

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.*

JUDGMENT

Final Written Decision
Determining All Challenged Claims Unpatentable
35 U.S.C. § 318(a)

MicroSurgical Technology, Inc. (“Patent Owner”) is the owner of U.S. Patent 10,123,905 B2 (“the ’905 patent,” Ex. 1001). Paper 18, 1 (“Response” or “Resp.”). New World Medical, Inc. (“Petitioner”) filed a Petition for an *inter partes* review of claims 1–7 (all claims) of the ’905 patent. Paper 1 (“Pet.”). Trial was instituted on March 16, 2022. Paper 11 (“Institution Decision” or “DI”). Patent Owner filed a Response to the Petition. Paper 18. Petitioner filed a Reply to Patent Owner’s Response (Paper 24, “Reply”) and Patent Owner filed a respective Sur-Reply (Paper 33, “Sur-Reply”). The parties also each filed respective motions to exclude the other’s evidence, which were each denied. Papers 40, 41, and 51. A final hearing was held on January 10, 2022, where each party presented oral argument. Paper 50 (“Hr’g Tr.).

We have authority under 35 U.S.C. § 6. This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73.

Petitioner bears the burden of proving unpatentability of the challenged claims, and the burden of persuasion never shifts to Patent Owner. *Dynamic Drinkware, LLC v. Nat’l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015). To prevail, Petitioner must prove unpatentability by a preponderance of the evidence. *See* 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d) (2019). After considering the parties’ arguments and supporting evidence, we conclude that Petitioner proves by a preponderance of the evidence that claims 1–7 of the ’905 patent are unpatentable. 35 U.S.C. § 316(e).

I. INTRODUCTION

A. REAL PARTIES-IN-INTEREST

Petitioner identifies itself, “New World Medical, Inc.,” as the real party-in-interest. Pet. viii. Patent Owner also identifies itself, “MicroSurgical Technology, Inc.,” 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 case 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.

The final hearing consolidated oral arguments for this and each of these other *inter partes* review proceedings. Hr’g Tr. 1, 3:3–12.

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 existing procedures for treating glaucoma “intended to improve drainage of aqueous humor from the anterior chamber include[ing] trabeculoplasty, trabeculectomy, goniotomy and shunt implantation.” *Id.* at 2:6–8. The Specification explains, as background, 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

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.

which bypasses the trabecular meshwork and the normal drainage channels” and, “[i]n goniotomy, 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 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 μ m to about 200 μ m 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 goniotomy 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 goniotomy 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 goniotomy 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 mentions 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 (emphasis added); *see also id.* at 3:45–61 (summarizing the same). No other textual description of a knife-blade device is provided in the '905 patent. *See generally id.*

The '905 patent provides figures, such as Figure 3F, showing a cutting apparatus without (or 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:

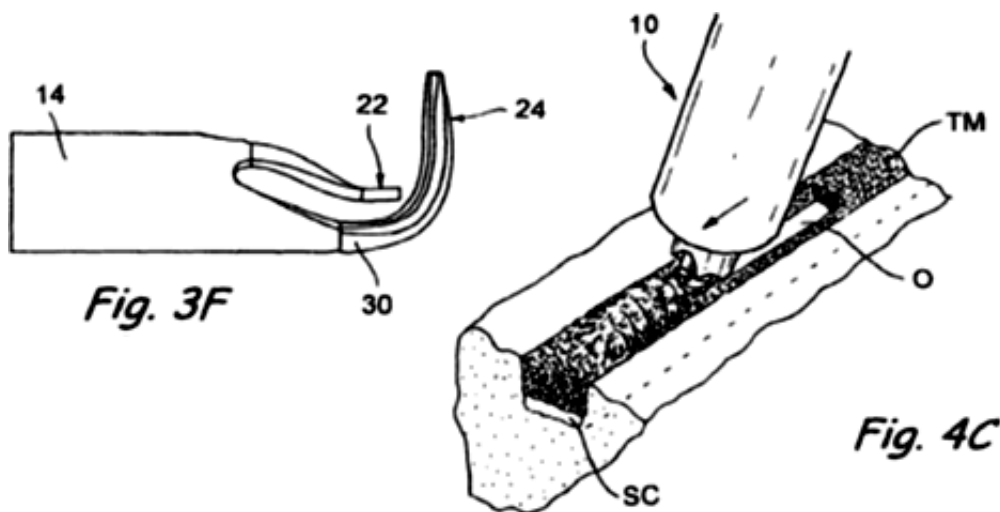


Figure 3F, above left, shows “an example of [a stage in] a method for manufacturing an electrosurgical goniectomy device of the present invention,” and Figure 4C, above right, shows “an enlarged view of a distal portion of the device being used to remove trabecular meshwork tissue from an eye during a goniectomy procedure.” *Id.* at 6:45–47, 6:53–55.

Figure 3F shows tube-fabricated 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 other than that the tissue cutting apparatus is located adjacent to the first side of the protector (the second side of the protector faces the tissue, e.g., Schlemm’s Canal, when used) and is “disposed generally within the distal end or distal portion of the probe 3.” *See generally id.; see also id.* at 2:66–3:9, 6:66–7:2, 9:3–28. No figure in the ’905 patent shows knife blades. 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, above, shows “an example of a goniectomy procedure that may be performed to treat glaucoma, using the device 10 . . . [t]his goniectomy 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

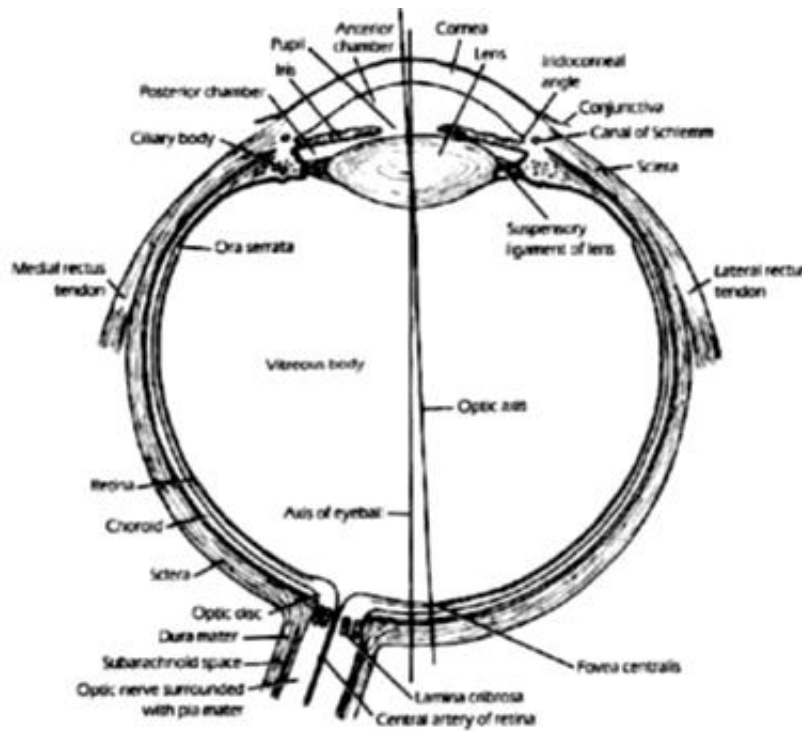
a plurality of knife blades positioned to cut tissue that passes over the first side of the protector member;

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.

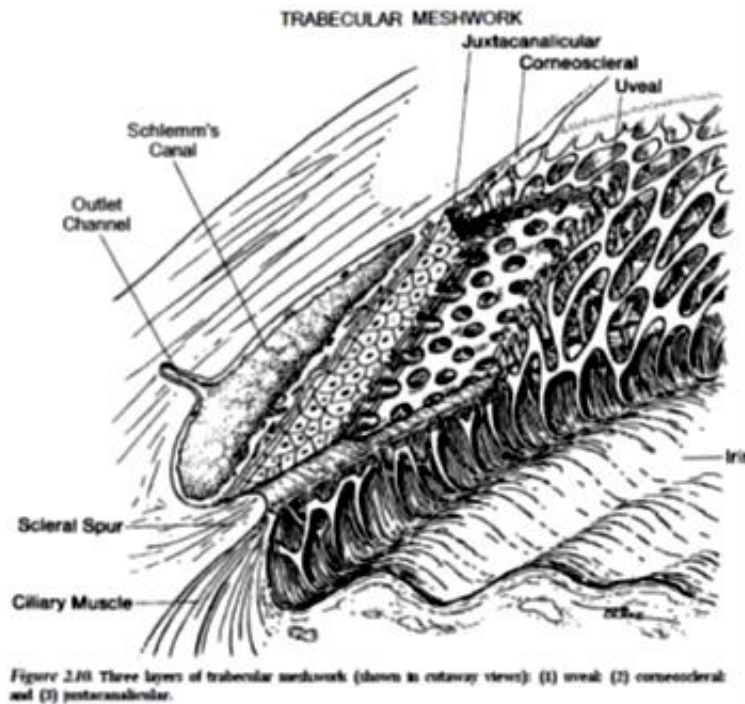
For context as to the '905 patent's disclosed and claimed invention, Petitioner's witness, Dr. Peter Netland, in his First Declaration, provides a cross-sectional, labeled illustration of a human eye, which we reproduce below:



Ex. 1003 ¶ 32; *see also* Ex. 1008, 8–9 (cited by Dr. Netland as the source of the figure). The figure above shows and labels anatomical features of a human eye, including of note (from top of the figure to bottom, i.e., anatomically anterior to posterior), a cornea defining an anterior chamber over an iris and pupil, which themselves define a posterior chamber over a lens, a vitreous body making up the great volume of the eye's interior behind the lens, and the retina and optic nerve at the back of the vitreous body. *See* Ex. 1003 ¶¶ 32–37. The sclera (the opaque white part of an eye) and ciliary body (a vascular layer) are also shown and labeled as adjacent and

connected to the lens, and immediately above the ciliary body, adjacent the iris and iridocorneal angle, the Canal of Schlemm (Schlemm's Canal) is shown and labeled. *Id.*

The '905 patent's invention relates to more specific parts of the eye, namely, Schlemm's Canal and trabecular meshwork. Dr. Netland's First Declaration also provides a higher resolution illustration of these features, which we reproduce below:



Ex. 1003 ¶¶ 38–40; see also Ex. 1011 (identified by Dr. Netland as the source of the figure). As explained by Dr. Netland, the figure above “shows a cutaway view of the layers of the trabecular meshwork and Schlemm’s Canal” (as noted above, Schlemm’s Canal was shown in cross-section in the first figure of the eye above, adjacent the iridocorneal angle). Ex. 1003 ¶ 39. As described in the above figure itself, three layers of trabecular meshwork (uveal, corneoscleral, and juxtacanalicular) are adjacent to and in contact

with the iris, scleral spur, and ciliary muscle, and in front of Schlemm's Canal. *Id.*

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
3	1–7	103(a)	Jacobi, ⁴ Knowledge of a Person of Ordinary Skill in the Art

See Pet. 4.

Petitioner's Grounds 2 and 3, summarized above, reference the knowledge of a person of ordinary skill in the art as a distinguishing basis for being a separate ground. Analyzing whether claims would have been

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"). Herein, we reference the added pagination at the lower right corner of the document, as has Petitioner.

⁴ Philipp C. Jacobi et al., *Technique of goniosurgery: a potential treatment for advanced chronic open angle glaucoma*, 81 BRIT. J. OPHTHALMOLOGY 302–07 (1997). Ex. 1007 ("Jacobi"). Herein, we reference the added pagination at the lower right corner of the document, as has Petitioner.

obvious and whether it would have been obvious to combine or modify prior art is always from the perspective of an ordinarily 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 consider “the background knowledge possessed by a person having ordinary skill in the art”).

In support of the grounds for unpatentability Petitioner submits, *inter alia*, two Declarations of Dr. Peter Netland. Ex. 1003 (“First Netland Declaration”); Ex. 1030 (“Second Netland Declaration”). We conclude 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* Ex. 1003 ¶¶ 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).

In support of its positions, Patent Owner submits the Declaration of Dr. Garry P. Condon. Ex. 2019 (“Condon Declaration”). Dr. Condon’s testimony was the subject of a motion to exclude by Petitioner (Paper 41, “Pet. Mot.”) and, although that motion was denied (Paper 51, “Order”), it did highlight certain cross-examination testimony by the witness evidencing that his direct testimony is deficient or unreliable on several issues. In denying Petitioner’s motion, we “agree[d] with Petitioner’s characterizations of Dr. Condon’s testimony on cross-examination and also [found] Petitioner’s assertions regarding this testimony and its applicability to interpreting Dr. Condon’s direct testimony to be accurate.” Order 12. For example, our Order stated:

Petitioner asserts that on cross-examination by deposition, Dr. Condon testified, *inter alia*, that he had not carefully read the challenged patent(s), he was unsure in some respects as to what the claims of the challenged patent(s) require, did not know the difference between device and method claims, did not understand anticipation or obviousness, had not seen at least some portions of the challenged patent's prosecution history, did not understand what a patent file history is, did not understand or had not analyzed at least some claim language of the challenged patent(s), was not capable of interpreting the meaning of at least some claim language, and presented internally-conflicting testimony on the proper reading of Petitioner's asserted prior art. Pet. Mot. 3–9 (see citations to Exs. 1041–1043 therein). Petitioner asserts that, under FRE 702 and 37 C.F.R. §§ 42.62, 42.65, Dr. Condon's direct testimony is insufficient regarding his knowledge, basis in facts and data, and reliability because the witness does not understand the legal concepts of anticipation and obviousness to which he testifies, had not considered or analyzed evidence he had purported in his direct testimony to have considered and analyzed, and does not fully understand the challenged claims. *Id.* at 9–13.

Id. at 10–11; *see also* Pet. Mot. 3–9 (and citations therein).

We “conclude[d] that the better course is to have a complete record of the evidence,” and, therefore, denied Petitioner's Motion, but also explained that “to the extent that Dr. Condon's testimony and Patent Owner's reliance thereon ventures into areas the witness has conceded he either does not understand or has inadequately analyzed,” we would accord it “little weight,” as distinguished “from that relating to Dr. Condon's technical expertise in, for example, anatomy, eye surgery, and his own reading of evidence.” Order 13. Therefore, it is through this lens that we consider Dr. Condon's testimony here.

We review Petitioner's asserted prior art below.

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. *Id.*; *see generally* 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-tip needle device in such a procedure; this figure is reproduced below:

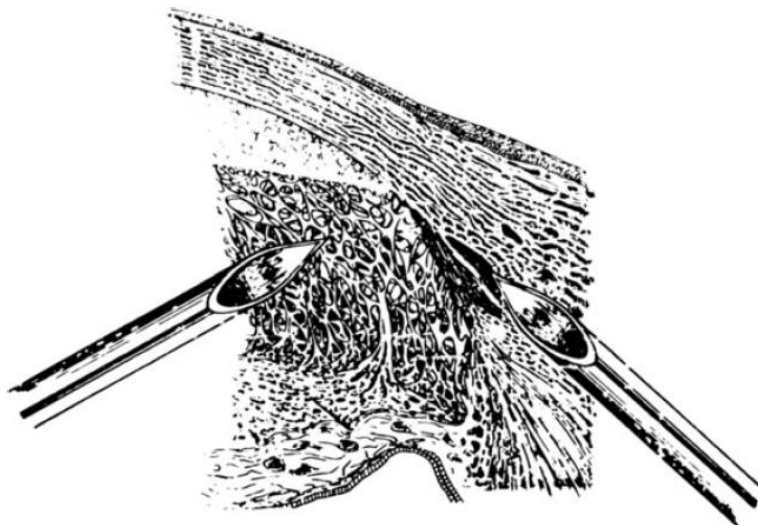


Fig. 1. Schematic drawing comparing the tangential approach to the perpendicular approach as in classic goniotomy or goniotrabeculotomy.

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:

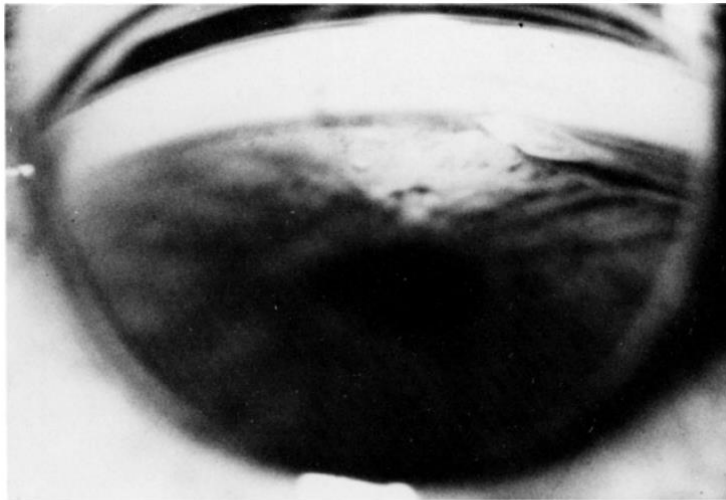


Fig. 2. Goniophotography at operation. The tip of the needle stripping the trabecular meshwork.

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 slowly, gently and easily from the canal's lumen towards the anterior chamber as the needle progresses." *Id.* at 4. Quintana concludes, "our results show that goniotrabeculotomy, although highly successful in the first postoperative month, is in the end a partially successful procedure.

