Trials@uspto.gov
571.272.7822

Paper 11
Date: March 16, 2021

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NEW WORLD MEDICAL, INC.,
Petitioner,

v.

MICROSURGICAL TECHNOLOGY, INC.,
Patent Owner.

IPR2021-00065
Patent 10,123,905 B2

Before JAMES A. TARTAL, JAMES A. WORTH, 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 1–7 (all claims) of U.S. Patent 10,123,905 B2 ("the '905 patent," Ex. 1001). Paper 1 ("Pet."). MicroSurgical Technology, Inc. ("Patent Owner") filed a Preliminary Response. Paper 9 ("Prelim. Resp.").

Under 37 C.F.R. § 42.4(a), we have authority to determine whether to institute trial in an *inter partes* review. We may institute an *inter partes* review if the information presented in the petition filed under 35 U.S.C. § 311, and any preliminary response filed under § 313, shows that there is a reasonable likelihood that Petitioner would prevail with respect to at least one of the claims challenged in the petition. 35 U.S.C. § 314. After reviewing the parties' submissions, we conclude that Petitioner demonstrates a reasonable likelihood that it would prevail in showing that claims of the '905 patent are unpatentable under at least one ground. Therefore, we institute *inter partes* review of all challenged claims (1–7) 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").

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. viii.

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 10,123,905 ("the '905 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 9,107,729 ("the '729 patent"), U.S. Patent 9,358,155 ("the '155 patent"), U.S. Patent 9,820,885 ("the '885 patent"), and U.S. Patent 9,999,544 ("the '544 patent") against NWM in that case. NWM was served with the complaint on August 5, 2020.
>
> NWM filed a petition for *inter partes* review ("IPR") regarding the '729 patent on September 4, 2020. *See* IPR No. 2020-01573. NWM filed a petition for IPR regarding the '155 patent on October 2, 2020. *See* IPR No. 2020-01711. NWM also filed a petition for IPR regarding the '885 patent on October 2, 2020. *See* IPR No. 2021-00017.

Pet. viii.

Patent Owner identifies the same litigation in the District of Delaware and the same *inter partes* review proceedings as related matters, but also adds that "IPR2021-00066 (regarding U.S. Patent No. 9,999,544)" is another related matter. Paper 4.

C. THE '905 PATENT

The '905 patent issued on November 13, 2018, from U.S. Application 14/923,302, which was filed on October 26, 2015, and, ultimately, claims

priority to U.S. Provisional Application 60/477,258, filed on June 10, 2003.[1] Ex. 1001, codes (45), (21), (22), (60), (62). The '905 patent's Abstract states:

> A device and method for cutting or ablating tissue in a human or veterinary patient includes an elongate probe having a distal end, a tissue cutting or ablating apparatus located adjacent within the distal end, and a tissue protector extending from the distal end. The protector generally has a first side and a second side and the tissue cutting or ablating apparatus is located adjacent to the first side thereof. The distal end is structured to be advanceable into tissue or otherwise placed and positioned within the patient's body such that tissue adjacent to the first side of the protector is cut away or ablated by the tissue cutting or ablation apparatus while tissue that is adjacent to the second side of the protector is not substantially damaged by the tissue cutting or ablating apparatus.

Id. at Abstract.

Regarding the *cutting tissue* feature of the invention, in the Background of the Invention section, the Specification describes several then-existing procedures for treating glaucoma "intended to improve drainage of aqueous humor from the anterior chamber include[ing] trabeculoplasty, trabeculectomy, goniectomy and shunt implantation." *Id.* at 2:6–8. The Specification explains that, "[i]n trabeculectomy, the surgeon removes a tiny piece of the wall of the eye, which may include a portion of the trabecular meshwork, thereby creating a new drainage channel which bypasses the trabecular meshwork and the normal drainage channels" and, "[i]n goniectomy, a tissue cutting or ablating device is inserted into the anterior chamber of the eye and used to remove a full thickness strip of the

[1] Petitioner acknowledges this priority claim to June 10, 2003, and does not challenge it as the effective date of the '905 patent. Pet. 23, 28.

tissue from the trabecular meshwork overlying Schlemm's canal. In many cases, a strip of about 2 mm to about 10 mm in length and about 50 μm to about 200 μm in width is removed." *Id.* at 1:18–45.

