

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NEW WORLD MEDICAL, INC.,
Petitioner,

v.

THE REGENTS OF THE UNIVERSITY OF CALIFORNIA,
Patent Owner.

IPR2021-00066
Patent 9,999,544 B2

Before JAMES A. WORTH, ROBERT A. POLLOCK, and
DEVON ZASTROW NEWMAN, *Administrative Patent Judges*.

POLLOCK, *Administrative Patent Judge*.

FINAL WRITTEN DECISION

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

I. INTRODUCTION

This is a Final Written Decision in an *inter partes* review challenging the patentability of claims 1–11 of U.S. Patent 9,999,544 B2 (“the ’544 patent,” Ex. 1001). We have jurisdiction under 35 U.S.C. § 6.

Petitioner has the burden of proving unpatentability of a claim by a preponderance of the evidence. 35 U.S.C. § 316(e) (2018). Having reviewed the arguments of the parties and the supporting evidence, we find that Petitioner has demonstrated by a preponderance of the evidence that the challenged claims are unpatentable.

A. Procedural Background

New World Medical, Inc., (“Petitioner”) filed a Petition for an *inter partes* review of claims 1–11 of the ’544 patent. Paper 1 (“Pet.”). The Regents of the University of California (“Patent Owner”) filed a Preliminary Response. Paper 9 (“Prelim. PO Resp.”).¹ In view of the then-available, preliminary record, we concluded that Petitioner satisfied the burden, under 35 U.S.C. § 314(a), to show that there was a reasonable likelihood that Petitioner would prevail with respect to at least one of the challenged claims. Accordingly, on behalf of the Director (37 C.F.R. § 42.4(a) (2018)), and in accordance with *SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348, 1353 (2018) and the Office’s Guidance on the Impact of SAS on AIA Trial Proceedings (Apr.

¹ Papers filed in this proceeding also refer to Petitioner and Patent Owner, by the abbreviations “NWM” and “Regents” respectively. *See, e.g.*, Pet. ix, Prelim. PO Resp. 1. We apply those abbreviations as convenient.

26, 2018) (“Guidance”).² we instituted an *inter partes* review of claims 1–11 on all the asserted grounds. Paper 10 (“Inst. Dec.”), 36.

After institution, Patent Owner filed a Response to the Petition. Paper 17 (“PO Resp.”). Petitioner filed a Reply to Patent Owner’s Response (Paper 25, “Reply”) and Patent Owner filed a respective Sur-reply (Paper 32, “Sur-reply”).

Patent Owner filed a motion to exclude evidence (Paper 38); Petitioner opposed (Paper 41); and Patent Owner filed a reply in support of its motion (Paper 43). Petitioner also filed a motion to exclude evidence (Paper 39); Patent Owner opposed (Paper 40); and Petitioner filed a reply in support of its motion (Paper 42). We addressed (and denied) the parties’ motions to exclude in Paper 49.

On January 10, 2022, the parties presented arguments at oral hearing, the transcript of which is of record. Paper 48 (“Tr.”).

B. Party Identification of Real Parties-in-Interest

Petitioner identifies itself, New World Medical, Inc., as the sole real party-in-interest. Pet. ix.

Patent Owner, The Regents of the University of California, identifies “MicroSurgical Technology, Inc.” (abbreviated as “MST”) as a real party-in-interest. Paper 5.

C. Related Matters

According to Petitioner, Patent Owner and MST (collectively “Plaintiffs”) filed a complaint asserting infringement of U.S. Patent 9,999,544 (“the ‘544 patent”) (Ex.1001) against NWM in the U.S. District Court for the

² <https://www.uspto.gov/patents-application-process/patent-trial-and-appeal-board/trials/guidance-impact-sas-aia-trial>.

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 10,123,905 (“the ‘905 patent”), against NWM in that case. NWM was served with the complaint on August 5, 2020.

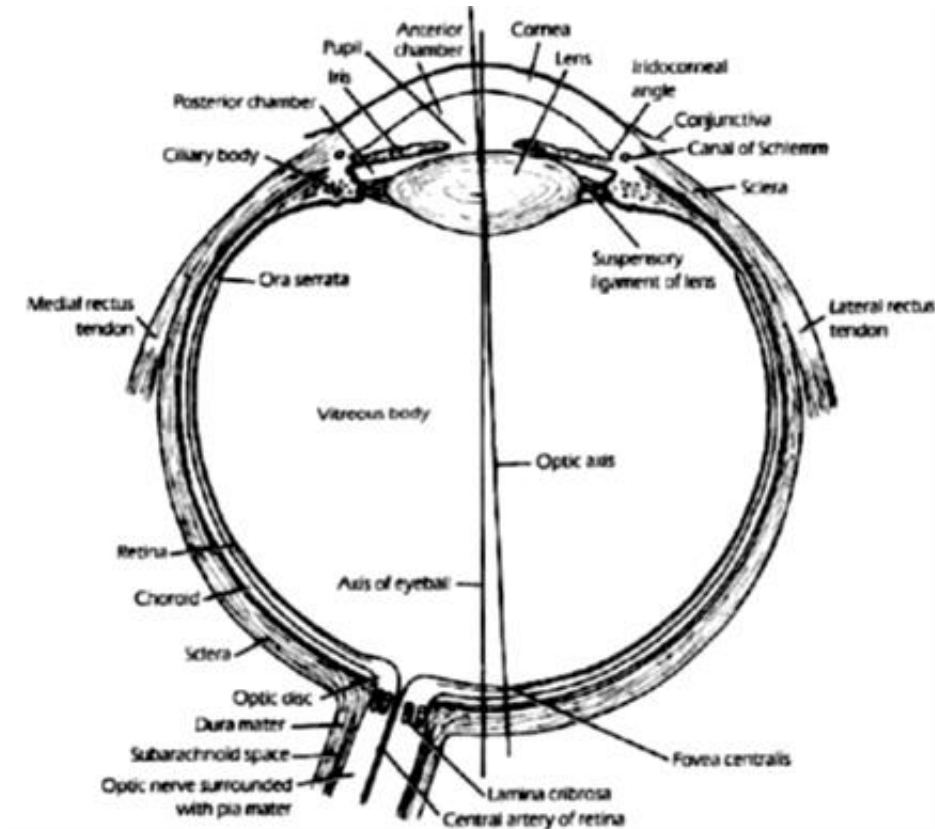
Pet. ix. Patent Owner identifies the same case in the District of Delaware as a related matter, but indicates that the recited patents are “unrelated” with respect to priority. Paper 5. In addition to the ’544 patent at issue here, NWM has challenged claims of the “unrelated” ’729, ’155, ’855, and ’905 patents in IPR2020-01573, -01711, IPR2021-00017, and -00065, respectively. *See* Pet. ix; Prelim. PO Resp. 1–2 n.1; Paper 5. The final hearing consolidated oral arguments for this and each of these other *inter partes* review proceedings. Tr. 1, 3:3–12.

D. The ’544 Patent and Relevant Background

The ’544 patent issued to George Baerveldt and Roy Chuck on June 19, 2018, from a series of continuation applications ultimately claiming priority to U.S. Provisional Application 60/263,617, filed on January 18, 2001. Ex. 1001, codes (45), (21), (22), (60), (63). Petitioner does not challenge this chain of priority. *See* Pet. 22. We presume, without further analysis, that the ’544 patent is entitled to a priority date of January 18, 2001.

The ’544 patent relates generally to surgical methods and devices for treating glaucoma, a degenerative condition of the eye. *See generally*, Ex. 1001, Title, Abstract, 1:48–53. For context as to the ’544 patent’s disclosed and claimed invention, we provide the following background on the structure of the human eye. Reproduced below is a cross-section, labeled

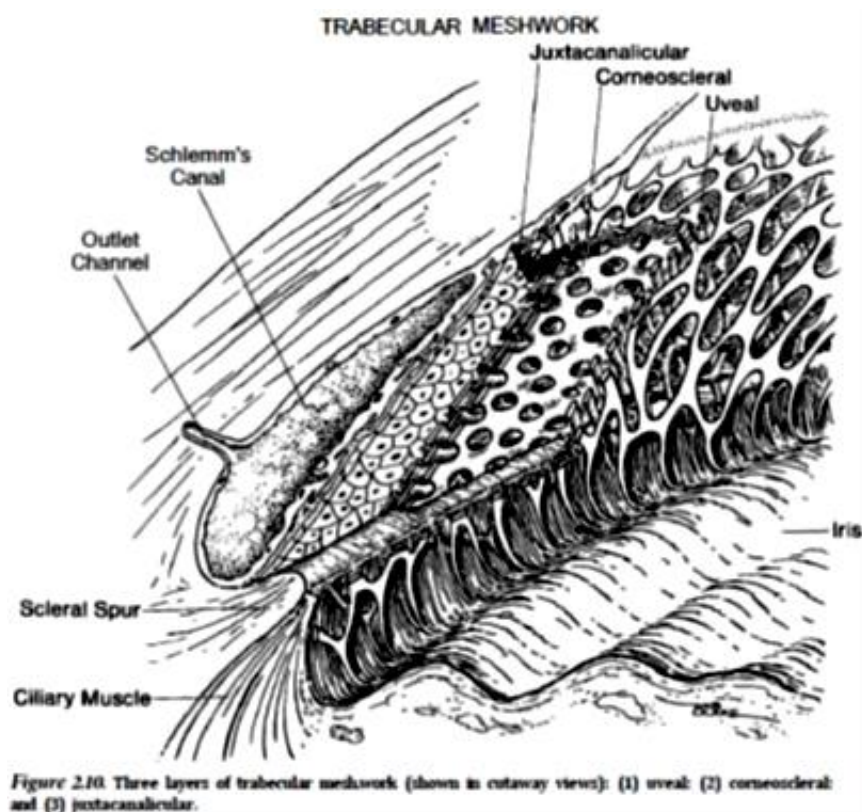
illustration of a human eye, excerpted from the First Declaration of Petitioner's witness, Dr. Peter Netland.



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 many anatomical features of a human eye, including of note (from top of the figure to bottom, i.e., anterior to posterior), a cornea defining an anterior chamber (“AC”) 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 ¶¶ 34–37. 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; immediately above the ciliary body, and adjacent to the iris, the Canal of Schlemm (Schlemm's Canal) is shown and labeled. *Id.*

The '544 patent relates more specifically to treatment of the trabecular meshwork and Schlemm's Canal, which normally drain excess aqueous humor from the posterior chamber of the eye. *See, e.g.*, Ex. 1001, 4:46–61; Ex. 1003 ¶ 39. Dr. Netland's First Declaration provides an illustration of these features in the higher magnification illustration of an eye, reproduced 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). Ex. 1003 ¶ 39. As described in the above figure itself, it shows three layers of trabecular meshwork (uveal, corneoscleral, and juxtacanalicular) adjacent to and in contact with the iris, scleral spur, and ciliary muscle, and in front of Schlemm's Canal. *Id.* Dr. Netland further explains that increased resistance to aqueous humor outflow across the trabecular meshwork-Schlemm's Canal system results in elevated intraocular pressure—"one of the primary risk factors for the development and progression of glaucoma." *Id.* ¶ 41.

According to the '544 Specification, glaucoma causes "progressive atrophy of the optic nerve head leading to visual field loss, and ultimately, blindness. Glaucoma is generally associated with elevated intraocular pressure, which is an important risk factor for visual field loss because it causes further damage to optic nerve fibers." *Id.* at 1:48–53; *see also* Ex. 1003 ¶¶ 42–44. In the most prevalent type of glaucoma, primary open angle glaucoma, "aqueous humor drainage is impaired through obstruction of the trabecular meshwork." Ex. 1001, 1:64–2:1.