Further studies are necessary to disclose the ‘in vivo’ behavior of the sectioned trabecular meshwork.” *Id.* at 8.

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 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. LEVEL OF ORDINARY 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).⁵ Patent Owner states that it “agrees with the Board’s preliminary acceptance in its institution decision of Petitioner’s proposed definition of a POSA for purposes of this IPR.” Resp. 9, n.3.

We accept, as has Patent Owner, Petitioner’s proposed definition of the person of ordinary skill in the art, or ordinarily skilled artisan, which appears to be consistent with the level of skill in the art reflected in the prior art of record and the disclosure of the '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

⁵ Petitioner uses “POSITA” and Patent Owner uses “POSA” to refer to the person of ordinary skill in the art.

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 states:

Patent Owner submits that all of the terms in the Challenged Claims should be accorded their plain and ordinary meanings to a POSA.^[1] Patent Owner agrees with the Board’s preliminary determination in its Institution Decision not to adopt Petitioner’s proposed definitions of “knife blades.” See Paper 11 at 14-17 (Section II.B.). The ’905 Patent sets forth no particularized definitions for this term, and Petitioner has offered no justification for departing from the plain and ordinary meanings of this term.

Resp. 9–10 (footnote omitted).

We decline to expressly adopt any proposed construction of the claim language, 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 supports that the person of ordinary skill in the art would have understood this term and that it needs no special interpretation.

To summarize, 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. This is consistent with our preliminary determinations as set forth in our Institution Decision (at 15–17) and the parties’ understanding of the claims at trial. *See generally* Resp.; Reply; Sur-Reply; *see also* Hr’g Tr. 49:21–50:10 (Petitioner adopting the Board’s understanding of *knife blade*).

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*, 800 F.3d at 1378 (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).

Evaluating anticipation is not restricted to only the literal teachings of the prior art reference, but we also may consider the inferences the skilled artisan would draw from it. *Eli Lilly and Co. v. Los Angeles Biomedical Res. Inst. at Harbor-UCLA Med. Ctr.*, 849 F.3d 1073, 1074–75 (Fed. Cir. 2017) (holding that the “dispositive question regarding anticipation is whether one skilled in the art would reasonably understand or infer from a prior art reference that every claim element is disclosed in that reference”); *In re Graves*, 69 F.3d 1147, 1152 (Fed. Cir. 1995) (“A reference anticipates a claim if it discloses the claimed invention ‘such that a skilled artisan could take its teachings in combination with his own knowledge of the particular art and be in possession of the invention.’” (emphasis omitted)). Moreover, “a reference can anticipate a claim even if it does not expressly spell out all the limitations arranged or combined as in the claim, if a person of skill in the art, reading the reference, would at once envisage the claimed arrangement or combination.” *Kennametal, Inc. v. Ingersoll Cutting Tool Co.*, 780 F.3d 1376, 1381 (Fed. Cir. 2015) (internal quotation marks and alterations omitted).

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 ordinarily skilled artisan and claim interpretation discussed above, we address Petitioner’s challenges below.

D. PETITIONER’S PATENTABILITY CHALLENGES

As summarized above, Petitioner asserts three 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 addresses claims 1–7 (all claims) of the ’905 patent and details, with citation to the asserted prior art and, *inter alia*, the supporting testimony of the Netland Declarations, how the claims are allegedly anticipated or rendered obvious by the prior art. *See* Pet. 30–69; Reply. Where asserted

⁶ There is no dispute as to the ordinary level of skill in the art. *See supra* Section II.A.

⁷ There is no asserted evidence pertaining to objective indicia of non-obviousness. *See* Resp.

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

We review below Petitioner’s challenges and Patent Owner’s arguments in view of the evidence.

1. *ANTICIPATION BY AND OBVIOUSNESS OVER QUINTANA*

Petitioner’s Grounds 1 and 2, together, challenge claims 1–7 (all claims) 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*

Petitioner asserts that Quintana anticipates independent claim 1. Pet. 30–48.

Claim 1 begins with the following 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 (emphasis added).

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

Quintana even provides an illustration (Fig. 1) and a photograph (Fig. 2) of its device inserted into the eye's anterior chamber and opening trabecular meshwork, as recited by claim 1's preamble. *Id.* at 39 (citing Ex. 1003 ¶¶ 100–101; Ex. 1004, Figs. 1, 2).

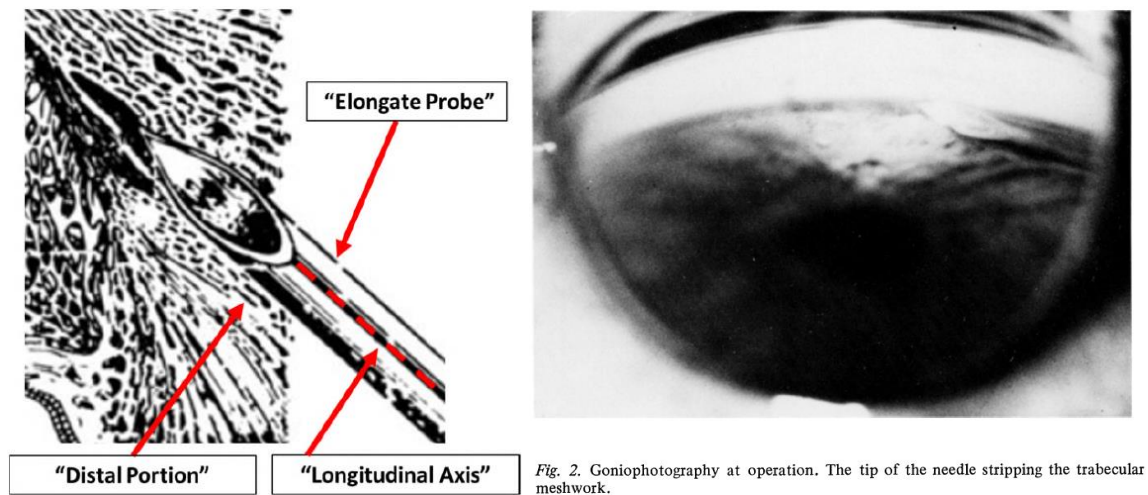
Patent Owner presents no arguments directed to this part of claim 1 or Petitioner's assertions thereover. *See generally* Resp.

“Generally, the preamble does not limit the claims.” *Allen Eng'g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1346 (Fed. Cir. 2002). Here, the preamble of claim 1 *may* be considered limiting because “[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” recites or, at a minimum, implies, “essential structure or steps” required for the claimed device, including where anatomically the later claimed device is insertable and used. *See Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002).

Regardless of whether the preamble is limiting here, Petitioner shows that Quintana discloses the subject matter of claim 1's preamble. Dr. Netland's testimony, as asserted by Petitioner, is credible and establishes that Quintana teaches, and even provides images of, a device (bent-tip needle) inserted into the anterior chamber of an eye, which then forms an opening in the trabecular meshwork, as claimed. Ex. 1003 ¶ 100 (discussing Quintana and its Figs. 1 and 2); *see also* Pet. 35–37 (citing and discussing Ex. 1003 ¶¶ 86, 88–90, which, in turn, discuss Quintana's Fig. 2).

After the preamble, 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 (emphasis added).

Petitioner asserts that Quintana's bent-tip needle extending from a syringe discloses an elongate probe with a longitudinal axis and distal portion, insertable into an eye's anterior chamber. Pet. 40 (citing Ex. 1004, 3–4, Fig. 1; Ex. 1003 ¶¶ 102–103). To illustrate this, Petitioner provides an annotated version of Quintana's Figure 1, and points to Quintana's Figure 2, which we reproduce side-by-side below:



Pet. 40 (citing Ex. 1004, Fig. 1; Ex. 1003 ¶ 102). Petitioner's annotated version of Quintana's Figure 1 is a partial view of the figure, showing the needle device being used in the "tangential" approach to the trabecular meshwork, and is labeled by Petitioner (and Dr. Netland) to identify the needle as an elongate probe, its longitudinal axis running lengthwise down the needle, and its distal portion as the needle's tip section shown at the tissue. *Id.* Figure 2 is discussed above at Section I.E, and shows the needle inserted into the anterior chamber of the eye.

Patent Owner presents no arguments directed to this part of claim 1 or Petitioner's assertions thereover. *See generally* Resp.

