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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

JOHNSON & JOHNSON SURGICAL VISION, INC., Petitioner,

v.

ALCON INC., Patent Owner.

IPR2021-01053 Patent 9,427,356 B2

Before GRACE KARAFFA OBERMANN, CHRISTOPHER M. KAISER, and JAMIE T. WISZ, *Administrative Patent Judges*.

OBERMANN, Administrative Patent Judge.

JUDGMENT Final Written Decision Determining No Challenged Claims Unpatentable 35 U.S.C. § 318(a)

I. INTRODUCTION

This is a Final Written Decision in an *inter partes* review of claims 1 and 2 of U.S. Patent No. 9,427,356 B2 (Ex. 1001, "the '356 patent"). We have jurisdiction under 35 U.S.C. § 6 and enter this Decision pursuant to 35 U.S.C. § 318(a). For the reasons that follow, we determine that Petitioner does not establish that either challenged claim is unpatentable.

A. Procedural History

Petitioner filed a Petition (Paper 2, "Pet.") requesting institution of an *inter partes* review of claims 1 and 2 of U.S. Patent No. 9,427,356 B2 (Ex. 1001, "the '356 Patent"). Patent Owner filed a Preliminary Response. Paper 8. With Board pre-authorization (Ex. 1020), the parties submitted additional briefing (Papers 14, 15) limited to addressing whether the Board should exercise its discretion and deny review under 35 U.S.C. § 325(d).

We entered an Institution Decision (Paper 16, "Dec.") instituting review of both challenged claims based on all grounds of unpatentability asserted in the Petition. Thereafter, in timely sequence, Patent Owner filed a Response (Paper 27, "Resp."), Petitioner filed a Reply (Paper 35, "Reply"), and Patent Owner filed a Sur-reply (Paper 41, "Sur-reply"). In addition, briefing was received in connection with each party's objections to the other party's evidence. *See* Papers 18–20, 30, 36.

With Board pre-authorization (Paper 38), Patent Owner submitted an identification of allegedly non-responsive evidence and arguments in the Reply and Petitioner submitted a response thereto. *See* Papers 41, 42. In similar fashion, Petitioner submitted an identification of allegedly non-

responsive evidence and arguments in the Sur-reply and Patent Owner submitted a response thereto. *See* Papers 47, 50.

The Petition sets forth four grounds of unpatentability, reproduced below, and each is based on obviousness under 35 U.S.C. § 103.¹

Ground	Claims Challenged	References	
1	1, 2	Frey ² ,	
		Knowledge in the Art	
2	1, 2	Frey, Koschmieder ³ ,	
		Knowledge in the Art	
3	1, 2	Blumenkranz ⁴ , Frey,	
		Knowledge in the Art	
4	1, 2	Blumenkranz, Frey,	
		Koschmieder,	
		Knowledge in the Art	

Pet. 3. The Board heard final oral arguments in an in-person hearing conducted on September 9, 2022. *See* Paper 51 ("Tr.").

B. Real Parties-in-Interest

The Petition indicates that Johnson & Johnson Surgical Vision, Inc.,

AMO Development, LLC, AMO Manufacturing USA, LLC, and AMO

¹ The Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112-29, 125 Stat. 284 (September 16, 2011), includes revisions to Section 103 that became effective on March 16, 2013. Petitioner assumes that the pre-AIA statutory provisions apply in this proceeding. Pet. 13, 25–26 n.7. Neither party directs us to information indicating that the result would change based on which version of the statute is applied in this case.

² WO 2007/084602 A2, published July 26, 2007 (Ex. 1006).

³ US Pub. 2006/0170867 A1, published Aug. 3, 2006 (Ex. 1007).

⁴ US Pub. 2006/0195076 A1, published Aug. 31, 2006 (Ex. 1008).

Sales and Service, Inc. are real parties-in-interest. Pet. 60. Patent Owner's Mandatory Notice indicates that Alcon, Inc., Alcon Vision, LLC, and Alcon Research, LLC are real parties-in interest. Paper 4, 1.

C. Related Matters

Both parties identify as a related matter co-pending district court litigation in *AMO Development, LLC v. Alcon LenSx, Inc.*, No. 1:20-cv-00842-CFC (D. Del.). Pet. 60; Paper 4, 1.

II. BACKGROUND

A. The '356 Patent (Ex. 1001)

The '356 patent is titled "Photodisruptive Laser Fragmentation of Tissue." Ex. 1001, code (54). The written description discusses "techniques and systems for laser surgery on the crystalline lens" of an eye "via photodisruption caused by laser pulses." *Id.* at 3:25–26. Specifically, "[i]n a laser-induced lens fragmentation process, laser pulses interact with the lens tissue to generate gas in [the] form of cavitation bubbles." *Id.* at 3:43–45. The '356 patent describes a method of applying laser pulses to generate "cells" within the lens tissue by "a non-uniform laser distribution process," resulting in a "localized tissue effect" that "can improve the precision of the laser surgery." *Id.* at 3:42–4:35.

The challenged claims relate to a method of laser-induced fragmentation. *See id.* at 12:6–22 (claims 1 and 2). A pulsed laser generates a pulsed laser beam, which "an optics module" directs "towards a target region in the lens tissue." *Id.* at 12:6–18. "[A] system control module" controls the optics module "to form a regular array of cells in the target

region." *Id*. Cells are formed in the claimed method "by creating layers of photodisrupted bubbles to generate cell boundaries." *Id*.

This case turns on the meaning and application of a claim limitation directed to "creating layers of photodisrupted bubbles to generate cell boundaries," where those "layers are created by scanning the pulsed laser with [an] optics module according to *a curvature of the focal plane of the optics module* to track the natural curvature of the lens." *Id.* (Board's emphasis). A question arises regarding the meaning of the emphasized term in the context of the adjacent phrase "to track the natural curvature of the lens." *Id.*; Pet. 11–18 (proposing alternative constructions for this limitation), 24–55 (asserting four challenges, each of which turns on the construction of this limitation). The express claim language provides that layers forming the cell boundaries "are created by scanning the pulsed laser with the optics module according to" that curvature. Ex. 1001, 12:15–18.

B. Challenged Claims

Petitioner challenges claims 1 and 2 of the '356 patent. Pet. 6. We reproduce below the challenged claims.

1. A method of fragmenting lens tissue of an eye with a laser surgical system, the method comprising:

generating a pulsed laser beam with a pulsed laser;

- directing the laser beam with an optics module towards a target region in the lens tissue; and
- controlling the optics module by a system control module to form a regular array of cells in the target region by creating layers of photodisrupted bubbles to generate cell boundaries, wherein

> the layers are created by scanning the pulsed laser with the optics module according to a curvature of the focal plane of the optics module to track the natural curvature of the lens.

Ex. 1001, 12:6–18.

2. The method of claim 1, the forming the regular array of cells comprising:

forming the cells with a size suitable for extraction by aspiration without additional lens fragmentation.

Id. at 12:19–22.

III. ANALYSIS

A. Overview of the Asserted Prior Art References

1. Frey

Frey discloses a method for providing a shaped structural weakening of the human eye lens with a laser. Ex. 1006, code (54) (Title). In the method of Frey, a laser beam is delivered to a lens "in a plurality of sectional patterns" by directing the laser beam toward a first lens portion "in a first predetermined sectional pattern" and toward a second lens portion "in a second predetermined sectional pattern." *Id.* ¶ 18; *see id.* ¶ 23 (further describing the "first shot pattern" and the "second shot pattern").

Frey delivers "shot patterns" that "are composed of 'individual shots'—*i.e.*, individual points where the laser achieves photodisruption in the tissue." Resp. 5 (quoting Ex. 1006 ¶ 93). Frey's laser system performs "point-by-point scanning to achieve photodisruption, and a collection of individual points comprises a shot pattern." *Id.*; *see* Ex. 2033 ¶ 84 (Dr. Dhalla's declaration testimony).

As Petitioner acknowledges, "In Frey, the pulsed laser is applied in a grid-like shot pattern, to fragment the lens into an array of cubes." Pet. 21 (citing Ex. 1006 ¶ 91 ("A shot pattern that cuts the lens into small cubes, which cubes can then be removed from the lens capsule is provided.")). Frey's "shot pattern thus forms a regular array of cells, as shown in Figure 25 of Frey." *Id.* Specifically, "Frey uses its pulsed laser to create layers of photodisrupted bubbles to generate cell boundaries within its grid-like shot pattern 2502" (*id.* at 22), as illustrated in Petitioner's annotated version of Frey's Figure 25, which we reproduce below.



Pet. 22. Figure 25 illustrates "a cross-section drawing of a lens showing the placement of a cube laser shot pattern in accordance with the teachings of" Frey. *Id.* ¶ 44. Petitioner adds annotations to Figure 25, which highlight that "[t]he cells of tissue (shaded in blue) are formed by the grid-like laser shot pattern (highlighted in green)." Pet. 22 (citing Ex. 1004 ¶ 82). Figure 25 shows curved outer surface 2501 of the eye lens, as well as flat layers created by shot pattern 2502 and cuts 2503. *Id.* ¶ 116. In Figure 25, the z

axis runs top (lens anterior) to bottom (lens posterior), and the x-y axis runs left to right. *Id.* ¶¶ 6, 116, Figs. 1, 2, 9.

Frey's Figure 25 discloses a single shell cut (denoted element 2504) that tracks the natural curvature of the lens. However, as shown in Figure 25, Frey generates "layers" that are essentially flat along the x-y axis. *See* Ex. 1001, 12:15–18 (requiring an optics module having a curved focal plane that tracks the natural curvature of the lens). As explained in our analysis, Frey employs "flat field optics," which undisputedly "have a flat focal plane," to create both the curved and flat cuts shown in Figure 25. Reply 4.

2. Blumenkranz

Similar to Frey, Blumenkranz uses flat-field optics to generate layers of photodisrupted bubbles in eye tissue at pre-determined z-depths to form a grid-like array of cells. Pet. 13–18, 39–43, 51–55 (including citations to Frey and Blumenkranz); Ex. 1004 ¶¶ 50–59, 121–128, 168–174. The laser systems of Frey and Blumenkranz are the same in all respects material to this Decision. *See* Resp. 12–14 & n.2 (and citations to the record therein); Ex. 2033 ¶ 121.

