

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NEW WORLD MEDICAL, INC.,
Petitioner,

v.

MICROSURGICAL TECHNOLOGY, INC.,
Patent Owner.

IPR2020-01573
Patent 9,107,729 B2

Before JAMES A. TARTAL, ROBERT A. POLLOCK, and
RYAN H. FLAX, *Administrative Patent Judges*.

FLAX, *Administrative Patent Judge*.

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

New World Medical, Inc. (“Petitioner”) filed a Petition for an *inter partes* review of claims 1–10 (all claims) of U.S. Patent 9,107,729 B2 (“the ’729 patent,” Ex. 1001). Paper 1 (“Pet.”). MicroSurgical Technology, Inc. (“Patent Owner”) filed a Preliminary Response. Paper 16 (“Prelim. Resp.”).¹ Petitioner filed an authorized Reply to Patent Owner’s Preliminary Response (“Reply,” Paper 19) and Patent Owner filed an authorized, responsive Sur-Reply (“Sur-Reply,” Paper 20). *See* Paper 17 (Order Authorizing the Reply and Sur-Reply).

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 that Petitioner demonstrates a reasonable likelihood that it would prevail in showing that claims of the ’729 patent are unpatentable under at least one ground. Therefore, we institute *inter partes* review of all challenged claims (1–10) on all 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”).

¹ Paper 16 is a sealed, unredacted version of Patent Owner’s Preliminary Response. A redacted, public version having the same pagination is available as Paper 14.

I. INTRODUCTION

A. REAL PARTIES-IN-INTEREST

Petitioner identifies itself, “New World Medical, Inc.,” which Petitioner abbreviates in its briefing as “NWM,” as the real party-in-interest. Pet. ix.

Patent Owner also identifies itself, “MicroSurgical Technology, Inc.,” which Patent Owner abbreviates in its briefing as “MST,” as the real party-in-interest. Paper 4.

B. RELATED MATTERS

Petitioner states:

Microsurgical Tech., Inc. (“MST” or “Patent Owner”) and The Regents of the University of California (collectively “Plaintiffs”) filed a complaint asserting infringement of U.S. Patent 9,107,729 (“the ‘729 patent”) (Ex.1001) against NWM in the U.S. District Court for the District of Delaware (No. 20-cv-00754) on June 4, 2020. *See* Ex.1017. Plaintiffs also asserted U.S. Patent 9,358,155 (“the ‘155 patent”), U.S. Patent 9,820,885 (“the ‘885 patent”), U.S. Patent 9,999,544 (“the ‘544 patent”), and U.S. Patent 10,123,905 (“the ‘905 patent), against NWM in that case. NWM was served with the complaint on August 5, 2020.

Pet. ix. Patent Owner identifies the same litigation in the District of Delaware as a related matter. Paper 4.

Although neither party identifies them as directly related matters, we note the following other pending *inter partes* reviews, filed by Petitioner, challenging Patent Owner’s patents at issue in the aforementioned district court litigation: IPR2020-01711 regarding U.S. Patent 9,358,155 B2; IPR2021-00017 regarding U.S. Patent 9,820,885 B2; and IPR2021-00065 regarding U.S. Patent 10,123,905 B2; and IPR2021-00066 regarding U.S. Patent 9,999,544 B2.

C. THE '729 PATENT

The '729 patent issued on August 18, 2015, from U.S. Application 14/481,754, which was filed on September 9, 2014, and, ultimately, claims priority to U.S. Provisional Application 60/477,258, filed on June 10, 2003.² Ex. 1001, codes (45), (21), (22), (60), (62). The '729 patent's Abstract states:

Methods and devices for cutting strips of tissue from masses of tissue inside or outside of the bodies of human or animal subjects. The device generally comprises a) an elongate cutting tube that has a distal end and a lumen that opens through an opening in the distal end and b) first and second cutting edges formed on generally opposite edges of the distal end of the cutting tube and separated by a distance D. The device is advanced through tissue to cut a strip of tissue of approximate width W. Width W is approxima[t]ely equal to distance D.

Id. at Abstract.

Regarding the indicated feature of the invention of cutting strips of tissue, in its Background of the Invention section, the Specification explains that “[t]here are numerous medical and surgical procedures in which it is desirable to cut and remove a strip of tissue of controlled width from the body of a human or veterinary patient” and that

[o]ne surgical procedure wherein a strip of tissue of a known width is removed from an anatomical location within the body of a patient is an ophthalmological procedure used to treat glaucoma. This ophthalmological procedure is sometimes refer[r]ed to as a goniecto[m]y. In a goniecto[m]y procedure, a device that is operative to cut or ablate a strip of tissue of approximately 2-10 mm in length and about 50-200 μ m in width is inserted into the anterior chamber of the eye and used to

² Petitioner acknowledges this priority claim to June 10, 2003, and does not challenge it as the effective date of the '729 patent. Pet. 21, 24.

remove a full thickness strip of tissue from the trabecular meshwork.

Id. at 1:18–45. The Specification further states that “there remains a need in the art for the development of simple, inexpensive and accurate instruments useable to perform the goniotomy procedure.” *Id.* at 1:66–2:2.