The '544 patent describes "a surgical instrument and minimally invasive surgical method to remove at least a portion of the trabecular meshwork of the eye, providing for aqueous drainage in the treatment of glaucoma." *Id.* at 4:46–49; *see id.* at 1:22–26. Such procedures are generally referred to as "goniotomy"³ and, "goniectomy" or "excisional goniotomy,"

³ The art generally distinguishes "goniotomy" from "goniectomy." *See e.g.*, Ex. 1007, 302 (defining incisional surgery of the eye as "goniotomy"); Ex. 1006 (disclosing "goniectomy instrument" for "removing tissue from the anterior chamber angle of the eye"); *see also* Ex. 2021, 88:21–89:14 (Dr. Netland's testimony that, when used accurately, goniotomy refers to an incision in eye tissue, whereas goniectomy involves "some excision of tissue or removal of tissue").

as they involve visualizing the operation using a “goniolens.” See Pet. 14–18 (further discussing history and practice of goniotomy (involving at least a slit-like incision in the trabecular meshwork) and “excisional” goniotomy or goniectionomy (involving removal of trabecular meshwork tissue)); Ex. 1003 ¶¶ 51–59 (same).

The Specification discloses a surgical instrument used to perform a goniectionomy “by removing a portion of the trabecular meshwork consisting of the pigmented trabecular meshwork, allowing free access of aqueous [humor] from the anterior chamber through to the scleral portion of Schlemm’s canal that contains the endothelial cells and most importantly the collector channels that lead back to the episcleral venous system.” Ex. 1001, 5:6–13. The instrument may also allow for fluid infusion and aspiration systems to remove ablated tissue and debris during surgery. *Id.* at 4:57–66. An aspiration system “may be directly linked to either a cutting mechanism, such as a guillotine cutting machine, laser probe, a piezo-electric crystal producing sonic or ultrasonic energy, or cautery element. These modalities are capable of substantially complete tissue removal by mechanical means, cautery, vaporization, or other tissue destruction techniques.” *Id.* at 4:66–5:5.

In a preferred embodiment, the surgical instrument or “goniectionomy cauterization probe” illustrated in Figure 7, is inserted

through a small corneal incision transcamerally under direct visualization to ablate the trabecular meshwork. The instrument may include a foot plate, such that the instrument can penetrate the trabecular meshwork into Schlemm’s canal. The footplate may also act as a protective device for the endothelial cells and collector channels lining the scleral wall of Schlemm’s canal.

Id. at 4:50–58. Figure 7 of the Specification is reproduced below.

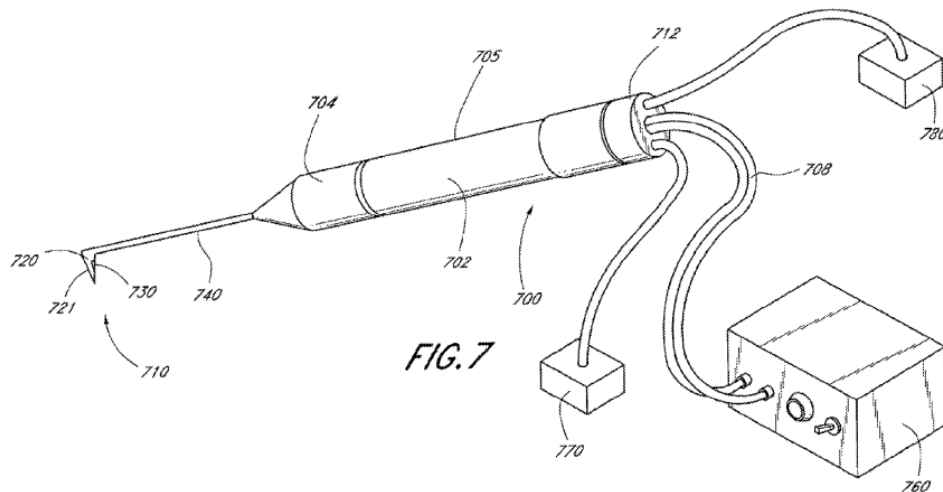


Figure 7 is a perspective view of the gonnectomy cautery probe discussed above. *Id.* at 5:44–45. The device includes “probe tip 710 . . . connected to the main body of the handle 705. The probe tip further comprises a footplate 721, which protects the collector channels, penetrates the trabecular meshwork, and serves as a guide in Schlemm’s canal.” *Id.* at 9:24–27.

Figure 18 of the Specification is reproduced below.

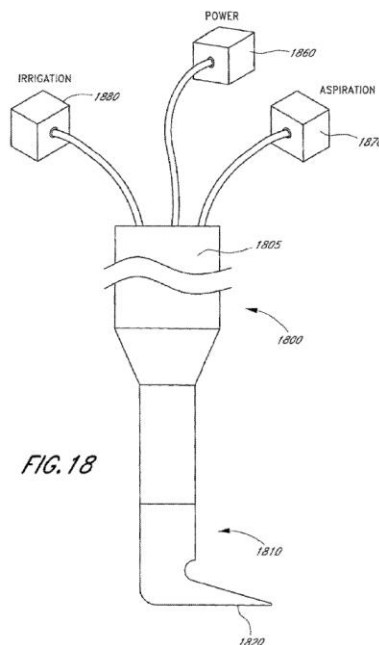


Figure 18 is a partial, perspective view of another preferred embodiment described as “a goniotomy cutting probe, used to cut and remove trabecular meshwork.” *Id.* at 6:14–15, 13:43–45. Figure 18 highlights probe tip 1810, including footplate 1820. *Id.* at 13:53–54. According to the Specification, the footplate “protect[s] endothelial cells and collector channels lining the scleral wall of Schlemm’s canal . . . [F]ootplate . . . serves as a guide in Schlemm’s canal” and “[t]he sharpened end of the footplate is used to penetrate the trabecular meshwork.” *Id.* at 13:54–58.

E. Challenged Claims

Petitioner challenges all 11 claims of the ’544 patent, which are reproduced in Petitioner’s Claim Appendix with added paragraphing and paragraph numbering. Pet. 4, Claims Appendix, 1. Independent claim 1, from which claims 2–7 depend, recites:

[1.p] A device useable to create an opening in the trabecular meshwork of the eye comprising:

[1.a] an elongate surgical instrument comprising a probe shaft having a distal end and a longitudinal axis; and

[1.b] a foot member which comprises a platform on the distal end of the probe shaft, said platform having a tip, an upper side, a lower side and being set at an angle relative to the longitudinal axis of the probe shaft;

[1.c] wherein the foot member is insertable, tip first, from a position within the anterior chamber, through the trabecular meshwork, and into Schlemm’s Canal such that the lower side is next to the scleral wall of Schlemm’s Canal and the upper side is next to the trabecular meshwork; and

[1.d] wherein, after being so inserted in Schlemm’s Canal, the foot member is then advancable [sic], tip first, through Schlemm’s Canal to facilitate performance of a surgical procedure using the surgical instrument.

Ex. 1001, 23:4–20 (paragraphing and numbering as added in Petitioner’s Claims Appendix). Claim 8, from which claims 9–11 depend, is a method claim involving the use of the “a device according to any of claims 1 through 7.” *Id.* at 24:6–24. In particular, claim 8 recites:

[8.p] A method for performing a surgical procedure within the eye of a subject, said method comprising the steps of:

[8.a] A) obtaining or providing a device according to any of claims 1 through 7;

[8.b] B) forming an opening into the anterior chamber of the eye;

[8.c] C) inserting the surgical instrument, distal end first, through the opening and into the anterior chamber of the eye;

[8.d] D) inserting the foot member, tip first, from a position within the anterior chamber, through the trabecular meshwork, and into Schlemm’s Canal such that the lower side is next to the scleral wall of Schlemm’s Canal and the upper side is next to the trabecular meshwork; and, thereafter,

[8.e] E) advancing the foot member through Schlemm’s Canal to facilitate performance of the surgical procedure using the surgical instrument.

Id. (paragraphing and numbering as added in Petitioner’s Claims Appendix).

F. Asserted Grounds of Unpatentability

Petitioner asserts three grounds of unpatentability (Pet. 4):

Ground	Claim(s) Challenged	35 U.S.C. §	References/Basis
1	1–11	102 ⁴	Quintana ⁵
2	1–11	103	Quintana, Knowledge of a Person of Ordinary Skill in the Art
3	1–11	103	Jacobi, ⁶ Knowledge of a Person of Ordinary Skill in the Art

With respect to Petitioner’s reliance on the knowledge of a person of ordinary skill in the art in its summary of Grounds 2 and 3, we note that an analysis of whether claims would have been obvious and whether it would have been obvious to combine or modify prior art, must *always* be from the perspective of one of ordinary skill in the art and in view of the knowledge generally available to the skilled artisan. *See KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007) (one must often consider “the background

⁴ The Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) (“AIA”), amended 35 U.S.C. §§ 102 and 103. Because the challenged claims of the ’544 patent have an effective filing date before the effective date of the applicable AIA amendments, we refer to the pre-AIA versions of 35 U.S.C. § 103 throughout this Decision. Whether pre-AIA or the AIA version of the statute applies is not determinative of our decision in this case.

⁵ Manuel Quintana, *Gonioscopic Trabeculotomy. First Results* in DOCUMENTA OPHTHALMOLOGICA PROCEEDINGS SERIES 43, SECOND EUROPEAN GLAUCOMA SYMPOSIUM 255–71 (E.L. Greve et al. eds. 1985) (Ex. 1004). We refer to the numbers at the lower right-hand corners of each page that appear to have been added by Petitioner.

⁶ Philipp C. Jacobi et al., *Technique of gonioscurettage: a potential treatment for advanced chronic open angle glaucoma*, 81 BRIT. J. OPHTHALMOLOGY 302–07 (1997) (Ex. 1007). As with Quintana, we refer herein to the non-original pagination added to the lower right-hand corners of each page.

knowledge possessed by a person having ordinary skill in the art”). Because “knowledge of a person of ordinary skill in the art” is always a consideration, and not an independent basis for an obviousness challenge, Petitioner’s express recitations of “knowledge of a person of ordinary skill in the art” in its summaries of Grounds 2 and 3, collapse into obviousness in view of Quintana and Jacobi, respectively.

In addition to Petitioner’s reliance on Quintana and Jacobi, Petitioner further relies, *inter alia*, on two Declarations of Dr. Peter Netland. Ex. 1003 (“First Netland Declaration”); Ex. 1030 (“Second Netland Declaration”). Considering the record before us, 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 Ex. 1003 ¶¶ 1–17, 24, 32–61, (Dr. Netland’s statements as to his background and qualifications, definition of the person of ordinary skill in the art, background on the relevant technology, and professional history), Appendix A (*curriculum vitae*).

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 39, “Pet. Mot.”) and, although that motion was denied (Paper 49, “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 and analyze Dr. Condon's testimony here.

G. Overview of Quintana, Jacobi, and Lee

Grounds 1–3 expressly rely on Quintana or Jacobi. Pet. 4. Although not part of any recited Ground, Petitioner cites extensively to the teachings of Lee⁷ in its Background Technology section and with respect to certain dependent claims. See Pet. 3, 7–9, 15, 59, 80. We consider such citations indicative of the knowledge of one of ordinary skill in the art. Accordingly, we review Quintana, Jacobi, and Lee, below.

