

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NEW WORLD MEDICAL, INC.,
Petitioner,

v.

MICROSURGICAL TECHNOLOGY, INC.,
Patent Owner.

IPR2020-01573
Patent 9,107,729 B2

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

FLAX, *Administrative Patent Judge*.

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 9,107,729 B2 (“the ’729 patent,” Ex. 1001). Paper 29, 1 (“Response” or “Resp.”). New World Medical, Inc. (“Petitioner”) filed a Petition for an *inter partes* review of claims 1–10 (all claims) of the ’729 patent. Paper 1 (“Pet.”). Trial was instituted on March 16, 2022. Paper 22 (“Institution Decision” or “DI”). Patent Owner filed a Response to the Petition. Paper 29. Petitioner filed a Reply to Patent Owner’s Response (Paper 35, “Reply”) and Patent Owner filed a respective Sur-Reply (Paper 20, “Sur-Reply”). The parties also each filed respective motions to exclude the other’s evidence, which were each denied. Papers 51, 52, and 63. A final hearing was held on January 10, 2022, where each party presented oral argument. Paper 62 (“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 the unpatentability of 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 the evidence, we conclude that Petitioner proves by a preponderance of the evidence that claims 1–10 of the ’729 patent are unpatentable. 35 U.S.C. § 316(e).

I. INTRODUCTION

A. REAL PARTIES-IN-INTEREST

Petitioner identifies itself, “New World Medical, Inc.,” as a real party-in-interest. Pet. ix. Patent Owner also identifies itself, “MicroSurgical Technology, Inc.,” as a real party-in-interest. Paper 4; Paper 33.

B. RELATED MATTERS

Petitioner states:

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

Pet. ix. Patent Owner identifies the same case in the District of Delaware as a related matter. Paper 4; Paper 33.

Although neither party identifies them as directly related matters, we note the following other *inter partes* reviews, filed by Petitioner, challenging Patent Owner’s patents at issue in the aforementioned district court case:

IPR2020-01711 regarding U.S. Patent 9,358,155 B2; IPR2021-00017 regarding U.S. Patent 9,820,885 B2; IPR2021-00065 regarding U.S. Patent 10,123,905 B2; and IPR2021-00066 regarding U.S. Patent 9,999,544 B2.

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 '729 PATENT

The '729 patent issued on August 18, 2015, from U.S. Application 14/481,754, which was filed on September 9, 2014, and ultimately claims priority to U.S. Provisional Application 60/477,258, filed on June 10, 2003.¹ Ex. 1001, codes (45), (21), (22), (60), (62). The '729 patent's Abstract states:

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

Id. at Abstract.

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

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

¹ Petitioner acknowledges this priority claim to June 10, 2003, and does not challenge it as the effective date of the '729 patent. Pet. 21, 24.

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

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

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

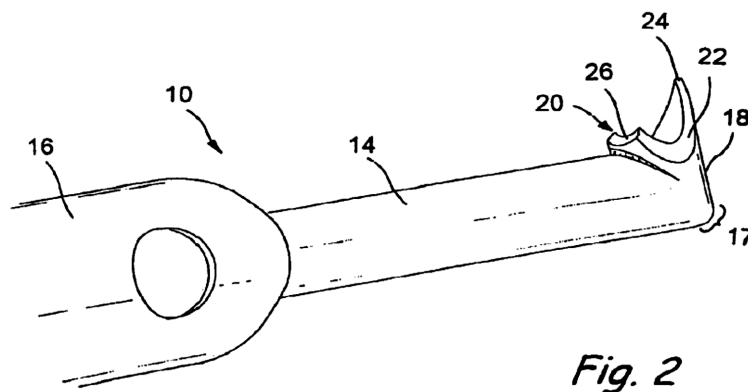


Figure 2 shows needle cutter device 10 having cutting tube 14 at an end of outer tube 16. *Id.* at 3:3–43. Cutting tube 14 terminates in an end having two cutting edges 20, 22, which are sharp to cut tissue and are positioned on opposite sides of cutting tube 14, blunt protruding tip 24, and blunt edge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

² The bend angle was expressly identified by the inventors during the prosecution of the '729 patent as the angle of degrees from straight. Ex. 1002, 331 (Amendment dated May 14, 2015, remarks).

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

The '729 patent describes methods of manufacturing (or at least aspects thereof) such a cutter device 10. *Id.* at 4:61–5:14, Figs. 3A–3D. For example, the cutting tube 14 can be made of “standard tubing (e.g., stainless steel hypodermic tubing).” *Id.* at 4:61–63. Cutting edges 20, 22 may be formed by cutting the distal end of a tube and “if it is desired to have one or more bends or curves in the cutting tube 14,” the tubing can either be angularly cut, bent, and re-adhered, or “the tube 14 may be directly bent to form said curves or bends without the use of angular cut out(s).” *Id.* at 4:63–5:9.

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

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

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

forming an opening into an anterior chamber of the eye;

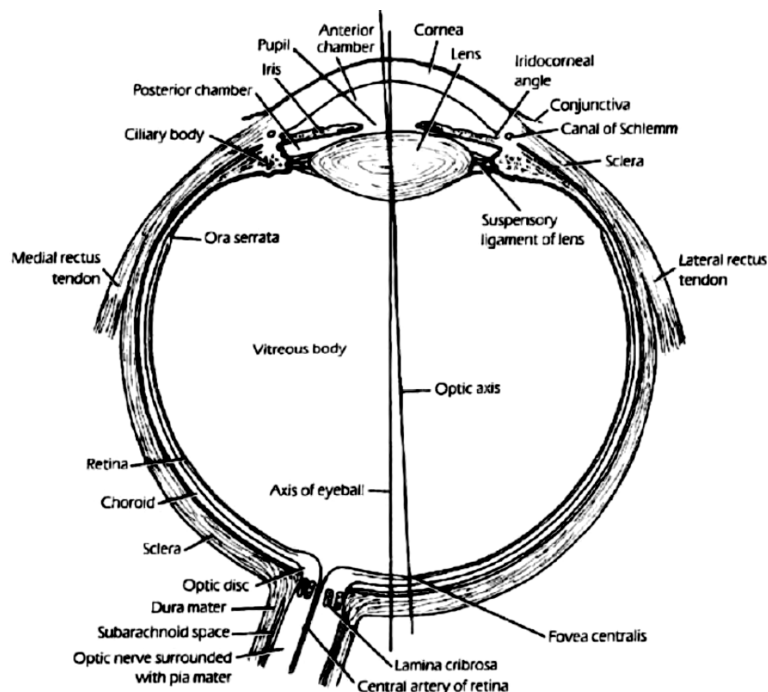
inserting the elongate probe through the opening and into the anterior chamber;

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

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

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

For context as to the '729 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, reproduced below:



Ex. 1003 ¶ 34; *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 ¶¶ 34–39. 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 '729 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 an illustration of these features in higher resolution, which we reproduce below:

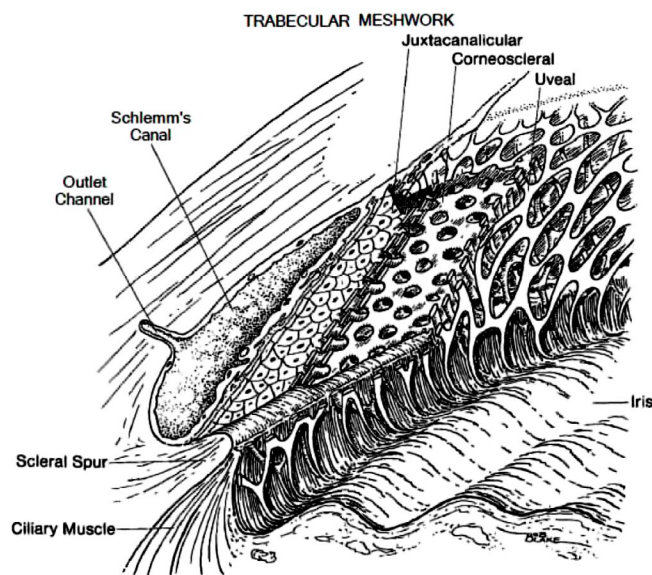


Figure 2.10. Three layers of trabecular meshwork (shown in cutaway views): (1) uveal; (2) corneoscleral; and (3) juxtacanalicular.

Ex. 1003 ¶¶ 40–42; *see also* Ex. 1011 (cited by Dr. Netland as the source of the figure). As Dr. Netland explains, the figure above “shows a cutaway view of the layers of the trabecular meshwork and Schlemm’s Canal” (Schlemm’s Canal was shown in cross-section in the first figure of the eye above, adjacent the iridocorneal angle). Ex. 1003 ¶ 41. 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 several grounds for the unpatentability of claims 1–10 of the ’729 patent, as follows:

GROUND	CLAIMS CHALLENGED	35 U.S.C. §³	REFERENCE(S)/BASIS
1	1–4, 7–9	102	Quintana ⁴
2	4–6, 10	103(a)	Quintana, Knowledge of a Person of Ordinary Skill in the Art
3	1–4, 7–9	103(a)	Quintana, Lee ⁵

³ The ’729 patent indicates 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.

⁴ 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 cite Quintana’s added pagination at the lower right corner of the document, as has Petitioner.

⁵ U.S. Patent 4,900,300 (issued Feb. 13, 1990). Ex. 1006 (“Lee”).