Like Frey, Blumenkranz's laser surgical system creates layers of photodisrupted tissue in the lens tissue of a human eye by focusing a laser beam at "multiple focal points in the eye tissue at multiple depths." Ex. 1008 ¶ 19. Like Frey, Blumenkranz employs flat-field optics, having a flat focal plane, to direct laser pulses "consecutively" at set z depths. *Id.* ¶ 20. And also like Frey, Blumenkranz describes "making an incision in eye tissue" by "generating a beam of light, focusing the beam at a first focal point located at a first depth in the eye tissue, scanning the beam in a pattern on the eye

while focused at the first depth," then "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 in the pattern on the eye while focused at the second depth." *Id.* ¶ 13.

Blumenkranz employs flat-field optics which do *not* employ a focal plane that tracks the natural curvature of the lens of the eye. *See* Reply 4 (Petitioner's admission that "'flat field optics' have a flat focal plane"). That is illustrated, for example, in Blumenkranz's Figure 7A, reproduced below.



FIG. 7A

Ex. 1008, Fig. 7A. Figure 7A from Blumenkranz illustrates "multisegmented lenses for focusing the laser beam into 3 points *along the same axis*." *Id.* ¶ 29 (Board's emphasis).

Petitioner, in the Petition, does not argue that Blumenkranz materially differs from Frey. Pet. 51–54. Similarly, in the Reply, Petitioner does not distinguish between the disclosures of Frey and Blumenkranz, but centers its

arguments on the disclosures of Frey.⁵ Reply 16–28. Our analysis likewise focuses on Frey but applies with equal force to Blumenkranz.

3. Koschmieder

Koschmieder is titled "Arrangement for Improving the Image Field in Ophthalmological Appliances." Ex. 1007, code (54). The reference "is directed to an arrangement by means of which the image field of the illumination components and irradiation components of ophthalmic instruments for diagnosis and therapy is improved." *Id.* ¶ 3. For example, in the case of "slit lamps," Koschmieder explains, "[a] light section is generated in the interior of the eye being examined by means of slit image projection." *Id.* ¶ 5. "To ensure an exact evaluation of the section images generated in this way, a sharp imaging of the slit image is required on the visual axis as well as in the edge areas of the eye." *Id.*

Koschmieder addresses a blurriness problem that arises when imaging a lens near the edges of a wide field of view, away from the visual axis. Ex. 1007 ¶¶ 13, 23. Koschmieder teaches that this problem of blurriness in the periphery of the image applies to ophthalmic instruments that lack "uniformly high image quality over *broad regions* of the eye" due to loss of focus at points removed from the "center of the image." *Id.* ¶¶ 3 (Board's emphasis); *see id.* ¶¶ 13, 14 (similar disclosures). Stated somewhat differently, Koschmieder addresses a problem of peripheral blurriness that occurs in ophthalmic applications when imaging "*the entire extent* of the

⁵ The one exception is a reference to Blumenkranz's disclosure of an "elongated focusing column," however, no discussion of that asserted difference is necessary to this Decision. Reply 22.

human eye" (*id.* ¶ 8 (Board's emphasis)), by employing "one or more diffractive optical elements" that adapt the image plane "to the spherical contour of the eye" (*id.* at code (57)).

Koschmieder's wide-field imaging technique is achieved by employing diffractive optical elements, as shown below in Figure 1.



Figur 1

Ex. 1007, Fig. 1. Figure 1 is a schematic view of an illumination beam path with a diffractive optical element according to the wide-field imaging technique of Koschmieder. *Id.* ¶ 20. Figure 1 illustrates "the beam path proceeding from the respective illumination pattern 1," where "the illumination beams travel to" diffractive optical element 3 "through optics 2 serving as a first imaging system." *Id.* ¶ 22. Significantly, for purposes of this Decision, the beam paths shown in Figure 1 terminate at "spherically curved image plane 5," which is "adapted to the curvature of the eye 7." Ex. *Id.* ¶¶ 23, 29.

Here, it may be useful to compare Koschmieder's beam paths in Figure 1, above, to the beam paths shown in Blumenkranz's Figure 7A, reproduced *supra* at 9. That comparison indicates that wide-field imaging

systems, such as Koschmieder's, incorporate diffractive optical elements that curve the focal plane of the optics to *simultaneously* illuminate laser beams across *the entire target field*, whereas point-by-point imaging systems, such as Blumenkranz's (and Frey's), employ flat-field optics having a flat focal plane, which scan in a *sequential*, laser-shot-by-laser-shot pattern *of points* across the x-y axis while holding constant the z plane.

B. Level of Ordinary Skill in the Art

The level of ordinary skill in the art at the time of the invention is a factual determination that provides a primary guarantee of objectivity in an obviousness analysis. *Al-Site Corp. v. VSI Int'l Inc.*, 174 F.3d 1308, 1324 (Fed. Cir. 1999) (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966); *Ryko Mfg. Co. v. Nu-Star, Inc.*, 950 F.2d 714, 718 (Fed. Cir. 1991)).

Based on the information presented, we find that the asserted prior art itself is sufficient to demonstrate the level of skill in the art at the time of the invention. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (the prior art itself can reflect the appropriate level of ordinary skill in the art). To the extent a more precise definition is required, we adopt Petitioner's definition because, on this record, it appears consistent with the disclosures of the asserted prior art and the written description of the invention provided in the '356 patent. Pet. 10 (Petitioner's asserted definition of the ordinarily skilled artisan). Neither party, however, advances information explaining how or why the result in this case would change based on the definition selected by the Board.

Petitioner relies on declarations provided by Georg Schuele, Ph.D., and Julie L. Bentley, Ph.D. Exs. 1004, 1046, 1048. Patent Owner relies on a

declaration provided by Al-Hafeez Dhalla, Ph.D. Ex. 2033.⁶ Based on their respective statements of qualifications and *curricula vitae*, we determine that all three witnesses—Dr. Schuele, Dr. Bentley, and Dr. Dhalla—are qualified to opine about the perspective of a person of ordinary skill in the art at the time of the invention. *See* Ex. 1004 ¶¶ 1–11, Ex. 1046 ¶¶ 3–9, Ex. 1048 ¶¶ 1–3, Ex. 2003 ¶¶ 5–16 (statements of qualifications); *see also* Exs. 1005, 1047, 2034 (*curricula vitae*).

C. Lesser Weight Assigned to Dr. Bentley's Opinions

Patent Owner asserts that Dr. Bentley "cannot provide reliable opinions regarding whether there would have been a reasonable expectation of success for Petitioner's combination" of prior art references. Sur-reply 8 (citing cases). We agree with Patent Owner that, based on the record presented, Dr. Bentley "has no experience designing laser-based systems for eye surgery" and, further, that a question arises as to whether Dr. Bentley "even understand[s] what photodisruption is" within the context of claim 1. *Id.* at 7–8 (and citations therein to Exs. 1004, 1046, 1047, and 2051).

Although Dr. Bentley possesses excellent credentials in optics generally, this witness reports no experience with surgical optics, much less optics for laser surgery of the eye. Ex. 1046 ¶¶ 3–9; *see generally* Ex. 1047 (*curriculum vitae*). Dr. Bentley currently advises students working on optics for "microscope objectives, digital and film camera lenses, zoom lenses, fisheye lens, riflescopes," and other devices—but none, on this record, is

⁶ The record also includes a declaration of Edward A. DeHoog, Ph.D. (Ex. 2001), which Patent Owner filed with the Preliminary Response but does not advance in the Response. *See generally* Resp.

demonstrated by Petitioner as applicable to laser surgery, much less a method of laser surgery whereby layers of photodisrupted bubbles are generated within eye tissue. Ex. 1047, 1; *see* Ex. 2051, 45:8–21 (Dr. Bentley's deposition transcript). Dr. Bentley's prior experience includes, for example, working on optics related to "broadband zoom lens for cancer screening, several high-resolution broadband infrared cameras," and "a multi-photon endoscope objective," but includes no work, on this record, that relates to optics for laser surgery of the eye. *Id*.

We recognize that Dr. Bentley is named on four patents and frequently lectures and publishes articles on optical imaging in general, but the list of patents and publications persuades us that Dr. Bentley possesses little, if any, experience with surgical optics. *Id.* ¶¶ 3, 5–9. We agree with Patent Owner, moreover, that during Dr. Bentley's deposition, it became clear that this witness "is not an expert in laser-based systems for photodisrupted surgery" and has no experience with, or specific knowledge about, optics that perform "photodisruption" of lens tissue. Sur-reply 8 (citing Ex. 2051, 61:17–62:17, 65:12–17, 66:18–68:21, 72:4–72:20, 73:10– 73:19, 75:11–76:13, 80:9–16, 81:13–83:25, 85:13–86:3, 89:25–92:7, 94:25– 95:23, 121:3–121:12 (deposition transcript)).

By contrast, Patent Owner's witness, Dr. Dhalla, has "many years of experience in developing optical imaging modalities in both industry and academia." Ex. 2033 ¶ 6; *see* Ex. 2034, 1–6 *(curriculum vitae)*. Dr. Dhalla possesses "particular expertise in optical imaging applied to ophthalmology and ophthalmic surgery," and has "designed systems for other medical applications as well as non-medical applications." Ex. 2033 ¶ 6; *see* Ex. 2034, 1–6. Dr. Dhalla's "doctoral dissertation focused on advanced

methods of imaging the anterior and posterior eye." Ex. 2033 ¶ 7. Dr. Dhalla has extensive experience "in the optical imaging space." *Id.* ¶ 11; *see id.* ¶¶ 5–9, 11–16; *see also* Ex. 2034, 1–6 (*curriculum vitae*). In particular, Dr. Dhalla has "extensive experience in the design of optical systems with curved image planes." Ex. 2033 ¶ 16; *see* Ex. 2034, 1–6.

Significantly, Dr. Dhalla is "[r]esponsible for the development of a machine vision solution for automated robotic cataract surgery." Ex. 2034, 2. Dr. Dhalla also is "[r]esponsible for all day-to-day operations and R&D" for a business "that aims to commercialize" imaging "systems, primarily for applications in pediatric and neonatal ophthalmology." *Id*. Perhaps most significantly, unlike Dr. Bentley, Dr. Dhalla has experience in "engineering design" and "prototype construction" specific to "medical optical imaging devices" that are used in "surgical applications." *Id*.

A comparison of the totality of information reflected in their *curricula vitae* casts some doubt on the relative reliability of Dr. Bentley's opinions as compared to Dr. Dhalla's. *Compare* Ex. 1047, *with* Ex. 2034. We accord somewhat less weight, therefore, to Dr. Bentley's opinions, as compared to Dr. Dhalla's, where their opinions conflict on issues pertaining to laser eye surgery or optics modules employed to photodisrupt lens tissue during surgery of the human eye.