As meeting this asserted need, the '729 patent's Specification describes “a needle cutter device 10,” which is illustrated in its Figures 1–4. Figure 2 is an exemplary illustration and it is reproduced below:

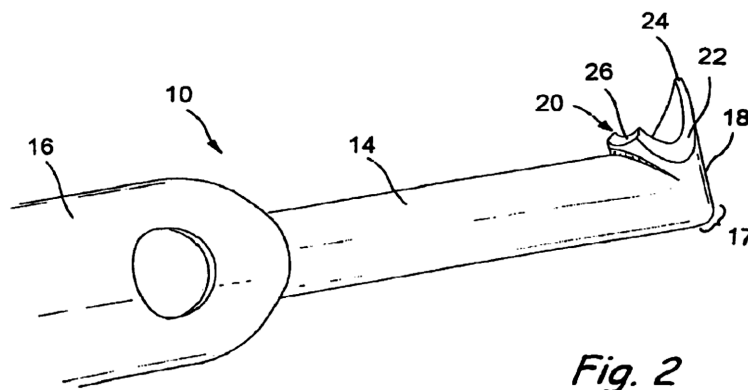


Figure 2 shows needle cutter device 10 having cutting tube 14 at an end of outer tube 16. *Id.* at 3:3–43. Cutting tube 14 terminates in an end having two cutting edges 20, 22, which are sharp to cut tissue and are positioned on opposite sides of cutting tube 14, blunt protruding tip 24, and blunt edge 26. *Id.* Cutting tube 14 has bend 17 of approximately 90 degrees at a point proximal to these features.³ *Id.* The Specification describes that such a device is used “[t]o perform a goniotomy procedure.” *Id.* at 5:19–6:27. The result of using such a device to perform a goniotomy is the cutting by

³ The bend angle to be measured was expressly identified by the inventors as the angle of degrees from straight during the prosecution of the '729 patent. Ex. 1002, 331 (Amendment dated May 14, 2015, remarks).

edges 20, 22 of a strip of tissue of, e.g., about 2–10 mm, proximate to the eye's trabecular meshwork and Schlemm's Canal, which is disconnected and removed from the patient. *Id.* at 6:15–27.

The '729 patent's sole independent claim, claim 1, reads as follows:

1. An ab interno method for forming an opening in trabecular meshwork of a patient's eye, said method comprising the steps of:

obtaining a dual blade device which comprises a) an elongate proximal portion sized to be grasped by a hand of a human operator and b) an elongate probe extending from the proximal portion, wherein the elongate probe comprises i) a shaft, ii) a distal protruding tip that extends from a distal end of the shaft to form a bend or curve having an angle of at least 30 degrees, said distal protruding tip being sized to be inserted in Schlemm's Canal and iii) first and second cutting edges located at a junction of the shaft and the distal protruding tip, said first and second cutting edges being formed at spaced-apart locations on the distal end of the shaft, said first and second cutting edges being separated by a distance D;

forming an opening into an anterior chamber of the eye;

inserting the elongate probe through the opening and into the anterior chamber;

advancing the elongate probe through the anterior chamber, while the anterior chamber is filled with fluid, to an operative position where the distal protruding tip is positioned within Schlemm's Canal and the first and second cutting edges are contacting the trabecular meshwork; and, thereafter

causing the distal protruding tip to advance through a sector of Schlemm's Canal with the first and second cutting edges concurrently cutting, from the trabecular meshwork, a strip of tissue having approximate width W, said approximate width W being approximately equal to the distance D between the first and second cutting edges.

Id. at 6:43–7:6. In addition to claim 1, the ’729 patent includes dependent claims 2–10, which more specifically define aspects of the claimed method and device used therefor. *Id.* at 7:7–8:18.

D. PETITIONER’S ASSERTED GROUNDS FOR UNPATENTABILITY

Petitioner asserts six grounds for the unpatentability of claims 1–10, of the ’729 patent, as follows:

GROUND	CLAIMS CHALLENGED	35 U.S.C. § ⁴	REFERENCE(S)/BASIS
1	1–4, 7–9	102	Quintana ⁵
2	4–6, 10	103(a)	Quintana, Knowledge of a Person of Ordinary Skill in the Art ⁶

⁴ The ’729 patent has a priority date of June 10, 2003, which is before the AIA revisions to 35 U.S.C. §§ 102 and 103 took effect. Therefore, the pre-AIA version of Sections 102 and 103 apply.

⁵ Manuel Quintana, *Gonioscopic Trabeculotomy. First Results* in DOCUMENTA OPHTHALMOLOGICA PROCEEDINGS SERIES 43, SECOND EUROPEAN GLAUCOMA SYMPOSIUM 265–71 (E.L. Greve et al. eds. 1985). Ex. 1004 (“Quintana”). Quintana has original pagination and also pagination at the lower right-hand corners of each page that appears to have been added. Herein, we reference the added pagination at the lower right corner of the document, as has Petitioner.

⁶ When analyzing whether claims would have been obvious and whether it would have been obvious to combine or modify prior art, it must always be from the perspective of a skilled artisan and one must consider knowledge generally available to one of ordinary skill in the art. *See KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007) (one must often consider “the background knowledge possessed by a person having ordinary skill in the art”). The “knowledge of a person of ordinary skill in the art” is always a consideration and is not a basis for a separate challenge for obviousness. Therefore, we do not separately analyze a challenge where “knowledge” is the only basis for it being separately presented, and consider obviousness over the cited prior art from the perspective of the skilled artisan.