1. Quintana (Ex. 1004)

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

According to Quintana, “[i]ncreased resistance to the outflow of aqueous through the trabecular meshwork is the most accepted pathogenic mechanism in the majority of open angle glaucomas (‘trabecular glaucomas’). Thus, the rational treatment of the trabecular glaucomas should consist in opening the trabecular meshwork (TM).” Ex. 1004, 3. To treat this type of glaucoma, 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.” *Id.*

Quintana describes that, with the assistance of a goniolens, a bent “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.” *Id.* at 3–4. Quintana’s Figure 1, reproduced below, compares the application of the bent-needle device using this

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

“tangential approach” (right-hand side), with “the perpendicular approach as in classic goniotomy or goniotrabeculotomy” (left-hand side). *Id.* at 4.

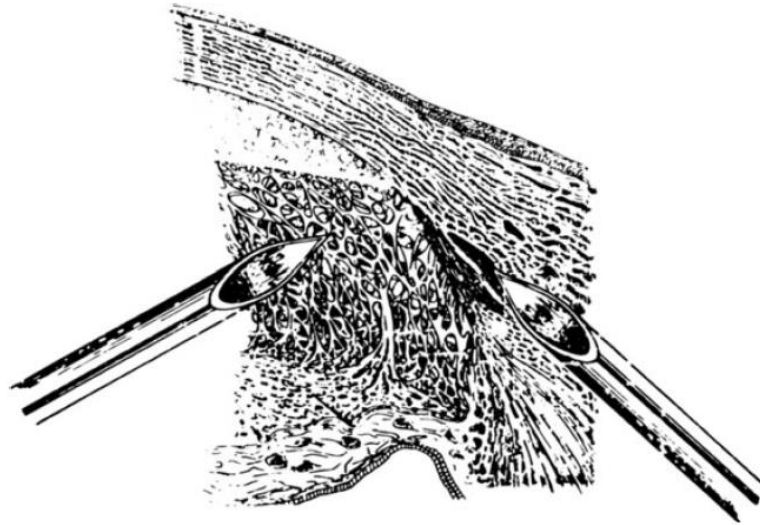


Fig. 1. Schematic drawing comparing the tangential approach to the perpendicular approach as in classic goniotomy or goniotrabeculotomy.

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” (described by Quintana as “a good wetting agent between cornea and goniolens”). Ex. 1004, 3–4. The right-hand side of 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 anterior chamber so as to not cause damage. *Id.* at 4. With this procedure, “100-120° trabeculotomy can be achieved. Healon can be injected at will at any time if the surgeon wants to deepen the angle. There is usually no chamber loss, but if this is the case, healon is injected.” *Id.*

Figure 2 of Quintana, reproduced below, is a photograph of the procedure showing the tip of the needle in operation.

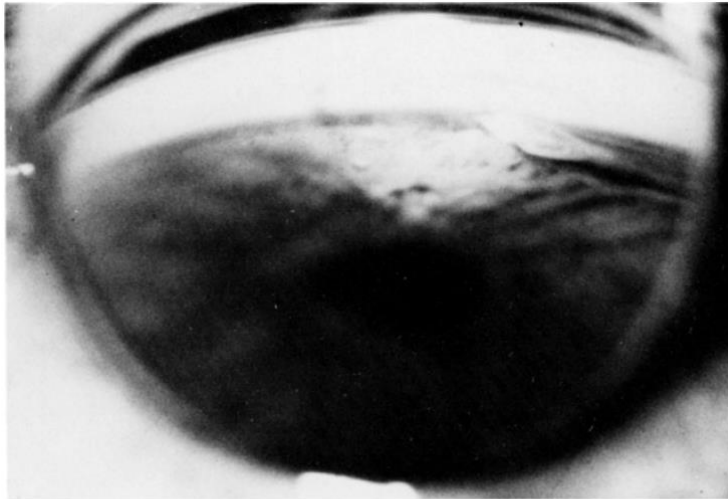


Fig. 2. Goniophotography at operation. The tip of the needle stripping the trabecular meshwork.

Id. at 5. Figure 2 shows the tip of the bent needle instrument introduced in 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 to the edge of the image) and the trabecular network being stripped away "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' behaviour of the sectioned trabecular meshwork." *Id.* at 8.

2. Jacobi (Ex. 1007)

Jacobi was published in 1997. Ex. 1007, 1. Jacobi is prior art to the claims of the '729 patent under 35 U.S.C. § 102(b); Patent Owner does not argue otherwise. *See generally* PO Resp.

Jacobi discloses a procedure for a “[g]onioscopically controlled ab interno abrasion of the trabecular meshwork” using an instrument “designed to scrape pathologically altered trabecular meshwork from the scleral sulcus as a potential treatment in primary open angle glaucoma.” Ex. 1007, 1. This device, designated a “gonioscraper,” is shown in Figure 1, reproduced below:



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

Id. at 2. Jacobi explains that the gonioscraper as shown in Figure 1,

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 μ m 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 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).

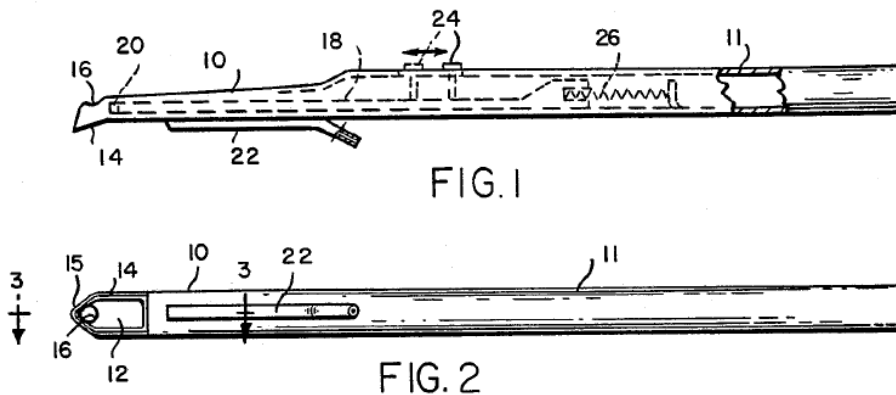
Id. Figure 2 shows the gonioscraper device inserted into an eye, performing the gonioscurettage procedure. *Id.*

3. Lee (Ex. 1006)

Lee issued as U.S. Patent on February 13, 1990, from U.S. Application 315,190, which was filed February 24, 1989, and claims priority to U.S. Application 70,325, which was filed July 6, 1987. Ex. 1006, codes (45), (21), (22), (63). Lee is prior art to the claims of the '729 patent under 35 U.S.C. § 102(b); Patent Owner does not argue otherwise. *See generally* PO Resp.

Lee is directed to “the design and application of a goniotomy instrument for the purpose of diagnostically and therapeutically removing tissue from the anterior chamber angle of the eye and for retrieving this tissue for further examination.” Ex. 1006, Abstract. Lee’s surgical instrument comprises “a hollow, tapered shaft having a cutting edge at one end as an integral part thereof; a retractable stylet contained within the hollow interior of the tapered shaft; and an irrigation port running along the outside of the tapered shaft.” *Id.* Lee describes this instrument as “useful for excising tissue to relieve an obstruction blocking the outflow of aqueous humor from the eye as well as for providing specimens of the excised tissue for histopathological examination.” *Id.*

Lee illustrates such an instrument in Figures 1 and 2, which are reproduced below:

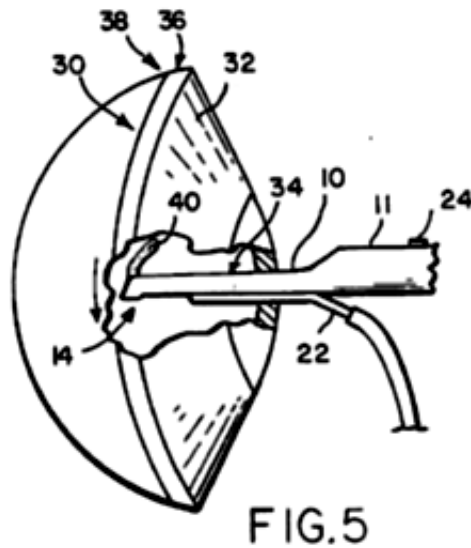


“FIG. 1 is a schematic side view of the surgical instrument of this invention” and “FIG. 2 is a schematic bottom view of the surgical instrument of this invention.” *Id.* at 3:62–65. Lee states that Figures 1 and 2 show “the surgical instrument” having “a more or less cylindrical hollow shaft 10[,] which is tapered from a larger diameter at the handle end 11 to a smaller diameter at the forward cutting end,” which is about 0.5 to 2 mm in diameter. *Id.* at 4:18–27. The tip end’s taper is 5–15 degrees. *Id.* at 4:32–33.

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

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

Lee provides a drawing of such a procedure at Figure 5, which we reproduce below:



Lee states that “FIG. 5 is a schematic side view of an eyeball with the surgical instrument of this invention in place and ready to begin cutting and removing a tissue segment from the trabecular meshwork.” *Id.* at 4:3–6. Figure 5 shows an eyeball with cornea 30, iris 32, anterior chamber 34, trabecular meshwork 36, and Schwalbe’s line 38, and an instrument having shaft 10, handle 11, cutting edge 14, irrigation port 22, and lever 24 in the process of surgically removing tissue segment 40. *Id.* at 5:1–65. More specifically, Lee discloses the surgical process includes placing a gonioscope over the cornea, forming an incision into the anterior chamber through the cornea, introducing the goniotomy instrument into the anterior chamber through that incision under constant irrigation to maintain anterior chamber fluid level, using cutting edge 14 to excise the angle tissue 40 for approximately one-third of the angle circumference as the cutting edge 14 is advanced (the excised tissue is guided through aperture 16 or into hollow shaft 10 as cutting edge 14 is advanced), and the excised tissue 40 is removed by the instrument when it is withdrawn from the anterior chamber. *Id.* at 6:3–62.

II. ANALYSIS ON THE MERITS

A. Legal Standards

“In an [*inter partes* review], 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) (2012) (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).

To show anticipation under 35 U.S.C. § 102, each and every claim element, arranged as in the claim, must be found in a single prior art reference. *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359 (Fed. Cir. 2008). The prior art need not, however, use the same words as the claims to find anticipation. *In re Gleave*, 560 F.3d 1331, 1334 (Fed. Cir. 2009). In evaluating anticipation, it is permissible to take into account not only the literal teachings of the prior art reference, but also 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).

A claim is unpatentable under 35 U.S.C. § 103(a) if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which that subject matter pertains. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) objective evidence of nonobviousness, if any. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

In analyzing the obviousness of a combination of prior art elements, it can be important to identify a reason that would have prompted one of skill in the art “to combine . . . known elements in the fashion claimed by the patent at issue.” *KSR*, 550 U.S. at 418. A precise teaching directed to the specific subject matter of a challenged claim is not necessary to establish obviousness. *Id.* Rather, “any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed.” *Id.* at 420.

Accordingly, a party that petitions the Board for a determination of unpatentability based on obviousness must show that “a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so.” *In re Magnum Oil Tools Int’l, Ltd.*, 829 F.3d 1364, 1381 (Fed. Cir. 2016) (internal quotations omitted).

We address Petitioner’s challenges with these standards in mind, and in view of the definition of the skilled artisan and the claim constructions discussed below.

B. Level of Ordinary Skill in the Art

In determining the level of skill in the art, we consider the type of problems encountered in the art, the prior art solutions to those problems, the rapidity with which innovations are made, the sophistication of the technology, and the educational level of active workers in the field. *Custom Accessories, Inc. v. Jeffrey-Allan Indus. Inc.*, 807 F.2d 955, 962 (Fed. Cir. 1986); *Orthopedic Equip. Co. v. United States*, 702 F.2d 1005, 1011 (Fed. Cir. 1983).