D. Claim Construction

For petitions such as this one, filed after November 13, 2018, claims "shall be construed using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. 282(b)." *See* Changes to the Claim Construction Standard for Interpreting Claims in Trial

Proceedings Before the Patent Trial and Appeal Board, 83 Fed. Reg. 51,340, 51,340, 51,358 (Oct. 11, 2018) (amending 37 C.F.R. § 42.100(b) effective November 13, 2018) (now codified at 37 C.F.R. § 42.100(b) (2019)).

Under that standard, the "words of a claim 'are generally given their ordinary and customary meaning," which is "the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc) (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). We construe terms in controversy only to the extent necessary to resolve the controversy. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co. Matal*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (quoting *Vitvid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)).

Petitioner proposes two alternative meanings for the claim limitation that includes the phrase "track the natural curvature of the lens." Pet. 11–12. Patent Owner, by contrast, "does not believe that any claim terms" require express construction for purposes of deciding whether the challenged claims are unpatentable and, on that basis, submits that the terms should "be given their plain and ordinary meaning." Resp. 19. For reasons that follow, we determine that some discussion of the meaning of the claim limitation, which includes the phrase "track the natural curvature of the lens," is necessary to this Decision. Ex. 1001, 12:15–18 (entirety of the limitation).

Petitioner, in the Petition, advances a first construction under which the phrase "track the natural curvature of the lens" is satisfied when "the boundary of the overall pattern of photodisrupted bubbles matches the curvature of the eye lens." Pet. 11. Petitioner identifies no intrinsic support

for that construction, but relies on a single extrinsic source, namely, Patent Owner's initial infringement contentions in the co-pending district court litigation. *Id.* (citing Ex. 1013, 49–81). That "construction is the basis for Grounds 1 and 3 in [the] Petition." *Id.* at 12. We reject that construction because it is not tethered adequately to the words that appear in claim 1, which do not refer to "the boundary of the overall pattern of photodisrupted bubbles," much less specify that such a boundary must match "the curvature of the eye lens." *Id.* at 11; *see* Ex. 1001, 12:6–18 (claim 1).

Petitioner, in the Petition, advances a second, alternative construction under which "the 'curvature of the focal plane' must 'track the natural curvature of the lens." Pet. 12. Petitioner asserts that this second "construction is the basis for Grounds 2 and 4 in [the] Petition." *Id*. Petitioner's second proposed construction repeats, word-for-word, language that appears in claim 1. *Compare id*. ("curvature of the focal plane' must 'track the natural curvature of the lens'"), *with* Ex. 1001, 12:17–18 ("curvature of the focal plane" will "track the natural curvature of the lens"). That suggests to us that Petitioner, in advancing this alternative construction, agrees with Patent Owner that those words can, and should, "be given their plain and ordinary meaning." Resp. 19. We agree with the parties' suggestions that those words, as they appear in the full claim limitation at hand, are clear and unambiguous.

The challenged claims require multiple "layers of photodisrupted bubbles," which "form a regular array of cells in the target region" defining "cell boundaries," and wherein those "layers are created by scanning the pulsed laser with the optics module according to a *curvature* of the focal

plane of the optics module to track the natural *curvature* of the lens." Ex. 1001, 12:13–18 (Board's emphasis).

Where the same word, "curvature," appears in two phrases within claim 1, namely, "curvature of the focal plane" and "curvature of the lens," we determine that the phrases relate to one another and that the word should be assigned a single, cohesive meaning. *Id*. Read fairly, this limitation indicates that the layers of photodisrupted bubbles that form the cell boundaries are generated by scanning a pulsed laser according to a *single* curvature – a curvature that characterizes *both* the focal plane of the optics module *and* the natural bend of the lens. *Id*.

Accordingly, on this record, we determine that the "curvature of the focal plane" *itself* must "track the natural curvature of the lens." *Id*. Other evidence of record supports that determination. Most notably, the record of examination includes this unequivocal statement: "It was Applicant's inventive idea to design the laser surgical system such that the curvature of its focal plane tracks the curvature of the eye." Ex. 1002, 133.⁷

In addition, Petitioner directs us to a construction in the co-pending district court litigation, supported by citations to the intrinsic record, under which the layers of photodisrupted bubbles are generated by using a focal plane having a curvature that matches "the natural curvature of the lens." Ex. 2003, 11–14 (Petitioner's proposed construction in district court litigation, including citations to the intrinsic record). Petitioner advances a construction in the district court litigation under which the curvature of the

⁷ We refer to page numbers added by Petitioner.

focal plane *itself* tracks the curvature of the lens (*id*.), without explaining why we should adopt a different construction in this forum (Pet. 11–12).⁸

The "layers of photodisrupted bubbles" that form the "cell boundaries" in the claimed method "are created by scanning the pulsed laser with the optics module according to a curvature of the focal plane" that *itself* is adapted "to track the natural curvature of the lens." Ex. 1001, 12:15–18; *see* Pet. 12 (Petitioner's second proposed construction). Of the two alternative meanings proposed by Petitioner in the Petition (*see* Pet. 11–12), only this second alternative aligns with the actual words appearing in claim 1. Ex. 1001, 12:15–18.

For the above reasons, we apply here the same claim construction as we did in our Institution Decision. Significantly, in the Reply, Petitioner acknowledges, for the first time, that the claim construction assigned by the Board in the Institution Decision "is correct." Reply 2. Petitioner now admits that claim 1 requires that "the curvature of the focal plane *itself* must track the natural curvature of the lens." *Id*. (Petitioner's emphasis).

In the Reply, Petitioner expressly abandons the claim construction advanced in the Petition in connection with Grounds 1 and 3, under which "only the overall fragmentation pattern must track the natural lens curvature." Reply 4 n.1. Petitioner avers that this alternative is an "incorrect"

⁸ Petitioner proposes a district court construction that includes a further requirement that the claimed method creates "curved layers." Ex. 2003, 11–14; *but see* Ex. 1002, 265 (argument during examination that the invention is not directed to "any 'curved layers"). Claim 1 does not specify curved layers, but specifies a "curvature of the focal plane" that *itself* tracks "the natural curvature of the lens." Ex. 2003, 11–14. We agree with Patent Owner that claim 1 does not *expressly* specify "curved layers." Tr. 50:10–11.

construction that the Board properly "rejected." *Id.* at 2, 4 n.1. In so doing, Petitioner abandons Grounds 1 and 3, which are based on the abandoned claim construction, under which the layers, not necessarily the focal plane of the optics module, may track the natural curvature of the lens. *Id.*; *see* Pet. 13–32, 39–51 (Grounds 1 and 3). In other words, at this stage of the proceeding, there is agreement that claim 1 requires that *the focal plane of the optics module* (not necessarily the plurality of layers) must curve "to track the natural curvature of the lens." Ex. 1001, 12:15–18.

E. Analysis of the Patentability Challenges

Petitioner asserts four grounds of unpatentability. Pet. 3. We organize our discussion into two parts, addressing first the grounds that apply the correct construction of "track the natural curvature of the lens" (Grounds 2 and 4) and then the grounds that apply an admittedly incorrect construction of that phrase (Grounds 1 and 3). *See* Pet. 12 (asserting a construction gleaned from Patent Owner's infringement contentions in co-pending litigation, which "is the basis for Grounds 1 and 3," and, in the alternative, a construction gleaned from the words that actually appear in claim 1, which "is the basis for Grounds 2 and 4"); Reply 2, 4 n.1 (Petitioner, disavowing the claim construction that forms the basis for Grounds 1 and 3).

In a nutshell, for reasons that follow, we find that a person of ordinary skill in the art would not have been led to modify the surgical system of Frey or Blumenkranz to include an optics module in which "the curvature of the focal plane *itself* must 'track the natural curvature of the lens." *Supra* at 19 (claim construction analysis). In the alternative, we find that the ordinarily skilled artisan would not have possessed the technical acumen or know-how

to attain a modified system that would perform the specified laser surgical method "of fragmenting lens tissue of an eye" with a reasonable expectation of success. Ex. 1001, 12:6–7.

1. Grounds 2 and 4

Petitioner alleges that claims 1 and 2 are unpatentable as obvious over Frey and Koschmieder (Ground 2) or Blumenkranz, Frey, and Koschmieder (Ground 4). Pet. 3. As explained *supra* at 9–10, our analysis of Frey applies with equal force to Blumenkranz, therefore, in this section, we focus on Petitioner's proposed reasons to combine the teachings of Frey and Koschmieder in the manner claimed.

We begin by explaining why the preponderance of the evidence does *not* support Petitioner's view that Frey's point-by-point laser scanning system creates "layers of photodisrupted bubbles . . . by scanning the pulsed laser with the optics module *according to a curvature of the focal plane of the optics module* to track the natural curvature of the lens." Ex. 1001, 12:11–18 (claim 1) (Board's emphasis). We then assess the features of Koschmieder's wide-field imaging technique, which involves the use of diffractive optical elements that may curve the focal plane of an optics module. Finally, based on the totality of information presented by the parties, we resolve whether an ordinarily skilled artisan would have undertaken the task of modifying Frey's laser surgical system, in view of Koschmieder's technique, with a reasonable expectation of success in achieving the claimed "method of fragmenting lens tissue of an eye with a laser surgical system." Ex. 1001, 12:6–7.

a) Frey Employs Flat-Field Corrected Optics To Generate Flat and Curved Layers of Photodisrupted Bubbles

As Petitioner acknowledges, "Frey's laser system sequentially creates layers of photodisrupted bubbles (called 'z planes') at a given z-depth, before moving to the next depth on the z-axis." Pet. 22–23. The "layers" created in that manner "form a regular array of cells." Ex. 1001, 12:12–13; *see, e.g.*, Ex. 1006, Fig. 25, reproduced *supra* at 7, illustrating a regular array of cells. In this subpart, we explain why the "focal plane" of Frey's "optics module" is *not* curved and does *not* "track the natural curvature of the lens" as required by claim 1. Ex. 1001, 12:15–18.

As Petitioner also acknowledges, "In addition to shooting the laser in anterior z planes then moving posterior," Frey's laser system allows the surgeon "to essentially drill down anterior to posterior," that is, along the z axis, "and then move in x/y and drill down again." Pet. 23 (quoting Ex. 1006 ¶ 116; Petitioner's emphasis omitted). Petitioner's own description informs that Frey employs "flat field optics" having a flat focal plane that does *not* follow the natural curvature of the lens. Ex. 1006 ¶ 65 (Frey); *see* Pet. 27; Reply 4 (Petitioner's admissions that flat-field optics *avoid* a curved focal plane and *employ* a flat focal plane); *see also* Resp. 5–12 (Patent Owner's persuasive information on that point).