GROUND	CLAIMS CHALLENGED	35 U.S.C. § ⁴	REFERENCE(S)/BASIS
3	1–4, 7–9	103(a)	Quintana, Lee ⁷
4	4–6, 10	103(a)	Quintana, Lee, Knowledge of a Person of Ordinary Skill in the Art ⁸
5	1–4, 7, 8	102	Jacobi ⁹
6	5, 6, 9, 10	103(a)	Jacobi, Knowledge of a Person of Ordinary Skill in the Art

See Pet. 4. In support of these grounds for unpatentability Petitioner submits, *inter alia*, the Declaration of Dr. Peter Netland. Ex. 1003. At this stage of the proceeding, we determine that Dr. Netland is qualified to offer testimony on the knowledge of one of ordinary skill in the art at the time of the invention. See *id.* ¶¶ 1–17, 26–27, 34–61 (Dr. Netland’s statements as to his background and qualifications, definition of the person of ordinary skill in the art, and background on the relevant technology).

E. QUINTANA

Quintana was published in 1985. Ex. 1004, 2. Quintana is prior art to the claims of the ’729 patent under 35 U.S.C. § 102(b); Patent Owner does not argue otherwise at this stage of the proceeding. *Id.*; see generally

⁷ U.S. Patent 4,900,300 (issued Feb. 13, 1990). Ex. 1006 (“Lee”).

⁸ As noted above, “knowledge” is not a basis for a separate ground for unpatentability and we consider Ground 4 to be subsumed within Ground 3.

⁹ Philipp C. Jacobi et al., *Technique of gonioscurettage: a potential treatment for advanced chronic open angle glaucoma*, 81 BRIT. J. OPHTHALMOLOGY 302–07 (1997). Ex. 1007 (“Jacobi”). Jacobi has original pagination and pagination at the lower right-hand corners of each page that appears to have been added by Petitioner. Herein, we reference the added pagination at the lower right corner of the document, as has Petitioner.

Prelim. Resp. Quintana “describe[s] a surgical method of goniotrabeculotomy[,] which achieves a section of the trabecular meshwork without damage to the external wall of Schlemm’s canal.” Ex. 1004, 3.

Quintana’s Figure 1 illustrates the use of a bent needle device in such a procedure; this figure is reproduced below:

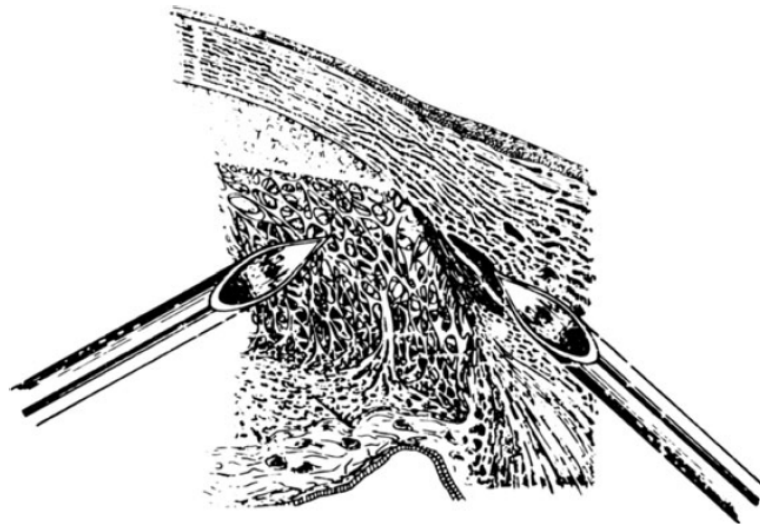


Fig. 1. Schematic drawing comparing the tangential approach to the perpendicular approach as in classic goniotomy or goniotrabeculotomy.

Id. at 4. According to Quintana, Figure 1 shows a “trabeculotome,” i.e., a tool for opening the trabecular meshwork of an eye to treat glaucoma, which consists of a 0.4 x 15 mm needle, or insulin-type needle, bent by 20–30° at the tip using a needle-holder, inserted into a syringe filed with “healon” (a wetting agent according to Dr. Netland (Ex. 1003 ¶ 92)). Ex. 1004, 3–4. Figure 1 shows this device penetrating the anterior chamber of an eye, running parallel to Schlemm’s canal, incising and stripping the trabecular meshwork with the tip of the needle, while the convex side of the bent tip is pointed towards the external wall so as to not cause damage. *Id.* at 4.

Quintana states that the healon can be injected during the process at any time and that, after the procedure, the device is withdrawn. *Id.*

A photograph of such a procedure occurring is provided by Quintana at Figure 2, reproduced below:

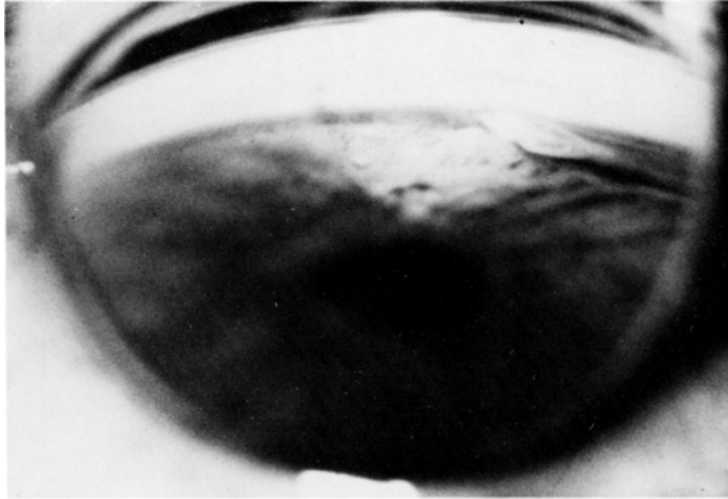


Fig. 2. Goniophotography at operation. The tip of the needle stripping the trabecular meshwork.