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

See Pet. 4.

Petitioner’s Grounds 2, 4, and 6, summarized above, each reference the knowledge of a person of ordinary skill in the art as a distinguishing basis for their being separate grounds. When analyzing whether claims would have been obvious and whether it would have been obvious to combine or modify prior art, it 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 considers “the background knowledge possessed by a person having ordinary skill in the art”). The “knowledge of a person of ordinary skill in the art” is always a consideration and is not a basis for a separate challenge for obviousness. Therefore, we do not separately analyze a challenge where such “knowledge” is the only basis for it being separately presented, and consider obviousness over the cited prior

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 (“Jacobi”). Herein, we reference Jacobi’s added pagination at the lower right corner of the document, as has Petitioner.

art from the perspective of the ordinarily skilled artisan. Thus, Grounds 2 and 4 are subsumed by and merged into Ground 3, as discussed herein.

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, 26–27, 34–61 (Dr. Netland’s statements as to his background and qualifications, definition of the person of ordinary skill in the art, and background on the relevant technology).

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 52, “Pet. Mot.”) and, although that motion was denied (Paper 63, “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 '729 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:

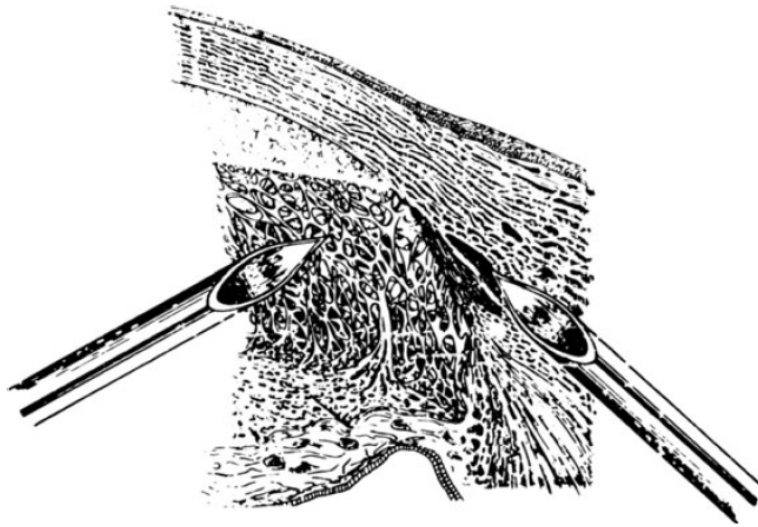


Fig. 1. Schematic drawing comparing the tangential approach to the perpendicular approach as in classic goniotomy or goniotrabeculotomy.

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:

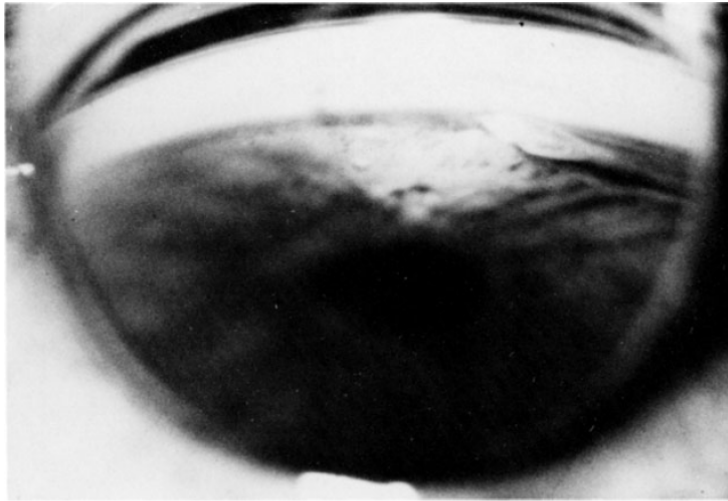


Fig. 2. Goniophotography at operation. The tip of the needle stripping the trabecular meshwork.

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. LEE

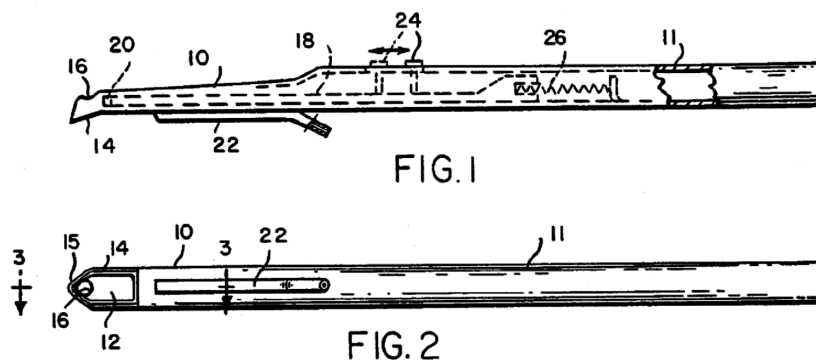
Lee issued as U.S. Patent 4,900,300 on February 13, 1990, from U.S. Application 315,190, which was filed February 24, 1989, and claims priority to U.S. Application 70,325, which was filed July 6, 1987. Ex. 1006, codes [45], [21], [22], [63]. Lee is prior art to the claims of the '729 patent under 35 U.S.C. § 102(b); Patent Owner does not argue otherwise. *See generally* Resp.

Lee states:

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

Ex. 1006, Abstract.

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

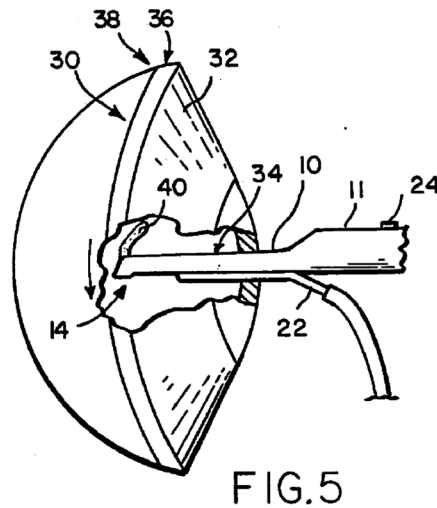


“FIG. 1 is a schematic side view of the surgical instrument of th[e] invention” and “FIG. 2 is a schematic bottom view of the surgical instrument of th[e] invention.” *Id.* at 3:62–65. Lee states that Figures 1 and 2 show “the surgical instrument” having “a more or less cylindrical hollow shaft 10[,] which is tapered from a larger diameter at the handle end 11 to a smaller diameter at the forward cutting end,” which is about 0.5 to 2 mm in diameter. *Id.* at 4:18–27. The tip end’s taper is 5–15 degrees. *Id.* at 32–33. The end of shaft 10 has “a parabolic, bowl-like cavity 12 having a sharpened rim[,] which creates a single, more or less U-shaped cutting edge 14 integral with the sides of shaft 10.” *Id.* at 4:38–41; *see also id.* at 7:34–35 (claim 1 reciting “rim is sharpened so as to form a cutting blade having side cutting edges and a distal tip”). “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. The bottom of cavity 12 includes a hole or aperture 16 through which tissue may pass. *Id.* at 4:56–57.

Lee states that this device is used “in glaucoma surgery to excise a piece of tissue from the anterior chamber angle (trabecular meshwork and the inner wall of Schlemm’s Canal) to therapeutically relieve the obstruction of the outflow of aqueous humor from the eye and to provide specimens of the abnormal tissues excised for histopathological examination.” *Id.* at

3:51–57. This process is disclosed to include introducing the instrument into the anterior chamber of the eye via a corneal incision, followed by excising angle tissue as cutting edge 14 is advanced. *Id.* at 5:61–6:36. The tissue samples are detached and 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 gonioleus over the cornea, forming an incision into the anterior chamber 34 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.

G. JACOBI

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

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.” Ex. 1007, 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 goniotomy procedure. *Id.*

II. DISCUSSION

A. ORDINARY SKILL IN THE ART

Petitioner states,

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

Pet. 23–24 (citing Ex. 1003 ¶ 27). Patent Owner states that it “agrees with the Board’s preliminary acceptance in its institution decision of Petitioner’s proposed definition of a [person of ordinary skill in the art] for purposes of this IPR.” Resp. 11, n.6.

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 ’729 patent. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (“the prior art itself [may] reflect[] an appropriate level” as evidence of the ordinary level of skill in the art) (quoting *Litton Indus. Prods., Inc. v. Solid State Sys. Corp.*, 755 F.2d 158, 163 (Fed. Cir. 1985)).

B. CLAIM CONSTRUCTION

The Board interprets claim terms in an *inter partes* review using the same claim construction standard that is used to construe claims in a civil action in federal district court. 37 C.F.R. § 42.100(b) (2019). In construing

claims, district courts and the Board here, by default, give claim terms their ordinary and customary meaning, which is “the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc).

Should claim terms require express construction, sources for claim interpretation include “the words of the claims themselves, the remainder of the specification, the prosecution history [i.e., the intrinsic evidence], and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art.” *Id.* at 1314 (quoting *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1116 (Fed. Cir. 2004)). “[T]he claims themselves [may] provide substantial guidance as to the meaning of particular claim terms.” *Id.* However, the claims “do not stand alone,” but are part of “‘a fully integrated written instrument,’ consisting principally of a specification that concludes with the claims,” and, therefore, the claims are “read in view of the specification.” *Id.* at 1315 (quoting *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 978–79 (Fed. Cir. 1995) (en banc)). Any special definition for a claim term must be set forth in the specification with reasonable clarity, deliberateness, and precision. *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994). Without such a special definition, however, limitations may not be read from the specification into the claims. *In re Van Geuns*, 988 F.2d 1181, 1184 (Fed. Cir. 1993). “[W]e need only construe terms ‘that are in controversy, and only to the extent necessary to resolve the controversy’” *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed.