As the name implies, flat-field optics scan a laser pattern along a flat plane, namely, by holding the z position constant and scanning along the x-y axis. Resp. 6–7; Ex. 2033 ¶¶ 85–88; Ex. 2030, 72:11–73:10. An ordinarily skilled artisan would have understood that Frey's flat-field optics include "aberration correction," which typically corrects "for field curvature through the use of a field-flattening lens (meniscus lens) and careful placement of stops." Resp. 9; *see* Ex. 2033 ¶¶ 43, 95; Ex. 1014, 92–93; Ex. 1012, 1, 10–

13. That artisan also would have understood that the three "focusing options" mentioned in Frey are flat-field corrected over the desired field of view. Ex. 1006 ¶ 65; *see* Resp. 7–11 & n.1 (and evidence cited therein).

Petitioner's opposing view that Frey's three "focusing options" (Ex. 1006 ¶ 65) suggest the alternate or additional use of optics, in which the focal plane is curved, rests on opinions provided by Dr. Bentley, which, for reasons explained above, we find less reliable than the opposing opinions provided by Dr. Dhalla. *Compare* Reply 5 n.3, 5 n.4; Ex. 1048 ¶¶ 31–33, *with* Resp. 5–12; Ex. 2033 ¶¶ 42–47, 49–51, 84–96, *and* Sur-reply 5; Ex. 2033 ¶¶ 85–89, 132–135. In any event, for reasons explained elsewhere in this Decision, Petitioner's position that Frey's disclosure of "conventional focusing options" *itself* suggests "an optics module" that employs "a curved focal plane" is unpersuasive on this record. *See* Pet. 24–27 (Petitioner's arguments); *see infra* at 33–36 (Board's assessment of those arguments).

To the contrary, the intrinsic record supports a finding that Frey's laser system executes a point-by-point, laser-shot-by-laser-shot scan pattern by "using what is known as flat-field corrected optics," which "iteratively" scan "the laser along 'z planes" from top to bottom, ""mov[ing] in x/y' directions," from left to right, "then 'drill[ing] down' in the z-direction again, and so on" to create a grid-like pattern of cells characterized by flat layers of photodisrupted bubbles, as illustrated in Figure 25 (shaded green by Petitioner in the reproduction of Figure 25 set forth below). Resp. 6; *see* Ex. 1006 ¶¶ 18, 44, 116, Fig. 25 (Frey) *see also* Ex. 2033 ¶¶ 85–97 (Dr. Dhalla's persuasive declaration testimony).



Pet. 37. Frey's Figure 25 illustrates "outer surface 2501 and thus an outer shape of the lens. There is further provided a shot pattern 2502 that creates grid like cuts, the end of which cuts 2503 essentially follows the shape of the lens." Ex. 1006 ¶ 116. Figure 25 also illustrates "one shell cut 2504, which is integral with the grid like cuts." *Id.* The above version of Frey's Figure 25 includes Petitioner's color annotations, which shade green Frey's flat, grid-like layers of photodisrupted bubbles, shade magenta "shell cut 2504," and shade blue "outer surface 2501," which tracks "an outer shape of the lens." *Id.* Petitioner labels the anterior (top) and posterior (bottom) of the lens.

The single shell cut, identified as element 2504 in Frey's Figure 25, which Patent Owner shades magenta in the above annotated version, is emphasized by Petitioner throughout the Petition. *See* Pet. 3, 17–18, 28, 36–

37, 50, 53. That is the only cut in Frey's Figure 25 that tracks the natural curvature of the lens. *See* Ex. 1006, Fig. 25. We are not persuaded that Frey's laser system generates that single, curved cut using an optical module having a curved focal plane. *See* Pet. 16–18, 28–29, 36–38; *see also* Ex. 1006 ¶ 83 (Frey, discussing "mathematical modeling and actual observation data regarding . . . the shape of the lens").

As even Petitioner acknowledges, Frey generates "curved layers" by adjusting "the z focusing device" (Pet. 37), an adjustment consistent with the use of flat-field optics (Resp. 59; Ex. 2033 ¶¶ 185–187). As Petitioner also readily acknowledges, "To form subsequent layers, a 'z focusing device' is used to move to the next depth" in Frey's process. *Id.* at 24 (citing Ex. 1004 ¶ 91; Ex. 1006 ¶¶ 65, 116). On this record, we find that Frey employs the *same* optics module to produce shell cut 2504, and the *same* point-by-point laser scanning technique, that is used to create the flat cuts that form the grid-like pattern shaded green in Petitioner's annotated version of Figure 25.

To be clear, "Frey's focal plane is flat-field" and "Frey executes the shell cuts (and *any* cut that is not a horizontal plane) by moving the z-focusing device." Sur-reply 5 (citing Ex. 1006 ¶ 116; Resp. 5–7, 11, 33–35; Ex. 2033 ¶¶ 85–89, 132–135) (Board's emphasis); *see* Pet. 37 (admitting that Frey generates "curved layers" by adjusting "the z focusing device."). We expressly reject Petitioner's suggestion that a flat-field optics module, such as Frey's, necessarily employs a curved focal plane when generating curved layers. *See, e.g.*, Pet. 17–18, 22–24, 27–31; *see especially* Reply 4–9.

Frey's optics module operates "by holding the Z constant, scanning in X-Y, going to the next Z, scanning in X-Y," and so on. Tr. 52:1–16 (Patent Owner's counsel). Frey employs flat-field optics, corrected for aberrations

including lens curvature by adjusting the focus of the z coordinate at each predetermined depth, to generate *all* of its layers of photodisrupted bubbles, including shell cut 2504 in Figure 25. Petitioner does not establish that Frey employs optics having a curved focal plane to generate curved cuts in lens tissue. To the contrary, Frey's optics employ a *flat* focal plane that generates *both* the flat cuts *and* the curved shell cut illustrated in Figure 25. *See* Reply 4–7 (Petitioner, failing to persuasively show that Frey generates layers by any method other than holding the z-plane constant and scanning in the x-y direction, the hallmark of flat-field corrected optics).

It is worth repeating here: The shell cut denoted as element 2504 in Frey's Figure 25 does *not* suggest a method of forming "layers" that "are created by scanning the pulsed laser with the optics module according to a curvature of the focal plane of the optics module to track the natural curvature of the lens" as required by the challenged claims. Ex. 1001, 12:15– 18 (claim 1) (Board's emphasis). We find that *all* of the cuts in Figure 25, including curved shell cut 2504, are created by scanning "an x,y pattern in a *flat* z-plane by maintaining a constant z-position but varying the x,y positions." Resp. 6 (Patent Owner's emphasis); *see id.* at 11–12 & n.1 (and evidence cited therein); Ex. 2033 ¶¶ 85–88 (Dr. Dhalla's supporting opinion testimony); Ex. 1006 ¶ 116 (Frey's supporting disclosure).

It also is worth reiterating that even Petitioner agrees that flat-field optical systems "*avoid* a curved focal plane." Pet. 27 (Board's emphasis); *see* Reply 4 ("It is undisputed that 'flat field optics' have a flat focal plane."). Petitioner does not demonstrate that Frey, in fact, employs a curved focal plane to generate shell cut 2504, as illustrated in Figure 25, or any other curved scan pattern illustrated in Frey. *See* Pet. 24–27; Reply 1, 4–9

(directing us to examples of curved scanning patterns in Frey, but no persuasive evidence that Frey's optics have a curved focal plane).⁹

To summarize, even though Frey employs an optics module capable of generating curved layers (such as shell cut 2504 in Figure 25), that does not establish that those curved layers, *ipso facto*, are generated by Frey's method using "an optics module" having a curved "focal plane." Ex. 1001, 12:9, 12:17. To the contrary, Frey generates *all* of its layers of photodisrupted bubbles, whether flat or curved, using "flat field optics" that employ "a flat focal plane" by holding constant the z-plane as the laser scans in the x-y direction. Reply 4 ("flat field optics" have a flat focal plane").

For these reasons, we determine that Frey employs optics having "a flat focal plane" that holds constant the z-plane as the laser scans in the x-y direction. *Id.* (Petitioner's own observation that "flat field optics' have a flat focal plane"); *see* Ex. 1006 ¶¶ 65, 116 (Frey); Ex. 2033 ¶¶ 43–97 (Dr. Dhalla's well-supported declaration testimony on point).

⁹ The parties dispute whether Petitioner, in the Reply, improperly relies for the first time on Frey's Figures 16, 17, and 37 to make out new arguments about Grounds 2 and 4. *See* Reply 1, 7–9 (reply arguments at issue); *see also* Sur-reply 1, 7–9; Paper 41 (Patent Owner's positions); Paper 42 (Petitioner's positions); Tr. 67:9–68:3, 78:16–82:22 (counsel's opposing positions at the final hearing). We need not resolve that dispute because Petitioner, in the Reply, ineffectively raises those figures only to show that Frey's optics are capable of generating curved cuts. *See* Sur-reply 7–9 (section titled "Frey's Laser Cutting Patterns Include Curved Layers"); *see especially id.* at 8 (arguing only that Frey's optics are capable of creating "curved cuts that follow the curvature of the lens"). To the extent that Petitioner argues that these allegedly new figures from Frey demonstrate that Frey's optics employ a curved focal plane (*see* Sur-reply 1, 7–9), we find that argument unpersuasive for reasons provided in connection with Frey's Figure 25.

b) Koschmieder's Diffractive Optical Element

Koschmieder discloses a "diffractive optical element," which, in Petitioner's view, would have suggested a technique by which a person of ordinary skill in the art at the time of the invention would, and could, have advantageously adapted Frey's (or Blumenkranz's) focal plane to track the natural curvature of a lens. Pet. 34–35, 51.¹⁰

Koschmieder relates to ophthalmic instruments for diagnosis and treatment of the eye, including "laser scanners." Ex. 1007, code (57) (Abstract), ¶ 34. Koschmieder discusses instruments that illuminate "curved areas of the eye." *Id.* ¶ 17. We agree with Patent Owner that Koschmieder, read in its entirety, is concerned with "wide-field imaging systems," wherein "the entire field of interest is simultaneously illuminated or irradiated," and is not concerned with systems that "scan individual spots sequentially (point-by-point) over the field of interest." Resp. 15; Ex. 2003 ¶ 109; *see generally* Ex. 1007. A question arises, however, as to whether an ordinarily skilled artisan, reading the references together in their entirety, would have understood that Koschmieder's technique would, and could, have been applied to improve Frey's point-by-point scanning system.