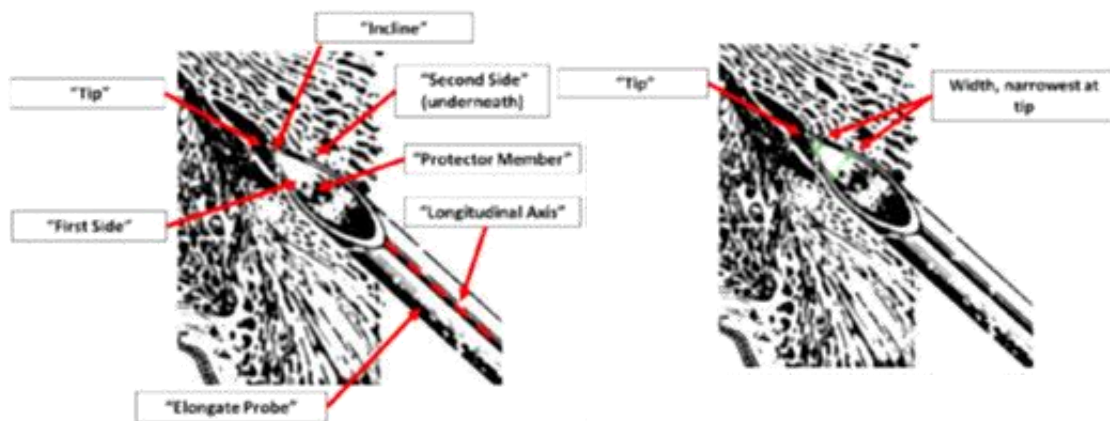
We find that Petitioner sufficiently shows that this claim limitation is met by Quintana's bent-tip needle, which has a longitudinal axis and a distal portion and is insertable into the anterior chamber of the eye, as shown in the reproduced figures above. Pet. 40; Ex. 1003 ¶¶ 102–103; Ex. 1004, 3–4, Figs. 1, 2.

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 (emphasis added).

Petitioner asserts that the convex, outside, side of the bent-tip needle device of Quintana is a disclosure of a *protector member* as claimed. Pet. 41–44 (citing Ex. 1001, 2:66–3:8, 9:18–23, 13:21–35, Figs. 5A, 5B; Ex. 1003 ¶¶ 104–109; Ex. 1004, 3–4, Fig. 1;). 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). For added clarity of its position, Petitioner provides the following two annotated versions (by Petitioner and Dr. Netland) of Quintana's Figure 1:



Pet. 42 (citing Ex. 1003 ¶ 105; Ex. 1004, Fig. 1). Petitioner’s first annotations to Quintana’s Figure 1 (above-left) label the needle to identify it as an elongate probe having a protector member at its tip region, and also identify the first side of the protector member as the side facing out of the plane of the drawing, which is the inside of the hypodermic needle’s tube where its opening is provided. *Id.* Petitioner labels this first side as having an incline from the needle’s tip up its beveled sides, which slopes upwardly (the needle gets larger in a cross-section) from the distal-most tip toward the proximal end of the needle where the handle/syringe would be. *Id.* at 41–42. Petitioner also labels the second side of the protector member, indicating it is the opposite side of the needle from the first side, which is the convex outer surface of the tip end of the needle facing into the plane of the drawing and facing the adjacent tissue (of Schlemm’s Canal). *Id.* Petitioner’s second annotations to Quintana’s Figure 1 (above-right) show that the distal end of the needle, i.e., the protector member, tapers to a point in a direction toward the tip. *Id.* at 43–44.

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 argues that Quintana does not disclose having a protector member because the reference does not indicate where its needle's tip is bent and because Quintana's needle's tip cannot be both a protector member and knife blades, also arguing that it would be the alleged knife blades that incline in Quintana's device rather than a protector member, according to Petitioner's assertions. Resp. 26–28 (citing Ex. 2019 ¶¶ 20, 22, 65–69).

We do not agree with Patent Owner's arguments and we agree with Petitioner that the evidence, as identified above and discussed below, supports its assertion that Quintana's disclosed needle has a "protector member," as claimed.

The '905 patent describes embodiments of its claimed "protector member" at, for example, Figures 2, 3F, and 5A–5B, and in use at Figure 4C. *See supra* Section I.E (discussing Quintana and reproducing Figures 3F and 4C). These figures show and the related disclosure of the '905 patent describes that the protector member, which the '905 patent labels as reference 24 or 54, is, for example, a convex outer surface of bent hypodermic tubing. *See* Ex. 1001, 8:33–40, 9:9–17, 12:4–9; *see also* Ex. 1003 ¶¶ 63–66, 104 (describing the '905 patent's "protector member"). The protector member's structure *may* be more complex than this, for example, it may be coated or insulated, but need not be. *See generally* Ex. 1001. We also note that, other than indicating that the protector member

has “a first side located adjacent to the cutting or ablating apparatus, and a second side located on a distal-most portion of the device,” the ’905 patent does not specify any structural relationship between the protector member and knife blades and no drawing of the patent shows these features together, or knife blades at all. *See, e.g., id.* at 8:60–9:17.

In view of the above, we agree with Petitioner’s assertions as to how Quintana teaches a protector member, as claimed, for example as shown in Petitioner’s annotated versions of Quintana Figure 1, above. We agree that Quintana’s bent-tip needle’s convex outer surface, which would face the Schlemm’s Canal tissue when used, is disclosed by the reference as specifically configured to have a protector member, as follows:

The needle penetrates the anterior chamber at 6 hours (right eye) or 12 hours (left eye) through the *scleral* side of the limbus; this is in order to run parallel to Schlemm’s canal. Penetration at 6 or 12 hours allows a *tangential* approach (Fig. 1) to the angle; this avoids the pupillary field and the convexity of the lens. Penetration is carried on under direct control, to avoid the prismatic effect of the goniolens. . . . The TM is incised with the tip of the needle. From now on, and ***with the concavity of the tip towards the surgeon, the trabeculotome is progressively introduced in the angle.*** Only the ***tip of the instrument is introduced into Schlemm’s canal, and the TM is stripped slowly, gently and easily from the canal’s lumen towards the anterior chamber as the needle progresses in the angle (Fig. 2).*** ***Since the convexity of the tip is facing the external wall of the canal, this structure is not damaged. This is why we bend the tip and we point it towards the anterior chamber.***

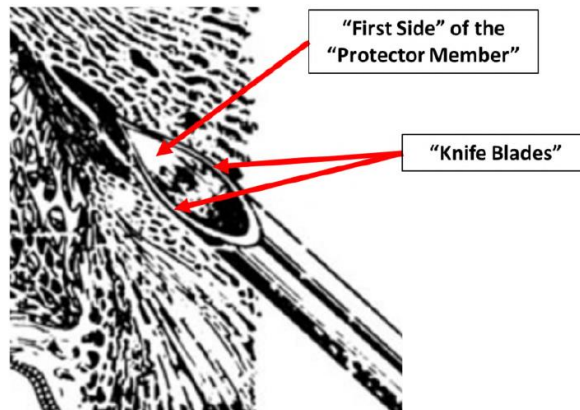
Ex. 1004, 4 (emphasis added). Patent Owner’s argument as to where the needle is bent is both incorrect and irrelevant because Quintana explicitly states that the needle is bent at “the tip” and no claim requires needle bending in any specific location—Quintana explicitly teaches that the

needle's *tip* is bent to provide the same protection to Schlemm's Canal as described in the '905 patent for its protector member. See Ex. 1004, 3; Ex. 1001, 3:20–38. As for Patent Owner's argument that the protector member cannot be structurally integrated with knife blades, on this the '905 patent is not explicit and there is no claim limitation requiring these elements to be structurally separate.

We find Petitioner's above-discussed assertions, and those of its witness, credible as to what parts of Quintana's device are a protector member as claimed and that the asserted protector member is shown to have all the elements required by the claim. See Pet. 41–44; Ex. 1001, 2:66–3:8, 8:33–40, 8:60–9:23, 12:4–9, 13:21–35, Figs. 2, 3F, 4C, 5A–5B; Ex. 1003 ¶¶ 63–66, 104–109; Ex. 1004, 3–4, Figs. 1, 2.

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 (emphasis added).

Petitioner asserts that Quintana's bent-tip needle has *knife blades* as claimed, because the opposite sides of the needle's beveled tip are cutting edges, which in use 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.* Petitioner provides the following annotated Quintana Figure 1 to highlight its points:



Pet. 45. Petitioner here annotates Quintana’s Figure 1 to label the sides of the needle’s beveled opening as knife blades, and illustrates their position with respect to the first side of the protector member, which is the inside of the hypodermic needle’s tube at its opening and adjacent the beveled sides. *Id.* Petitioner asserts that Quintana establishes these sides of its needle’s opening are for cutting and, so, are knife blades where the reference states “only the tip of the instrument is introduced into Schlemm’s canal, and the T[rabecular] M[eshwork] is stripped slowly, gently and easily from the canal’s lumen towards the anterior chamber as the needle progresses in the angle,” because, as the bent tip of the needle advances through the Schlemm’s Canal, the trabecular meshwork passes over the top surface of the needle’s tip and contacts the cutting edges, which cut strips of trabecular meshwork tissue. *Id.* at 45–46; *see also* Ex. 1004, 4.