Cir. 2017) (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)).

Petitioner proposes that the claim language “ab interno,” which is recited in the preamble of independent claim 1, should be expressly construed as meaning “approaching TM [(trabecular meshwork)] through the AC [(anterior chamber)].” Pet. 25. Further, Petitioner proposes that the claim language “dual blade device,” which is recited by claim 1, should be expressly construed to mean the device “has two edges capable of cutting tissue.” *Id.* at 26.

Patent Owner states that it “submits that all of the terms in the Challenged Claims should be accorded their plain and ordinary meanings to a POSA.” Resp. 11 (footnote omitted).

We decline to expressly adopt any proposed construction of the claim language. *Vivid Techs.*, 200 F.3d at 803 (“[O]nly those terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy.”).

Based on the evidence of record, the term “ab interno” is a well-understood term of art in the ophthalmological field. *See, e.g.*, Ex. 1005, 1; Ex. 1013, 1; Ex. 1018, 1; Ex. 1020, 1. The ’729 patent does not expressly assign a special meaning to the term “ab interno.” Ex. 1001. As Patent Owner states, quoting Petitioner’s witness Dr. Netland, “[p]ersons of ordinary skill in the art would have understood the term ‘ab interno’ to generally mean *from the inside . . .*” Resp. 31 (quoting Ex. 1003 ¶ 74 (emphasis in original)). 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.

The language “dual blade device” is readily understandable on its face; *dual* refers to two, and *blade*, in context, refers to a cutting part. The evidence of record does not indicate that this term has any special meaning different than what the plain language in context would suggest. The ’729 patent does not expressly assign a special meaning to the language “dual blade device.” Ex. 1001. We find that the record 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. 50:9–10 (Petitioner adopting the Board’s understanding of *dual blade*), 53:17–22 (Petitioner adopting the Board’s understanding of *ab interno*), 70:17–18 (Patent Owner adopting the Board’s understanding of *dual 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).

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;⁷ and (4) considering objective evidence indicating obviousness or non-obviousness.⁸ *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 several grounds for unpatentability of the claims of the ’729 patent. *See supra* Section I.D; *see also* Pet. 4. Under these asserted grounds for unpatentability, Petitioner addresses claims 1–10 (all claims) of the ’729 patent and details, with citation to the asserted prior art and to the supporting testimony of the Netland Declarations, how the claims are allegedly anticipated or rendered obvious by the prior art. Pet. 27–94. Where asserted unpatentability is based on obviousness and a modification or combination of prior art, Petitioner also details the motivation to modify or combine references and why the person of ordinary skill in the art would have had a reasonable expectation of success. *See id.* at 52–73, 90–94.

⁷ There is no dispute as to the level of ordinary skill in the art. *See supra* Section II.A.

⁸ There is no asserted evidence pertaining to objective indicia of non-obviousness. *See Resp.*

As noted above (*supra* Section I.D), Petitioner’s Grounds 1–4 assert the unpatentability, ultimately, of claims 1–10 as anticipated by Quintana and as obvious over Quintana, individually, and in combination with Lee. Similarly, Petitioner’s Grounds 5 and 6 assert the unpatentability of these claims over Jacobi, individually, as anticipated and obvious. Therefore, with the understanding that the legal requirements of anticipation and obviousness differ, below we address Petitioner’s challenges by grouping Grounds 1–4 together and 5 and 6 together, because the facts for each of these groupings are common, as are Patent Owner’s arguments thereover. *See* Resp. 12 (“In view of their overlap and similarity, the six grounds may be viewed in two groups – asserted invalidity based on Quintana (Grounds 1-4) or Jacobi (Grounds 5-6)”).

1. OBVIOUSNESS OVER QUINTANA AND LEE

Petitioner’s Grounds 1–4 challenge claims 1–10 (all claims) of the ’729 patent as anticipated by Quintana and obvious over Quintana, individually, and combined with Lee. These grounds are largely based on the same evidence, although one is based on anticipation and the others obviousness. Because, as discussed below, we conclude that the challenged claims would have been obvious over Quintana and Lee, as asserted by Petitioner, we address the obviousness grounds and do not reach a conclusion on anticipation, as unnecessary.

a. Combining Quintana and Lee and Reasonable Expectation of Success

As we discuss in detail below (*see infra* Sections II.D.1.b–c), Petitioner cites Quintana as teaching or suggesting the limitations of every claim, and cites Lee as supplementing Quintana’s disclosure, *for example*, to clarify that the Quintana-disclosed procedure would have been understood to

be *ab interno* and involve cutting and removing strips of trabecular meshwork, that the edges of the Quintana device used would have been understood to provide dual, sharp, cutting blades, that anterior chamber fluid levels would have been understood to be maintained during the Quintana procedure, and that it was known that the tip of the Quintana device may be bent at any angle demanded by surgery needs. *See, e.g.*, Pet. 53, 59–61, 64–68, 71–72. As an initial matter, however, we address whether Petitioner has established that the ordinarily skilled artisan would have been motivated to combine Quintana and Lee and whether they would have had a reasonable expectation of success. For the reasons discussed below, we find Petitioner has done so.

Petitioner asserts that an ordinarily skilled artisan would have been motivated to combine Quintana and Lee, and to modify Quintana's disclosed methods and devices as taught by Lee to improve eye surgery, for example, to make it safer and more convenient. Pet. 57–58, 60–62, 64–73 (citing Ex. 1003 ¶¶ 56, 101–102, 173–176, 181–182, 188, 196, 204, 207–208, 216–218, 220–221, 227–229; Ex. 1004, 4; Ex. 1006, Abstract, 1:39–47, 1:54–2:7, 3:39–42, 3:50–57, 4:18–48, 5:61–65, 6:14–40, Figs. 2, 3, 5). Petitioner asserts that, in addition to the two references being directed to closely related subject matter, modifying Quintana in view of Lee would have required mere simple substitutions of known procedures and structures, or minor adjustments to disclosed devices (e.g., ensuring sharp edges, additional bending), and success would have been expected. *See, e.g., id.* at 60, 62.

Patent Owner argues that there would have been no motivation to modify Quintana's device because, of the cited prior art, only Quintana mentions using a standard hypodermic needle to create or remove a strip of

trabecular meshwork. Resp. 35–36 (citing Ex. 2019 ¶¶ 86 (testimony that the prior art lacks teaching of a hypodermic needle), 154). We do not agree with Patent Owner’s conclusory argument. Whether using a modified hypodermic needle or not, Lee’s disclosure is nevertheless directed to a very similar tool to Quintana’s (Lee’s: “a more or less cylindrical hollow shaft” having a “handle end” and a “cutting edge end”; Lee’s device may have a tip of 0.5 mm diameter and Quintana’s device may have a tip 0.4 mm wide) for use in a substantially identical procedure as Quintana. *See, e.g.*, Ex. 1003 ¶¶ 171, 175–175, 177–178; Ex. 1004, 3-4; Ex. 1006, 4:18–22.

Patent Owner argues that modifying Quintana would not yield a predictable result; however, it is unclear upon what Patent Owner bases this argument as there is no immediate citation to evidence. Resp. 36. In any event, we do not agree with Patent Owner’s arguments. Quintana’s tool and its use, as with Lee’s, is sufficiently simple and well explained that we disagree that there would have been any significant unpredictability in modifying Quintana’s tool and procedure in view of Lee’s disclosure, as *ab interno* eye procedures were well known and Dr. Netland explicitly testified that success would have been expected by the ordinarily skilled artisan. Ex. 1003 ¶¶ 173, 175.

Patent Owner argues Quintana actually discouraged modifying its bent-tip needle to sharpen its edges because there would have been some “fear of reducing the effectiveness of the device in working for its intended purpose in the tangential approach . . . including increasing the risk of undesirable injury.” Resp. 36. We do not agree with Patent Owner. We agree with Dr. Netland’s express testimony that ensuring Quintana’s needle had sharp edges would have been obvious as it would make the device

“more effective,” and that modifying Quintana in view of Lee would have been predictable, expectedly successful, and also that the ordinarily skilled artisan would “not have been dissuaded from modifying Quintana’s method.” Ex. 1003 ¶¶ 175, 177, 180.

Patent Owner’s arguments that the ordinarily skilled artisan would not have been motivated to combine Quintana and Lee and would not have had a reasonable expectation of success (Resp. 39–45) do not so much assert that these references would not be combined or expected to be successful, but rather that their combination does not meet the claim elements. We have noted above that there would have been reasons to combine Quintana and Lee and the evidence supports that there also would have been a reasonable expectation of success.