Koschmieder describes "[a]n arrangement for improving the image field in ophthalmic instruments" by providing "an illumination beam path"

¹⁰ Petitioner, in the Petition, relies solely on embodiments in Koschmieder that involve the use of diffractive optical elements. *See generally* Pet. Petitioner, for the first time in the Reply, advances Koschmieder's disclosure of embodiments that involve "non-diffractive" optical elements. *See* Reply 14–15. To the extent that Petitioner raises those embodiments to establish the unpatentability of any challenged claim, we reject that attempt as untimely because it should have been included in the Petition. *See* Paper 41 (Patent Owner's contentions); Sur-reply 20.

as well as "one or more diffractive optical elements" arranged "in the illumination beam path for deliberate shaping of the image plane" in the eye that is "irradiated." *Id.* code (57), ¶ 36; Pet. 34. We agree with Patent Owner that Figure 1 is "the only figure illustrating Koschmieder's" diffractive optical elements and, plainly, "uses wide-field illumination," as shown in Figure 1, reproduced *supra* at 11.

In particular, Figure 1 "shows traced rays that illuminate the entire surface **5**, and Koschmieder describes element **1** as an 'illumination *pattern*,' not a spot or point." Resp. 16 (citing Ex. 2033 ¶¶ 110–112; Ex. 1007 ¶ 22) (Patent Owner's emphasis). An ordinarily skilled artisan "would have understood that the entire surface of" the targeted eye tissue "must ideally be *simultaneously* illuminated (as it is in Figure 1) to produce the desired effect." *Id.* (citing Ex. 2033 ¶ 56, 110–112; Ex. 2030 140:18–142:7) (Patent Owner's emphasis). A key dispute, on this record, is whether an ordinarily skilled artisan would have recognized a diffractive optical element, which is designed for wide-field imaging, as suitable for use "with a point-by-point scanning system" as disclosed in Frey (or Blumenkranz). *Id.*

Figure 2 of Koschmieder illustrates eye 7 and "an image plane 5 that is adapted to the rear surface of the eye lens." *Id.* ¶ 22, Fig. 2; Pet. 34 (reproducing Fig. 2). We reproduce that figure below.



Id., Fig. 2. Figure 2 illustrates curved image plane 5 that is "adapted to the eye" and, in particular, "to the rear surface of the eye lens." *Id.* ¶¶ 21–22. Figure 2 shows that Koschmieder's diffractive optical element produces curved image plane 5 that *itself* tracks the posterior curvature of the lens of the eye. *Id.* ¶¶ 22, 27, 34. Specifically, "[t]he shape of the illumination beams is changed by" diffractive optical element 3 (illustrated in Figure 1, reproduced *supra* at 11) "in such a way that an image plane 5 adapted to the curvature of the respective element to be irradiated results in the eye 7 to be irradiated." *Id.* ¶ 22. We take note, however, that Koschmieder does not describe "the focal plane of" any "optics module" or suggest the applicability of its diffractive optical element in "a laser surgical system." Ex. 1001, 12:7, 12:16–17 (claim 1).

A central point of contention, which we turn to next, is whether an ordinarily skilled artisan would have had a reason to modify Frey's point-by-point laser scanner to include a diffractive optical element as suggested by Koschmieder—and would have undertaken that modification with a reasonable expectation of success in arriving at "[a] method for fragmenting lens tissue of an eye" in a manner that meets the "curvature" limitation of claim 1. *Id.* at 12:6, 12:16 (claim 1); *see id.* at 12:19–22 (claim 2, inheriting that limitation through dependence on claim 1); *compare* Pet. 35–39, 52–55, *and* Reply 10–29, *with* Resp. 22–58, *and* Sur-reply 4–32.

c) Reasons to Combine the References

The '356 patent describes and claims a method for fragmenting lens tissue with a laser surgical system, whereby "layers" of photodisrupted eye tissue are created by scanning a "pulsed laser with [an] optics module

according to a curvature of the focal plane of the optics module to track the natural curvature of the lens." Ex. 1001, 1:18–41 (written description), 12:6–22 (challenged claims); Resp 1.

As explained in our discussion of claim construction, this means that the optics module must utilize a curved focal plane that tracks the natural curvature of the lens. *See supra* at 15–20. In the Reply, Petitioner agrees that this claim construction, assigned by the Board in the Institution Decision, "is correct" and that "the curvature of the focal plane *itself* must track the natural curvature of the lens." Reply 2 (Petitioner's emphasis). Petitioner disavows an alternative construction, presented in the context of Grounds 1 and 3, under which "only the overall fragmentation pattern must track the natural lens curvature." *Id.* 4 n.1.

Frey discloses a point-by-point laser scanning method carried out by a surgical system that employs optics having a flat focal plane to sequentially create—laser-shot-by-laser shot—points of photodisrupted bubbles in the eye tissue, which form layers that may be flat or curved. *See* Ex. 1006 ¶¶ 18, 23, 116, Fig. 25. Koschmieder discusses advantages associated with diffractive optical elements that generate a curved focal plane in ophthalmic instruments, including laser scanners, to illuminate wide-field imaging planes across "extensive areas" of eye tissue, but does not suggest how those wide-field optics would have been adapted to accomplish a point-by-point laser scan pattern such as Frey's. *See* Ex. 1007 ¶¶ 3, 22–23, 34, Figs. 1, 2.

In our Institution Decision, we remarked that "[a] close question" arises as to whether an ordinarily skilled artisan "would have been led to modify the flat-field focusing optics of Frey" to incorporate Koschmieder's "curved focal plane." Dec. 15. The trial record is replete with conflicting

opinion testimony on that dispositive issue. *Compare* Ex. 1004 ¶¶ 112–118, 170–176 (Dr. Schuele's testimony supporting Petition), Ex. 1048 ¶¶ 51–65 (Dr. Schuele's testimony supporting Reply), *and* Ex. 1046 ¶¶ (Dr. Bentley's testimony supporting Reply), *with* Ex. 2033 ¶¶ 120–195 (Dr. Dalla's testimony supporting Response). Taking account of the extrinsic opinion testimony through the lens of the intrinsic disclosures of Frey, Blumenkranz, and Koschmieder, we tease out whether the preponderance of the evidence supports that an ordinarily skilled artisan would have been led to modify, with a reasonable expectation of success, Frey's flat-field optics to include a curved focal plane generated by a diffractive optical element.

In the analysis that follows, we address the reasons, identified in the Petition, that allegedly would have prompted the proposed modification of Frey in view of Koschmieder. *See* Pet. 24–27, 35–39. We organize our analysis into four subparts, addressing, in turn, whether:

(i) Frey itself suggests "an optics module" that employs "a curved focal plane" based on its disclosure of "conventional focusing optics" (*id*. at 24–27);

(ii) "Koschmieder itself" supplies the reason to combine because an ordinarily skilled artisan would have understood from Koschmieder's disclosure that a diffractive optical element "would improve the laser focus" to the lens in "edge areas" that "become blurred" when generating "the grid-like shot pattern of Frey" (*id.* at 35–36);

(iii) an ordinarily skilled artisan would have recognized that incorporating Koschmieder's wide-field imaging technique into Frey's sequential, point-by-point optics would generate Frey's "shell cuts more quickly and efficiently" (*id.* at 37–38); and

(iv) an ordinarily skilled artisan would undertake the proposed modification of Frey's flat-field corrected "optics module" to include a "diffractive optical element," which generates a curved focal plane, with a reasonable expectation of success (*id.* at 38–39).

In a fifth subpart (v), we set forth our conclusions on Petitioner's proposed reasons to combine the asserted prior art references.

i. Frey's Disclosure of "Conventional Focusing Optics" Does Not <u>Suggest That Frey's Laser System Uses a "Curved Focal Plane"</u>

Petitioner argues that Frey's reference to "conventional focusing optics" (Ex. 1006 ¶ 65) itself suggests an optics module having a curved focal plane (Reply 4–7). We disagree. Patent Owner persuasively shows that Frey's "laser traces an x,y pattern in a *flat* z-plane by maintaining a constant z-position" to minimize "the number of z-adjustments." Resp. 6–7. If Frey employed "a curved focal plane, each horizontal plane would require adjusting the laser focus in all three directions (x, y, and z)," a process nowhere described in Frey. *Id.* at 7; *see generally* Ex. 1006. We find persuasive Patent Owner's well-supported arguments that Frey's reference to "conventional focusing optics" does *not*, on this record, suggest optics having a curved focal plane. Resp. 7–8 (and citations to evidence therein).

On the one hand, Petitioner acknowledges that systems which employ "flat field optics," such as Frey's, by definition "avoid a curved focal plane." Pet. 27. On the other hand, Petitioner submits that Frey's reference to "conventional focusing optics" suggests a preference for "a curved focal plane." *Id.* As an initial matter, we observe, Petitioner does not address adequately that internal inconsistency in its arguments. *Id.* at 24–27.

We also observe that Petitioner's arguments about Frey's "conventional focusing optics" rest largely on extrinsic opinions provided by Dr. Bentley, whose opinions, as explained *supra* at 13–15, are somewhat unreliable. Reply 4–7 (and citations to evidence therein). In any event, Petitioner's arguments, and Dr. Bentley's supporting testimony, do not disturb the unambiguous intrinsic disclosures in Frey, which plainly describe an optical system having a flat focal plane. *Compare id., with* Ex. 1006 ¶¶ 65, 116.

On that point, we agree with Patent Owner that Frey's reference to "'conventional' focusing optics" relates to optical elements that correct for field curvature (and other primary aberrations) over the relatively narrow field of view at issue in Frey. Resp. 8. Frey's disclosure of "conventional focusing optics" is not a reference to an optics module having a curved focal plane, but is fully consistent with Frey's description of flat-field corrected optics. Ex. 1006 ¶ 65. That is confirmed by the sentence that immediately precedes Frey's reference to "conventional focusing optics," which discusses components that include "an xy scanner; a z focusing device; and, focusing optics." *Id.* Frey's mention of those components together strongly suggests a method that employs optics having a flat focal plane to scan in the x-y direction at constant z-depths. *Id.* In other words, the surrounding intrinsic disclosures of Frey confirm Patent Owner's view that Frey's "conventional focusing optics" do *not* suggest optics having a curved focal plane. *Id.*

Alternatively, to the extent there exists some ambiguity about whether the intrinsic disclosures of Frey suggest optics having a curved focal plane, that ambiguity tips the scales in favor of Patent Owner because Petitioner

bears the burden of establishing that Frey, in fact, suggests optics having a curved focal plane.