The Specification further states that

> Trabeculoplasty, trabeculectomy and shunt implantation procedures are sometimes unsuccessful due to scarring o[r] closure of the surgically created channels or holes and/or clogging of the drainage tube. Because it involves removal of a full thickness strip from the trabecular meshwork, the goniectomy procedure is less likely to fail due to scarring or natural closure of the surgically created channel. Although the previously described devices can be used to successfully perform goniectomy procedures, there remains a need in the art for the development of new tissue cutting and ablation instruments that may be used to perform the goniectomy procedure as well as other procedures where it is desired to remove a strip of tissue from the body of a human or veterinary patient.

Id. at 2:44–57.

As meeting this asserted need, the '905 patent's Specification primarily describes a tool having electrodes that emit energy to cause the cutting or ablation of tissue. *See id. passim*. However, the claims of the '905 patent do not require such a tool, and instead, as shown below, are directed to a device with "a protector member" and "knife blades to cut tissue." *Id.* at 14:12–38. The Specification does mention such an embodiment, stating:

> It is contemplated that alternative embodiments of the invention may include any other suitable mechanism or apparatus that is operative to cut or ablate tissue, for example a strip of tissue, such as a monopolar electrode mechanism, a radiofrequency tissue cutting or ablation apparatus, apparatus (e.g., a light guide and/or lens) that emits light energy to cause thermal cutting or ablation of tissue (e.g., pulsed or non-pulsed optical incoherent high intensity light, pulsed or non-pulsed laser

> light, light that is infrared, visible and/or ultraviolet, etc.), mechanical tissue cutting or ablation apparatus (e.g., knife blade(s), scissor(s), rotating cutter(s), etc.), ultrasonic cutting or ablation apparatus (e.g., an ultrasound transmission member that extends through the device to a location adjacent the first side of the protector and undergoes axial or radial ultrasonic vibration) or others.

Id. at 8:60–9:8; *see also id.* at 3:45–61 (summarizing the same). No other textual description of such a device is provided in the ’905 patent. *See generally id.*

The’905 patent provides figures, such as Figure 3F, showing a cutting apparatus without (possibly before) including the electrode element most focused upon in the disclosure. Figures 3F and 4C, which are also reproduced on the ’905 patent’s cover, are reproduced below:

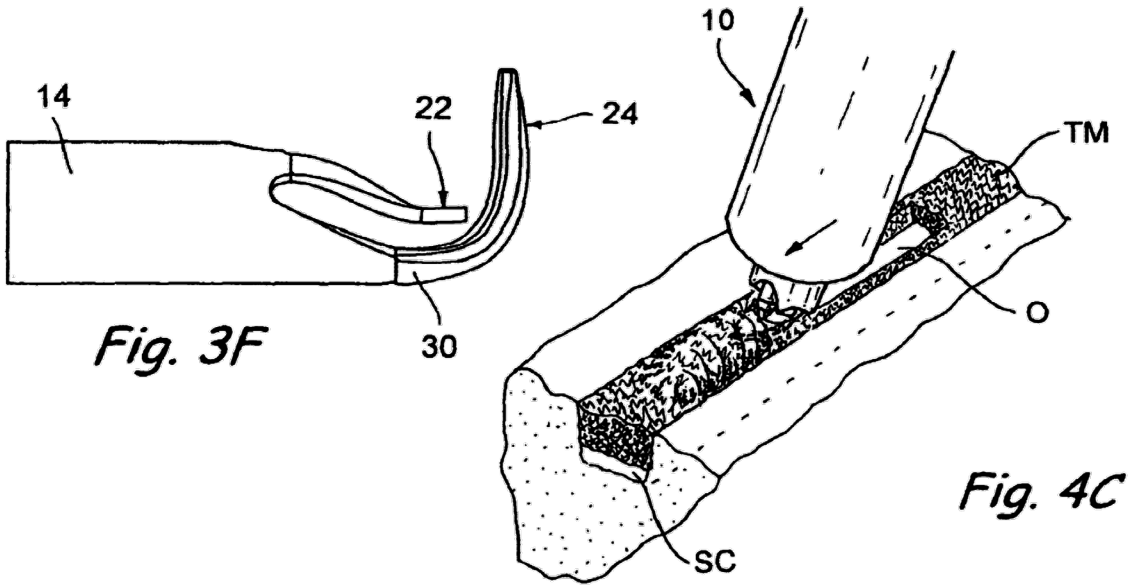

Fig. 3F

Fig. 4C

Figure 3F, above left, shows “an example of [a stage in] a method for manufacturing an electrosurgical goniectomy device of the present invention,” and Figure 4C, above right, shows “an enlarged view of a distal

portion of the device being used to remove trabecular meshwork tissue from an eye during a goniectomy procedure." *Id.* at 6:45–47, 6:53–55.