Petitioner contends that a person of ordinary skill in the art would have possessed:

(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.

Pet. 22 (citing Ex. 1003 ¶ 24). On page 18 of our Institution Decision, we provisionally accepted Petitioner’s proposed definition, which was not

opposed by Patent Owner, and is consistent with the level of skill in the art reflected in the prior art of record and the disclosure of the '544 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)). As Patent Owner expressly agrees with our analysis, we apply Petitioner’s proposed definition here. See PO Resp. 11, n.4.

C. Claim Construction

We interpret a claim “using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. § 282(b).” 37 C.F.R. § 42.100(b). Under this standard, we construe the claim “in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent.” *Id.* We address, below, Petitioner’s proposed construction of “[a] device useable to create an opening in the trabecular meshwork of the eye” and “*ab interno*.” See Pet. 23–26.

1. “A device useable to create an opening in the trabecular meshwork of the eye”

Independent claim 1 is directed to “[a] device useable to create an opening in the trabecular meshwork of the eye” and having a “foot member . . . advanceable, tip first, through Schlemm’s Canal to facilitate performance of a surgical procedure using the surgical instrument.” Ex. 1001, 23:4–5, 23:18–20. As an initial matter, we consider the preamble of claim 1 limiting here because a device that “create[s] an opening in the trabecular meshwork” recites or, at a minimum, implies, “essential structure

or steps” required for the insertion and advancement of the instrument through Schlemm’s Canal as set forth in [1.d]. See *Catalina Mktg. Int’l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002).⁸

With respect to the claimed “device,” Petitioner asserts that it is well known to use “static-mechanical cutting devices” (e.g., knife blades) to create such openings in the trabecular meshwork but, nonetheless, argues that we should limit the cutting mechanism of the device to (1) tissue ablating mechanisms (e.g., laser or micro-cautery) and (2) dynamic-mechanical mechanisms (e.g., guillotine or rotating blade devices) because only the latter two types of mechanism are recited in the Specification. Pet. 23–26 (citing, e.g., Ex. 1001, 4:67–5:5, 8:52–9:53, 13:43–14:21, 15:10–17, 14:43–15:9, 15:17–49, 17:34–48, Figs. 7–27, 29–35). Patent Owner correctly points out that the ’544 patent provides “no particularized definition[.]” for this term, and argues that we should apply the plain and ordinary meaning. PO Resp. 11.

In seeking this narrow construction, Petitioner references infringement allegations in the parallel district court proceeding involving the stationary cutting components of its accused device. Pet. 25. But, with respect to *this* proceeding, Petitioner asserts that the claims are unpatentable under either construction. *Id.* at 25–26. As such, and on the record before us, the limiting construction advocated by Petitioner is not necessary to our Decision, and such analysis would not be helpful in understanding the record before us. See *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d

⁸ Because Petitioner has, by a preponderance of the evidence, identified the preamble elements in Quintana, the outcome of this proceeding does not depend on whether the preamble is limiting. See section II.D.2, below.

1013, 1017 (Fed. Cir. 2017) (“[W]e need only construe terms ‘that are in controversy, and only to the extent necessary to resolve the controversy.’” (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999))). Accordingly, we apply the ordinary meaning to “[a] device useable to create an opening in the trabecular meshwork of the eye.”

2. “*ab interno*”

Claim 4 defines the surgical instrument of claim 1 as “useable to perform an ab interno procedure to form an opening in the trabecular network.” Ex. 1001, 23:27–29. Relying on the testimony of Dr. Netland, Petitioner states that one of ordinary skill in the art “would understand ‘ab interno’ to mean **from the inside** and ‘ab externo’ to mean **from the outside**” and, as used in the context of the ’544 patent, “specify whether target tissue was being approached from inside the eye (‘ab interno’) or outside of eye (‘ab externo’). Pet. 26 (citing Ex. 1003 ¶ 79). Petitioner further proposes that the claimed “ab interno procedure” more particularly indicates an approach to the trabecular meshwork from within the anterior chamber of the eye. *Id.* (citing Ex. 1001, 5:6–26, 13:1–5; Ex. 1003 ¶¶ 79, 83). Petitioner then contrasts this usage with an “ab externo” procedure that “approaches the [trabecular meshwork] through an opening on the **outside** of the eye.” *Id.* (citing Ex. 1003 ¶¶ 80–82); *see also* Tr. 53:17–22 (Petitioner adopting the Board’s understanding of *ab interno* as “from the inside”).

Patent Owner argues that the ’544 patent provides “no particularized definition[]” for this term, and that the plain and ordinary meaning should apply. PO Resp. 11. In this respect, Dr. Condon agrees with Dr. Netland’s testimony that

[t]he term ‘ab interno’ [] and the related term ‘ab externo’ had common, well-understood meanings to persons of ordinary skill

in the art at the time of filing of the '544 patent. Persons of ordinary skill in the art would have understood the term 'ab interno' to generally mean **from the inside** and would have understood the term 'ab externo' to generally mean **from the outside**.

Ex. 2019 ¶ 43 (quoting Ex. 1003 ¶ 79).

We agree with Patent Owner that the '544 patent does not expressly assign a special meaning to the term "ab interno." Ex. 1001. The evidence of record, however, indicates that "ab interno" is a well-understood term of art in the ophthalmological field and consistent with Petitioner's use of the term. *See, e.g.*, Ex. 1003 ¶ 79; Ex. 2019 ¶ 43; Ex. 1007, 1, 5, Fig 2; Ex. 1013, 1,⁹ Fig. 2; Ex. 1018, 1¹⁰; Ex. 1020, 1¹¹. We find that the record before us supports that the person of ordinary skill in the art would have understood this term (as evidenced by each party's witness's use of the term consistent with "from the inside") and that it needs no special interpretation in this proceeding.

D. Anticipation by Quintana (Ground 1)

As Ground 1, Petitioner challenges claims 1–11 as anticipated by Quintana. Pet. 27–52. Petitioner's challenge includes a detailed mapping of the teachings of Quintana to each limitation of the claims. *Id.* at 36–52 (citing *e.g.*, Ex. 1003 ¶¶ 106–146). Patent Owner opposes. PO Resp. 12–34; Sur-reply 7–20. We address below Patent Owner's arguments with respect to

⁹ Philipp C. Jacobi et al., *Perspectives in trabecular surgery*, 14 EYE, 519–30 (2000).

¹⁰ E. Ferrari et al., *Ab-interno trabeculo-canalectomy: surgical approach and histological examination*, 12 Eur. J. Ophthalmology 401–05 (2002).

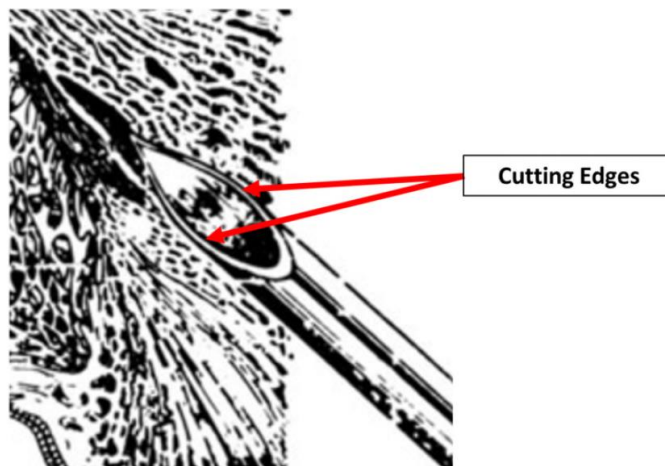
¹¹ Thomas Shute et al., *A Novel Technique for Ab Interno Trabeculectomy: Description of Procedure and Preliminary Results*, Am. Glaucoma Soc. 29th Ann. Meeting Poster Abstracts 34–35 (2019).

representative claims, beginning with independent claim 1 and applying Petitioner's paragraphing convention as convenient. See Section I.F, above.

1. Claim 1

[1.p] “A *device useable to create an opening in the trabecular meshwork of the eye comprising*”

With respect to [1.p], Petitioner refers to an annotated version of Quintana's Figure 1, reproduced below.



The above figure shows the right-hand portion of Quintana's Figure 1 as annotated on page 36 of the Petition. Pet. 36 (citing Ex. 1004, Fig. 1). Relying on the testimony of Dr. Netland, Petitioner contends that the illustration discloses “two stationary cutting edges (*i.e.*, knife blades) on opposite sides of the needle tube.” *Id.* (citing Ex. 1003 ¶ 107). According to Dr. Netland:

As Quintana's needle is manually advanced through Schlemm's Canal by a surgeon, trabecular meshwork tissue comes into contact with the end of Quintana's needle and specifically, spaced-apart edges fixed on opposite sides of the end of Quintana's needle. These edges act as cutting blades that contact the trabecular meshwork as the needle is advanced through Schlemm's Canal and concurrently cut the trabecular meshwork to excise a strip of trabecular meshwork tissue.

Ex. 1003 ¶ 107. Petitioner concludes that “under a broad interpretation of the claims in which the claimed devices can create openings in the [trabecular meshwork] using cutting elements beyond those disclosed in the ‘544 patent (*e.g.*, stationary cutting elements/blades) . . . Quintana discloses this limitation.” Pet. 37 (citing Ex. 1003 ¶ 107).

Patent Owner responds that “Quintana never mentions creating or removing a strip of trabecular meshwork (‘TM’), and therefore, does not create an opening in the TM of the eye” as required by the preamble to claim 1. PO Resp. 1–2, 18–30. Patent Owner bases this argument on Petitioner’s reference to “two stationary cutting edges (*i.e.*, knife blades)” that excise a strip of trabecular meshwork tissue. *See id.* at 2, n.1, 18–19; Pet. 36; Ex. 1003 ¶ 107. Yet as Patent Owner admits, the claims of the ‘544 patent “neither recite removing a strip of [trabecular meshwork] from a patient’s eye, nor any particular mechanism for doing so (such as by cutting edges or knife blades).” PO Resp. 2, n.1. We are not persuaded by Patent Owner’s argument.

Here, Petitioner points to Quintana’s Figures 1 and 2 as support for the preamble language. Pet. 36–37. We agree that Figure 1, for example, unambiguously shows Quintana’s needle creating an opening in the trabecular meshwork of the eye. *See* section I.G.1, above, Ex. 1004, 4, Fig. 1. Moreover, in explaining this procedure, Quintana states that “[t]he [trabecular meshwork] is incised with the tip of the needle,” and using this technique, “100-120° trabeculotomy can be achieved.” Ex. 1004, 4.

Consistent with the clear teaching of the reference, Petitioner asserts “***there is no dispute that [Quintana’s] procedure creates an opening in the [trabecular meshwork]***” as required by the preamble of claim 1. *See* Sur-

reply 10 (citing e.g., Dr. Condon’s testimony that “Quintana . . . is a tech designed to create an opening in the trabecular . . . meshwork of the eye”); Reply 10 (“[T]here is no dispute that Quintana describes a hand-bent standard hypodermic needle using only the tip to incise the [trabecular meshwork]”). As such, we are persuaded that that Quintana discloses a “device useable to create an opening in the trabecular meshwork of the eye,” as set forth in claim 1.