In that regard, without sufficient reasoning, Petitioner argues that Frey's reference to "conventional focusing optics" indicates that Frey's system includes optics having a curved focal plane, as shown in the following textbook illustration:



Pet. 25; Ex. 1014, Fig. 3.5. The above textbook illustration shows an image of an off-axis object point, indicating that, even if some primary aberrations are eliminated, the image surface is parabolic in shape "*without correction* for field curvature." Ex. 1014, 40 (Board's emphasis).

That textbook illustration does not alter Frey's disclosure, which is concerned with flat-field optics in which the *correction* of aberrations, including field curvature, would have been "[t]he 'conventional' practice." Resp. 10; *see id.* at 7–12 (and citations therein to persuasive evidence); *see also* Ex. 2033 ¶¶ 37–48, 160–167 (Dr. Dhalla's well-supported opinions (cited Resp. 47)). Petitioner's arguments overlook the actual method by which Frey's surgical system operates, namely, by drilling down to a given z-plane and applying "point-by-point" laser pulses in the x-y direction to photodisrupt "a collection of individual points" that "comprises a shot pattern." Resp. 5; *see id.* at 7 (citing Ex. 1006 ¶ 65; Ex. 2033 ¶¶ 49–51, 91).

We credit Dr. Dhalla's testimony that an ordinarily skilled artisan "would not consider a curved focal plane as a standard" lens design because "conventional imaging systems are not designed to be used with a curved field." Ex. 2033 ¶ 43 (Dr. Dhalla's testimony); *see* Resp. 47 (citing that testimony). That is "why field curvature is characterized in optical design textbooks as an aberration—a deviation from the desired and ideal performance." Ex. 2033 ¶ 43; Resp. 47. "The standard practice for focusing optical systems is to correct field curvature" by "using a field flattening lens. Having a curved focal plane is not generally desirable nor is it a standard practice." Ex. 2033 ¶ 43; Resp. 47; *see* Ex. 2033 ¶¶ 46, 47. 160–167 (Dr. Dhalla's well-supported opinions on that point); *see also* Resp. 47 (citing those opinions).

Accordingly, we agree with Patent Owner that Frey's reference to "conventional focusing optics, and/or flat field optics and/or telecentric optics" (Ex. 1006 ¶ 65) indicates that, after correction for field curvature, Frey describes a flat-field optical system that employs a flat focal plane. Resp. 7–11 & n.1, 47 (and evidence cited therein). Frey's optics are corrected for field curvature by refocusing the laser, as necessary, each time the laser "drill[s] down anterior to posterior" along the z-plane. Ex. 1006 ¶ 116; *see id.* ¶¶ 18, 44, 65, 70, Fig. 25 (confirming disclosures). That finding comports with Petitioner's own observations that (1) "'flat field optics' have a flat focal plane" (Reply 4); and (2) Frey's optics create "curved layers" by "adjust[ing] the z focusing device" (Pet. 37).

ii. Koschmieder Itself Does Not Supply a Reason to Use a Diffractive Optical Element with Frey's Optical Module to Improve Laser Focus

Petitioner asserts that "Koschmieder itself" provides "[t]he motivation to combine" the references. Pet. 35 (quoting Ex. 1007 ¶ 13). Koschmieder, in that regard, refers to "outer areas and edge areas" of "*straight*" image planes that "become blurred and lose intensity to an appreciable extent." *Id*. (Petitioner's emphasis). In this section, we explain why we agree with Patent Owner that an ordinarily skilled artisan "would not have been motivated to incorporate Koschmieder's teachings into Frey" because Frey's system, which employs flat-field corrected optics, does not suffer "from the problem Koschmieder is attempting to fix." Resp. 23.

Koschmieder "purports to address a blurriness problem that arises when imaging at the edges of a wide field of view, away from the visual axis." Resp. 14 (citing Ex. 1007 ¶¶ 13–14, 23; Ex. 2033 ¶ 102). As Patent Owner points out, "Koschmieder's blurriness is the result of a mismatch between the curvature of the image plane and the surface to be imaged." *Id.* (citing Ex. 1007, code (57) (Abstract), ¶¶ 23, 32; Ex. 2030, 133:18–124:22; Ex. 2033 ¶¶ 103–105). In other words, when imaging the *curved* surface of the eye with optics having a *curved* focal plane, which does not match that surface curvature, "there is blurriness at the outer edges where the mismatch is most apparent." *Id.* at 15; Ex. 1007 ¶ 13; Ex. 2030, 78:14–81:1, 88:21– 89:7; Ex. 2033 ¶¶ 103–104).

Frey's optics module, by contrast, employs a *flat* focal plane that corrects for curvature by refocusing at predetermined z-depths. Frey does not contemplate inclusion of optics having a *curved* focal plane. *See supra* at 33–36 (explaining our finding that Frey employs flat-field corrected optics having a flat focal plane); Resp. 28–30 (Patent Owner's well-supported

arguments that curving Frey's focal plane would cause "more mismatch and more blurriness"). We agree with Patent Owner that Frey's flat-field corrected optics, therefore, would not suffer from the blurriness problem, identified by Koschmieder, that is caused by "a mismatch between" a *curved* focal plane and a *curved* "surface to be imaged." Resp. 14.

The problem of mismatch simply "is not present in flat-field corrected systems that are imaging a flat surface because there is no mismatch. As a result, Frey and Blumenkranz do not have the blurriness problem Koschmieder describes." Resp. 15 (citing Ex. 2030, 88:21–89:7; Ex. 2033 ¶ 104). Furthermore, the proposed modification of Frey's system would have been expected to "cause blurring or defocusing" to occur "when used with a pulsed laser source" system, such as Frey's, that employs a laser-shot-by-laser-shot scan pattern to generate, point-by-point, layers of photodisrupted tissue in the eye. Ex. 2033 ¶ 122. Accordingly, on this record, we find that an ordinarily skilled artisan would not "have been motivated to modify Frey with Koschmieder's solution to address a problem of laser focus that is non-existent in Frey." *Id*.

In reaching that determination, we are not persuaded that the proposed modification would "improve the laser focus (and resulting delivery of laser power) to the lens when creating the grid-like shot pattern of Frey" or "allow the laser system to create these curved layers without having to adjust the z focusing device." Pet. 36–37. We agree with Patent Owner, "At bottom, the Petition identifies no support in the prior art or in" persuasive "expert opinion for" Petitioner's argument that an ordinarily skilled artisan "would have considered Koschmieder's teaching to be pertinent to any problem suffered by Frey or Blumenkranz." Resp. 30–31 n.6 (citing Pet. 36, 52;

Ex. 1004 ¶¶ 114, 171). Koschmieder describes structures that "become blurred and lose intensity" at "the outer areas and edge areas" of the field, when using optical elements that image "over extensive areas proceeding from the optical axis to the edge areas of the eye." Ex. 1007 ¶¶ 13, 23.

Here again, we are not persuaded that those problems are present in the systems of Frey or Blumenkranz, which "use flat-field corrected optics" to generate "flat plane shot patterns." Resp. 15 (and evidence cited therein). In "wide-field imaging systems," such as Koschmieder's, "the entire filed of interest is *simultaneously* illuminated or irradiated," which is not the case in laser scanning systems, such as Frey's or Blumenkranz's, which "scan individual spots *sequentially (point-by-point)* over the field of interest." *Id*. (citing Ex. 2033 ¶ 109) (Board's emphasis).

To be clear, Koschmieder's Figure 1, reproduced *supra* at 11, "teaches a solution only applicable for wide-field systems." Ex. 2033 ¶ 110. We reproduce below Patent Owner's annotated version of Koschmieder's Figure 1, which drives home that point.



Ex. 2033 ¶ 112. The above illustration is Patent Owner's annotated version of Koschmieder's Figure 1, in which "illumination pattern 1" projects a beam path (shaded green by Patent Owner) "projecting onto the curved surface 5," demonstrating a wide-field imaging technique in which the illustrated rays "remain distributed across the field at 5." Ex. 2033 ¶¶ 111–112; *see* Ex. 1007 ¶ 22 (Koschmieder).

As shown in Figure 1, illumination pattern 1 "exists simultaneously across the field," consistent with "a wide field system." Ex. 2033 ¶ 111. The background references discussed in Koschmieder make plain that Koschmieder's subject matter is concerned with "widefield, rather than point-by-point, methods of illumination or irradiation." *Id.* ¶ 113. An ordinarily skilled artisan would not have recognized that Frey's (or Blumenkranz's) point-by-point laser scanning optics could be improved by adding a diffractive optical element that directs a beam across a wide field of the eye tissue. Pet. 38–39 (bridging paragraph, arguing "that the diffractive optical element of Koschmieder is well suited for the optical system of Frey" but nowhere addressing that Koschmieder is concerned with wide-field imaging applications as opposed to point-by-point laser scanning applications); Reply 16–23 (ignoring the incongruity of importing optical elements from Koschmieder's wide-field imaging technique into Frey's sequential, point-by-point laser surgical technique).

In sum, Koschmieder pertains to an arrangement whereby "a uniformly high image quality" is obtained "over extensive areas" of eye tissue "proceeding from the topical axis to the edge areas of the eye." Ex. 2033 ¶ 123 (quoting Ex. 1007 ¶ 23). Specifically, "Koschmieder's teachings apply to wide-field illumination systems." *Id.* ¶ 138. Koschmieder relates to "*curved areas of the eye*" that are "illuminated over a large area" and, in particular, "the problem of blurry edges" that arises "*when illuminating a curved surface of the eye*." *Id.* ¶ 103 (quoting Ex. 1007 ¶¶ 13, 17, 32; citing Ex. 2030, 133:18–134:22) (Dr. Dhalla's emphasis).

That stands in contrast "to 'point-by-point' laser scanning systems," wherein "small regions of" eye tissue "are scanned sequentially, point by

point, usually through the use of scanning mirrors, such as galvanometers, that translate a focused beam of light across the sample" of tissue. *Id.* ¶ 109. We detect the taint of impermissible hindsight reconstruction in Petitioner's view that an ordinarily skilled artisan would have been prompted to import Koschmieder's diffractive optical element, which improves "widefield imaging systems," into Frey's system, which does not "simultaneously illuminate or irradiate the entire field of interest." *Id.*

We acknowledge that Koschmieder refers to "laser scanners" as instruments that may benefit from the "improved image field" produced by Koschmieder's diffractive optical element. Ex. 1007, code (57) (Abstract), ¶ 34. We are not persuaded, however, that an ordinarily skilled artisan would have recognized that diffractive optical elements, which facilitate Koschmieder's wide-field imaging technique, would have improved Frey's point-by-point method of laser scanning along flat z-planes. Where "the surface to be imaged is flat" in Frey, "*any* curvature" of the focal plane would have been recognized as "a mismatch that creates blurriness." Resp. 29 (citing Ex. 2030, 88:21–89:7) (Patent Owner's emphasis). The preponderance of the evidence supports Patent Owner's view that the proposed modification, in fact, would cause a blurriness problem in Frey's or Blumenkranz's system.

iii. Koschmieder's Wide-Field Imaging Technique Would Not Improve <u>The Speed or Efficiency of Frey's Sequential, Point-by-Point Optics</u>

Petitioner also argues that the proposed modification of Frey's or Blumenkranz's system, in view of Koschmieder, would have been understood to advantageously increase surgical speed. Pet. 37. Patent Owner counters that an application of Koschmieder's teachings would have made

Frey's scanning patterns slower and more complicated. Resp. 32–36. We find credible and persuasive Dr. Dhalla's well-supported opinion that the proposed modification would have been understood to disadvantageously slow down and complicate Frey's method of point-by-point laser scanning. Ex. 2033 ¶¶ 130–137.

