70, 72–73, 75; Ex. 2007, 4:65–67, 5:30–36; Ex. 2011, 4:1–6;

Ex. 2013; Ex. 2014, 15:53–58, 16:12–18; Ex. 2015, 875, 896, 898; Ex. 2019).

Patent Owner's first argument is that Freeman's laser is for cornea surgery, not lens surgery, and thus could not and would not be used for the claimed cataract surgery (as confirmed by Petitioner's own positions before the Office). *Id.* at 31–40 (citing, e.g., Ex. 2002 ¶¶ 33, 41–44, 61–62, 64–65, 67; Ex. 2007, 4:65–67, 5:30–36; Ex. 2011; Ex. 2013; Ex. 2014, 15:53–58, 16:12–18; Ex. 2015, 875, 896, 989; Ex. 2019). At this stage of the proceeding, this argument does not dissuade us from instituting trial, but there is evidence of record both tending to support and refute this argument, which we highlight below.

Petitioner's position on the Freeman-Swinger combination appears to be that, on the one hand, Freedman's OCT and laser systems would be used for cataract surgery because it was known to the ordinarily skilled artisan that such was possible, and also that, on the other hand, Freedman does not disclose the "specific parameters of the laser system for tissue ablation" or performing an anterior capsulotomy and Swinger does and such teachings would be combined to adapt Freedman's system for cataract surgery. Pet. 56–57. Thus, it appears that Petitioner at once acknowledges Swinger's system's design (particularly the suitability of its laser) for cataract surgery, but chooses Freedman's system for such a task, merely programmed for the use. This is emphasized by Petitioner's citation to Freedman, not Swinger, for the limitations of, for example, claim 1 directed to a laser system (limitation 1.1), laser generator (limitation 1.2), and operating the laser (limitation 1.7). *Id.* at 58–61. This all renders Petitioner's position somewhat ambiguous.

If the Freedman-Swinger combination requires Freedman's radial keratotomy laser (likely an excimer laser) and associated optics to be used for cataract surgery, Patent Owner's argument would weigh against obviousness. However, it is not entirely clear that that is so or that Petitioner's challenge is necessarily premised on using Freedman's cornea laser and optics system without any modification.

"In determining whether obviousness is established by combining the teachings of the prior art, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art." *In re GPAC Inc.*, 57 F.3d 1573, 1581 (Fed. Cir. 1995) (internal quotations omitted). The obviousness analysis "can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *KSR*, 550 U.S. at 418. "A person of ordinary skill is also a person of ordinary creativity, not an automaton." *Id*. at 421. The preliminary record appears to support that the claimed hardware and its known uses are disclosed in the prior art, but it is unclear that Petitioner combines the prior art in such a way so as to achieve the claimed invention of a system that would function properly.

The parties may wish to further explore and explain such issues at trial.

Patent Owner also argues that "operat[ing] the imaging device to generate image data for the patient's crystalline lens" as recited by the '648 patent's claims, is not taught by the prior art. Prelim. Resp. 41–42 (addressing, e.g., limitation 1.5) (alterations Patent Owner's). Petitioner's challenge asserts that once Freedman and Swinger are combined so that Freedman's OCT imaging system is used for cataract surgery, e.g., in place of Swinger's ultrasound imaging, "Freedman discloses a control system (48) configured to operate the imaging device (16, 18, or 66) to generate image data of the patient's ocular tissue," and that "[w]hen using Freedman's system to perform an anterior capsulotomy and lens fragmentation . . . it would have been obvious to a POSA to use Freedman's OCT imaging system to image the lens." Pet. 59; Ex. 1001 ¶ 500. As we understand from other evidence of record, i.e., Baikoff, such OCT imaging can indeed acquire such data. *See, e.g.*, Ex. 1041, 1845. Therefore, this argument does not dissuade us from instituting trial.

Patent Owner also argues that the Freedman-Swinger combination does not teach "process[ing] the image data to determine an anterior capsule incision scanning pattern for scanning a focal zone of the laser beam for performing an anterior capsule incision." Prelim. Resp. 42–43 (addressing, e.g., limitation 1.6). Petitioner asserts that "[w]hen using Freedman's system to perform an anterior capsulotomy," the ordinarily skilled artisan "would have known to configure Freedman's controller to process the image data from the lens to determine an anterior-capsule-scanning pattern, as taught by Swinger." Pet. 60 (citing Ex. 1001 ¶ 501). Based on the preliminary record, we understand that this would be the case because if the surgeon were to have and use a wholly computer-controlled imaging and laser system, as would be the case upon combining the systems of methods of Freedman and Swinger, that system would have to construct a cutting plan, as claimed, for the surgery to be performed. Ex. 1001 ¶¶ 500–501. Therefore, this argument does not dissuade us from instituting trial.

In view of the above, we take no position at this stage of the proceeding on whether Petitioner's challenge under Ground 4 is reasonably likely to succeed at trial nor need we as we have found such under Petitioner's Ground 1. As noted above, the parties may wish to further explore and explain the issues noted above at trial.

4. Obviousness of Claims 6–11 over Freedman and Swinger, also adding Hoppeler or L'Esperance (Grounds 5 & 6)

Similar to Ground 4, under Grounds 5 and 6 Petitioner asserts that claims 6–11 would have been obvious over Swinger and Freedman, also adding Hoppeler or L'Esperance (as with Grounds 2 and 3). Pet. 66–69 (citing, *inter alia*, Ex. 1001 ¶¶ 172–173, 188–189, 522–524; Ex. 1039, 35:66–36:2; Ex. 1040, 5:49–53; Ex. 1043, 4).[16] Petitioner accounts for the motivation for and reasonable expectation of success in combining the prior art and for its teachings of all claim limitations.

Grounds 5 and 6 appear to largely stand or fall with ground 4. Patent Owner does not separately argue over these grounds or the claims challenged therein. As we find that, on the preliminary record, Petitioner has shown how the claim limitations are taught or suggested by the cited prior art combinations, we will not address these grounds further herein. However, this is not a signal that we will not consider these grounds at trial and in a final decision.

III. CONCLUSION

Petitioner demonstrates a reasonable likelihood of prevailing at trial in showing that at least some of claims 1–15 of the '648 patent would have been obvious over the cited prior art. Our decision at this stage derives from our review of the preliminary record before us. In accordance with the

[16] Petitioner cites the same portions of Hoppeler and L'Esperance under Grounds 5 and 6 as cited for Grounds 2 and 3.

Court's decision in *SAS*, 138 S. Ct. at 1359–60, and Office Guidance,[17] we institute *inter partes* review of all challenged claims (1–15) of the '648 patent on all grounds asserted by Petitioner.[18]

This decision does not reflect a final determination on the patentability of the claims. No arguments from the Preliminary Response carry over to trial and any arguments not made in Patent Owner's Response may be considered waived.

ORDER

Accordingly, it is hereby:

ORDERED that, pursuant to 35 U.S.C. § 314, an *inter partes* review of claims 1–15 of the '648 patent, in accordance with all grounds in the Petition, is hereby instituted; and

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

[17] Guidance, *supra* at 2–3 ("If the PTAB institutes a trial, the PTAB will institute on all challenges raised in the petition," and "for pending trials . . . , the panel may issue an order supplementing the institution decision to institute on all challenges raised in the petition.").

[18] The Board must institute on all grounds and all claims if it does so for any. Patent Owner should address each ground at trial or else risk waiving arguments. In the interest of efficiency, Petitioner has the option to reconsider whether to pursue all grounds asserted in the Petition as the proceeding enters the trial stage.

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