As noted above, we do not agree with Patent Owner’s arguments and, for reasons below, we agree with Petitioner that Quintana and Lee would have been combined with a reasonable expectation of success. Quintana, Lee, and the invention claimed by the ’729 patent each are directed to the same field of endeavor, i.e., glaucoma eye surgery and tools for such procedures or, even more particularly, eye surgery tools for stripping trabecular network to treat glaucoma. *See* Ex. 1001, Abstract, 1:35–39, 1:66–2:3, 6:43–7:6 (claim 1); Ex. 1003 ¶¶ 91–103, 175, 181, 192; Ex. 1004, 3–3; Ex. 1006, Abstract, 3:50–57. We agree with Petitioner that the ordinarily skilled artisan would have looked to Quintana and Lee’s teachings together and would have, for example, modified Quintana’s device or procedure in view of Lee for the advantages expressed by the references themselves, such as providing sharp cutting edges to better excise tissue.

Quintana's disclosed device, a bent-tip hypodermic needle, is a simple tool, and the reference explains its use to strip delicate trabecular meshwork tissue to treat glaucoma. Ex. 1004, 3–4. Quintana is not explicit about some features of its bent-tip needle, for example, just how sharp its cutting edges are, or how exactly the device should enter the eye's anatomy to strip the trabecular meshwork tissue. *Id.* Thus, if supporting information was desired, the ordinarily skilled artisan would certainly have looked to Lee for details for a trabecular meshwork stripping tool and method because that is exactly what Lee teaches designing and using a tool for. *See supra* Section I.F; *see also* Ex. 1003 ¶ 181 (discussing Lee's *ab interno* goniotomy surgery with a dual blade device). “[I]f a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill.” *KSR*, 550 U.S. at 417. Here, ordinarily skilled artisans would have recognized that the advantageous structures and techniques of Lee would improve Quintana's device and methods because Lee clarifies, for example, that *ab interno* techniques were well known as useful for goniotomy procedures and were established to be successful and improved patient comfort, recovery time, and safety, and because Lee also clarifies that using a sharp, dual blade device for such a procedure enables the extraction of large intact tissue samples of trabecular meshwork. *See, e.g.*, Ex. 1003 ¶¶ 174–176, 181. These advantages of Lee's device and technique would also have improved Quintana's trabecular meshwork stripping goniotrabeculotomy device and technique. *Id.* 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. We do not find that it would have taken much, if any, creativity on the part of the ordinarily skilled artisan to have modified, if necessary, Quintana’s tool and its use (e.g., to have two sharp sides and to use it in an *ab interno* procedure) in view of Lee because each reference teaches a very simple device and explains its use. Such modification to Quintana, however, would likely not have been necessary because, as discussed herein (*see infra* Section II.D.1.b), Quintana teaches its device has sharp sides and is used in an *ab interno* procedure.

The simplicity of Quintana’s device and the straightforwardness of Lee’s disclosure supports Petitioner’s position that the ordinarily skilled artisan would have had a reasonable expectation of success as “[t]he 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; *see, e.g.*, Ex. 1003 ¶¶ 175, 181 (testifying that modifying Quintana in view of Lee would amount to simple substitutions of known procedures or structural features and ordinarily skilled artisans would have expected success).

For the reasons above and the rationale set forth in the aforementioned portions of the Petition (as supported by the First Netland Declaration and other evidence cited in the Petition), we agree with Petitioner that the ordinarily skilled artisan would have had reason to combine the teachings of Quintana and Lee with a reasonable expectation of success.

We analyze below Petitioner’s assertions as to how Quintana and Lee teach or suggest the limitations of the challenged claims and Patent Owner’s arguments thereover.

b. Independent Claim 1

Independent claim 1's preamble states "[a]n *ab interno* method for forming an opening in trabecular meshwork of a patient's eye." Ex. 1001, 6:43–45 (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, to treat glaucoma by incising the trabecular meshwork of an eye, by accessing it with an instrument via penetration through the anterior chamber. Pet. 27–37 (citing Ex. 1004, 3–4, Figs. 1, 2; Ex. 1003 ¶¶ 91–100; Ex. 1020; Ex. 1021). Petitioner asserts that, to the extent there is any dispute regarding whether Quintana discloses an *ab interno* procedure, performing Quintana's goniotomy procedure in an *ab interno* way would have been obvious to the skilled artisan, particularly in view of Lee, which teaches an *ab interno* procedure for glaucoma treatment called goniectionomy, which includes using a dual-bladed, hollow tool to excise and remove tissue from the eye's trabecular meshwork via access through the eye's anterior chamber. *Id.* at 57–58 (citing Ex. 1006, Abstract, 1:54–2:7, 3:50–57, 4:18–48, 5:61–65, 6:14–27, Figs. 2, 3; Ex. 1003 ¶¶ 101–103).

Patent Owner argues Quintana does not teach an *ab interno* procedure. Resp. 31. Patent Owner's position is that the ordinarily skilled artisan would not have known whether Quintana's procedure was *ab interno* or not because the reference is not clear on the matter. *Id.* at 32–34 (citing Ex. 2019 ¶¶ 47–49).

"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]n *ab interno*

method for forming an opening in trabecular meshwork of a patient's eye" recites or, at a minimum, implies, "essential structure or steps" required for the claimed method steps, including anatomically where the later claimed device is inserted 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, individually and combined with Lee, discloses "[a]n *ab interno* method for forming an opening in trabecular meshwork of a patient's eye," as recited by claim 1. Ex. 1001, 6:43–45; Ex. 1003 ¶¶ 114–119, 172–178. We agree with Petitioner and Dr. Netland that 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; Ex. 1003 ¶¶ 113–115. Moreover, as we concluded above, it would have been obvious to combine Lee with Quintana, and Lee quite clearly discloses an *ab interno* procedure, both describing a process of inserting its surgical instrument through the cornea and into the anterior chamber to remove a strip of tissue from the trabecular meshwork, and illustrating the process. Ex. 1006, 1:50–54, 5:55–6:45, Fig. 5.

After the preamble, the first limitation of independent claim 1 is:

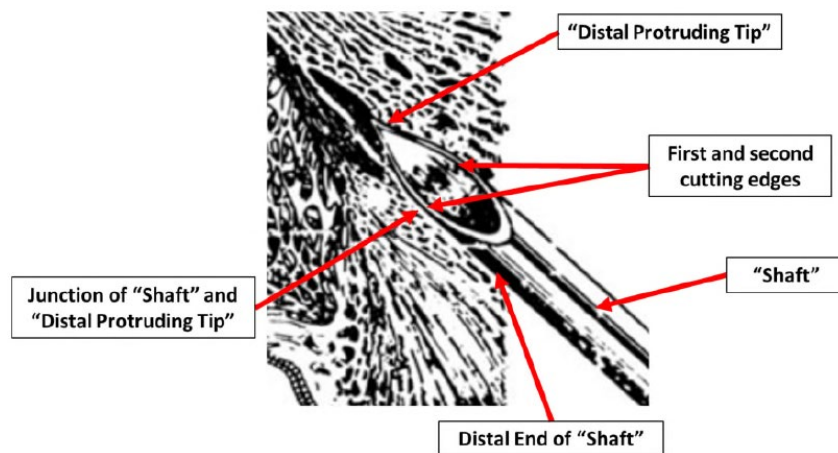
obtaining a dual blade device which comprises a) an elongate proximal portion sized to be grasped by a hand of a human operator and b) an elongate probe extending from the proximal portion, wherein the elongate probe comprises i) a shaft, ii) a distal protruding tip that extends from a distal end of the shaft to form a bend or curve having an angle of at least 30 degrees, said distal protruding tip being sized to be inserted in

Schlemm's Canal and iii) first and second cutting edges located at a junction of the shaft and the distal protruding tip, said first and second cutting edges being formed at spaced-apart locations on the distal end of the shaft, said first and second cutting edges being separated by a distance D;

Ex. 1001, 6:46–58 (emphasis added).

Petitioner asserts that Quintana discloses obtaining a device as claimed in teaching using “a 0.4 x 15 mm needle, or an insulin[]-type needle” with its “tip [bent] 20–30° with a needle holder,” where the needle’s tip has two, spaced-apart (by a distance) cutting edges, and the needle extends from a syringe (a handle therefor), and that Quintana discloses using this device by inserting it through the anterior chamber of an eye into the Schlemm’s Canal to strip trabecular meshwork from the canal’s lumen, while protecting the tissue adjacent the needle’s bend from damage. Pet. 27–35, 37–45 (citing Ex. 1003 ¶¶ 91–96, 98–100, 120–130; Ex. 1004, 3–4, Fig. 1).

Petitioner provides the following portion of Quintana’s Figure 1, annotated to label what it identifies as the claimed cutting edges and other structural parts:



Pet. 38; *see also id.* at 44; Ex. 1003 ¶¶ 121, 129. The image above is a portion of Quintana's Figure 1, zoomed into the tip of a needle with trabecular meshwork there-behind; a text box is added to show that the side edges of the needle's beveled end are the "first and second cutting edges," according to Petitioner. Pet. 38, 44. Text boxes also identify the needle's shaft and its junction with a distal protruding tip. *Id.*

Petitioner asserts that Quintana teaches this device is to be grasped by a hand of a human operator, that the needle constitutes an elongate probe extending from the syringe, which is an elongate proximal portion, that the needle has a shaft and a distal protruding tip at the end of the tube, and that this device is configured to be placed into the Schlemm's Canal of the eye and advanced therein, as claimed. *Id.* at 39–42 (citing, *inter alia*, Ex. 1003 ¶¶ 123–124, 126). Further, Petitioner asserts that Quintana explicitly discloses its device's tip is bent, e.g., 30°, so the convex back of the needle faces the Schlemm's Canal in use to protect the tissue from damage, where the tip is sized for insertion into the canal, as claimed. *Id.* at 42–43 (citing, *inter alia*, Ex. 1003 ¶¶ 127–128). Moreover, regarding cutting edges, Petitioner asserts Quintana's needle's beveled tip's edges on opposite sides of the tube's opening, are spaced apart (by a distance, i.e., the needle's opening) at a junction of the shaft and a distal protruding tip, as claimed. *Id.* at 44–45 (citing, *inter alia*, Ex. 1003 ¶¶ 129–130).