Id. at 5. Figure 2 shows the tip of the afore-discussed needle instrument introduced into the Schlemm's canal of an eye (see upper right quadrant of image, needle's tip points toward center line of image and needle's shaft extends toward the edge of the image) and the trabecular meshwork being stripped away "slowly, gently and easily from the canal's lumen towards the anterior chamber as the needle progresses." *Id.* at 4.

F. LEE

Lee issued as U.S. Patent on February 13, 1990, from U.S. Application 315,190, which was filed February 24, 1989, and claims priority to U.S. Application 70,325, which was filed July 6, 1987. Ex. 1006, codes [45], [21], [22], [63]. Lee is prior art to the claims of the '729 patent under

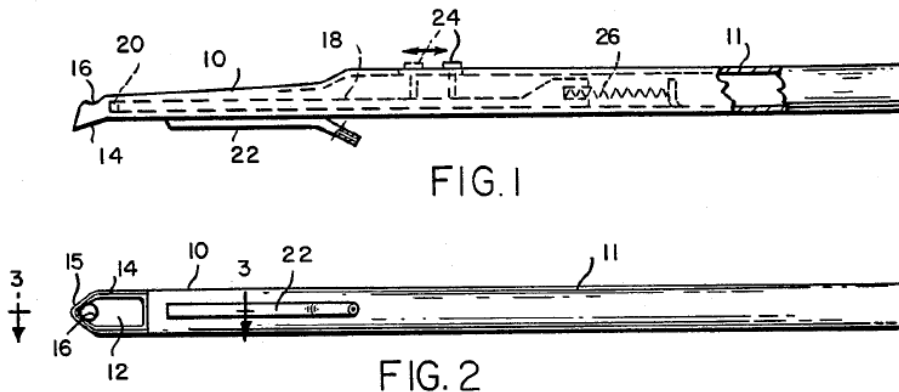
35 U.S.C. § 102(b); Patent Owner does not argue otherwise at this stage of the proceeding.

Lee states:

This invention relates to the design and application of a goniectomy instrument for the purpose of diagnostically and therapeutically removing tissue from the anterior chamber angle of the eye and for retrieving this tissue for further examination. The surgical instrument of this invention comprises in combination: a hollow, tapered shaft having a cutting edge at one end as an integral part thereof; a retractable stylet contained within the hollow interior of the tapered shaft; and an irrigation port running along the outside of the tapered shaft. This instrument is useful for excising tissue to relieve an obstruction blocking the outflow of aqueous humor from the eye as well as for providing specimens of the excised tissue for histopathological examination.

Id. at Abstract.

Lee shows such an instrument at Figures 1 and 2, which are reproduced below:



“FIG. 1 is a schematic side view of the surgical instrument of th[e] invention” and “FIG. 2 is a schematic bottom view of the surgical instrument of th[e] invention.” *Id.* at 3:62–65. Lee states that Figures 1 and 2 show “the surgical instrument” having “a more or less cylindrical hollow shaft

10[,] which is tapered from a larger diameter at the handle end 11 to a smaller diameter at the forward cutting end,” which is about 0.5 to 2 mm in diameter. *Id.* at 4:18–27. The tip end’s taper is 5–15 degrees. *Id.* at 32–33. The end of shaft 10 has “a parabolic, bowl-like cavity 12 having a sharpened rim[,] which creates a single, more or less U-shaped cutting edge 14 integral with the sides of shaft 10.” *Id.* at 4:38–41. “The cutting edge is softly rounded at its distal end and is generally parabolic in shape in order to avoid damage to the outer wall of Schlemm’s Canal.” *Id.* at 4:45–48. “[T]he plane of the tip of cutting edge 14 [is] at an acute angle of about 5 to 45 degrees with respect to the plane of shaft 10,” but may vary to a greater or smaller angle depending on surgical requirements. *Id.* at 4:49–54. Irrigation port 22 is also shown, indicated as functioning to maintain fluid levels in the anterior chamber of the eye during a procedure. *Id.* at 5:6–12.

Lee states that this device is used “in glaucoma surgery to excise a piece of tissue from the anterior chamber angle (trabecular meshwork and the inner wall of Schlemm’s Canal) to therapeutically relieve the obstruction of the outflow of aqueous humor from the eye and to provide specimens of the abnormal tissues excised for histopathological examination.” *Id.* at 3:51–57. This process is disclosed to include introducing the instrument into the anterior chamber of the eye via a corneal incision, followed by excising an angle of tissue as cutting edge 14 is advanced. *Id.* at 5:61–6:36. The tissue samples are removed from the eye. *Id.* at 6:37–49.

G. JACOBI

Jacobi was published in 1997. Ex. 1007, 1. Jacobi is prior art to the claims of the ’729 patent under 35 U.S.C. § 102(b); Patent Owner does not argue otherwise at this stage of the proceeding.

Jacobi discloses a procedure for a “[g]onioscopically controlled ab interno abrasion of the trabecular meshwork” using an “instrument resemble[ing] a modified cyclodialysis spatula with a bowl-shaped tip, 300 μm in diameter, and with its edges sharpened.” *Id.* at 1. Jacobi calls this device a “gonioscraper,” and shows it at Figure 1, reproduced below:



Figure 1 The tip of the ‘gonioscraper’. The bowl is 300 μm in diameter with its edges sharpened.