Petitioner asserts that Koschmieder's teachings would have suggested a method that allows Frey's laser system to create "curved layers without having to adjust the z focusing device." Pet. 37; see Ex. 1004 ¶¶ 114–116 (Dr. Schuele's opinions). As explained *supra* at 33–36, Frey generates cuts, whether flat or curved, by holding the z plane constant, scanning a horizonal plane across the x-y direction, drilling down to a second z plane, scanning across a horizontal plane again in the x-y direction, and so on. "If one modified Frey to have a curved focal plane, each horizontal plane would require adjusting the laser focus in all three directions (x, y, and z)." Resp. 7 (citing Ex. 1006 ¶ 116). This indicates that the proposed modification would entail "a redesign" of Frey's system "that changes the principles under which [the reference] was designed to operate," a circumstance that may constitute "evidence of non-obviousness." Id. at 50 (citing TCT Mobile, Inc. v. Fundamental Innovation Sys. Int'l LLC, IPR2021-00597, Paper 8 (PTAB Aug. 25, 2021)). We agree with Patent Owner that the proposed modification to implement "curved field optics would have required a change to Frey's principle of operation." Id. (and evidence cited therein); Ex. 2033 ¶ 173.

Furthermore, the preponderance of the evidence supports Patent Owner's position that Frey's surgical method incorporates flat, horizontal cuts to take "advantage of the fast speed of the x,y galvanometers to

minimize movement of the slow z-focusing device," which "is made possible because horizontal cuts" (shaded yellow in Patent Owner's annotated version of Frey's Figure 25, reproduced below) "occur along a single z-depth." Resp. 51 (citing Ex. 2033 ¶ 174; Pet. 38). This is true even when generating curved layers, such as shell cut 2504 in Figure 25, where Frey's optical system is shown, on this record, to employ "flat field optics," which undisputedly incorporate "a flat focal plane." Reply 4. We reproduce below Patent Owner's highlighted version of Frey's Figure 25.



Resp. 36, 51. The above version of Frey's Figure 25 shades yellow the horizontal shell cuts, shades magenta a posterior shell cut, labeled element 2504, and shades blue an anterior shell cut, labeled 2503. Shell cuts 2504 and 2503 are curved.

As Patent Owner observes, "Frey creates the horizontal cuts (yellow) in Figure 25 by scanning the laser beam in x, y along different 'z-planes' and then 'drill[ing] down' in the z-direction in a stepwise manner." *Id.* at 51. That method "takes advantage of the fast speed of the x,y galvanometers to minimize movement of the slow z-focusing device, and is made possible because horizontal cuts (yellow) occur along a single z-depth." *Id.* (citing Ex. 2033 ¶ 174; Pet. 38).

Patent Owner argues that Frey demonstrates a "systemic preference for horizontal cuts," as shown in Figure 23, reproduced below.



Resp. 52. The above illustration is Patent Owner's annotated version of Frey's Figure 23, which is a cross-section drawing of a lens that shows the placement of volumetric removal laser shot patterns. Ex. 1006 ¶ 43.

According to Patent Owner, Figure 23 illustrates Frey's preference for flat, horizontal cuts (shaded yellow by Patent Owner) that terminate along the curve of the adjacent lens (shaded blue by Patent Owner) over curved cuts that would follow the curvature of the lens. Resp. 51.

We find persuasive Patent Owner's information that "Frey's flat-field corrected optics are the fastest and most efficient way to make flat, horizontal cuts." *Id.* Petitioner's own witness, Dr. Schuele, essentially agreed with that proposition during cross-examination. Ex. 2030, 74:9–75:24, 1987:22–199:21 (cited at Resp. 51).

We further agree with Patent Owner that Frey suggests a preference for horizontal cuts, over curved cuts, because "horizontal cuts are faster and more efficient with the system's flat-field corrected optics." Resp. 52 (citing Ex. 2033 ¶ 175). We are persuaded, moreover, that "creating horizontal cuts with a curved focal plane would have required the system to be reprogrammed to adjust the z-coordinate with each new point (or shot)." *Id.*; Ex. 2033 ¶ 177. A preponderance of the evidence supports Patent Owner's view that, because each laser shot would require an adjustment of all three coordinates (x, y, and z), the overall treatment time, when creating horizontal cuts, "would be slower." Resp. 52; Pet. 38; Ex. 2030, 202:05–17.

On this record, "Petitioner proposes to transform Frey from a system for making fast flat cuts to a system that makes slow flat cuts." Resp. 53. "Rather than undertake the complex redesign required to implement the curved focal plane of Koschmieder for no apparent benefit," we agree with Patent Owner that the ordinarily skilled artisan instead "would have left Frey's principle of operation undisturbed." *Id.*; Ex. 2033 ¶ 177.

vi. Petitioner Does Not Establish that An Ordinarily Skilled Artisan Would Have Undertaken The Proposed Modification of Frey with a Reasonable Expectation of Success

Petitioner's own witness, Dr. Schuele, indicated during crossexamination that "he did not know whether Koschmieder's advantage would be present in his proposed modified system." Resp. 31 n.6 (citing Ex. 2030, 164:7–18) (Dr. Schuele's testimony that "definitely" an ordinarily skilled artisan "would be compelled" to combine the references, but whether that "design exercise at the end turns out positive or negative, I don't know."). Indeed, a significant question arises as to whether an ordinarily skilled artisan would have understood that Koschmieder's teachings, which apply to wide-field imaging of extensive areas of the eye, are compatible with flatfield optics, such as Frey's, which generate a precise, sequential, point-bypoint pattern of photodisrupted bubbles in the eye.

Even if we accept that Koschmieder's wide-field imaging technique is compatible with the point-by-point laser scanning method of Frey or Blumenkranz, that is not enough to show that an ordinarily skilled artisan would have possessed the technical acumen or know-how necessary to modify those flat-field laser surgical systems in view of Koschmieder to achieve the method of the claimed invention with a reasonable expectation of success. As Patent Owner points out, Petitioner "offers no prior art diffractive optics capable of working in" the flat-field optical systems of Frey or Blumenkranz at the time of the invention. Sur-reply 2.

In any event, the proposed combination does not take account of the fact that Frey's and Blumenkranz's flat-field systems are specifically "designed to create photodisrupted regions point-by-point along flat planes." Resp. 1. Implementing Koschmieder's diffractive optical element solution in

a laser surgical system that employs flat-field optics would have required the ordinarily skilled artisan "to undertake a complex design exercise that even Petitioner's expert admits would not necessarily work or be advantageous." *Id.* at 1–2. We emphasize here that Petitioner's own witness, Dr. Schuele, "testified repeatedly that the [ordinarily skilled artisan] would have had to undergo an extensive 'design exercise' to determine whether a diffractive optical element could be used in" the systems of Frey or Blumenkranz "to curve the focal plane." Resp. 54–55 (citing Ex. 2030, 154:21–157:23, 158:02–159:24, 161:11–163:13, 174:23–177:5, 231:20–235:1).

Frey and Blumenkranz use "photodisruptive energies to break up the tissue in the eye" in a surgical process of precision that incorporates "laser scanning *by design*." Resp. 36 (Patent Owner's emphasis); Ex. 2033 ¶¶ 35–36, 138–139; Ex. 1006 ¶ 65; Ex. 1008 ¶ 76. Patent Owner directs us to persuasive evidence that an ordinarily skilled artisan would not have deemed it "possible to perform" Frey's "photodisruptive eye treatments without sequential, point-by-point laser scanning." Resp. 36–37 (citing Ex. 2033 ¶ 139; Ex. 2030, 60:18–65:22). "Wide-field illumination," using diffractive optical elements as disclosed in Koschmieder, would irradiate "the entire surface" of the eye tissue "all at once or simultaneously." *Id.* at 37 (citing Ex. 2033 ¶¶ 115, 140). Critically lacking on this record is any persuasive information explaining how an optics module, designed to irradiate "the entire surface" of the eye tissue "all at once or simultaneously," would have, or could have, been adapted for use in Frey's laser surgical system, which depends on precise irradiation across set points in the eye tissue. *Id.*

For example, Koschmieder's diffractive optical element images "extensive areas" from "the optical axis to the edge" of the eye. Ex. 1007

¶ 23. We recognize that an ordinarily skilled artisan "is not an automaton" and would have brought "ordinary creativity" to the task. *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 421 (2007). But it is not at all clear, on this record, that an ordinarily skilled artisan would have possessed the technical acuity to determine how a diffractive optical element could be incorporated into Frey's system to carry out "[a] method of fragmenting lens tissue of an eye" by "controlling the optics module . . . to form a regular array of cells in the target region by creating layers of photodisrupted bubbles to generate cell boundaries." Ex. 1001, 12:5, 12:11–13 (claim 1).

Petitioner's own witness, Dr. Schuele, testified that neither Frey nor Blumenkranz provides enough information for an ordinarily skilled artisan to even conduct such an exercise. Resp. 55 n.9 (citing Ex. 2030, 156:3– 159:24, 162:12–163:13, 232:6–233:17). Furthermore, Dr. Schuele was unable to provide a single example of a diffractive optic element, available at the time of the invention, that could be successfully imported into a flatfield laser surgical system. Sur-Reply 7 (citing Ex. 2030, 100:13–104:1, 110:12–118:9, 124:4–`0, 167:12–168:14; Ex. 2033 ¶ 155).