Petitioner further asserts that, in addition to Quintana's disclosure on these elements (e.g., the needle's cutting edges, bend, and procedure), Lee also discloses a (handheld) dual blade device as claimed, used for the same purpose in much the same fashion as Quintana and, so, Quintana's device would have been obvious to use and modify in view of Lee's disclosure so

as to have met the claim limitations, if necessary. *Id.* at 57–58, 61–64 (citing Ex. 1003 ¶¶ 56, 101–103, 181–186, 188; Ex. 1006, 1:39–47, 1:54–2:7, 3:39–42, 3:50–57, 4:18–48, 5:61–65, 6:14–40, Figs. 2, 3, 5; Ex. 1016, 1:43–48). Petitioner asserts that “[a] POSITA would have recognized that one way of [refining Quintana’s procedure] would have been by modifying the cutting edges of Quintana’s needle to improve the cutting edges’ ability to strip TM [(trabecular meshwork)] tissue from SC [(Schlemm’s Canal)], such as by sharpening the edges.” *Id.* at 61 (citing Ex. 1003 ¶ 180).

Petitioner asserts that Lee’s dual blade device and its use to extract large, intact segments of trabecular meshwork eliminated an issue in traditional surgical approaches, which included scarring that blocked the trabecular meshwork incision. *Id.* at 61, 63–64 (citing, *inter alia*, Ex. 1003 ¶¶ 56, 181–182, 187–188).

Patent Owner argues Quintana does not disclose a dual blade device. Resp. 21. Patent Owner’s position is that either Quintana fails to disclose the sides of its device’s tip are sharp and can cut tissue, i.e., are cutting edges, or that Quintana’s needle’s beveled edge can only be considered a single blade rather than dual blades, arguing that only an improper hindsight reading of Quintana would interpret it as having two blades. *Id.* at 21–22, 25, 27 (citing Ex. 2019 ¶¶ 22–24, 28). Patent Owner also argues that Quintana does not disclose a device having a bend with an angle of at least 30°, as claimed, because the reference does not specify where its needle is bent. *Id.* at 30 (citing Ex. 2019 ¶ 81).

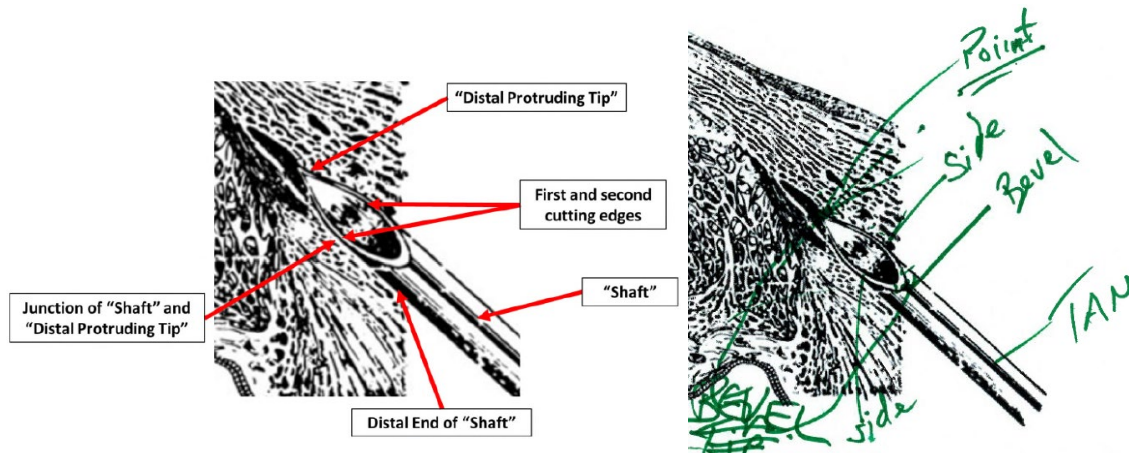
Patent Owner argues that there would have been no motivation to modify Quintana to have first and second cutting edges, as claimed. Resp. 35–36 (citing Ex. 2019 ¶ 86). Patent Owner also argues that combining Lee

with Quintana does not cure the lack of disclosure of a dual blade device or the claimed bend of at least 30 degrees. Resp. 38. Patent Owner takes the position that Lee does not teach a dual blade device because Lee's U-shaped terminal end constitutes a single blade, not two. *Id.* at 40–42 (citing Ex. 2019 ¶¶ 59, 61). Patent Owner also takes the position that there is simply no bend of at least 30° in Lee's shaft. *Id.* at 39–40.

Considering the record in this proceeding in its entirety and each party's positions, we are persuaded by Petitioner's assertions and do not agree with any of Patent Owner's arguments.

We find Quintana does disclose obtaining the dual blade device of the claim. Each party's witness appears to largely agree on how to generally classify the structural parts of Quintana's bent 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 ¶¶ 121–130. 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 annotated the figure during his deposition. Ex. 1043, 192; Ex. 1041, 3:17, 23:3–34:15. Dr. Netland annotated Quintana's Figure 1 to label a distal protruding tip, a shaft, a junction of the distal protruding tip and the shaft, and first and second cutting edges as the sides of the needle's beveled end. *See* Ex. 1003 ¶¶ 121–130. Dr. Netland's testimony is that this device is the dual blade device defined by the claims and that it is used in the manner claimed. *Id.* ¶¶ 112–170. Dr. Condon similarly labeled Quintana's Figure 1 as having a point, a bevel, 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. 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, which clearly discloses a needle having *its tip* bent by 30° as claimed, and 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. 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 of the claimed dual blade device. We find there is ample evidence here that they are so sharp, and that it would be obvious to use such sharp cutting edges.

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).⁹ Dr. Netland provided annotated still screen shots of the videos of these procedures, which we reproduce below:

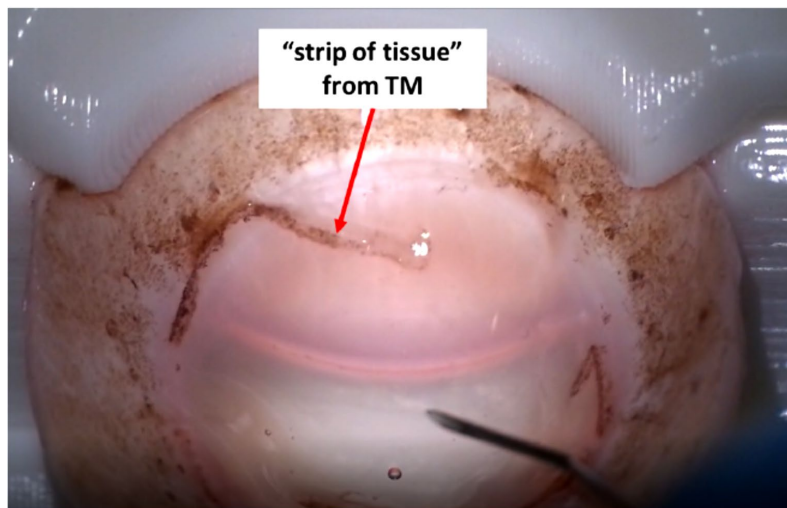


Figure 1

⁹ 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.

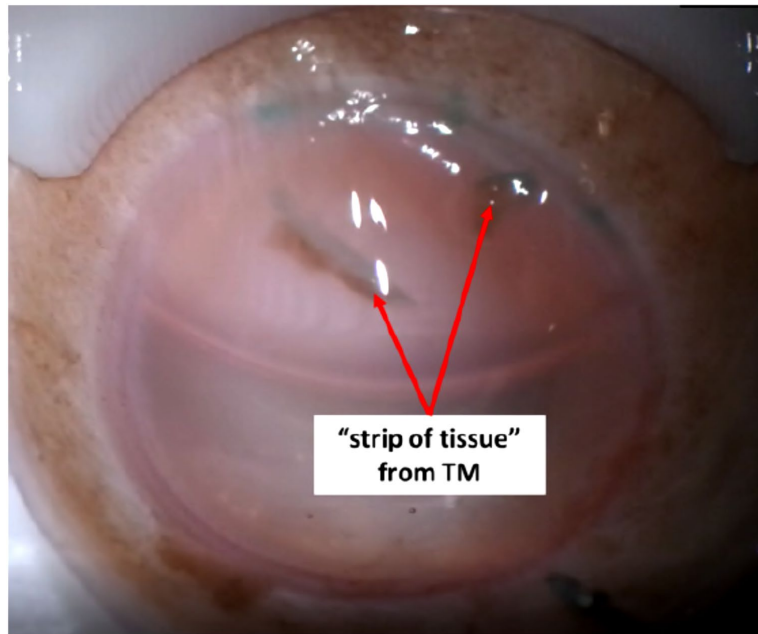


Figure 2

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.