Id. at 2. Jacobi explains that, as shown in the figure above:

The ‘gonioscraper’ consists of a small handle and a slightly convex-shaped arm for intraocular use and very much resembles a cyclodialysis spatula. However, the tip of the instrument is shaped as a tiny bowl with 300 μm diameter and with its edges sharpened (Fig 1). In order to abrade clockwise and anticlockwise the scoop is angulated vertically at 90 degrees to the left and right, respectively.

Id.

The device is used “to abrade rather than incise uveal meshwork; this novel method, therefore, is termed gonioscurettage.” *Id.* Jacobi explains that the gonioscraper is inserted into the anterior chamber of an eye through a corneal incision, and then positioned against the trabecular meshwork and used to peel off trabecular meshwork by passing the device there-over. *Id.*

This results in “strings of trabecular tissue” being removed from the eye. *Id.*
A stage of this procedure is shown at Figure 2, reproduced below:



Figure 2 With the aid of an operating microscope and under gonioscopic control ab interno gonioscurettage is performed. Following abrasion an irregular pattern of a glistening white band corresponding to the ‘denuded’ grey-white sulcus scleralis can be seen (black arrows).

Id. Figure 2 shows the gonioscraper device inserted into an eye, performing the gonioscurettage procedure. *Id.*

II. DISCUSSION

A. ORDINARY LEVEL OF SKILL IN THE ART

Petitioner states,

A POSITA would have: (1) a medical degree and at least two years’ experience with treating glaucoma and performing glaucoma surgery; or (2) an undergraduate or graduate degree in biomedical or mechanical engineering and at least five years of work experience in the area of ophthalmology, including familiarity with ophthalmic anatomy and glaucoma surgery. Ex.1003, ¶27.

Pet. 23–24 (citing Ex. 1003 ¶ 27 (Netland Declaration)). Petitioner uses the acronym POSITA to refer to the person of ordinary skill in the art.

Patent Owner, at this stage of the proceeding, takes no position on the definition of the person of ordinary skill in the art. *See generally* Prelim. Resp.

For purposes of this Decision, at this stage of the proceeding, we accept Petitioner’s proposed definition of the person of ordinary skill in the art, or skilled artisan, which is not opposed by Patent Owner and appears to be consistent with the level of skill in the art reflected in the prior art of record and the disclosure of the ’729 patent. *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)).

B. CLAIM CONSTRUCTION

The Board interprets claim terms in an *inter partes* review using the same claim construction standard that is used to construe claims in a civil action in federal district court. 37 C.F.R. § 42.100(b) (2019). In construing claims, district courts and the Board here, by default, give claim terms their ordinary and customary meaning, which is “the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc).

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

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

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

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

Petitioner proposes that the claim language “ab interno,” which is recited in the preamble of independent claim 1, should be expressly construed as meaning “approaching TM [(trabecular meshwork)] through the AC [(anterior chamber)].” Pet. 25. Further, Petitioner proposes that the claim language “dual blade device,” which is recited by claim 1, should be expressly construed to mean the device “has two edges capable of cutting tissue.” *Id.* at 26. Patent Owner does not expressly object to Petitioner’s

proposed interpretations, nor does it offer any other proposed claim constructions. *See generally* Prelim. Resp.

We decline to expressly adopt any proposed construction of the claim language at this time, but instead, based on the information presented, assign the claim language its ordinary meaning as it would have been understood by a person of ordinary skill in the art. *Vivid Techs.*, 200 F.3d at 803 (“[O]nly those terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy.”).

Based on the evidence of record, the term “ab interno” appears to be a well-understood term of art in the ophthalmological field. *See, e.g.*, Ex. 1005, 1; Ex. 1013, 1; Ex. 1018, 1; Ex. 1020, 1. The ’729 patent does not expressly assign a special meaning to the term “ab interno.” Ex. 1001. We find that the record at this stage supports that the person of ordinary skill in the art would have understood this term and that it needs no special interpretation at this point in the proceeding.

The language “dual blade device” is readily understandable on its face; *dual* refers to two, and *blade*, in context, refers to a cutting part. The evidence of record does not indicate that this term has any special meaning different than what the plain language in context would suggest. The ’729 patent does not expressly assign a special meaning to the language “dual blade device.” Ex. 1001. We find that the record at this stage supports that the person of ordinary skill in the art would have understood this term and that it needs no special interpretation at this point in the proceeding.

To summarize, at this stage of the proceeding, we find there is no need to expressly interpret the claim language in any way different from its

ordinary meaning as 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 anticipation, our reviewing court has held:

a patent is invalid [or unpatentable] as anticipated if “the [claimed] invention was described in” a patent or published application “before the invention by” the patentee. 35 U.S.C. § 102(e). In order to anticipate the claimed invention, a prior art reference must “disclose all elements of the claim within the four corners of the document,” and it must “disclose those elements ‘arranged as in the claim.’” *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1369 (Fed. Cir. 2008) (quoting *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548 (Fed. Cir. 1983)).

Microsoft Corp. v. Biscotti, Inc., 878 F.3d 1052, 1068 (Fed. Cir. 2017); *see also Purdue Pharma L.P. v. Epic Pharma, LLC*, 811 F.3d 1345, 1358–59 (Fed. Cir. 2016) (distinct, but directly related disclosures of a reference may be combined in an optional, anticipating embodiment, e.g., a controlled-release pharmaceutical formulation specifically disclosed as an embodiment with claimed components *directly relates* to a disclosed list of therapeutic compounds useable therewith).

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;¹⁰ and (4) considering objective evidence indicating obviousness or non-obviousness.¹¹ *KSR*, 550 U.S. at 406.