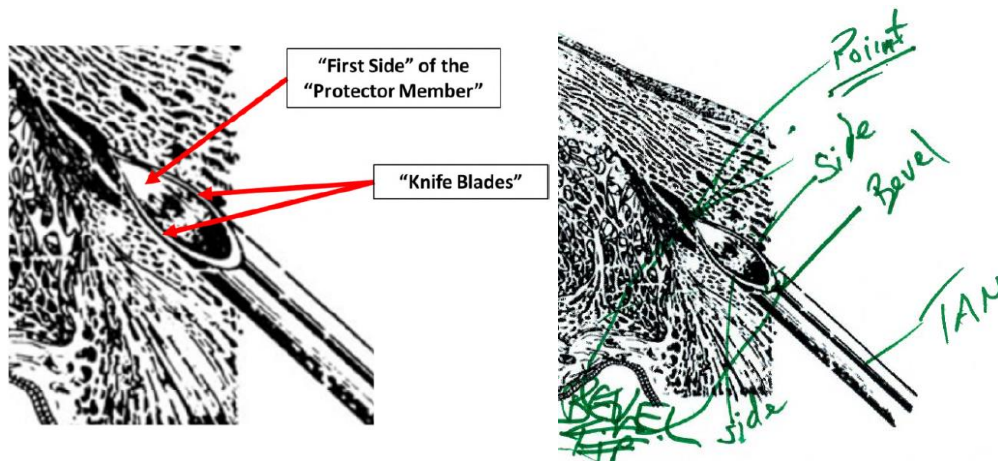
Patent Owner, at once acknowledging that “[t]he ‘tip of the needle’ is the operational element of the device used in the Quintana method,” goes on to argue that Quintana’s device does not have knife blades because the reference (1) does not precisely indicate where or along what axis the needle’s tip is bent, (2) Quintana is not explicit that the beveled edges of its

needle's tip are sharp, and (3) in any event, the beveled end of Quintana's needle can only be considered a single blade. Resp. 19–23 (citing Ex. 2019 ¶¶ 20–23, 27). Patent Owner also argues that Petitioner has not established that Quintana's needle's beveled tip's sides contact the trabecular meshwork in use or are configured so as to be spaced apart and cut a similarly wide strip of tissue. *Id.* at 24–25 (citing Ex. 2019 ¶¶ 41–42, 122–123).

We agree with Petitioner's above-discussed assertions and evidence regarding what parts of Quintana's device disclose the claimed knife blades and do not agree with Patent Owner's arguments, as discussed below.

As noted above, no claim of the '905 patent requires that a needle be bent in any certain location to be its claimed device; however, Quintana expressly states that the needle is bent at "the tip." Ex. 1004, 3. As to whether Quintana's needle's tip has one or two cutting surfaces that can be considered "a plurality of knife blades," we find the record supports that there are a plurality of knife blades.

Each party's witness appears to largely agree on how to generally classify the structural parts of Quintana's bent-tip needle, which is used for stripping trabecular meshwork, according to Quintana. *See supra* Section I.E (discussing Quintana); Ex. 1004, 4 ("Only the tip of the instrument is introduced into Schlemm's canal, and the TM is stripped slowly, gently and easily from the canal's lumen towards the anterior chamber as the needle progresses"). For context, we reproduce Dr. Netland's (Petitioner's witness) and Dr. Condon's (Patent Owner's witness) annotated versions of Quintana's Figure 1, side-by-side, below:



Dr. Netland's annotated Quintana Figure 1 is reproduced above at the left and (as discussed above) is annotated with textboxes and red arrows labeling the structural parts of the illustrated needle device. See Ex. 1003 ¶¶ 110–113. Dr. Condon's annotated Quintana Figure 1 is reproduced above at the right and is labeled (by him) in green to identify the same structures as he considered the figure during his deposition. Ex. 1043, 192; Ex. 1041, 3:17, 23:3–34:15. Dr. Netland's annotated Quintana's Figure 1 (immediately above as well above relating the previous clause of claim 1) labels the knife blades as the two sides defining the opening of the needle's beveled end, and also shows their relationship to the above-discussed protector member's first side. See Ex. 1003 ¶¶ 110–113. Dr. Netland's testimony is that this is the bladed device defined by the claims and that it is used in the manner claimed. *Id.* ¶¶ 81–88, 100–101, 110–113. Dr. Condon similarly labeled Quintana's Figure 1 as having a point, a bevel, *two sides* at the beveled end, and identified that this needle was illustrated being used in a tangential approach to the tissue. Ex. 1043, 192; Ex. 1041, 3:17, 23:3–34:15. Dr. Condon equivocated somewhat on whether what he labeled as the

“sides” of the beveled end were sharp. Ex. 1041, 34:7–15. Thus, the two witnesses agree, generally, on the structural parts of Quintana’s disclosed device and they also agree that the Quintana device is used to surgically remove trabecular meshwork in some way, with Dr. Netland opining that it is used to remove a strip of the trabecular meshwork and Dr. Condon characterizing the procedure as creating a slit and producing some spreading effect as the tip enters the meshwork. Ex. 1003 ¶¶ 121–130; Ex. 1041, 23:3–34:15.

We find Dr. Netland’s testimony credible and more persuasive than Dr. Condon’s. Dr. Netland’s testimony is supported by a plain reading of Quintana as clearly disclosing a needle, bent at the tip by 30°, having a distal end sharp enough to penetrate and incise trabecular meshwork and strip it away as the device is moved along Schlemm’s Canal, while also protecting the tissue of Schlemm’s Canal. Ex. 1004, 3–4. Further, the beveled ends of hypodermic needles, as disclosed by Quintana, are sharp and intended to cut tissue. *See, e.g.*, Hr’g Tr. 73:16 (Patent Owner acknowledging that a needle tip is sharp: “sharp and intended to cut tissue.”). The only open issue is whether the two sides of a hypodermic needle’s end (defining its opening), as disclosed by Quintana and confirmed by each party’s witness as having two sides (*see figures above*), are sufficiently sharp to form two cutting edges for the claimed *plurality of cutting blades*. We find there is ample evidence here that they are sharp.

Dr. Netland’s Second Declaration presents testimony confirming that a hypodermic needle, bent by 30° and used in a surgical procedure as disclosed by Quintana, has two sharp sides and cuts strips of trabecular meshwork having a generally regular width that generally matches the

distance between the needle's beveled sides. Ex. 1030 ¶¶ 7–26; Exs. 1031–1033 (videos of procedure); *see also* Reply (discussing Dr. Netland's Second Declaration). Dr. Netland testified to the similarities and necessary differences between experimental procedures he performed seeking to closely reproduce Quintana's techniques and the procedure taught by Quintana, *for example*, Dr. Netland used portions of cadaver eyes rather than live patients' eyes. Ex. 1030 ¶¶ 13–16. We find that, considering these similarities and differences, Dr. Netland's experiments are useful to show how a bent hypodermic needle's beveled end interacts with trabecular meshwork when used in a method as disclosed by Quintana.

Dr. Netland video recorded these procedures and the videos are a part of the record. Exs. 1031–1033; Ex. 1030 ¶ 19; *see also* Reply 1, 5, 13–15 (discussing this evidence).⁸ Dr. Netland provided annotated still screen shots of the videos of these procedures, which we reproduce below:

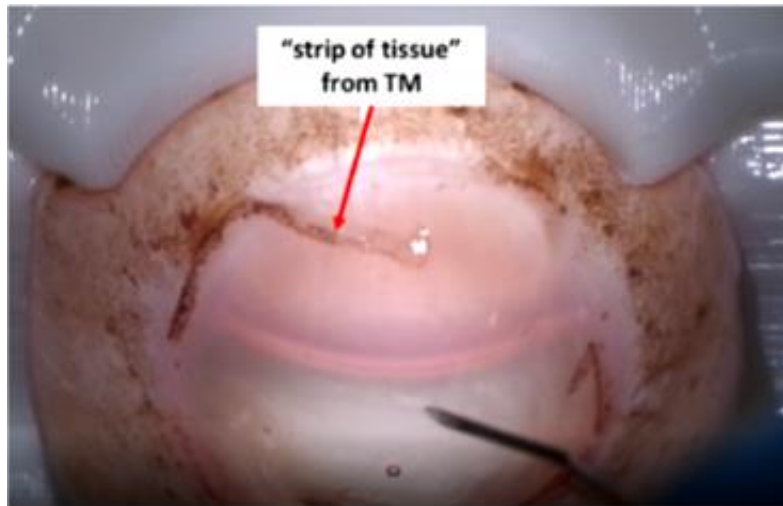


Figure 1

⁸ We note Patent Owner's objections to and arguments over this evidence, but are not persuaded for the reasons discussed in our Order. Sur-Reply 1–4; Order, 3–9 (denying Patent Owner's motion to exclude).