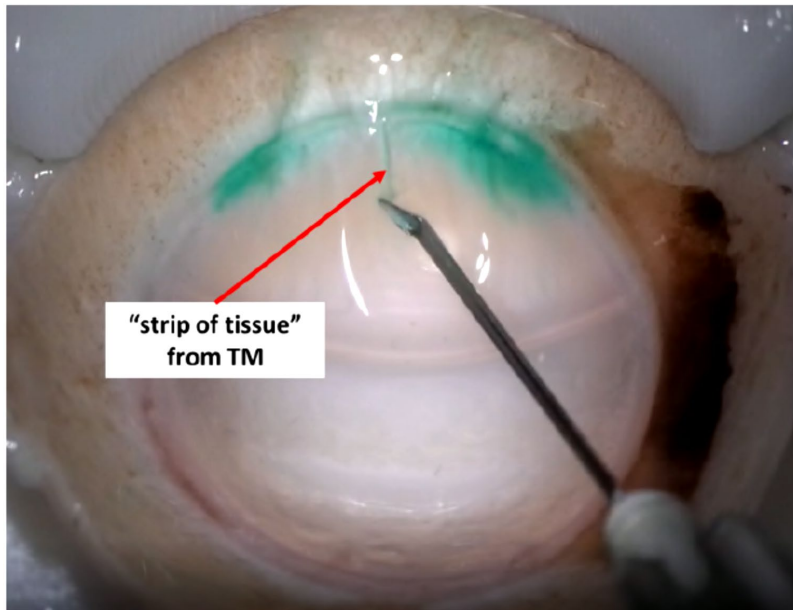


Figure 3

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 position that Quintana teaches obtaining the dual blade device of claim 1.

Although we are persuaded that Quintana teaches a bent-tip needle having two sharp edges for cutting trabecular meshwork tissue, the obviousness of such an arrangement is underscored by the combination of Quintana with Lee. *See* Pet. 57–58, 61–64 (citing, *inter alia*, Ex. 1003 ¶¶ 65, 101–103, 181–182); Reply 18–19 (citing Ex. 1002, 320). We have concluded above that it would have been obvious to combine Quintana and Lee and modify one in view of the other. Thus, it would have been obvious to the ordinarily skilled artisan to use Quintana's bent needle with sharp

edges in an *ab interno* procedure to strip trabecular meshwork, like Lee discloses using a similar device, as asserted by Petitioner.

Lee teaches a device used for the same purpose as Quintana's needle, i.e., to strip trabecular meshwork tissue from Schlemm's Canal in the eye, and Lee teaches that the tip of its device has a cutting edge with a sharpened rim having two sharpened sides (meeting in a distal end 15). *See supra* Section I.F (discussing Lee). The objective of Lee's device is to excise a strip of tissue by cutting it with the sides and tip of its device; the strip of tissue passes through these sharpened sides and an aperture defined thereby. *Id.* Because Quintana's needle is used for this same purpose, it would have been obvious to use sharpened edges like Lee, which Dr. Netland's above-discussed experiments (Ex. 1031–1033) prove they would have been. Either way, the dual blade device would have been obvious over Quintana and Lee.

The next pair of limitations of claim 1 requires “*forming an opening into an anterior chamber of the eye*” and “*inserting the elongate probe [of the dual blade device] through the opening and into the anterior chamber.*” Ex. 1001, 6:59–61 (emphasis added).

Petitioner asserts that these steps are disclosed by Quintana in its disclosure of using its needle to penetrate the anterior chamber at 6 hours (right eye) and 12 hours (left eye), and then that the needle is progressively introduced in the angle.¹⁰ Pet. 45, 64 (citing Ex. 1004, 4; Ex. 1003 ¶¶ 131–132).

¹⁰ 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 ¶¶ 44–45; *see also supra* Section I.C (figures illustrating the trabecular meshwork and angle region).

Patent Owner presents no arguments addressing these limitations of claim 1. *See generally* Resp.

We agree with Petitioner's assertions regarding Quintana teaching these limitations of claim 1 because they are supported by the evidence. We also note that Lee teaches opening the eye's anterior chamber through the cornea and then inserting its device into the anterior chamber through that opening. *See supra* Section I.F (discussing Lee).

Claim 1 next requires "*advancing the elongate probe through the anterior chamber, while the anterior chamber is filled with fluid, to an operative position where the distal protruding tip is positioned within Schlemm's Canal and the first and second cutting edges are contacting the trabecular meshwork.*" Ex. 1001, 6:62–67 (emphasis added).

Petitioner asserts that this is also disclosed by Quintana, and shown in a photograph therein. Pet. 46–48 (citing Ex. 1003 ¶¶ 98–100, 133–137; Ex. 1004, 4, Fig. 2; Ex. 1011, 34–35, 51–52 (Quintana's "healon" is the claimed fluid)). Regarding the recited "fluid," Petitioner also asserts that Lee discloses maintaining fluid levels in the AC to protect the eye from injury and, thus, provides motivation to perform the claimed method step. *Id.* at 65 (citing Ex. 1006, 5:6–15; Ex. 1003 ¶ 192).

Patent Owner presents no new arguments addressing this limitation of claim 1. *See generally* Resp.

We agree with Petitioner's assertions regarding Quintana teaching this limitation of claim 1 because they are supported by the evidence. Quintana (and Lee, for that matter) teaches advancing a respective trabecular meshwork stripping device through the anterior chamber to Schlemm's Canal while the anterior chamber is filled with fluid—healon in Quintana's

disclosure (more generally, “fluid levels” in Lee’s disclosure). Ex. 1004, 4; *see also* Ex. 1006, 5:6–12. (Lee’s similar disclosure)

Claim 1’s concluding clause states,

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

Ex. 1001, 7:1–6 (emphasis added).

Petitioner asserts that the process disclosed by Quintana results in trabecular meshwork being cut (sectioned) as the device is advanced through the Schlemm’s Canal, and that, as claimed, a strip of tissue having a width (i.e., “W”) approximating the distance (i.e., “D”) between Quintana’s device’s cutting edges would result, as claimed. Pet. 36–37, 47–48 (citing Ex. 1003 ¶¶ 98–100, 113–119, 136–137; Ex. 1004, 3–4, Figs. 1, 2). Similar to its assertions over the preamble, Petitioner also asserts that, in addition to Quintana’s disclosure, *ab interno* procedures were well known by 2003, that Lee discloses such a procedure, and that Lee discloses using a double-bladed device in an *ab interno* procedure to concurrently cut and extract regular segments of trabecular meshwork (e.g., of a width of an aperture 16). *Id.* at 59–62 (citing Ex. 1001, 1:35–65, 5:19–26; Ex. 1003 ¶¶ 173–176; Ex. 1006, 5:61–6:45, Fig. 5; Ex. 1007, 5; Ex. 1015 ¶¶ 77–78).

Patent Owner argues Quintana does not disclose creating or removing a strip of trabecular meshwork. Resp. 13 (citing Ex. 2019 ¶ 19); *see also id.* at 27–30 (arguing no strip of a certain width is cut). 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.

Ex. 1004, 4 (emphasis added). Regarding this disclosure, Patent Owner argues that the term "stripped" does not mean cutting and producing a strip of trabecular meshwork that is removed, but merely that an incision is made and the trabecular meshwork is opened to "section" the tissue, and that tissue is merely "moved away" from Schlemm's Canal. Resp. 13–14, 17–18 (citing Ex. 2019 ¶¶ 32, 39; Ex. 2023 (dictionary definition of "section"); Ex. 2024 (dictionary definition of "section")). Patent Owner also argues that Quintana's term "goniotrabeculotomy" means cutting and incising, as opposed to "goniotrabeculectomy," which refers to excising tissue. *Id.* at 16 (citing Ex. 2019 ¶¶ 35–36). Patent Owner also argues that combining Lee with Quintana does not cure Quintana's failure to teach removing a strip of trabecular meshwork (of the width of the distance between the cutting edges). Resp. 38.

Regardless of the term Quintana uses to label its procedure, we do not agree with Patent Owner that Quintana fails to teach stripping trabecular meshwork, or that it merely teaches moving the tissue, because the term "stripped" on its face indicates a strip of tissue is cut and Dr. Netland's experiments demonstrate that this happens when Quintana's procedure is followed. We also do not agree with Patent Owner that combining Lee with Quintana fails to teach that, when the device is used as intended, a strip of trabecular meshwork having a width approximating the width between the devices cutting edges will be cut and removed as the device is moved along Schlemm's Canal and each edge simultaneously cuts trabecular meshwork.

This is the entire point of Lee's disclosure and, also, Dr. Netland's experiments showed that this is just what happens when Quintana's procedure is followed. *See supra* Section I.F (discussing Lee); *see also* Ex. 1030 ¶¶ 7–26; *see also* Exs. 1031–1033 (Dr. Netland's videos).