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

With these standards in mind, and in view of the definition of the skilled artisan and claim interpretation discussed above, we address Petitioner’s challenges below.

D. PETITIONER’S PATENTABILITY CHALLENGES

As summarized above, Petitioner asserts several grounds for unpatentability of the claims of the ’729 patent. *See supra* Section I.D; *see also* Pet. 4. Under these asserted grounds for unpatentability, Petitioner

¹⁰ At this stage of the proceeding, there is no dispute as to the ordinary level of skill in the art. *See supra* Section II.A.

¹¹ At this stage of the proceeding, there is no evidence pertaining to objective indicia of non-obviousness. *See* Prelim. Resp.

addresses claims 1–10 of the ’729 patent and details, with citation to the asserted prior art and to the supporting testimony of the Netland Declaration, how the claims are allegedly anticipated or rendered obvious by the prior art. Pet. 27–94. Where asserted unpatentability is based on obviousness and a modification or combination of prior art, Petitioner also details the motivation to modify or combine references and why the person of ordinary skill in the art would have had a reasonable expectation of success. *See id.* at 52–73, 90–94. Patent Owner has not (and was not required to), at this stage of the proceeding, attempted to rebut any of Petitioner’s patentability challenges. *See* Prelim. Resp. We review the Petitioner’s asserted prior art’s relevant disclosure, as identified in the Petition, below.

I. ANTICIPATION BY QUINTANA AND OBVIOUSNESS OVER QUINTANA, INDIVIDUALLY, AND IN COMBINATION WITH LEE

Petitioner’s Grounds 1–4 challenge claims 1–10 (all claims) of the ’729 patent as anticipated by Quintana and obvious over Quintana, individually, and combined with Lee. We address these grounds together because they are largely based on the same evidence, with the understanding that the necessary showing differs between anticipation and obviousness.

a. Independent Claim 1

Petitioner asserts that independent claim 1’s preamble is disclosed by Quintana, which discloses an ab interno procedure called a goniotomy, or goniotrabeculotomy, to treat glaucoma by incising the trabecular meshwork of an eye, by accessing it with an instrument via penetration through the anterior chamber. Pet. 27–37 (citing Ex. 1004, 3–4, Figs. 1, 2; Ex. 1003 ¶¶ 91–100; Ex. 1020; Ex. 1021). Petitioner asserts under a separate ground that, to the extent there is any dispute regarding whether Quintana discloses an “ab interno” procedure, performing Quintana’s goniotomy procedure in

an ab interno way would have been obvious to the skilled artisan, particularly in view of Lee, which teaches ab interno procedures for glaucoma treatment, called goniotomy, which include using a dual-blade-tipped, hollow tool to excise and remove tissue from the eye's trabecular meshwork via access through the eye's anterior chamber. *Id.* at 57–58 (citing Ex. 1006, Abstract, 1:54–2:7, 3:50–57, 4:18–48, 5:61–65, 6:14–27, Figs. 2, 3; Ex. 1003 ¶¶ 101–103).

Petitioner asserts various reasons why the skilled artisan would have been motivated to combine Lee and Quintana, including that they are directed to similar methods and that modifying Quintana's steps or device's elements in view of Lee would have been merely simple substitutions of known procedures, and that such substitutions would make the procedure safer or more convenient or improve recovery, and Petitioner also asserts that success would have been expected. *Id.* at 60 (citing Ex. 1003 ¶¶ 175–176).

“Generally, the preamble does not limit the claims.” *Allen Eng'g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1346 (Fed. Cir. 2002). Regardless of whether the preamble is limiting here, Petitioner shows that Quintana, individually and combined with Lee, discloses “[a]n ab interno method for forming an opening in trabecular meshwork of a patient's eye,” as recited by claim 1. Ex. 1001, 6:43–45. As noted above, Patent Owner does not, at this stage, dispute Petitioner's assertions.

After the preamble, the first limitation of claim 1 is a clause defining the “dual blade device” to be used for the claimed method. Ex. 1001, 6:46–58. Petitioner asserts that Quintana discloses this device in teaching using “a 0.4 x 15 mm needle, or an insuline-type [*sic*] needle” with its “tip [*bent*] 20–

30° with a needle holder,” where the needle’s tip has two, spaced-apart (by a distance) cutting edges, and the needle extends from a syringe (a handle therefor), and that Quintana discloses using this device by inserting it through the anterior chamber of an eye into the Schlemm’s Canal to strip trabecular meshwork from the Canal’s lumen, while protecting the tissue adjacent the needle’s bend from damage. Pet. 37–45 (citing Ex. 1004, 3–4, Fig. 1; Ex. 1003 ¶¶ 120–130). Petitioner further asserts that, should shortcomings be found in Quintana’s disclosure, Lee also discloses a dual blade device as claimed, used for the same purpose in much the same fashion as Quintana and, so, Quintana’s device would have been obvious to modify in view of Lee’s disclosure so as to have met the claim limitation. *Id.* at 61–64 (citing Ex. 1006, 1:39–47, 1:54–60, 3:39–42, 3:50–57, 6:28–40, Fig. 5; Ex. 1016, 1:43–48; Ex. 1003 ¶¶ 56, 181–186, 188). As noted above, Patent Owner does not, at this stage, dispute Petitioner’s assertions.