Figure 3F shows device 10 (reference number not shown) having inner tube 14, which "may comprise about 25 gauge stainless steel hypotubing," and may have "a length L of between 1 mm and about 4 mm, and more preferably 2.5 mm." *See, e.g.*, *id.* at 6:63–8:40. Device 10 is shown having protector 24 element, optional coating 30 element, and first electrode 22 element. *Id.* at 8:45–48, 9:9–28; *see also id.* at 11:34–13:20 (describing the processing steps to manufacture device 10). The Specification does not specify where, exactly, knife blades are provided in device 10. *See generally id.* The Specification does states that the "exposed surfaces of the distal end of the device are preferably formed and/or treated such that they include substantially no sharp portions." *Id.* at 8:22–27.

Figure 4C shows "an example of a goniectomy procedure that may be performed to treat glaucoma, using the device 10 . . . [t]his goneictomy procedure is an ab interno surgical procedure wherein a sector of the trabecular meshwork TM is removed from the eye of the patient." *Id.* at 9:62–67. Figure 4C shows device 10 advancing in Schlemm's Canal (SC), cutting an opening (O) in the trabecular meshwork (TM). *Id.* at 9:58–10:57. The Specification explains that protector 24 allows device 10's placement in Schlemm's Canal to facilitate guiding the device in use, and protects and shields the underlying walls of Schlemm's Canal from trauma during the procedure. *Id.* at 10:65–11:5.

The '905 patent's sole independent claim, claim 1, reads as follows:

> 1. A device that is insertable into the anterior chamber of an eye and useable to form an opening in the trabecular meshwork of that eye, said device comprising:

> an elongate probe having a longitudinal axis and a distal portion that is insertable into the anterior chamber of the eye;
>
> a protector member on a distal end of the distal portion of the probe, said protector member being oriented in a lateral direction relative to said longitudinal axis and having a first side, a second side and a tip, wherein the first side of the protector member comprises an incline which slopes upwardly from the tip and wherein the protector member has a width which tapers to its narrowest point at the tip; and
>
> a plurality of knife blades positioned to cut tissue that passes over the first side of the protector member;
>
> wherein the protector member is configured such that, after an insertion of the distal portion of the elongate probe into an anterior chamber of an eye, the protector member is insertable, tip first, through the trabecular meshwork and into Schlemm's Canal, the distal end of the probe being thereafter moveable in the lateral direction thereby causing the protector member to advance through Schlemm's Canal such that trabecular meshwork tissue passes over the incline and a strip of trabecular meshwork tissue becomes cut by said knife blades.

Id. at 14:12–38. In addition to claim 1, the '905 patent includes dependent claims 2–7, which more specifically define aspects of the claimed device. *Id.* at 14:39–55.

D. PETITIONER'S ASSERTED GROUNDS FOR UNPATENTABILITY

Petitioner asserts three grounds for the unpatentability of claims 1–7, of the '905 patent, as follows:

GROUND	CLAIMS CHALLENGED	35 U.S.C. §[2]	REFERENCE(S)/BASIS
1	1–3, 6, 7	102	Quintana[3]
2	2, 4, 5	103(a)	Quintana, Knowledge of a Person of Ordinary Skill in the Art[4]
3	1–7	103(a)	Jacobi,[5] 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

[2] The '905 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.

[3] 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.

[4] 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").

[5] Philipp C. Jacobi et al., *Technique of goniocurettage: 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.

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, 23–24, 32–59 (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 '905 patent under 35 U.S.C. § 102(b); Patent Owner does not argue otherwise at this stage of the proceeding. *Id.*; *see generally* 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:

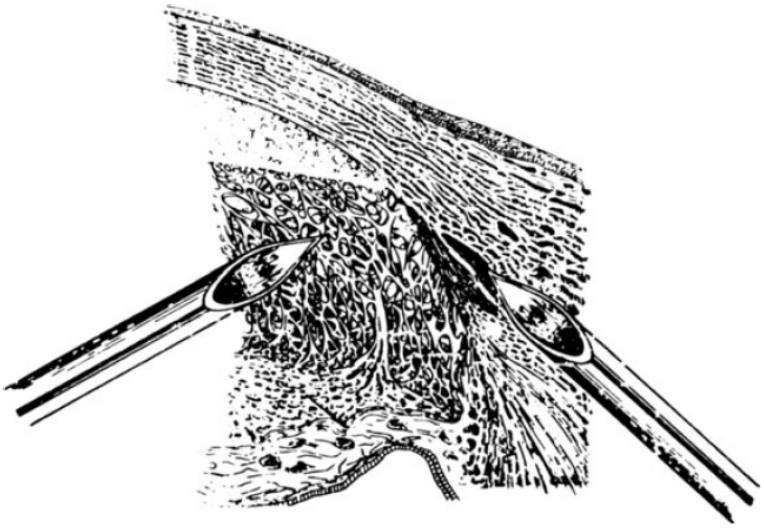

Fig. 1. Schematic drawing comparing the tangential approach to the perpendicular approach as in classic goniotomy or goniotrabeculotomy.

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, 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 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:

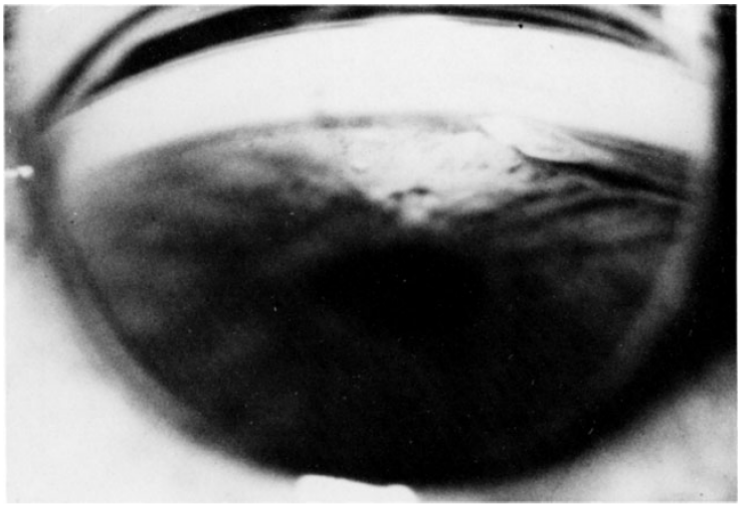

Fig. 2. Goniophotography at operation. The tip of the needle stripping the trabecular meshwork.

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. JACOBI

Jacobi was published in 1997. Ex. 1007, 1. Jacobi is prior art to the claims of the '905 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 goniocurettage." *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 goniocurettage 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 goniocurettage 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, ¶24.

Pet. 28 (citing Ex. 1003 ¶ 24 (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 '905 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 "knife blades," recited in independent claim 1 and dependent claim 7, should be expressly construed as meaning "blades in fixed positions on a device used for manual cutting of tissue." Pet. 29–30. 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.").

The claim language "knife blades" is readily understandable on its face; *knife* refers to a cutting instrument, and *blades*, in context, refers to plural cutting parts. 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 '905 patent does not expressly assign a special meaning to the language "knife blades." 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;[6] and (4) considering objective evidence indicating obviousness or non-obviousness.[7] *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 '905 patent. *See supra* Section I.D; *see also* Pet. 4. Under the grounds for unpatentability asserted, Petitioner

[6] 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.
[7] At this stage of the proceeding, there is no evidence pertaining to objective indicia of non-obviousness. *See* Prelim. Resp.

addresses claims 1–7 (all claims) of the '905 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. *See* Pet. 30–69. Where asserted unpatentability is based on obviousness and a modification of prior art, Petitioner also details the motivation to modify references and why the person of ordinary skill in the art would have had a reasonable expectation of success. *See id.* at 51–53, 61–62, 64–68 (citing Ex. 1003 ¶¶ 127–129, 131, 133–134, 148–150, 152, 156–158, 161–162, 164, 166).

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.

1. ANTICIPATION BY AND OBVIOUSNESS OVER QUINTANA

Petitioner's Grounds 1 and 2, together, challenge claims 1–7 of the '905 patent as anticipated by and obvious over Quintana. 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

Claim 1 begins with the preamble, "[a] device that is insertable into the anterior chamber of an eye and useable to form an opening in the trabecular meshwork of that eye." Ex. 1001, 14:12–14. Petitioner asserts that independent claim 1's preamble is disclosed by Quintana, which discloses an ab interno procedure called a goniotomy, or goniotrabeculotomy, which uses a bent needle to section trabecular

meshwork to treat glaucoma; the trabecular meshwork is accessed via penetration through the anterior chamber. Pet. 30–39 (citing Ex. 1004, 3–4, Figs. 1, 2; Ex. 1003 ¶¶ 81–90; Ex. 1020).