As discussed above, we are persuaded by Petitioner's assertions and evidence regarding the obviousness of independent claim 1 over Quintana and Lee because it is supported by the evidence. We have considered Patent Owner's arguments as set forth in the Response and Sur-Reply and they are not persuasive. We conclude Petitioner has established by a preponderance of the evidence that claim 1 is unpatentable.

c. Dependent Claims 2–10

Petitioner also asserts that dependent claims 2–10 would have been obvious over Quintana, individually, and in combination with Lee, and has detailed how such prior art discloses and teaches each element or step of these claims. Pet. 48–57, 66–73 (citing Ex. 1001, 1:35–45, 1:60–65; Ex. 1004, 3–4; Ex. 1003 ¶¶ 35–36, 139–170, 196–212, 216–229; Ex. 1005, 2, 8; Ex. 1006, 1:54–2:7, 3:50–57, 4:49–54, 5:6–15, 6:14–27; Ex. 1007, 2; Ex. 1009, 4, 6, 9, Fig. XXV-1; Ex. 1010, 5; Ex. 1015 ¶ 23; Ex. 1016 ¶ 23; Ex. 1018, 1–2). In these same portions of the Petition, Petitioner also identifies why the skilled artisan would have been motivated to modify or combine the prior art, where necessary, and asserts that the skilled artisan would have had a reasonable expectation of success. *Id.*

We address Petitioner's assertions regarding these dependent claims and any argument by Patent Owner thereon below.

Claim 2

Claim 2 depends directly from independent claim 1 and recites “*further comprising the step of infusing fluid into the anterior chamber under controlled pressure to keep the anterior chamber filled with fluid during performance of the method.*” Ex. 1001, 7:7–10 (emphasis added).

Petitioner notes claim 2’s dependence from claim 1 and that claim 1’s limitations are taught by Quintana and Lee. Pet. 48, 66. Regarding claim 2’s additional limitation, Petitioner asserts that Quintana teaches injecting healon “under controlled pressure,” as claimed, because the reference discloses a surgeon injecting this fluid during the procedure via the syringe to which the cutting needle is attached. Pet. 48–49 (citing Ex. 1003 ¶¶ 139–140; Ex. 1004, 3–4). Petitioner asserts that the pressure used to inject this fluid must be “controlled” or else the procedure may lead to chamber loss or extreme deepening, which are both undesirable. *Id.* Petitioner also asserts that Lee likewise teaches maintaining fluid levels in the anterior chamber to protect the cornea and lens from injury, thus the ordinarily skilled artisan would have been motivated to perform Quintana’s method while so maintaining fluid levels. *Id.* at 66 (citing Ex. 1003 ¶ 196; Ex. 1006, 5:6–15).

Patent Owner does not specifically argue over claim 2. *See generally* Resp.

We agree with Petitioner that the evidence supports that Quintana and Lee teach the subject matter of claim 2 and that the claim would have been obvious over this prior art. *See* Ex. 1003 ¶¶ 139–140, 196; Ex. 1004, 3–4; Ex. 1006, 5:6–15.

Claim 3

Claim 3 depends directly from independent claim 1 and recites “*wherein the strip of tissue cut from the trabecular meshwork has a length of about 2 to 10 millimeters.*” Ex. 1001, 7:11–13 (emphasis added).

Again noting that Quintana and Lee render obvious independent claim 1, Petitioner asserts that Quintana discloses the added limitation of claim 3 because Quintana’s procedure is described as a 100°–120° trabeculotomy, which would achieve the claimed 2–10 mm strip of trabecular meshwork tissue given that the circumference of the Schlemm’s Canal and its associated trabecular meshwork is about 36 mm. Pet. 49, 66–67 (citing Ex. 1003 ¶¶ 144, 199–200; Ex. 1004, 4; Ex. 1010, 5). Similarly, we note that Lee teaches excising trabecular meshwork tissue “for approximately one-third of the angle circumference.” Ex. 1006, 6:28–49 (one third of about 36 mm would be about 12 mm, which may be excised as one or multiple tissue samples).

Patent Owner, in its Response, presents no arguments specifically directed to this claim. *See generally* Resp. In its Sur-Reply, Patent Owner argues for the first time that cutting a strip of trabecular meshwork of about 2–10 mm is not disclosed by Quintana. Even were this argument not waived by Patent Owner, which it was as not presented in the Response, we do not agree.

We agree with Petitioner that Quintana (and Lee) discloses cutting a strip trabecular meshwork of 2–10 mm because the evidence supports that Quintana’s 100–120° trabeculotomy (and Lee’s approximately one-third of the angle circumference) teaches such subject matter. *See* Ex. 1003 ¶¶ 144,

199–200; Ex. 1004, 4; Ex. 1006, 6:28–49. We are persuaded by Petitioner that claim 3 would have been obvious over Quintana and Lee.

Claim 4

Claim 4 depends directly from claim 1 and recites “*further comprising the step of: removing the strip of tissue from the patient’s eye.*” Ex. 1001, 7:15–16 (emphasis added).

Again noting that the subject matter of claim 1 is taught by Quintana and Lee, Petitioner asserts that removing a strip of trabecular meshwork, as claimed, is taught by the prior art because doing so was well known in the art and “achieving” a section, as disclosed by Quintana, would mean removing the tissue from the patient’s body. Pet. 50–53, 67–68 (citing Ex. 1001, 1:35–45, 1:54–2:7, 3:50–57; Ex. 1003 ¶¶ 147, 157–159; Ex. 1004, 3–4; Ex. 1007, 2; Ex. 1015 ¶ 23; Ex. 1016 ¶ 23; Ex. 1018, 1–2). Petitioner asserts that, even if Quintana is not explicit about removing this tissue, it would have been obvious because doing so was so well known in the art, as exemplified by, for example, Lee, which discloses removing stripped tissue for histological examination, and because leaving stripped tissue in the patient’s eye was undesirable. *Id.* at 52–53, 67–68 (citing, *inter alia*, Ex. 1003 ¶¶ 157–159, 203–204; Ex. 1006, 1:54–2:7, 3:50–57).

We note, stripping, cutting, and removing tissue is expressly taught by Lee, which discloses providing a retractable stylet or hollow shaft and sleeve on its device for this purpose. Ex. 1006, Abstract, 1:57–60, 6:37–42, 6:58–7:6, 7:46–48 (claim 5), Figs. 4, 5–8.

Patent Owner argues that there was “[n]o motivation . . . in the art for modifying the Quintana method to include the step of removing a strip of

TM tissue from the patient's eye.” Resp. 43 (citing Ex. 2019 ¶ 187). We do not agree with Patent Owner's argument.

We agree with Petitioner's assertions. As stated by Petitioner, it would have been obvious to remove any stripped trabecular meshwork tissue from the eye, for example, to mitigate possible blockages if such tissue were left in the eye, or to provide a tissue sample for examination, as taught by Lee. See Ex. 1003 ¶¶ 157–159, 203–204; Ex. 1006, 1:54–2:7, 3:50–57. Thus, we agree with Petitioner that claim 4 would have been Obvious over Quintana and Lee.

Claim 5

Claim 5 depends from dependent claim 4 (discussed above) and, thereby, from independent claim 1, and recites “*after the first and second cutting edges have cut the strip of tissue from the trabecular meshwork, the strip of tissue remains connected to the trabecular meshwork and wherein the method further comprises the step of: disconnecting the strip of tissue such that it may be removed from the eye.*” Ex. 1001, 7:17–8:5 (emphasis added).

Petitioner asserts that the subject matter of claim 5, i.e., stripped tissue remains connected to the trabecular meshwork immediately after its initial cutting followed by its disconnection and removal, would have been obvious because such a scenario was well-known and any still connected trabecular meshwork tissue would have been removed to prevent obstructions to fluid outflow. Pet. 54 (citing Ex. 1003 ¶¶ 161–162; Ex. 1005, 8; Ex. 1007, 2). We also note that this scenario is expressly disclosed by Lee. Ex. 1006, 5:55–6:45, Fig. 5.

Patent Owner does not specifically argue over claim 5. *See generally* Resp.

We agree with Petitioner that the evidence supports that Quintana and Lee teach the subject matter of claim 5 and that the claim would have been obvious over this prior art. *See* Ex. 1003 ¶¶ 161–162; Ex. 1005, 8; Ex. 1006, 5:55–6:45, Fig. 5; Ex. 1007, 2.

Claim 6

Claim 6 depends from dependent claim 5 (discussed above) and, thereby from dependent claim 4 and independent claim 1, and recites “*wherein the disconnecting step comprises using a tissue severing apparatus to transect or sever the strip of tissue so as to disconnect it from the patient’s body.*” Ex. 1001, 8:6–9 (emphasis added).

Petitioner asserts that disconnecting stripped tissue using a severing apparatus, as claimed, would have been obvious to prevent blockage and that such an apparatus was well known as evidenced by Quintana’s needle, Jacobi’s scraper, and Ferrari’s forceps. Pet. 54–56 (citing Ex. 1003 ¶¶ 164–165); *see also* Ex. 1004 (Quintana); Ex. 1007 (Jacobi); Ex. 1018 (Ferrari). We note also that Lee expressly discloses at least two alternative apparatuses for severing a strip of trabecular meshwork tissue to disconnect it from the patient for subsequent examination. Ex. 1006, 3:50–57, 5:55–7:10, Figs. 4–8 (describing stylet 20 with tip 20, or sleeve 50).

Patent Owner does not specifically argue over claim 6. *See generally* Resp.

We agree with Petitioner that the evidence supports that Quintana and Lee teach the subject matter of claim 6 and that the claim would have been

obvious over this prior art. *See* Ex. 1003 ¶¶ 164–165; Ex. 1004; Ex. 1006, 3:50–57, 5:55–7:10, Figs. 4–8.

Claim 7

Claim 7 depends directly from independent claim 1 and recites “*wherein the step of forming an opening into the anterior chamber of the eye comprises forming an incision through a cornea of the eye.*” Ex. 1001, 8:10–12 (emphasis added).