The subsequent limitations of claim 1 are directed to performing the ab interno procedure and the first two of these require “forming an opening into an anterior chamber of the eye” and “inserting the elongate probe [of the dual blade device] through the opening and into the anterior chamber.” Ex. 1001, 6:59–61. Petitioner asserts that these steps are disclosed by Quintana. Pet. 45 (citing Ex. 1004, 4; Ex. 1003 ¶¶ 131–132). As noted above, Patent Owner does not, at this stage, dispute Petitioner’s assertions.

Claim 1 next requires advancing the “elongate probe” of the device through the anterior chamber, which is filled with fluid, to position it within the Schlemm’s Canal, which the claim recites is “an operative position,” such that “the first and second cutting edges are contacting the trabecular meshwork.” Ex. 1001, 6:62–67. Petitioner asserts that this is also disclosed

by Quintana, and shown in a photograph therein. Pet. 46–48 (citing Ex. 1004, 4, Fig. 2; Ex. 1011, 34–35, 51–52 (Quintana’s “Healon” is the claimed fluid); Ex. 1003 ¶¶ 98–100, 133–137). Regarding the recited “fluid,” Petitioner also asserts under a separate ground that Lee discloses maintaining fluid levels in the AC to protect the eye from injury and, thus, provides motivation to perform the claimed method step. *Id.* at 65 (citing Ex. 1006, 5:6–15; Ex. 1003 ¶ 192). As noted above, Patent Owner does not, at this stage, dispute Petitioner’s assertions.

Regarding claim 1’s concluding clause, Petitioner asserts that the process disclosed by Quintana results in trabecular meshwork being cut as the device is advanced through the Schlemm’s Canal, and that, as claimed, a strip of tissue having a width (i.e., “W”) approximating the distance (i.e., “D”) between Quintana’s device’s cutting edges would result, as claimed. Pet. 36–37, 47–48 (citing Ex. 1004, 3–4, Figs. 1, 2; Ex. 1003 ¶¶ 98–100, 113–119, 136–137). Similar to the preamble, under Ground 3 Petitioner asserts that, to the extent there is any question about Quintana’s disclosure, ab interno procedures were well known by 2003, and that Lee discloses such a procedure. *Id.* at 59–60 (citing Ex. 1001, 1:35–65, 5:19–26; Ex. 1006, 5:61–6:45; Ex. 1007, 5; Ex. 1015 ¶¶ 77–78; Ex. 1003 ¶¶ 173–176). As noted above, Patent Owner does not, at this stage, dispute Petitioner’s assertions.

b. Dependent Claims 2–10

As it has regarding claim 1, Petitioner also asserts that dependent claims 2–10 would have been anticipated by Quintana and obvious over Quintana, individually, and in combination with Lee and has detailed how such prior art discloses and teaches each element or step of these claims.

Pet. 48–57, 66–73 (citing Ex. 1001, 1:35–45, 1:60–65; Ex. 1004, 3–4; Ex. 1003 ¶¶ 35–36, 139–170, 196–212, 216–229; Ex. 1005, 2, 8; Ex. 1006, 1:54–2:7, 3:50–57, 4:49–54, 5:6–15, 6:14–27; Ex. 1007, 2; Ex. 1009, 4, 6, 9, Fig. XXV-1; Ex. 1010, 5; Ex. 1015 ¶ 23; Ex. 1016 ¶ 23; Ex. 1018, 1–2). In these same portions of the Petition, Petitioner also identifies why the skilled artisan would have been motivated to modify or combine the prior art, where necessary, and asserts that the skilled artisan would have had a reasonable expectation of success. *Id.* As with independent claim 1, Patent Owner does not, at this stage, dispute Petitioner’s assertions as to dependent claims 2–10 under these grounds.

2. *ANTICIPATION BY AND OBVIOUSNESS OVER JACOBI*

Petitioner further asserts under Grounds 5 and 6 that Jacobi, anticipates and would have rendered obvious claims 1–10 (all claims) of the ’729 patent. Pet. 74–94.

a. *Independent Claim 1*

Petitioner asserts that Jacobi discloses an ab interno procedure, much the same as the above-discussed goniotomy of Quintana and goniectomy of Lee, but called “goniocurettage” by Jacobi, which uses an instrument similar to the bent needle of Quintana or instrument of Lee, called a “gonioscraper,” to peel off strings of trabecular tissue to treat glaucoma. *Id.* Petitioner asserts that Jacobi’s gonioscraper is the dual blade device of claim 1 and that Jacobi discloses its method of use as being the same as the method steps of claim 1, detailing each claim limitation and how it is disclosed by Jacobi, as Petitioner did under Grounds 1–4. *Id.* at 74–88 (citing Ex. 1007, 1–2, 5, Figs. 1, 2; Ex. 1003 ¶¶ 104–, 230–252; Ex. 1006 4:38–41, Figs. 2–3;

Ex. 1002, 320; Ex. 1013, 2). Patent Owner does not, at this stage, dispute Petitioner's assertions.

b. Dependent Claims 2–10

Petitioner also asserts under Grounds 5 and 6 that Jacobi anticipates and rendered obvious each of dependent claims 2–10, detailing each claim limitation and how it is disclosed, taught, or suggested by this prior art. *Id.* at 88–94 (citing Ex. 1007, 2, 4, 5; Ex. 1001, 1:39–45, 1:60–65; Ex. 1004, 4; Ex. 1005, 8; Ex. 1006, 4:49–54; Ex. 1016 ¶ 23; Ex. 1003 ¶¶ 254–279).

Again, Patent Owner does not, at this stage, dispute Petitioner's assertions.