Figure 1 above is a still image from the video recording of Dr. Netland's Experiment 2 using a needle bent in the shaft proximal to the bevel. Ex. 1030 ¶ 20; Ex. 1031. Figure 1 above shows the tip of a needle in the lower right quadrant of the image, pointing towards its center (the side edges are visible as darker), and shows a strip of trabecular meshwork tissue (labeled) cut from the eye using the needle, which is approximately the same width as the needle's end. Ex. 1030 ¶¶ 20, 23–26.



Figure 2

Figure 2 above shows a second still image from another video recording of Dr. Netland's similar Experiment 3. Ex. 1030 ¶ 21; Ex. 1032. As in Figure 1, Figure 2 shows the tip of a bent needle in the lower right quadrant; its sides and width are discernable. Figure 2 also shows a strip of trabecular meshwork (TM) tissue cut away, i.e., stripped, using the needle. Ex. 1030

¶¶ 21, 23–26. The tissue strip has approximately the same width as the needle.

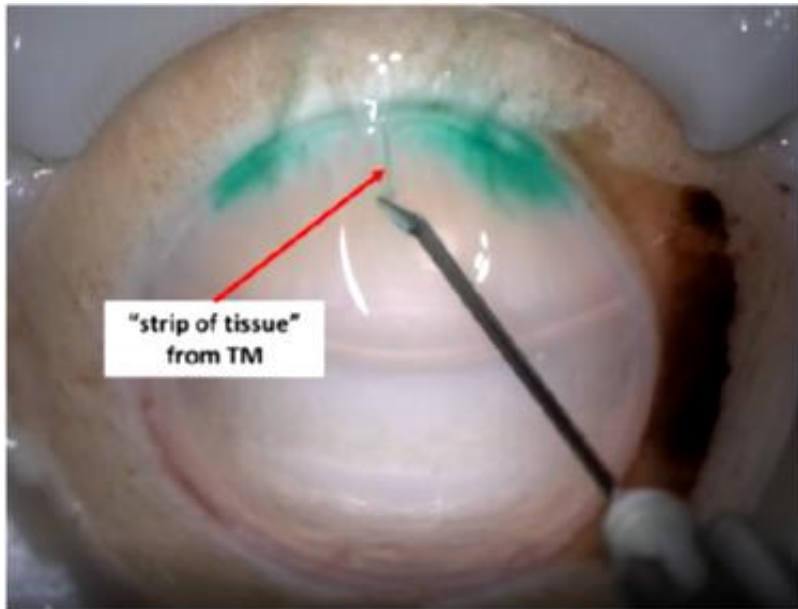


Figure 3

Figure 3 above is similar to Figures 1 and 2 and shows a strip of trabecular meshwork tissue approximately the width of the also-shown bent needle, cut away, i.e., stripped, from the eye using the needle, which is also visible in the figure as having two cutting edges.

This evidence supports Petitioner's, and its expert's, position that Quintana teaches a device (a bent-tip needle) having a plurality of (two) knife blades (sharp, cutting edges), that cut trabecular meshwork tissue as the tissue passes over that side of the bent-tip needle, as required by claim 1.

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 (emphasis added).

Petitioner asserts that Quintana's device is configured as claimed and is disclosed as being used to perform this claimed procedure. Pet. 39, 46–48 (citing Ex. 1004, 3–4, Figs. 1, 2; Ex. 1003 ¶¶ 88–90, 100, 101, 114–116).

Petitioner asserts that, as shown in Quintana's Figure 2, the surgeon advances the needle's tip laterally through Schlemm's Canal with its back-side "protector member" facing into the canal so that the trabecular meshwork passes over the front side of the needle's bent tip and over the inclined beveled edges where it is cut and stripped slowly from the canal's lumen. *Id.* at 47–48 (citing Ex. 1003 ¶¶ 88–90, 115–116; Ex. 1004, 3–4, Fig. 2).

Patent Owner argues that "Quintana does not disclose creating or removing a strip of [trabecular meshwork]." Resp. 11–19 (citing Ex. 2019 ¶¶ 19, 31–32, 34–35, 37–38). Under this argument, Patent Owner takes the positions that, although Quintana references stripping tissue, it also indicates its method achieves a "section of the trabecular meshwork," which means that only an incision is made and not a strip of tissue having any width is cut. *Id.* at 12–14. Patent Owner argues that the dictionary definition of "section" only invokes an incision. *Id.* (citing Ex. 2023, 605; Ex. 2024, 519). Patent Owner also argues that Quintana's term, "goniotrabeculotomy," for its procedure means it only incises tissue because the suffix "-otomy" indicates incising tissue, as opposed to the suffix "-ectomy," which would indicate excising tissue. *Id.* (citing Ex. 2019 ¶ 35). Finally, on this issue, Patent

Owner argues that Quintana merely teaches moving tissue away when it uses the term “stripped” or “stripping” regarding how its device interacts with trabecular meshwork. *Id.* at 15–16. We do not agree with these arguments.

We have concluded above that each preceding limitation of claim 1 was disclosed by Quintana and, collectively, the same evidence supports that Quintana also discloses the elements of this final clause of claim 1. We again quote a key passage of Quintana:

The ***needle penetrates the anterior chamber*** at 6 hours (right eye) or 12 hours (left eye) through the *scleral* side of the limbus; this is in order ***to run parallel to Schlemm’s canal***. Penetration at 6 or 12 hours allows a *tangential* approach (Fig. 1) to the angle; this avoids the pupillary field and the convexity of the lens. Penetration is carried on under direct control, to avoid the prismatic effect of the goniolens. Once the needle is in the anterior chamber, the goniolens is inserted, held with the surgeon’s left hand. A drop of “healon” is a good wetting agent between cornea and goniolens. The ***TM is incised with the tip of the needle***. From now on, and with ***the concavity of the tip towards the surgeon, the trabeculotome is progressively introduced in the angle***. Only ***the tip of the instrument is introduced into Schlemm’s canal***, and ***the TM is stripped slowly, gently and easily from the canal’s lumen towards the anterior chamber as the needle progresses in the angle*** (Fig. 2). ***Since the convexity of the tip is facing the external wall of the canal, this structure is not damaged. This is why we bend the tip and we point it towards the anterior chamber.***

Ex. 1004, 4 (emphasis added); see also Ex. 1003 ¶¶ 82–88, 114–116 (Dr. Netland testifying on this same subject matter). Dr. Netland’s opinion is that “Quintana’s procedure would without question have resulted in cutting ‘strips of tissue’ from the T[rebacular] M[eshwork]” and his experimental evidence, discussed above, demonstrates and establishes that he is correct. Ex. 1003 ¶¶ 88, 116; Ex. 1030 ¶¶ 7–26; Exs. 1031–1033 (the

still images captured from Exhibits 1031–1033, above, are quite persuasive, but still not as convincing as the videos themselves that Quintana’s device and technique teach the claimed subject matter).

In summary, we conclude Petitioner has shown and the evidence supports that Quintana teaches each element of claim 1 and anticipates the claim.

b. Dependent Claim 2

Petitioner asserts that claim 2 would have been obvious over Quintana. Pet. 50–52.

Claim 2, like each dependent claim, depends directly from claim 1; it recites “*wherein the knife blades are operative to cut a strip of tissue having a width from 50 μ m to 200 μ m, from the trabecular meshwork.*” Ex. 1001, 14:39–41 (emphasis added).

Noting initially that Quintana discloses the limitations of claim 1, Petitioner asserts that the reference also would have rendered claim 2 obvious because Quintana’s needle has a width/diameter of 0.4 mm (400 μ m), which defines the width between the cutting edges of the bent-tip needle in use, and although this is “slightly larger than the claimed range, a POSITA would have found it obvious to modify Quintana’s needle to produce strips between 50 and 200 μ m” because “use of a needle with a smaller diameter would involve simple substitution of one known element for another to obtain predictable results.” Pet. 50–51 (citing Ex. 1003 ¶¶ 126–129; Ex. 1004, 3). Petitioner asserts this needle substitution in Quintana’s device is a mere change in size, which would provide no patentable significance here and would not result in a different product. *Id.*

at 51–52 (citing *Gardner v. TEC, Syst., Inc.*, 725 F.2d 1338, 1349 (Fed. Cir. 1984); *In re Dillon*, 919 F.2d 688, 697–98 (Fed. Cir. 1990)).