Again noting that claim 1 would have been obvious over Quintana and Lee, Petitioner asserts that the subject matter of claim 7 is disclosed by Quintana’s teaching a procedure involving penetrating the anterior chamber with its needle through the scleral side of the limbus, which is part of the cornea. Pet. 50–51 (citing Ex. 1003 ¶¶ 35–36, 149; Ex. 1004, 4; Ex. 1007, 2; Ex. 1009, 4, 9, Fig. XXV-1). Petitioner also asserts that Lee teaches making an incision to the anterior chamber through the clear cornea through which devices may be introduced and that it would have been obvious to perform Quintana’s procedure using such a technique. *Id.* at 68 (citing, *inter alia*, Ex. 1003 ¶¶ 35–36, 206–208; Ex. 1006, 6:14–27); *see also* Ex. 1006, Fig. 5 (illustrating such an incision).

Patent Owner does not specifically argue over claim 7. *See generally* Resp.

We agree with Petitioner that the evidence supports that Quintana and Lee teach the subject matter of claim 7 and that the claim would have been obvious over this prior art. *See* Ex. 1003 ¶¶ 35–36, 149, 206–208; Ex. 1004, 4; Ex. 1006, 6:14–27, Fig. 5; Ex. 1007, 2; Ex. 1009, 4, 9, Fig. XXV-1.

Claim 8

Claim 8 depends directly from independent claim 1 and recites “*wherein the method is performed under direct visualization through a lens device positioned on an anterior aspect of the eye.*” Ex. 1001, 8:12–14 (emphasis added) (note, the line numbering in the ’729 patent is somewhat imprecise and this is the best approximation for citation thereto).

Again, with the understanding that the subject matter of claim 1 is taught by Quintana and Lee, Petitioner asserts that the subject matter of claim 8 is taught by Quintana in its disclosure of using a “Swann lens,” which is a goniolens placed on the eye, for visualizing Quintana’s disclosed procedure. Pet. 51–52, 68–69 (citing Ex. 1003 ¶¶ 151, 210; Ex. 1004, 3–4).

Patent Owner does not specifically argue over claim 8. *See generally* Resp.

We agree with Petitioner that the evidence supports that Quintana and Lee teach the subject matter of claim 8 and that the claim would have been obvious over this prior art. *See* Ex. 1003 ¶¶ 151, 210; Ex. 1004, 3–4.

Claim 9

Claim 9 depends directly from independent claim 1 and recites “*wherein the angle is less than approximately 90 degrees.*” Ex. 1001, 8:15–16 (emphasis added).

Petitioner asserts that Quintana discloses bending its needle’s tip up to 30°, which is less than the claimed 90°. Pet. 52, 69 (citing Ex. 1003 ¶¶ 153, 212; Ex. 1004, 3). We note also that Lee expressly teaches “the plane of the tip of cutting edge 14 will be at an acute angle of about 5 to 45 degrees with respect to the plane of shaft 10,” which also teaches an angled end of its device of less than 90°. Ex. 1006, 4:49–52.

Patent Owner generally argues that “Quintana does not describe or depict precisely where at the needle tip, or along what axis of the needle, the bend is made,” “does not necessarily disclose a bend or curve having an angle of at least 30° as required by the ’729 Patent claims,” and there was “[n]o motivation . . . in the art for modifying the Quintana device to create a bend beyond 20-30°.” Resp. 30, 37–38, 44–45 (citing Ex. 2019 ¶¶ 81–82, 214). We do not agree with Patent Owner’s arguments.

We agree with Petitioner that it would have been obvious to modify Quintana’s needle tip’s bend by any amount (e.g., 20°–30°, 5°–45°, 0°, greater than 45°) based upon the surgeon’s desires and surgical requirements, as taught by Lee. *See, e.g.*, Ex. 1003 ¶¶ 153, 167–170, 212; Ex. 1006, 4:49–54. Furthermore, precisely where the device is bent is not recited by any claim, therefore, the prior art’s alleged lack of such disclosure is not determinative.

Quintana discloses bending the needle’s tip by 30° (Ex. 1004, 3) and Lee discloses that its device’s cutting edges are angled (e.g., bent) with respect to the shaft to which it is attached (Ex. 1006, 4:49–54). Nothing more is required and Quintana and Lee render obvious claim 9 as asserted by Petitioner.

Claim 10

Claim 10 depends from dependent claim 9 and, thereby, from independent claim 1, and recites “*wherein the angle is approximately 90 degrees.*” Ex. 1001, 8:17–18. (emphasis added)

Petitioner asserts that, although Quintana teaches bending the tip of its needle only up to 30°, it was well-known and would have been obvious to further bend the tip to near a right angle to perform an *ab interno* procedure

for many reasons, such as varying Quintana's angle to expand or improve results and to permit a more perpendicular approach while still protecting tissue with the convex side of the needle, with expected success. Pet. 55–57 (citing Ex. 1003 ¶¶ 167–170; Ex. 1004, 4–4; Ex. 1005, 2; Ex. 1006, 4:49–54). Petitioner specifically cites Lee as teaching angling the end of the device “depending on surgical requirements.” *Id.* at 55 (citing Ex. 1006, 4:49–54). We note this portion of Lee states “[t]he angle of cutting edge 14, however, may vary from as little as 0 degrees to greater than 45 degrees depending on surgical requirements,” which evidences that such an angle is a result-effective, optimizable variable, which would have been obvious to modify in Quintana's or Lee's devices. Ex. 1006, 4:49–54; *see also* Ex. 1003 ¶¶ 167–170 (reaching this conclusion on modifying the bend angle of Quintana's device).

The same arguments by Patent Owner asserted for claim 9 apply to claim 10 and they are unpersuasive for the reasons above.

We agree with Petitioner that the evidence supports that Quintana and Lee teach the subject matter of claim 10 and that the claim would have been obvious over this prior art. *See* Ex. 1003 ¶¶ 167–170; Ex. 1004, 4–4; Ex. 1005, 2; Ex. 1006, 4:49–54.

d. Summary of Petitioner's Challenges Under Grounds 1–4

As discussed and for the reasons set forth above, reflecting the positions taken and evidence cited in the Petition, claims 1–10 would have been obvious under 35 U.S.C. § 103 over Quintana and Lee. Because we conclude that these references would have been combined with a reasonable expectation of success, and that claims 1–10 would have been obvious over

this prior art combination, we do not address whether any claims are anticipated by or would have been obvious over Quintana individually.

2. *ANTICIPATION BY AND OBVIOUSNESS OVER JACOBI*

Petitioner further asserts under Grounds 5 and 6 that Jacobi anticipates and would have rendered obvious claims 1–10 (all claims) of the ’729 patent. Pet. 74–94. For example, Petitioner asserts that Jacobi discloses an *ab interno* procedure, much the same as the above-discussed goniotomy of Quintana and goniectionomy of Lee, but called “goniocurettage” by Jacobi, which uses an instrument similar to the bent needle of Quintana or instrument of Lee, called a “gonioscraper,” to peel off strings of trabecular tissue to treat glaucoma. *Id.* Petitioner asserts that Jacobi’s gonioscraper is the dual blade device of claim 1 and that Jacobi discloses its method of use as being the same as the method steps of claim 1, detailing each claim limitation and how it is disclosed by Jacobi, as Petitioner did under Grounds 1–4. *Id.* at 74–88 (citing Ex. 1007, 1–2, 5, Figs. 1, 2; Ex. 1003 ¶¶ 104, 230–252; Ex. 1006 4:38–41, Figs. 2–3; Ex. 1002, 320; Ex. 1013, 2).

We have discussed Petitioner’s Grounds 1–4 above and concluded that claims 1–10 are each unpatentable over Quintana and Lee. Therefore, we do not address in detail or reach a conclusion on patentability for Petitioner’s Grounds 5 and 6 in view of Jacobi. *See* Hr’g Tr. 55:9–10 (during oral argument, Petitioner likewise did not “dwell on Jacobi” or discuss its merits).

III. CONCLUSION¹¹

Having considered the evidentiary record before us and the parties' respective positions on the grounds asserted in the Petition, we find that Petitioner has shown that claims 1–10 would have been obvious over Quintana and Lee. Therefore, Petitioner has shown by a preponderance of the evidence that claims 1–10 of the '729 patent would have been unpatentable in view of the cited prior art.

In summary:

Claims	35 U.S.C. §¹²	References	Claims Shown Unpatentable	Claims <u>Not</u> Shown Unpatentable
1–4, 7–9	102	Quintana		
4–6, 10	103	Quintana		
1–4, 7–9	103	Quintana, Lee	1–4, 7–9	

¹¹ 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).

¹² As noted above, the grounds for unpatentability based on Quintana's anticipation, obviousness over Quintana alone, and over the Jacobi reference are not reached because all claims are found to be unpatentable as obvious over Quintana and Lee.

Claims	35 U.S.C. §¹²	References	Claims Shown Unpatentable	Claims <u>Not</u> Shown Unpatentable
4–6, 10	103	Quintana, Lee	4–6, 10	
1–4, 7, 8	102	Jacobi		
5, 6, 9, 10	103	Jacobi		
Overall Outcome			1–10	

ORDER

Accordingly, it is hereby:

ORDERED that Petitioner has demonstrated by a preponderance of the evidence that claims 1–10 of the '729 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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Patent 9,107,729 B2

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