3. SUMMARY ON UNPATENTABILITY CHALLENGES

We find that, on the preliminary record, which is not disputed by Patent Owner at this stage of the proceeding, Petitioner shows “with particularity” “that there is a reasonable likelihood that Petitioner [will] prevail” in proving independent claim 1 and dependent claims 2–10 are anticipated by and would have been obvious over the asserted prior art, i.e., Quintana, Quintana and Lee, and Jacobi. 35 U.S.C. § 312(a)(3), § 314(a) (2019).

E. ALLEGED FAILURE TO NAME ALL REAL PARTIES-IN-INTEREST

Patent Owner argues, exclusively at this stage of the proceeding, that the Petition cannot or should not be considered because Petitioner has not identified The Regents of the University of Colorado (“Univ. CO”) as a real party-in-interest, citing 35 U.S.C. § 312(a)(2). *See* Prelim. Resp. 1–16. Petitioner's Reply and Patent Owner's Sur-Reply were authorized in this proceeding to further address this issue. Papers 17, 19, 20. For the reasons below, we are not persuaded by Patent Owner's arguments.

To summarize, Patent Owner argues that Petitioner and Univ. CO are, together, the primary competitors in the relevant market including a first product allegedly covered by the '729 patent and a second product allegedly covered by a patent (or patents) owned by Univ. CO and exclusively licensed by Petitioner. *See, e.g.*, Prelim. Resp. 1; Ex. 1022 (license agreement, sealed). Patent Owner argues that the relationship between Petitioner and Univ. CO is so close, and the financial incentive for Univ. CO to see the '729 patent's claims cancelled so strong, that Univ. CO must be considered and named a real party-in-interest to this trial. *See* Prelim. Resp. *passim*.

Patent Owner concedes that there would be no time-bar to this proceeding whether or not Univ. CO is a real party-in-interest. *Id.* at 14. Patent Owner argues that “[t]he estoppel concern is especially grave here,” but by “here” Patent Owner does not argue that there could be any estoppel in this proceeding, but rather argues that *under the circumstances* there are grave concerns that Univ. CO “remains armed with a ‘collective’ second bite at the apple” in the form of potential future *inter partes* review petitions over the '729 patent should Petitioner not prevail in this trial. *Id.* at 14–15. Patent Owner does not allege that either Petitioner or Univ. CO could or would be estopped from presenting a challenge in *this* proceeding, were both real parties-in-interest. *See* Prelim. Resp.; Sur-Reply.

Section 312(a)(2) requires that the “petition identif[y] all real parties in interest.” “This provision serves important notice functions to patent owners, to identify whether the petitioner is barred from bringing an IPR due to an RPI [(real party-in-interest)] that is time-barred or otherwise estopped, and to the Board, to identify conflicts of interests that are not readily

apparent from the identity of the petitioner.” *SharkNinja Operating LLC v. iRobot Corp.*, IPR2020-00734, Paper 11, 17 (PTAB Oct. 6, 2020) (precedential) (footnote omitted) (citations omitted) (“*SharkNinja*”).

Whether a non-party is a real party-in-interest is a highly fact-dependent question and must be considered on a case-by-case basis. *RPX Corp. v. Applications in Internet Time, LLC*, IPR2015-01750, Paper 128, 7–9 (Oct. 2, 2020) (precedential); *Ventex Co. v. Columbia Sportswear N. Am., Inc.*, IPR2017-00651, Paper 148 at 6 (PTAB Jan. 24, 2019) (Paper 148) (precedential). However, the question need not always be considered. The circumstance here is like that in *SharkNinja*, which is precedential authority for the Board.

As in *SharkNinja*, here the only argument asserted by Patent Owner against institution of trial is that Petitioner failed to name a third party as a real party-in-interest. *SharkNinja* at 18. As in *SharkNinja*, here, as to this proceeding, there is no time-bar or estoppel implication for any party, named a real party-in-interest or not. *See id.* at 18–19. As in *SharkNinja*, here Patent Owner does not identify any immediate advantage gained by Petitioner in this trial in purposefully omitting Univ. CO as a real party-in-interest. *See id.* at 19. As in *SharkNinja*, here Petitioner has offered to amend its identification of the real parties-in-interest, if necessary. Reply 9; *see SharkNinja* at 19.

Thus, as in *SharkNinja*, here it best serves the interest of cost and efficiency not to engage in a lengthy exercise to determine whether the Univ. CO should have been named a real party-in-interest, because, regardless of the result of such an analysis, nothing would foreclose this trial from

proceeding. *Id.* at 18–20. We need not and do not decide the issue of whether Petitioner has named all real parties-in-interest here.

III. CONCLUSION

Petitioner demonstrates a reasonable likelihood of prevailing at trial in showing that claims 1–10 of the ’729 patent are anticipated and would have been obvious over the cited prior art, if unrebutted by Patent Owner. Our decision at this stage derives from our review of the preliminary record before us. In accordance with the Court’s decision in *SAS Institute, Inc.*, 138 S. Ct. at 1359–60, and Office Guidance,¹² we institute an *inter partes* review of all challenged claims (1–10) of the ’729 patent on all grounds asserted by Petitioner. This decision does not reflect a final determination on the patentability of the claims.

ORDER

Accordingly, it is hereby:

ORDERED that, pursuant to 35 U.S.C. § 314, an *inter partes* review of claims 1–10 of the ’729 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 of the ’729 patent will commence on the entry date of this Order, and notice is hereby given of the institution of a trial.

¹² Guidance, *supra* at 2–3 (“At this time, 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.”).

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