Patent Owner argues that the ordinarily skilled artisan would not have been motivated to modify Quintana’s needle as asserted by Petitioner to make it narrower. Resp. 30 (citing Ex. 2019 ¶ 92). Further, Patent Owner argues that some undisclosed source taught away from so modifying Quintana’s device because there would have been a fear of reducing the effectiveness of the device and increasing injury risks. *Id.* We do not agree with Patent Owner’s arguments.

We agree with Petitioner’s assertions. Quintana discloses its needle to be “a 0.4 x 15 mm needle, or an insulin[]-type needle.” Ex. 1004, 3; *see also* Ex. 1003 ¶¶ 82, 102, 105, 108, 111, 125–127 (discussing the same). Thus, Quintana discloses using any sized insulin needle and its needle is not limited to only the specific 0.4 mm diameter. Dr. Netland testifies that “[p]ersons of ordinary skill in the art reviewing Quintana would have appreciated that needles of different size could be used to perform Quintana’s procedure and that it was common to modify surgical instruments based on the needs of the particular procedure being performed or the specific patient.” Ex. 1003 ¶ 127; *see also* Ex. 1007, 2 (Jacobi’s scraper has a diameter of 300 µm, i.e., smaller than 0.4 mm).

“‘[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.’ *Aller*, 220 F.2d at 456. [However,] [t]his rule is limited to cases in which the optimized variable is a ‘result-effective variable.’ *In re Antonie*, 559 F.2d 618, 620 (CCPA 1977).” *In re Applied Materials, Inc.*, 692 F.3d 1289, 1295 (Fed. Cir. 2012). On this issue, Dr. Netland also

testifies that the ordinarily skilled artisan would have known that the width of the device's cutting tip dictates the width of the strips of tissue that it cuts, thus, to produce strips of tissue 50–200 μm wide, the ordinarily skilled artisan would have known to adjust the width of the cutting tip. Ex. 1003 ¶ 128. Thus, Dr. Netland's testimony establishes that needle width is a result-effective, optimizable variable that can be tuned to cut resultant, similarly sized strips of tissue, as desired.

Patent Owner identifies no critical benefit to the range of tissue strip widths cut from trabecular meshwork and cites no evidence that supports there is actually any teaching away from selecting Quintana's needle width to cut 50–200 μm strips of tissue. See Resp. 30. In fact, the '905 patent indicates that cutting such sized strips of trabecular meshwork was routine in goniotomy procedures, stating in its Background Section that, "[i]n 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." Ex. 1001, 1:18–45. The obviousness analysis "can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *KSR*, 550 U.S. at 418. "A person of ordinary skill is also a person of ordinary creativity, not an automaton." *Id.* at 421. Petitioner asserts and Dr. Netland testifies that such ordinarily creative persons of ordinary skill in the art would have found it obvious to modify Quintana's needle by simply substituting another of a smaller size and, thus, produce the claimed range of stripped tissue. Pet. 51; Ex. 1003 ¶¶ 127–129.

"[W]hen the difference between the claimed invention and the prior art is the range or value of a particular variable," then a patent should not issue if "the difference in range or value is minor." *Iron Grip Barbell Co.*,

Inc. v. USA Sports, Inc., 392 F.3d 1317, 1322 (Fed. Cir. 2004) (quoting *Haynes Int'l v. Jessop Steel Co.*, 8 F.3d 1573, 1577 n. 3 (Fed. Cir. 1993)). Here, there is no persuasive evidence of teaching away from the claimed range and there is no evidence of unexpected results to support non-obviousness. *Id.* We find the balance of evidence here, as discussed above, supports Petitioner's position and find claim 2 would have been obvious over Quintana from the perspective of the ordinarily skilled artisan.

c. Dependent Claim 3

Petitioner asserts that claim 3 is anticipated by Quintana. Pet. 48–49.

Claim 3 depends from claim 1 and recites its device “*further comprising an irrigation lumen.*” Ex. 1001, 14:42–43 (emphasis added).

Noting again that Quintana discloses the limitations of claim 1, Petitioner asserts that Quintana discloses the claimed irrigation lumen because Quintana discloses its device is a needle inserted into a syringe filled with healon fluid, which *is* an irrigation lumen when the healon is injected during the disclosed procedure, as taught by Quintana. Pet. 48–49 (citing Ex. 1003 ¶ 118; Ex. 1004, 3–4, Fig. 1).

Patent Owner argues that the ordinarily skilled artisan would not have had motivation to add an irrigation lumen, aspiration lumen, or both, to Quintana's device (thus covering the subject matter of claims 3, 4, and 5) because there would be no reason to clear debris during Quintana's procedure. Resp. 30–31 (citing Ex. 2019 ¶¶ 96, 100). As with claim 2, Patent Owner similarly argues that such modification of Quintana's device was taught away from by some unidentified source for fear of reducing the effectiveness of the device and increasing risks of injury. *Id.*

We agree with Petitioner’s assertions and do not agree with Patent Owner’s arguments. Quintana very clearly discloses its device has an irrigation lumen in stating “[t]he needle is inserted into a syringe filled with ‘healon’” and “[h]ealon can be injected at will at any time if the surgeon wants to deepen the angle.” Ex. 1004, 3–4; *see also* Ex. 1003 ¶ 118 (testifying that Quintana’s needle is a lumen for injecting healon). Patent Owner’s arguments are not persuasive because whether there is motivation to have an irrigation lumen is irrelevant as it is disclosed by Quintana (and, we also note, there is no supporting evidence of any teaching away from having such a lumen).

d. Dependent Claim 4

Petitioner asserts that claim 4 would have been obvious over Quintana. Pet. 52.

Claim 4 depends from independent claim 1 and recites its device “*further comprising an aspiration lumen.*” Ex. 1001, 14:44–45 (emphasis added).

Noting again that Quintana discloses the limitations of claim 1, Petitioner asserts that in the relevant field in 2003, incorporating an aspiration lumen in eye surgery devices, like the device taught by Quintana, for aspirating fluid and debris was well known and it would have been obvious to the ordinarily skilled artisan to include such a feature. Pet. 52 (citing Ex. 1003 ¶ 131; Ex. 1007, 2). Petitioner asserts that the motivation for including such an aspiration lumen was that

It was known that leaving strips of tissue and debris within the eye could have negative implications such as the formation of scar tissue and blocking the aqueous outflow system, and thus incorporating an aspiration lumen for aspirating fluid and debris

from the eye would have been obvious to a POSITA to prevent these known issues.

Id. Petitioner further asserts that, regarding this modification, the ordinarily skilled artisan would have had a reasonable expectation of success because it would amount to “nothing more than combining prior art elements according to known methods . . . based on similar devices and techniques in the prior art,” like Jacobi, for example. *Id.*; *see also* Ex. 1003 ¶¶ 98, 131, 134, 164 (Dr. Netland discussing Jacobi’s example of a prior art irrigation-aspiration lumen); Ex. 1007, 2 (disclosing an irrigation-aspiration probe).

The same arguments by Patent Owner noted above for claim 3 also apply to claim 4. They are unpersuasive.

The evidence supports Petitioner’s assertion that there would be advantages, e.g., removal of debris caused by surgery, to including an aspiration lumen in a device such as Quintana’s bent-tip needle, and that such features were known in the art as of the ’905 patent. Pet. 52; Ex. 1003 ¶¶ 98, 131, 134, 164; *see also* Ex. 1011, 55 (Textbook of Glaucoma by Shields, published in 1988, also discloses that, in surgery of the anterior chamber angle, an irrigation-aspiration device for removal of material from the trabecular meshwork was described, known, and used); *see also* Ex. 1016, 2:25–38 (discloses that removing strips of tissue after using a trabeculotome to open the trabecular meshwork was known and preferred even as early as 1982). To the contrary, there is no persuasive evidentiary support for Patent Owner’s argument that such removal of surgery debris would be unwanted or that there was some teaching away from including an aspiration lumen in a device as taught by Quintana. *See generally* Resp.

For the reasons above, we find Petitioner establishes by a preponderance of the evidence that claim 4 would have been obvious over Quintana.

e. Dependent Claim 5

Petitioner asserts that claim 5 would have been obvious over Quintana. Pet. 53.

Claim 5 depends from independent claim 1 and combines the subject matter of claims 3 and 4, reciting its device “*further comprising an irrigation lumen and an aspiration lumen.*” Ex. 1001, 14:46–47 (emphasis added).

Noting again that Quintana discloses the limitations of claim 1, Petitioner asserts that, for the same reasons Quintana taught an irrigation lumen in its device and that it would have been obvious to the ordinarily skilled artisan to include an aspiration lumen in the device, including both would also be obvious to the ordinarily skilled artisan. Pet. 53 (citing, *inter alia*, Ex. 1003 ¶¶ 133–134).