"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 discloses the preamble of claim 1. As noted above, Patent Owner does not, at this stage, dispute Petitioner's assertions.

After the preamble, the claim's limitations are directed to defining the required elements of the device. The first limitation of claim 1 recites "an elongate probe having a longitudinal axis and a distal portion that is insertable into the anterior chamber of the eye." Ex. 1001, 14:15–17. Petitioner asserts that Quintana's trabeculotome device, i.e., the bent needle extending from a syringe, discloses this limitation. Pet. 40 (citing Ex. 1004, 3–4, Fig. 1; Ex. 1003 ¶¶ 102–103. As noted above, Patent Owner does not, at this stage, dispute Petitioner's assertions.

The next limitation of claim 1 recites "a protector member on a distal end of the distal portion of the probe, said protector member being oriented in a lateral direction relative to said longitudinal axis and having a first side, a second side and a tip, wherein the first side of the protector member comprises an incline which slopes upwardly from the tip and wherein the protector member has a width which tapers to its narrowest point at the tip." Ex. 1001, 14:18–25. Petitioner asserts that the convex, or outside, side of the bend of the needle tip of the trabeculotome device of Quintana is a disclosure of a *protector member* as claimed. Pet. 41–44 (citing Ex. 1004, 3–4, Fig. 1; Ex. 1001, 2:66–3:8, 9:18–23, 13:21–35, Figs. 5A, 5B; Ex. 1003

¶¶ 104–109). Petitioner identifies where each element of this limitation is taught in Quintana's device, i.e., the orientation of the protector member, the first and second sides, the tip, the incline, width, and taper. *See id.* at 42–44 (annotated Figure 1 of Quintana identifying elements). Petitioner asserts that "the needle is oriented such that the convexity of the tip faces the external wall of S[chlemm's] C[anal] during the procedure to avoid damaging the external wall of S[chlemm's] C[anal]" and "that by bending the needle tip and orienting it such that the convex, outer portion of the tip faces the wall of S[chlemm's] C[anal], tissue near the convex side of the tip is protected." *Id.* at 41 (citing Ex. 1003 ¶ 105). Patent Owner does not, at this stage, dispute Petitioner's assertions.

The next limitation of claim 1 recites "a plurality of knife blades positioned to cut tissue that passes over the first side of the protector member." Ex. 1001, 14:26-27. Petitioner assets that Quintana's bent needle has *knife blades* as claimed, because the opposite sides of the needle are cutting edges to cut the trabecular meshwork. Pet. 44–46 (citing Ex. 1004, 3–4, Figs. 1, 2; Ex. 1003 ¶¶ 111–113). Petitioner asserts that the needle's configuration allows for the cutting of strips of trabecular meshwork tissue as it is advanced through the Schlemm's Canal, as taught by Quintana. *Id.* Patent Owner does not, at this stage, dispute Petitioner's assertions.

The final limitation of claim 1 recites:

> wherein the protector member is configured such that, after an insertion of the distal portion of the elongate probe into an anterior chamber of an eye, the protector member is insertable, tip first, through the trabecular meshwork and into Schlemm's Canal, the distal end of the probe being thereafter moveable in the lateral direction thereby causing the protector member to advance through Schlemm's Canal such that trabecular

> meshwork tissue passes over the incline and a strip of trabecular meshwork tissue becomes cut by said knife blades.

Ex. 1001, 28–38. Petitioner asserts that Quintana's device is configured in this way and disclosed as being used to perform this procedure. Pet. 39, 46–48 (citing Ex. 1004, 3–4, Figs.1, 2; Ex. 1003 ¶¶ 88–90, 100, 101, 114–116). Patent Owner does not, at this stage, dispute Petitioner's assertions.

b. Dependent Claims 2–7

As it has regarding claim 1, Petitioner also asserts that dependent claims 2–7 would have been anticipated by and obvious over Quintana and has detailed how the prior art discloses and teaches each element or step of these claims. Pet. 48–53 (citing Ex. 1004, 3–4, Figs. 1, 2; Ex. 1003 ¶¶ 118, 120, 122, 123, 126–129, 131, 133–134; Ex. 1001, 2:25–30; Ex. 1002, 423; Ex. 1007, 2). In these same portions of the Petition, Petitioner also identifies why the skilled artisan would have been motivated to modify 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 2–7.