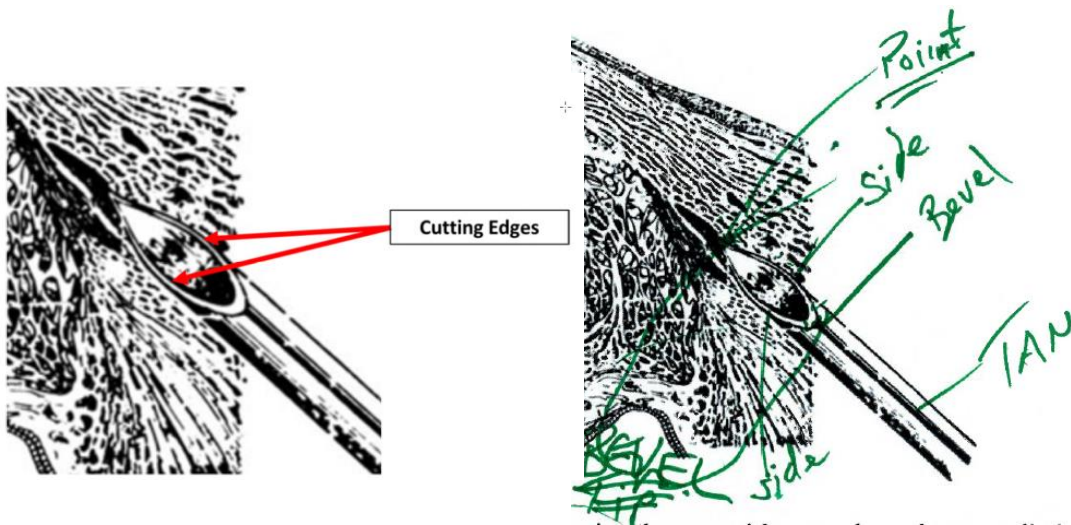
Given the above, it is irrelevant whether Petitioner correctly characterized *the mechanism* by which Quintana creates this opening. To the extent this mechanism is relevant, we are, nevertheless, persuaded that the “edges [of Quintana’s needle] act as cutting blades that contact the trabecular meshwork as the needle is advanced through Schlemm’s Canal and concurrently cut the trabecular meshwork to excise a strip of trabecular meshwork tissue.” See Ex. 1003 ¶ 107.

As an initial matter, a plain reading of Quintana’s disclosure that “[o]nly 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,” informs one of ordinary skill in the art that the beveled edges of the needle cut and remove a strip of trabecular meshwork tissue. See Ex. 1004, 4; see also *id.* at 8 (“[f]urther studies are necessary to disclose the ‘in vivo’ behaviour of the sectioned trabecular meshwork”), caption to Figure 2 (“[t]he tip of the needle stripping the trabecular meshwork”); see also, Ex. 1030 ¶¶ 7–10 (Dr. Netland discussing Quintana from the perspective of one of ordinary skill in the art).

The record further supports that the two sides of a hypodermic needle’s end are sufficiently sharp so as to form “two stationary cutting

edges,” and remove a strip of trabecular meshwork tissue. In this respect, each party’s witness appears to largely agree on how to classify the structural parts of Quintana’s bent needle, which is used for “stripping” trabecular meshwork, according to Quintana. *See supra* Section I.G.1 (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 . . .”).

We reproduce, below, two annotated versions of Quintana’s Figure 1.



The above panels show two versions of Quintana’s Figure 1. The left and right panels were annotated by Dr. Netland (Petitioner’s witness) and Dr. Condon (Patent Owner’s witness), respectively. Dr. Netland’s version is annotated with a textbox and red labeling cutting edges of the illustrated needle device. *See* Ex. 1003 ¶ 107. Dr. Condon’s version, annotated during his deposition, is labeled to identify the needle’s point, its bevel and two sides of the beveled end, and also to identify that this needle was shown being used in a tangential approach to the tissue. Ex. 1043, 192; Ex. 1041, 3:17, 23:3–34:15.

The two witnesses agree that the above-illustrated device is used, in some fashion, to surgically treat trabecular meshwork, 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 ¶ 107; Ex. 1041, 23:3–34:15.

We find Dr. Netland’s testimony more credible and persuasive than Dr. Condon’s because it is supported by the disclosure of Quintana, as explained below.

As indicated above, we read Quintana as clearly disclosing a needle, “bent by 20–30° at the tip,” having a distal end sufficiently sharp to penetrate and incise trabecular meshwork and strip it away as the device is moved along Schlemm’s canal. *See* Ex. 1004, 3–4. We further understand the beveled ends of hypodermic needles, as disclosed by Quintana, are sharp and intended to cut tissue. Dr. Netland provides support for this view in his Second Declaration, which includes experimental evidence that a hypodermic needle, bent by 30° at the tip and used in a surgical procedure as disclosed by Quintana, has sharp sides and cuts strips of trabecular meshwork having a generally regular width that generally match the distance between the needle’s beveled sides (on either side of the needle’s opening, as shown in the figures above). Ex. 1030 ¶¶ 7–26; Exs. 1031–1033 (videos of procedure); *see also* Reply 5, 14–17 (discussing Dr. Netland’s Second Declaration).

Dr. Netland testified to the similarities and necessary differences between his experimental procedures 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 person of ordinary skill in the art would have understood 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 5, 14–17 (discussing this evidence).¹² Dr. Netland provided annotated still screen shots of the videos of these procedures, which we reproduce below:



Figure 1

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

¹² We note Patent Owner's objections to and arguments over this evidence, but are not persuaded for the reasons discussed in our Order denying Patent Owner's motion. Sur-Reply 1–4; Paper 49, 3–9.

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. *Id.* ¶¶ 20, 23–26.

Dr. Netland's Figure 2 is reproduced below.

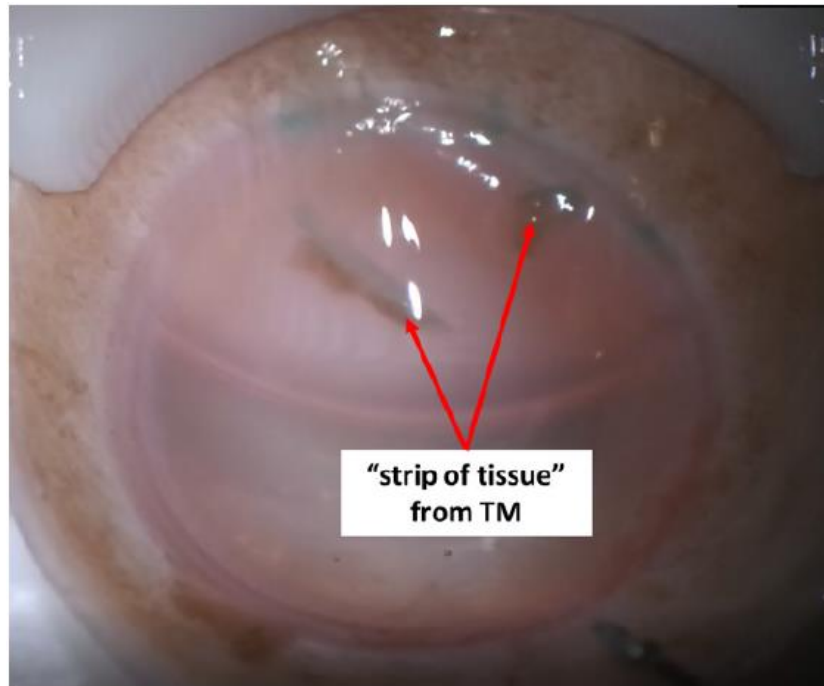


Figure 2

Figure 2 above shows a second still image from another video recording of Dr. Netland's 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.

Dr. Netland's Figure 3 is reproduced below.

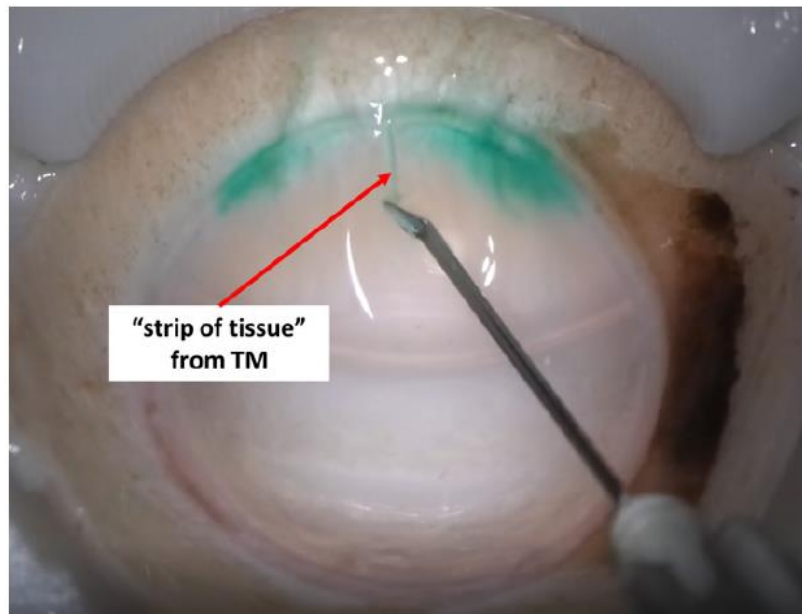


Figure 3

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

This evidence supports Petitioner's position that Quintana discloses a "device useable to create an opening in the trabecular meshwork of the eye," which comprises two cutting edges that act to remove a strip of trabecular meshwork tissue from the eye.

[1.a] *"an elongate surgical instrument comprising a probe shaft having a distal end and a longitudinal axis"*

With respect to claim 1's limitation [1.a], Petitioner points to a second annotated version of Quintana's Figure 1, reproduced below.

The above figure shows the right-hand portion of Quintana's Figure 1 as annotated, from on page 37 of the Petition. Pet. 37 (citing Ex. 1004, Fig. 1; Ex. 1003 ¶ 108). Referencing Quintana's disclosure that "[t]he needle is

inserted into a syringe,” Petitioner interprets the needle as the “elongate surgical instrument” recited in [1.a]. *Id.* (citing Ex. 1004, 3) (alteration in original). Referencing paragraph 108 of Dr. Netland’s First Declaration, Petitioner annotates Figure 1 to indicate that the needle further comprises “a probe shaft having a distal end and a longitudinal axis,” also as required by limitation [1.a]. *Id.*

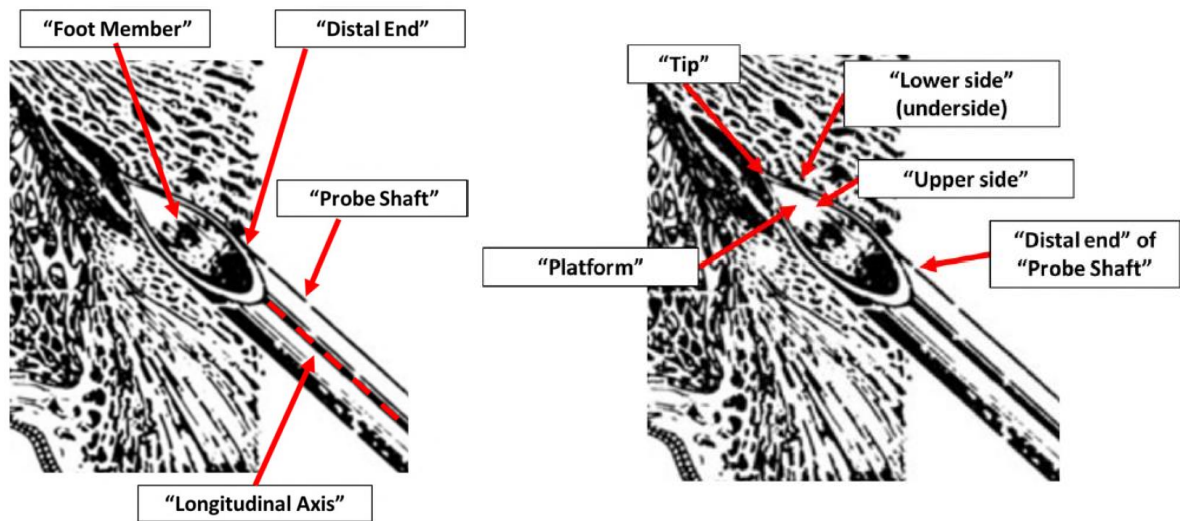
Patent Owner does not address this claim element. *See generally* PO Resp. We find Petitioner’s arguments supported by the evidence and adopt them as our own.