Patent Owner asserts that Petitioner "attempts to bridge" the evidentiary "gap" exposed during Dr. Schuele's deposition by introducing, with the Reply, Dr. Bentley's "12,000-word declaration," which is "devoted entirely to this issue and cit[es] 20 new exhibits." Sur-reply 7. Petitioner's pivot in the Reply toward Dr. Bentley's declaration and scores of new exhibits is prejudicial to Patent Owner, because Patent Owner was not permitted to submit with the Sur-reply any additional declaration testimony to counter that information. Although "the introduction of new evidence in the course of the trial is to be expected in *inter partes* review trial proceedings," *Genzyme Therapeutic Prods. LP v. Biomarin Pharm. Inc.*, 825 F.3d 1360, 1366 (Fed. Cir. 2016), the shifting of arguments is not, *Wasica Fin. GmbH v. Cont'l Auto. Sys., Inc.*, 853 F.3d 1272, 1286 (Fed. Cir. 2017).

Petitioner, in the Reply, violates our "rule against incorporation by reference by improperly citing extensive passages from" Dr. Bentley's "declaration with little explanation or discussion" of the subject matter "in the Reply brief itself." Sur-reply 8–9 (citing *3M Co. v. Evergreen Adhesives, Inc.*, 860 F. App'x 724, 728 (Fed. Cir. 2021). For example, "Petitioner block cites 31 paragraphs of Dr. Bentley's declaration for a single sentence contention" in the Reply. *Id.* at 9 n.5 (citing Reply 26 (line 1)).

Apart from the simple act of adding a diffractive optical element to the optics of Frey or Blumenkranz, Petitioner does not explain, in the Petition, how an ordinarily skilled artisan would have accomplished the method of the claimed invention using the modified apparatus of Frey or Blumenkranz. Pet. 38, 54; *see* Ex. 2033 ¶ 178. Against that backdrop, we credit Dr. Dhalla's testimony that an ordinarily skilled artisan would have "had to engage in significant reprogramming and reconfiguration" of the flat-field optical systems disclosed in Frey and Blumenkranz. Ex. 2033 ¶ 178. Dr. Dhalla's testimony persuades us that this extensive redesign exercise would have required more than a mere exercise of ordinary skill in the art. *Id.* ¶¶ 179–184. To the extent that Dr. Bentley's opinions on that issue conflict with those submitted by Dr. Dhalla, we credit Dr. Dhalla's testimony. *See supra* at 13–15 (our assessment of the relative qualifications of these two witnesses).

v. <u>Conclusions on the Proposed Reasons to Combine</u>

Regardless of whether an obviousness argument "is based on combining disclosures from multiple references, combining multiple embodiments from a single reference, or selecting from large lists of elements in a single reference," Petitioner must direct us to "a motivation to make the combination and a reasonable expectation that such a combination would be successful, otherwise a skilled artisan would not arrive at the claimed combination." *In re Stepan*, 868 F.3d 1342, 1346 n.1 (Fed. Cir. 2017). In the Institution Decision, we remarked, "A close question arises whether Petitioner shows sufficiently that an ordinarily skilled artisan would have been led to modify the flat-field focusing optics of Frey or Blumenkranz to incorporate the curved focal plane that Koschmieder discloses for use in laser scanners." Dec. 15. We further noted:

The reasons to combine the references introduce highly complex technical issues that implicate the veracity of conflicting opinion testimony provided by the parties' opposing declarants – testimony untested by cross-examination at this stage of the proceeding. Given that those issues may be a focus of the co-pending district court litigation, we select a prudent course and decline to provide detailed factual findings on those technical issues based on the preliminary record. Those issues are better suited for resolution on a full trial record, without any bias created by preliminary findings, and only as necessary to any final written decision.

Dec. 16. Based on the full trial record, we determine that Petitioner fails to establish adequately that an ordinarily skilled artisan would have been led to incorporate diffractive optical elements, which facilitate wide-field imaging "over the entire extent of the human eye" (Ex. 1007 ¶ 8), into a flat-field optical system, which sequentially delivers point-by-point laser shots to form a grid-like pattern of photodisrupted tissue (Ex. 1006 ¶ 18, Fig. 25).

We assess all of the evidence cited by the parties and consider the teachings of the prior art references as a whole in resolving Petitioner's challenges. On balance, we find that the preponderance of the evidence supports Patent Owner's view that an ordinarily skilled artisan would not have been prompted to modify Frey's (or Blumenkranz's) optics to incorporate a curved focal plane in view of Koschmieder's technique.

Petitioner directs us to no rational reason why an ordinarily skilled artisan would have undertaken such a modification of Frey's optics. The task of modifying Frey's flat optics plane to incorporate a diffractive optical element and, thereby, a curved focal plane, would not have been undertaken with a reasonable expectation of success. Ex. 2033 ¶¶ 35–184; *cf.* Pet. 35–39 (citing Ex. 1004 ¶¶ 112–118); Reply 16–28 (and evidence cited therein).

In particular, the preponderance of the evidence does not support that an ordinarily skilled artisan reasonably would have expected the modified apparatus to work by "controlling the optics module . . . to form a regular array of cells in the target region by creating layers of photodisrupted bubbles to generate cell boundaries" as required by the challenged claims. Ex. 1001, 12:11–14; *see generally* Pet. *and* Reply (neglecting to address adequately, if at all, why an ordinarily skilled artisan would have expected Koschmieder's wide-field imaging technique to have any utility in the systems of Frey or Blumenkranz, which generate, point-by-point, layers of photodisrupted bubbles in eye tissue in a surgical process of precision).

We acknowledge that "a given course of action often has simultaneous advantages and disadvantages, and this does not necessarily obviate motivation to combine." *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1165 (Fed. Cir. 2006). In this case, however, the preponderance of the

evidence supports Patent Owner's view that the modification proposed by Petitioner would "change the principle of operation of" Frey's (or Blumenkranz's) flat-field corrected laser system "without a reasonable expectation of success and without any purported advantage." Resp. 23; *see id.* at 22–58 (Patent Owner's arguments); Ex. 2033 ¶¶ 35–193 (Dr. Dhalla's supporting declaration testimony).

Accordingly, on this record, Petitioner does not establish that the method of claim 1 is unpatentable as obvious based on Ground 2 or 4. Because claim 2 depends on claim 1, adding only an additional feature related to the "size" of "the cells," our analysis applies with equal force to claim 2. Ex. 1001, 12:19–22.

2. Grounds 1 and 3

Grounds 1 and 3 are based on Petitioner's view, which we reject, that the claim phrase "track the natural curvature of the lens" (Ex. 1001, 12:17– 18) is met whenever "the boundary of the overall pattern of photodisrupted bubbles matches the curvature of the eye lens." (Pet. 11). *See* Pet. 27–31, 49–50 (Petitioner's information pertaining to that claim phrase in the context of Grounds 1 and 3). Petitioner asserts Grounds 1 and 3 only to the extent that we accept that incorrect construction, which we reject for reasons stated above in our claim construction analysis. *Id.* at 12. Accordingly, we determine that Petitioner does not demonstrate that any challenged claim is unpatentable in connection with these two remaining grounds. *See* Pet. 27– 31, 49–50 (Petitioner's arguments and evidence on point).

F. Secondary Considerations of Nonobviousness

Petitioner directs us to Patent Owner's contentions in related litigation regarding secondary considerations of non-obviousness. Pet. 55 (citing Ex. 1017, 35 (Patent Owner's Response to Interrogatory No. 15)). Specifically, Patent Owner there contends that a commercial product, marketed under the tradename LenSx, has garnered praise and enjoyed commercial success. Ex. 1017, 35–36. Patent Owner presents no arguments or evidence pertaining to secondary considerations. *See generally* Resp.

We need not consider secondary indicia of non-obviousness in this case because, even absent such indicia, the information developed during trial supports Patent Owner's view that neither claim 1 nor 2 is unpatentable based on the combined disclosures of the prior art asserted in the Petition.

G. Identification of Non-Responsive Evidence and Arguments

Each party identifies allegedly non-responsive evidence and arguments raised by the other party. *See* Papers 41, 42, 47, 50.

We agree with Patent Owner that Petitioner, in the Reply, introduces new arguments and evidence non-responsive to information raised in the Response. *See* Paper 41 (Patent Owner's identification of non-responsive evidence and arguments). Although Patent Owner was provided an opportunity to respond thereto in its Sur-reply, Patent Owner's ability to do so was hampered by the rule that prohibits filing with a sur-reply "new evidence other than deposition transcripts of the cross-examination of any reply witness." 37 C.F.R. § 42.23(b). Accordingly, in our analysis, we explain why we assign lesser weight to, or otherwise find unpersuasive, certain information advanced for the first time in the Reply.

Petitioner, for its part, identifies allegedly new information raised in Patent Owner's Sur-reply that, for the most part, is not discussed in this Decision. *See* Paper 47. The one exception is information in the Sur-reply raised in response to Dr. Bentley's testimony that "[t]here is no suggestion by Koschmieder" that the focal spots "need to extend simultaneously across the image plane," Ex. 1046 ¶ 50, as well as "comments on crossexamination of Dr. Bentley on this issue using Exhibit 4." Paper 50, 3 (citing Ex. 2051, 182:21–184:4, 192:2–198:14) (Item No. 7); *see id.* at 2 (Item No. 4) (same). For reasons articulated by Patent Owner, we find this material in the Sur-reply fairly responds to information raised in the Reply. *See* Paper 50, 2, 3 (and citations therein to the record). In any event, for reasons discussed above in our analysis of the challenges, whether we consider that disputed information or not, we find that Koschmieder discloses a wide-field imaging technique that is inapposite to the sequential, point-by-point imaging technique employed by Frey and Blumenkranz.

H. Objections to Evidence

Both parties filed objections to evidence. *See* Papers 18–20, 30, 36. Neither party preserved any objection by filing a motion to exclude as provided by our rules. *See* 37 C.F.R. § 42.64(c). All objections are waived.

IV. CONCLUSION

Petitioner does not establish by a preponderance of the evidence that claim 1 or claim 2 of the '356 patent is unpatentable. Therefore, we do not find any challenged claim unpatentable.

We summarize our decision in the following chart.

Claims	35 U.S.C. §	References	Claims Shown Unpatentable	Claims Not Shown Unpatentable
1, 2	103	Frey, Knowledge in the Art		1, 2
1, 2	103	Frey, Koschmieder, Knowledge in the Art		1, 2
1, 2	103	Blumenkranz, Frey, Knowledge in the Art		1, 2
1, 2	103	Blumenkranz, Frey, Koschmieder, Knowledge in the Art		1, 2

V. ORDER

It is

ORDERED that Petitioner has not proved by a preponderance of the evidence that claims 1 and 2 of the '356 patent are unpatentable; and

FURTHER ORDERED that, because this is a Final Written Decision, any party 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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