The same arguments by Patent Owner noted above for claim 3 also apply to claim 5. They remain unpersuasive.

We find that Petitioner establishes that claim 5 would have been obvious over Quintana for the same reasons claim 3 is anticipated and claim 4 would have been obvious over Quintana, as discussed above.

f. Dependent Claim 6

Petitioner asserts that claim 6 is anticipated by Quintana. Pet. 49.

Claim 6 depends from independent claim 1 and recites “*wherein the second side of the protector member is configured so as not to damage*

tissues adjacent thereto as the protector member is advanced through Schle[m]m's Canal.” Ex. 1001, 14:48–51 (emphasis added).

Noting again that Quintana discloses the limitations of claim 1, Petitioner asserts that Quintana discloses its “trabecul[o]tome is inserted into S[chlemm's] C[anal] oriented such that ‘the **convexity of the tip is facing the external wall of the canal**’” so that “**this structure is not damaged**” and that “the convex, outer portion of the needle tip includes the second side of the protector member,” as claimed. Pet. 49 (citing Ex. 1003 ¶ 120; Ex. 1004, 3–4). Thus, it is Petitioner's assertion that the outer, convex surface of Quintana's bent-tip needle is so configured to prevent damage to tissue as it is used in the fashion claimed. *Id.*

Patent Owner presents no new arguments not addressed above regarding claim 6 and Petitioner's assertions thereover.

Claim 6 adds no significant subject matter that has not already been addressed above regarding claim 1. As discussed above, Quintana states:

The TM is incised with the tip of the needle. From now on, and with the concavity of the tip *towards* the surgeon, the trabeculotome is **progressively introduced in the angle**. Only the tip of the instrument is introduced into Schlemm's canal, and the TM is stripped slowly, gently and easily from the canal's lumen towards the anterior chamber as the needle progresses in the angle (Fig. 2). **Since the convexity of the tip is facing the external wall of the canal, this structure is not damaged. This is why we bend the tip and we point it towards the anterior chamber.**

Ex. 1004, 4 (emphasis added). As discussed above, the outer side of Quintana's needle's tip that faces Schlemm's Canal in use is the second side of the protector member and the above passage confirms that it is configured so as not to damage tissues adjacent thereto as the protector member is

advanced through Schlemm's Canal, in the same way as claimed. *See, e.g.*, Ex. 1003 ¶ 120.

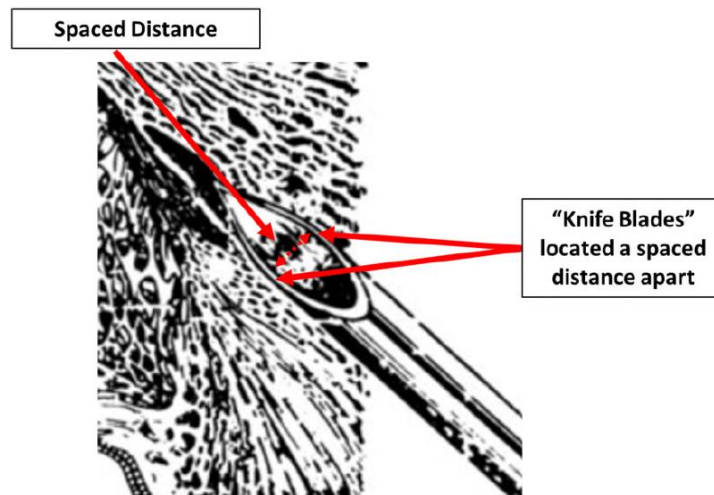
Petitioner establishes by a preponderance of the evidence that claim 6 is anticipated by Quintana.

g. Dependent Claim 7

Petitioner asserts that claim 7 is anticipated by Quintana. Pet. 49–50.

Claim 7 depends from independent claim 1 and recites “*wherein said knife blades are located a spaced distance apart to cut a strip of tissue the width of which is substantially equal to the distance between the first and second knife blades.*” Ex. 1001, 14:52–55 (emphasis added).

Noting again that Quintana discloses the limitations of claim 1, Petitioner asserts that “Quintana’s trabecul[o]tome has ‘knife blades’ on opposite sides of the needle which concurrently cut T[rabecular] M[eshwork] to produce strips” of that tissue, and that, as shown in Quintana’s figure 1, as annotated by Petitioner and Dr. Netland, the strips of tissue cut are as wide as the width between the side edges of Quintana’s needle’s opening:



Pet. 49–50; Ex. 1004, Fig. 1 (annotated by petitioner); *see also* Ex. 1003 ¶ 122 (same figure annotated by Dr. Netland). The figure shows a partial view of Quintana’s Figure 1 labeled to show knife blades as spaced-apart features. Petitioner asserts that this figure evidences Quintana’s needle’s tip has an opening defined by two sides that constitute “knife blades” (so labeled above), and that they are separated by spaced distance defined by that opening (also labeled above). Pet. 50. Petitioner asserts that “[t]he strip of tissue created when the cutting edges cut T[rebecular] M[eshwork] tissue would necessarily have a width that is ‘substantially equal’ to the distance between the cutting edges, as these cutting edges concurrently cut the T[rabecular] M[eshwork] tissue to achieve a strip of tissue that would have a width corresponding to the distance between the cutting edges.” *Id.* at 50 (citing Ex. 1003 ¶ 123).

Patent Owner presents no new arguments regarding claim 7 and Petitioner’s assertions thereover not already addressed above.

Claim 7 includes limitations substantially similar to features addressed above regarding claim 1. As discussed above, Dr. Netland both opined and then demonstrated by experimental evidence that Quintana’s disclosed knife blades are spaced apart and cut a strip of tissue substantially the width of the distance between the first and second knife blades, as claimed. Pet. 39, 46–50; Ex. 1003 ¶¶ 88–90, 100, 101, 114–116, 122–123; Ex. 1004, 3–4, Figs. 1, 2; Ex. 1030 ¶¶ 7–26; Exs. 1031–1033.

We conclude that Petitioner proves by a preponderance of the evidence that claim 7 is anticipated by Quintana.

*h. Summary of Petitioner’s Challenges Under
Grounds 2 and 3*

As discussed and for the reasons set forth above, reflecting the positions taken and evidence cited in the Petition, claims 1–7 would have been anticipated and obvious under 35 U.S.C. §§ 102 and 103 over Quintana as asserted by Petitioner.

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. Petitioner asserts, *inter alia*, that Jacobi discloses an *ab interno* procedure, much the same as the above-discussed goniotomy of Quintana, but called “goniocurettage” by Jacobi, which uses an instrument very similar to the bent needle of Quintana, called a “gonioscraper,” to peel off strings of trabecular tissue to treat glaucoma. *Id.* at 53–69 (citing, *inter alia*, Ex. 1002, 423; Ex. 1003 ¶¶ 94–97, 136–144, 146–153, 155–158, 160–162, 164, 166, 168, 170–171; Ex. 1006, 4:38–48, Figs. 2–3; Ex. 1007, 1–2, Figs. 1, 2; Ex. 1023, 320).

We have discussed Petitioner’s Grounds 1 and 2 above and concluded that claims 1–7 (all claims) of the ’905 patent are unpatentable over Quintana as anticipated and obvious. Therefore, we do not address the merits of or reach a conclusion on patentability for Petitioner’s Ground 3 in view of Jacobi.

III. CONCLUSION⁹

Having considered the evidentiary record before us and the parties' respective positions on the grounds asserted in the Petition, we find that Petitioner shows that claims 1–7 would have been anticipated by and obvious over Quintana. Therefore, Petitioner proves by a preponderance of the evidence that claims 1–7 of the '905 patent are unpatentable in view of the cited prior art.

In summary:

Claims	35 U.S.C. §¹⁰	References	Claims Shown Unpatentable	Claims <u>Not</u> Shown Unpatentable
1, 3, 6, 7	102	Quintana	1, 3, 6, 7	
2, 4, 5	103	Quintana	2, 4, 5	
1–7	103	Jacobi		
Overall Outcome			1–7	

⁹ Should Patent Owner wish to pursue amendment of the challenged claims in a reissue or reexamination proceeding subsequent to the issuance of this decision, we draw Patent Owner's attention to the April 2019 *Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding*. See 84 Fed. Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. See 37 C.F.R. § 42.8(a)(3), (b)(2).

¹⁰ As noted above, the ground for unpatentability based on the Jacobi reference is not reached because all claims are found to be unpatentable as anticipated by and obvious over Quintana.

ORDER

Accordingly, it is hereby:

ORDERED that Petitioner has demonstrated by a preponderance of the evidence that claims 1–7 of the '905 patent are unpatentable; and

FURTHER ORDERED that, because this is a Final Written Decision, parties to this proceeding seeking judicial review of our Decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

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