[1.b] *“a foot member which comprises a platform on the distal end of the probe shaft, said platform having a tip, an upper side, a lower side and being set at an angle relative to the longitudinal axis of the probe shaft”*

With respect to the “foot member” of claim 1’s clause [1.b], Petitioner notes that the ’544 Specification does not use this term, “but instead uses the term ‘footplate’ to describe a component at the distal end of a device shaft that penetrates the [trabecular meshwork], guides the device in [Schlemm’s Canal], and/or protects [Schlemm’s Canal] from damage that could be caused by the device’s cutting/ablating mechanism.” Pet. 38 (citing Ex. 1001, Abstract, 4:53–57, 9:25–27, 13:43–58, 15:42–48; Ex. 1003 ¶ 109). Petitioner points to Figure 7 (element 721) and Figure 18 (element 1820), as exemplifying the Specification’s use of “footplate.” *Id.* at 38–39; *see* Section I.F.1, above; Ex. 1001, 8:52–59, 9:24–29, 13:43–58. Petitioner similarly notes that the ’544 Specification “does not identify the ‘platform’ or even use the term at all outside the claims.” *Id.* at 39–40 (citing Ex. 1003 ¶ 110).

Accordingly, and relying on the testimony of Dr. Netland, Petitioner concludes that the footplate referenced in the Specification must refer to the “foot member” of claim 1, and “is simply a component at the distal end of the shaft capable of penetrating the [trabecular meshwork], guiding a device through [Schlemm’s Canal], and/or protecting [Schlemm’s Canal] from damage,” whereas the platform recited in [1.b] refers to “a portion of the foot member with an ‘upper side,’ a ‘lower side,’ and a ‘tip.’” *Id.* (citing Ex. 1003 ¶ 109).

Further with respect to the elements of [1.b], Petitioner points to a third and a fourth annotated version of Quintana’s Figure 1, each reproduced below.



The above figures each show the right-hand portion of Quintana’s Figure 1 as annotated by Petitioner (and Dr. Netland), from pages 40 and 41 of the Petition, respectively. Pet. 40–41 (citing Ex. 1004, Fig. 1; Ex. 1003 ¶¶ 111–112). Referencing the annotated figures, Petitioner contends that Quintana’s needle includes a foot member, which comprises a platform on the distal end of the probe shaft, wherein the platform has a tip, an upper side, and a lower side, as recited in [1.b]. *Id.*

Petitioner further contends that the tip of Quintana's needle is bent 20-30° to form an angled portion such that one of ordinary skill in the art would understand that Quintana's "foot member" and "platform" are "***set at an angle relative to the longitudinal axis of the probe shaft.***" *Id.* at 41-42 (citing Ex. 1004, 3; Ex. 1003 ¶ 113); *see id.* at 40 (further stating the Quintana's "needle tip . . . guides the needle as it 'progresses in the angle'") (citing Ex. 1004, 4).¹³

Patent Owner argues that "Quintana lacks a foot member with a platform set at an angle relative to the longitudinal axis of the probe shaft" as required by [1.b]. PO Resp. 14-17; Reply 9-12. Patent Owner appears to base its argument on the multiplicity of labels applied to regions of Quintana's needle and whether Quintana discloses "any distinct element" designed to protect the surfaces of Schlemm's canal. PO Resp. 14-17; Sur-reply 9-12. We do not find Patent Owner's arguments persuasive for the reasons identified by Petitioner and as further discussed below. *See* Pet. 38-42; Reply 7-9; *see also* Pet. 42-45 (discussing claimed characteristics of the foot member).

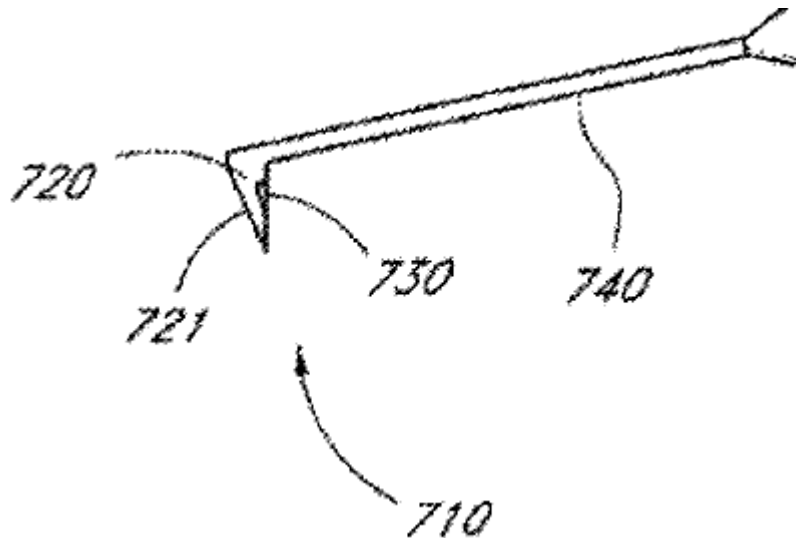
Referencing Petitioner's annotations of Quintana's Figure 1 (above), Patent Owner argues that "Petitioner confusingly designates the bent needle tip to be the foot member and every additional element of the foot member without any support." Sur-reply 11 (citing Reply 8-9). Representative of this argument is Patent Owner's contention that "[a] bent needle tip cannot be simply designated to be both the 'foot member' and 'tip', because such a

¹³ Quintana and Lee refer to the anterior chamber "angle," which is the anatomical angle between the tissue of the iris and cornea and is the area where the trabecular meshwork lies. Ex. 1004, 4; Ex. 1006, 6:10-42; Ex. 1003 ¶¶ 42-22.

conflation would improperly vitiate the distinct elements of the Challenged Claims.” *Id.*

As an initial matter, the ’544 patent’s only mention of “foot member” is in the challenged claims. At best, the Specification identifies a “footplate” as part of the goniectomy cauterization probe illustrated in Figure 7.

Ex. 1001, 4:50–58, 5:44–45, 8:52–55, 9:24–27; *see also id.* at 13:43–58, Fig. 18 (describing goniectomy cutting probe having footplate 1820). An excerpt of Figure 7 is reproduced below (*see* section I.D. for entire figure).



The above excerpt of Figure 7 shows the needle-like distal end of a goniectomy cauterization probe. The Specification identifies this region of the device as “probe tip 710,” which is connected to the main body of handle 705 (not labeled in this view). *Id.* at 9:24–25. The Specification further discloses that probe tip 710 “further comprises a footplate 721, which protects the collector channels, penetrates the trabecular meshwork, and serves as a guide in Schlemm’s canal,” as well as “cautery element 730, located at the distal end of probe tip 710.” *Id.* at 9:25–29; *see also id.* at 13:53–58, Fig. 18 (stating that footplate 1820 has a “sharpened end . . . used to penetrate the trabecular meshwork”).

We need not equate “probe tip 710” with the distal end of Quintana’s needle, nor do we presume that embodied “footplate 721” has the same scope as the claimed “foot member.” Nonetheless, the ’544 patent’s identification of “probe tip 710” as including various substructures (e.g., footplate 721 and cautery element 730),¹⁴ is entirely consistent with Petitioner’s and Petitioner’s expert’s labeling of the distal end of Quintana’s needle as including a foot member, wherein the foot member comprises a platform, and wherein the platform has a tip, an upper side, and a lower side.

Patent Owner further argues that Quintana fails to disclose a foot member because it “never mentions or suggests any *distinct* element of the Quintana device that ‘is designed to protect or prevent any substantial damage to surfaces of Schlemm’s canal while the device [] is being utilized to cut portions of the trabecular meshwork during a goniotomy procedure,’ as the ’544 Patent describes the function of the foot member,” and “the only portion of the Quintana device that serves a similar intended purpose is the ‘convexity of the tip’ which is created by bending of the needle tip.” PO Resp. 15. In this respect, Patent Owner refers to the ’544 patent’s description of a goniotomy instrument that “may include a *foot plate*, such that the instrument can penetrate the trabecular meshwork into Schlemm’s canal. The *footplate* may also act as a protective device for the endothelial cells and collector channels lining the scleral wall of Schlemm’s canal.” 4:53–57 (italics added). Yet Patent Owner does not persuade us that we should equate the “footplate” embodied in the Specification with the claimed “foot member,” let alone that we should import the footplate embodiment of

¹⁴ We note that the Specification further labels, but does not expressly identify, elements 720 and 740 on probe tip 710.

Figure 7 into the challenged claims. Rather, to the extent the foot member equates to the embodied footplate, we agree with Petitioner and Petitioner's expert that it "is simply a component of the distal end of the shaft capable of penetrating the [trabecular meshwork], guiding a device through [Schlemm's Canal], and/or protecting (Schlemm's Canal] from damage." See Pet. 39; Ex. 1003 ¶ 109.

As to Patent Owner's argument that the element Petitioner identifies as a foot member in Quintana is not a distinct element providing the functions of the '544 patent's footplate, we find persuasive Petitioner's argument that "the specification says nothing about a 'foot member' let alone that it must be a distinct element." Reply 8. We further find persuasive Petitioner's argument that Quintana's

bent needle is oriented such that the convexity of the tip faces the external wall of SC to avoid damaging it. Ex.1004, 4. By orienting the bent needle in this way, tissue near the convex side is protected. *Id.*; Ex.1003, ¶111. Thus, the portion at the needle's bottom extending laterally from the shaft is a "foot member" designed to prevent damage to [Schlemm's Canal]" Pet., 39-41.

Id. at 7–8.

Considering the record as a whole, we agree with Petitioner that one of ordinary skill in the art would have understood that Quintana discloses a foot member having the characteristics recited in [1.b]. See *Powell v. Home Depot U.S.A., Inc.*, 663 F.3d 1221, 1231–32 (Fed. Cir. 2011) (holding that the specification "does not suggest that the claim terms require separate structures"); *Linear Tech. Corp. v. ITC*, 566 F.3d 1049, 1055 (Fed. Cir. 2009) ("there is nothing in the claim language or specification that supports narrowly construing the terms to require a specific structural requirement or entirely distinct "second" and "third" circuits").

[1.c] “*wherein the foot member is insertable, tip first, from a position within the anterior chamber, through the trabecular meshwork, and into Schlemm’s Canal such that the lower side is next to the scleral wall of Schlemm’s Canal and the upper side is next to the trabecular meshwork*”

With respect to claim 1’s clause [1.c], Petitioner contends that Quintana’s “surgical procedure using the needle involves penetrating the [anterior chamber] with the tip of the needle (which includes the foot member), piercing the [trabecular meshwork] with the tip of the needle from within the [anterior chamber], and introducing the needle tip into [Schlemm’s Canal].” Pet. 42 (citing Ex. 1004, 3–4, Fig. 2 (annotated to indicate needle tip and footmember inserted in Schlemm’s Canal); Ex. 1003 ¶ 114). Petitioner further relies on the testimony of Dr. Netland in asserting that one of ordinary skill in the art would have understood that, “when in the operative position within [Schlemm’s Canal], Quintana’s needle is necessarily positioned ‘***such that the lower side is next to the scleral wall of Schlemm’s Canal and the upper side is next to the trabecular meshwork,***’” as required by [1.c]. *Id.* at 43 (citing Ex. 1003 ¶ 115; Ex. 1004, 4).