2. OBVIOUSNESS OVER JACOBI

Petitioner further asserts under Ground 3 that Jacobi would have rendered obvious claims 1–7 of the '905 patent. Pet. 53–69. As was the case with Petitioner's assertions as to Quintana, Patent Owner does not, at this stage, dispute Petitioner's assertions.

a. Independent Claim 1

Petitioner asserts that Jacobi discloses an ab interno procedure, much the same as the above-discussed goniotomy of Quintana (and also like a

goniectomy procedure of Lee, which is also prior art of record),[8] but called "goniocurettage" by Jacobi, which uses an instrument very 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.* at 53–55 (citing Ex. 1007, 1–2, Figs. 1, 2; Ex. 1003 ¶¶ 94–97). Thus, if claim 1's preamble is a limitation, Petitioner shows that Jacobi teaches it.

Regarding the limitations of claim 1 defining the device, Petitioner asserts that Jacobi's gonioscraper is the device of claim 1 having the claimed probe, protector member, knife blades, and configuration for cutting a strip of trabecular meshwork as advanced in the Schlemm's Canal, as claimed, detailing each claim limitation and each element thereof and how it is disclosed by Jacobi, as Petitioner has under Grounds 1 and 2. *Id.* at 55–64 (citing Ex. 1007, 1, 2, Figs. 1, 2; Ex. 1003 ¶¶ 136–153; Ex. 1006, 4:38–48, Figs. 2, 3; Ex. 1023, 320). Patent Owner does not, at this stage, dispute Petitioner's assertions.

Where Petitioner asserts modifications to Jacobi's disclosed device would have been required, Petitioner asserts that the person of ordinary skill in the art would have been motivated to do so and would have had a reasonable expectation of success. *See* Pet. 61–62, 64 (citing Ex. 1003 ¶¶ 149–150, 152). Patent Owner does not, at this stage, dispute Petitioner's assertions.

[8] U.S. Patent 4,900,300 (issued February 13, 1990) (Ex. 1006, "Lee"). Lee was considered during the prosecution of the application for the '905 patent. *See* Ex. 1001, 426.

b. Dependent Claims 2–7

Petitioner also asserts under Ground 3 that Jacobi rendered obvious dependent claims 2–7, detailing each claim limitation and how it is taught or suggested by this prior art. *Id.* at 64–69 (citing Ex. 1007, 2, Figs. 1, 2; Ex. 1001, 2:25–30; Ex. 1002, 423; Ex. 1003 ¶¶ 155–171; Ex. 1006, 5:6–15). Patent Owner does not, at this stage, dispute Petitioner's assertions.

Where Petitioner asserts modifications to Jacobi's disclosed device would have been required, Petitioner asserts that the person of ordinary skill in the art would have been motivated to do so and would have had a reasonable expectation of success. *See* Pet. 65–67 (citing Ex. 1003 ¶¶ 156–158, 164, 166). Patent Owner does not 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 2–7 are anticipated by and would have been obvious over the asserted prior art, i.e., Quintana 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).[9] *See* Prelim. Resp. 1–15. For the reasons below, we are not persuaded by Patent Owner's arguments.

[9] Regarding much of this argument, Patent Owner references the briefing and evidence of record in co-pending, related IPR2020-01573, where Patent

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 '905 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. 1–3. Patent Owner argues that the relationship between Petitioner and Univ. CO is so close, and the financial incentive for Univ. CO to see the '905 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 13. 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 '905 patent should Petitioner not prevail in this trial. *Id.* at 13–14. 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 generally* Prelim. Resp.

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,

---

Owner advanced similar allegations and arguments. *See* IPR2020-01573, Paper 14.

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*, it appears that here Petitioner has offered to amend its identification of the real parties-in-interest, if necessary. *See* IPR2020-01573, Paper 19; *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 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. *SharkNinja* 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 1–7 of the '905 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,[10] we institute an *inter partes* review of all challenged claims (1–7) of the '905 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 1–7 of the '905 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 '905 patent will commence on the entry date of this Order, and notice is hereby given of the institution of a trial.

[10] 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.").

For PETITIONER:

Todd R. Tucker
Kyle T. Deighan
CALFEE, HALTER & GRISWOLD LLP
ttucker@calfee.com
kdeighan@calfee.com
ipdocket@calfee.com

For PATENT OWNER:

Lawrence M. Sung
Mary Sylvia
Teresa M. Summers
WILEY REIN LLP
lsung@wileyrein.com
msylvia@wileyrein.com
tsummers@wileyrein.com