Patent Owner argues that this element is not satisfied because “Quintana does not conclusively show the absence of damage to Schlemm’s Canal.” PO Resp. 13–14. This argument is not persuasive because neither claim 1’s clause [1.c], nor any of the other challenged claims, expressly recites an “absence of damage” limitation. Nor does Patent Owner present persuasive evidence or argument that such a limitation must be read into any claim. *But see id.* at 15 (Patent Owner conceding that Quintana refers to the “convexity of the [needle] tip” as a means for “avoiding injury to the external wall of Schlemm’s Canal”).

[1.d] “wherein, after being so inserted in Schlemm’s Canal, the foot member is then advanceable, tip first, through Schlemm’s Canal to facilitate performance of a surgical procedure using the surgical instrument”

With respect to claim 1’s clause [1.d], Petitioner points to Quintana’s disclosure that, as “the **tip** of the instrument is introduced into Schlemm’s Canal, and the [trabecular meshwork] is stripped slowly, gently and easily from the canal’s lumen towards the anterior chamber as the **needle progresses in the angle** (Fig. 2).” Pet. 43–44 (quoting Ex. 1004, 4); see Ex. 1003 ¶ 116.¹⁵ Petitioner illustrates the point using the annotated version of Quintana’s Figure 2, reproduced below.

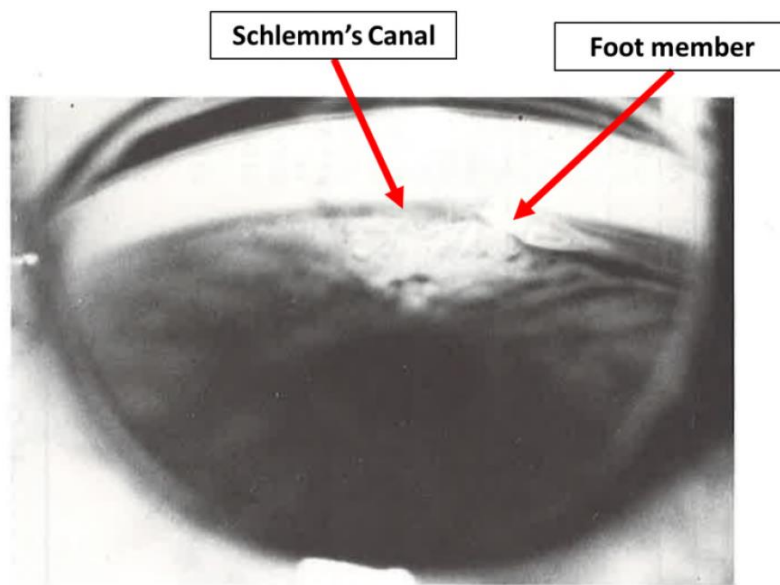


Fig. 2. Goniophotography at operation. The tip of the needle stripping the trabecular meshwork.

The above figure is a goniophotograph showing “[t]he tip of the needle stripping the trabecular meshwork” from an eye. Ex. 1004, Fig. 2. With reference to its annotations, Petitioner asserts Figure 2 “show[s] [the]

¹⁵ Insofar as it relates to a “tip,” the arguments and evidence in this section are also relevant to [1.b] and [1.c].

needle tip including the claimed foot member advancing through [Schlemm's Canal]." Pet. 44 (citing Ex. 1003 ¶ 116). Petitioner further contends that, in "advancing the tip of the needle (including the foot member) in [Schlemm's Canal]," Quintana "facilitates performance of a surgical procedure involving creating an opening in the [trabecular meshwork] of the eye." Pet. 44 (citing, e.g., Ex. 1003 ¶ 117).

Patent Owner does not expressly address [1.d]. To the extent its arguments are relevant to this claim language, they are addressed elsewhere and we find them unpersuasive. As above, we find Petitioner's arguments supported by the evidence and adopt them as our own.

2. Claim 2: "*A device according to claim 1 wherein the trabecular meshwork slides over the upper side as the foot member is advanced through Schlemm's Canal.*"

Petitioner contends that Quintana discloses that the tip of its needle "penetrates the [trabecular meshwork], enters [Schlemm's Canal], and progresses in the angle to 'strip[] [trabecular meshwork] tissue from the SC.'" Pet. 44 (citing Ex. 1004, 4). According to Petitioner, the annotated version of Figure 2, reproduced above, shows "the bent portion of Quintana's needle (including the foot member) in [Schlemm's Canal], with the needle's cutting edges contacting and 'stripping the [trabecular meshwork]'" *Id.* at 44–45. As such, Petitioner argues, "[trabecular meshwork] tissue necessarily passes over the upper side and comes into contact with the needle's cutting edges, resulting in 'stripping' of tissue from the [trabecular meshwork]'" *Id.* at 45 (citing Ex. 1003 ¶ 119).

Patent Owner argues that this limitation is not satisfied because "Petitioner cannot show that Quintana discloses that the beveled sides of the Quintana device tip definitively contact the [trabecular meshwork]." PO

Resp. 17–18. But, as Petitioner points out, claim 2 does require that the “upper side” slide over the trabecular meshwork and makes no mention of the tissue’s contact with beveled sides. Moreover, were that required, Dr. Condon conceded that edges at the tip of Quintana’s needle (“where the side[s] meet the point”) “may assist in creating that tearing away of the trabecular meshwork.” See Ex. 1041, 180:15–181:14.

Patent Owner further argues that one of ordinary skill in the art reading the challenged claim, “would recognize that the entire foot member is within Schlemm’s Canal,” whereas Quintana expressly states that “[o]nly the tip of the instrument is introduced into Schlemm’s canal.” Sur-reply 12 (citing Ex. 1004, 4). Patent Owner similarly asserts and “Figure 2 of Quintana clearly depicts only the needle tip inserted into the [trabecular meshwork], while the entire beveled portion of the needle obviously remains in the anterior chamber of the eye.” Sur-reply 13 (citing Ex. 1004, 5, Fig. 2). Petitioner has provided persuasive argument and evidence with respect to claim 2. In rebuttal, Patent Owner does not (1) explain why one of ordinary skill would have understood the challenged claims to require the entirety of a foot member to enter Schlemm’s Canal; (2) provide persuasive evidence as to how one of ordinary skill would have interpreted Quintana’s use of “tip of the instrument/needle;”¹⁶ or (3) provide more than attorney argument in interpreting the orientation of Quintana’s needle during the procedure illustrated in Figure 2.

¹⁶ At best, Patent Owner and its expert assert that Quintana’s “tip of the needle” is an “operational element” defining “the working end of its trabeculotome.” PO Resp. 27; Ex. 2019¶ 21. We do not find these general definitions helpful in the present context.

In considering all the evidence of record, we agree with Petitioner that Quintana discloses a procedure needle “tip (including the foot member and upper side) is within [Schlemm’s Canal] and that [trabecular meshwork] must necessarily pass over it as the tip advances.” Reply 10 (citing Ex. 1041, 43:22–44:9); Ex. 1003 ¶ 119.

3. Claim 3: “*A device according to claim 2 wherein a surface of the upper side of the foot member slopes upwardly from the tip toward the shaft.*”

For the elements of claim 3, Petitioner references Quintana’s Figure 1, reproduced below.

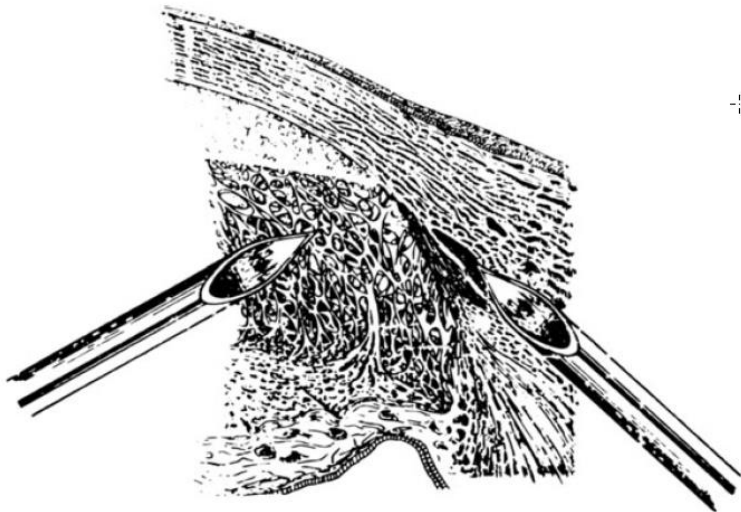


Fig. 1. Schematic drawing comparing the tangential approach to the perpendicular approach as in classic goniotomy or goniotrabeculotomy.

Figure 1 is Quintana’s “[s]chematic drawing comparing the tangential approach to the perpendicular approach as in classic goniotomy or goniotrabeculotomy.” Ex. 1004, 4, Figure 1. Petitioner contends that Figure 1 shows that “Quintana’s needle has a beveled distal end that slopes upwardly from the very tip to the portion where the bevel meets the needle shaft. Pet. 45–46. Petitioner argues that the claim elements “[t]he beveled portion of the needle forms part of the top of the needle tip (including the

upper side of the foot member)” and, thus, “a surface of the upper side of the foot member slopes upwardly from the tip toward the shaft,” are recited in claim 3. *Id.* (citing Ex. 1003 ¶ 121).

Patent Owner argues claim 3 (and similar claim 11) is not anticipated under Ground 1 “because Quintana lacks a foot member with an upper side that slopes upwardly from the tip toward the probe shaft.” As discussed above, in relation to the language of [1.b], we are persuaded that Quintana discloses these elements. Further with respect to “a surface of the upper side of the foot member slop[ing] upwardly from the tip toward the shaft,” we are persuaded by Dr. Netland’s testimony that “[a] person of ordinary skill in the art would understand that the bevel of a needle is sloped upwardly from the tip to the shaft to facilitate insertion of the needle into a tissue.” Ex. 1003 ¶ 121. As shown in Quintana’s Figure 1,

Quintana’s needles have[] an incline from the very end of the needle to the portion where the bevel meets the needle shaft. . . . This inclined bevel portion forms part of the upper side of the foot member and thus, . . . a surface of the upper side of the foot member of Quintana’s needle slopes upwardly from the tip toward the shaft, as claimed.

Id.

4. Claim 4: “*A device according to claim 1 wherein the surgical instrument is useable to perform an ab interno procedure to form an opening in the trabecular meshwork.*”

Relying on the testimony of Dr. Netland, Petitioner asserts that “Quintana’s procedure is ‘ab interno’ because the needle penetrates into the [anterior chamber] and approaches the [trabecular meshwork] from *within* the [anterior chamber].” Pet. 46–47 (citing Ex. 1004, 4; Ex. 1003 ¶¶ 126–127). Further relying on Dr. Netland’s testimony, Petitioner states that Quintana’s use of a gonioscope to visualize the needle angle “is only

necessary in ‘ab interno’ procedures.” *Id.* at 47 (citing Ex. 1003 ¶¶ 123–125).

Relying on the testimony of its expert, Dr. Condon, Patent Owner argues that one of ordinary skill in the art “would not have known definitively whether or not Quintana described an *ab interno* procedure.” PO Resp. 31–34;¹⁷ Sur-reply 19–20. Dr. Condon bases his opinion on Dr. Netland’s “particularized definition [of] *ab interno*” as indicating that an instrument “enter[s] the eye through the anterior chamber and approaching the trabecular meshwork from within the anterior chamber.” Ex. 2019 ¶¶ 43–44. Dr. Netland further testifies that “nothing in the Quintana text or figures provides a clear indication whether or not the Quintana trabeculotome enters the [trabecular meshwork] only after first entering Schlemm’s Canal, a POSA would be unable to conclude with certainty that Quintana’s surgical procedure must be *ab interno*.” *Id.* ¶ 45. Dr. Condon, thus, “disagree[s] with Dr. Netland’s statement in his declaration that ‘[t]he **only way** to interpret Quintana’s description is that the procedure is an ‘ab interno’ method. Persons of ordinary skill in the art **could not** interpret Quintana’s procedure as an ‘ab externo’ method.’” *Id.* ¶ 47 (citing Ex. 1003 ¶ 126).

Considering the arguments and evidence of record, we conclude that Petitioner shows that Quintana discloses “[a]n *ab interno* method for forming an opening in trabecular meshwork,” as recited in claim 4. Ex. 1003 ¶¶ 47, 57, 79–91, 123–127. We agree with Petitioner and Dr. Netland that

¹⁷ We disregard as irrelevant Patent Owner’s argument that Petitioner waived any argument as to whether the use of *ab interno* in the preamble is limiting because the term does not appear in the preamble of the challenged claims. *Id.* at 31, n.8.

one of ordinary skill in the art would have understood Quintana to disclose an *ab interno* procedure in light of, for example, its teaching that the “needle penetrates the anterior chamber” and then runs parallel to Schlemm’s Canal as it strips trabecular meshwork gently and easily from the canal’s lumen towards the anterior chamber. Ex. 1006, 4; *see, e.g.*, Ex. 1003 ¶¶ 124–127; *see also id.* ¶ 125 (Dr. Netland’s testimony that Quintana’s use of a gonioscope is indicative because this device “is only used in used in an ‘ab interno’ procedure because it is used to visualize the angle **within** the anterior chamber”).

5. Claim 5: “A device according to claim 4 wherein the surgical instrument comprises a goniotomy probe.”

According to Petitioner, “Quintana uses a needle to perform a ‘goniotrabeculotomy.’” Pet. 47 (citing Ex. 1004, 3). Relying on the testimony of Dr. Netland, Petitioner contends that one of ordinary skill in the art “would understand that a ‘goniotrabeculotomy’ is another name for a goniotomy procedure, as both excise tissue from the [trabecular meshwork], and thus Quintana’s needle functions as a goniotomy probe during the procedure.” *Id.* (citing Ex. 1003 ¶ 129).¹⁸

Patent Owner contends that Quintana does not disclose a goniotomy probe. PO Resp. 26–30. Although Patent Owner reprises many of the

¹⁸ We also note Dr. Netland’s testimony at deposition differentiating between “goniotrabeculotomy” and “goniotrabeculectomy” wherein, accurately used, the former involves “creating an opening” and the latter the removal of trabecular tissue. Dr. Netland explained, however, that the term “goniotrabeculotomy,” used in Quintana, is frequently “broadened to include removal of tissue.” Ex. 1041, 91:2–19. As such, Dr. Netland’s testimony further supports Petitioner’s position that Quintana’s needle functions as a goniotomy probe.

arguments made with respect to elements of claim 1, its argument appears to be encompassed by Dr. Condon's testimony that Quintana's device is not a goniectomy probe because it "does not disclose removing [trabecular meshwork], much less creating or removing a strip of [trabecular meshwork]." Ex. 2019 ¶ 97 (referencing *id.* ¶ 72). As set forth in our discussion regarding the language of claim 1's preamble [1.p], however, we are persuaded that the edges of Quintana's needle act as cutting blades that contact the trabecular meshwork as the needle is advanced through Schlemm's Canal and concurrently cut the trabecular meshwork to excise a strip of trabecular meshwork tissue. See section 1.D., above (citing Ex. 1003 ¶ 107).

Considering all the evidence of record, we find that Quintana discloses the goniectomy probe recited in claim 5.

6. Conclusion as to Ground 1

For the reasons set forth above and as argued in the Petition, Petitioner has shown by a preponderance of the evidence that claims 1–5 are unpatentable as anticipated by Quintana.

Patent Owner does not address with specificity any unique element of claims 6–11 under Ground 1; we find Petitioner's arguments with respect to those claims supported by the evidence and adopt them as our own. As such, Petitioner has shown by a preponderance of the evidence that claims 1–11 of the '544 patent are unpatentable under Ground 1 for anticipation by Quintana.

E. Obviousness in view of Quintana (Ground 2)

As Ground 2, Petitioner challenges claims 1–11 as obvious in view of Quintana and the knowledge of one of ordinary skill in the art. Pet. 53–65. Petitioner’s challenge includes a detailed mapping of the teachings of Quintana to each limitation of the claims, address motivation to modify Quintana, and why the person of ordinary skill in the art would have had a reasonable expectation of success. *Id.* Patent Owner opposes. PO Resp. 34–39; Sur-reply 20. We have concluded above (*see supra* Sections II.D.1 and II.D.4) that claims 1–11 are anticipated by Quintana. “It is well settled that ‘anticipation is the epitome of obviousness.’” *In re McDaniel*, 293 F.3d 1379, 1385 (Fed. Cir. 2002) (quoting *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548 (Fed. Cir. 1983)).¹⁹ Nevertheless, we address below Petitioner’s challenge under Section 103.

1. Arguments Contingent on Rejected Construction of “Device”

Petitioner explains that certain of its obviousness arguments are relevant only if we adopt its proposed construction of “device” as limited to the tissue ablating and dynamic-mechanical embodiments set forth in the ’544 patent. Pet. 53. Under this scenario, Petitioner’s reasoned argument and evidence that one of ordinary skill in the art would have found it “obvious to modify Quintana’s device to use alternate means for forming an opening in the [trabecular meshwork], such as tissue ablating mechanisms or dynamic-mechanical cutting mechanisms well-known in the art.” *Id.* at 54 (citing Ex. 1003 ¶ 151; Ex. 1012, 4–5 (glaucoma textbook); Ex. 1011, 41–52 (similar glaucoma textbook); Ex. 1023, 1 (Moses article on electrocautery puncture), Ex. 1022, 2:56–68, Figs. 1–5 (Peyman vitrectomy patent)).

¹⁹ Patent Owner does not advance any secondary considerations arguments.

In section II.D.1, we determined that Quintana discloses “[a] device useable to create an opening in the trabecular meshwork of the eye,” which comprises “an elongate surgical instrument” having certain enumerated features. Because we decline to limit the recited “device” to the specific embodiments urged by Patent Owner, we need not consider that portion of Petitioner’s obviousness analysis predicated on Patent Owner’s alternative construction. *See* Pet. 57, 63–64; section II.C.1, above. Nonetheless, for the reasons explained above, we find claim 1 is obvious in view of Quintana.

2. Claim 4: “A device according to claim 1 wherein the surgical instrument is useable to perform an *ab interno* procedure to form an opening in the trabecular meshwork.”

Other than the “device” limitation, discussed above, Petitioner only addresses with particularity the “*ab interno*” element as obvious over (as opposed to disclosed by) Quintana. *See* Pet. 58–60. Petitioner provides persuasive evidence that Quintana discloses an *ab interno* procedure because, *inter alia*, “the needle penetrates into the [anterior chamber] and approaches the [trabecular meshwork] from **within** the [anterior chamber].” *Id.* at 58–59 (citations omitted); section II.D.4, above. Relying on the testimony of Dr. Netland, Petitioner further contends that to the extent “Quintana does not expressly disclose an ‘***ab interno***’ procedure, it would have been obvious to perform Quintana’s procedure using an ‘*ab interno*’ approach.” Pet. 59 (citing Ex. 1003 ¶¶ 164–68).

According to Dr. Netland, *ab interno* goniotomy procedures were well known, and exemplified by Lee and Jacobi. Ex. 1003 ¶ 164 (citing Ex. 1006, 5:61–6:45; Ex. 1007, 2). Dr. Netland testifies that persons of ordinary skill in the art would have appreciated that the precise location entry into the eye is not crucial to Quintana’s method as long as the needle is

generally parallel to Schlemm's Canal upon entry into the anterior chamber.

Id. at ¶ 165. Accordingly, if such were necessary,

[m]odifying Quintana's procedure to use a different approach would be nothing more than simple substitutions of one known procedure (*e.g.*, Quintana's "scleral side of the limbus approach") for another (*e.g.*, Lee's or Jacobi's cornea approach) and persons of ordinary skill in the art would have expected success given the successful use of these alternate approaches in the prior art.

Id.

With respect to motivation, and further relying on the testimony of Dr. Netland, Petitioner asserts that one of ordinary skill in the art

would also have been motivated to modify Quintana by penetrating directly through the cornea to make the procedure safer and more convenient. [Ex. 1003 ¶ 166]. By 2001, it had become apparent that corneal incisions heal faster than other incisions and often result in fewer complications. *Id.*; Ex.1007, 5.

Pet. 60.

Patent Owner presents no argument directed specifically to Petitioner's obviousness arguments regarding claim 4, or the "ab interno" limitation. See PO Resp. 38–39. Moreover, the only paragraph in Dr. Condon's Declaration addressing Petitioner's Ground 2 challenge to claim 4 merely quotes the language of the claim. Ex. 2019 ¶ 144.

Considering the evidence, art, and argument of record, Petitioner has shown by a preponderance of the evidence that "ab interno" element of claim 4 is anticipated and/or obvious in view of Quintana.

3. Conclusion as to Ground 2

For the reasons set forth above and as argued in the Petition, Petitioner has shown by a preponderance of the evidence that claims 1 and 4 of the '544 patent are unpatentable as obvious in view of Quintana.

Patent Owner does not address with specificity any unique element of claims 3 and 5–11 under Ground 2; we find Petitioner's arguments with respect to those claims supported by the evidence and adopt them as our own. As such, Petitioner has shown by a preponderance of the evidence that claims 1–11 of the '544 patent are unpatentable under Ground 2 as obvious in view of Quintana.

F. Obviousness in view of Jacobi (Ground 3)

As Ground 3, Petitioner challenges claims 1–11 as obvious in view of Jacobi and the knowledge of one of ordinary skill in the art. Pet. 65–88. Petitioner's challenge includes a detailed mapping of the teachings of the reference to each limitation of the claims, addresses motivation to modify Jacobi and why the person of ordinary skill in the art would have had a reasonable expectation of success in doing so. *Id.* Patent Owner opposes. PO Resp. 39–48; Sur-reply 20–22.

We have discussed Petitioner's Grounds 1 and 2 above, and concluded that claims 1–11 are each unpatentable as anticipated and/or obvious over Quintana. Therefore, we do not address in detail or reach a conclusion on patentability for Petitioner's Ground 3 in view of Jacobi. *See* Tr. 55:9–10 (during oral argument, Petitioner likewise did not “dwell on Jacobi” or discuss its merits).

III. CONCLUSION²⁰

Having considered the evidentiary record before us and the parties' respective positions on each ground asserted in the Petition, we find that Petitioner has shown by a preponderance of the evidence that claims 1–11 of the '544 patent are unpatentable in view of the cited prior art. In summary:

Claims	35 U.S.C. §	References/Basis	Claims Shown Unpatentable	Claims <u>Not</u> Shown Unpatentable
1–11	102	Quintana	1–11	
1–11	103	Quintana	1–11	
1–11	103	Jacobi ²¹		
Overall Outcome			1–11	

²⁰ 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).

²¹ As discussed above, we do not reach the Jacobi ground because we have already found each of the challenged claims anticipated and obvious over Quintana.

IV. ORDER

Accordingly, it is hereby:

ORDERED that Petitioner has demonstrated by a preponderance of the evidence that claims 1–11 of the '544 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.

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