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Paper 50
Date: April 20, 2022

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NEW WORLD MEDICAL, INC.,
Petitioner,

v.

MICROSURGICAL TECHNOLOGY, INC.,
Patent Owner.

IPR2020-01711
Patent 9,358,155 B2

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

TARTAL, *Administrative Patent Judge*.

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

We have jurisdiction to conduct this *inter partes* review under 35 U.S.C. § 6. This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) (2018) and 37 C.F.R. § 42.73 (2020). For the reasons discussed below, we determine New World Medical, Inc., ("Petitioner")[1] has shown by a preponderance of the evidence that claims 1–7 ("the Challenged Claims") of U.S. Patent No. 9,358,155 B2 ("the '155 patent," Ex. 1001) are unpatentable.

I. INTRODUCTION

A. Summary of Procedural History

Petitioner filed a Petition pursuant to 35 U.S.C. §§ 311–319 requesting an *inter partes* review of the Challenged Claims. Paper 1 ("Pet."). We instituted an *inter partes* review of the Challenged Claims on all grounds of unpatentability asserted in the Petition. Paper 11. MicroSurgical Technology, Inc., ("Patent Owner")[2] filed a Patent Owner Response. Paper 17 ("Resp."). Petitioner filed a Reply to the Patent Owner Response. Paper 27 ("Reply"). Patent Owner filed a Sur-reply in support of the Patent Owner Response. Paper 34 ("Sur-reply").

Following oral argument, we entered a transcript of the hearing in the record. Paper 48 (Tr."). Petitioner bears the burden of proving unpatentability of each claim it has challenged by a preponderance of the evidence, and the burden of persuasion never shifts to Patent Owner. *See* 35 U.S.C. § 316(e) (2018); 37 C.F.R. § 42.1(d); *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015).

[1] Petitioner identifies no additional real parties in interest. Pet. x.
[2] Patent Owner identifies no additional real parties in interest. Paper 3, 1.

B. Related Matters

Patent Owner states that the '155 patent "is related to" U.S. Patent Nos. 9,107,729 ("the '729 patent") and 9,820,885 ("the '885 patent"). Paper 3, 1. The parties identify the '155 patent as a subject of *MicroSurgical Technology, Inc., et al. v. New World Medical*, Case No. 20-cv-00754 (D. Del., filed June 4, 2020). Pet. x; Paper 3, 1. Petitioner identifies four additional patents at issue in that district court proceeding, each of which is challenged by Petitioner in the following *inter partes* review proceedings: IPR2020-01573 regarding '729 patent; IPR2021-00017 regarding the '885 patent; IPR2021-00065 regarding U.S. Patent No. 10,123,905 B2; and IPR2021-00066 regarding U.S. Patent No. 9,999,544 B2. *See* Pet. x. All claims challenged in each of those *inter partes* reviews were found by a preponderance of the evidence to be unpatentable. *New World Medical, Inc. v. Microsurgical Technology, Inc.*, IPR2020-01573, Paper 64 (PTAB March 11, 2022); *New World Medical, Inc. v. Microsurgical Technology, Inc.*, IPR2021-00017, Paper 49 (PTAB April 20, 2022); *New World Medical, Inc. v. Microsurgical Technology, Inc.*, IPR2021-00065, Paper 52 (PTAB March 11, 2022); *New World Medical, Inc. v. The Regents of the University of California*, IPR2021-00066, Paper 50 (PTAB March 11, 2022).

C. The '155 Patent

The '155 patent issued on June 7, 2016, from U.S. Application No. 14/789,632, which was filed on July 1, 2015, and ultimately claims priority to U.S. Provisional Application 60/477,258, filed on June 10, 2003.[3]

[3] Petitioner acknowledges this priority claim to June 10, 2003, and does not challenge it as the effective date of the '155 patent. Pet. 21, 25.

Ex. 1001, codes (21), (22), (45), (60). The '155 patent is directed to a "dual blade device comprising an elongate probe having first and lateral second cutting edges and a blunt protruding distal tip, useable for performing an ab interno procedure to remove a strip of trabecular meshwork tissue from a human eye." *Id.* at code (57).

As background, the '155 patent 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." *Id.* at 1:23–26. The '155 patent further states as follows:

> One 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 referred to as a goniectomy. In a goniectomy 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 μm in width is inserted into the anterior chamber of the eye and used to remove a full thickness strip of tissue from the trabecular meshwork.

Id. at 1:37–46. The '155 patent also states that "there remains a need in the art for the development of simple, inexpensive and accurate instruments useable to perform the goniectomy procedure as well as other procedures where it is desired to remove a strip of tissue from a larger mass of tissue." *Id.* at 1:66–2:3. The '155 patent describes system 12 (shown in Figure 1) with needle cutter device 10 that may be used "to perform a variety of procedures," including a goniectomy, to form an incision of a desired width or to remove a strip of tissue of a desired width. *Id.* at 4:27–28, 5:13–19.

Figure 2 of the ’155 patent is reproduced below.

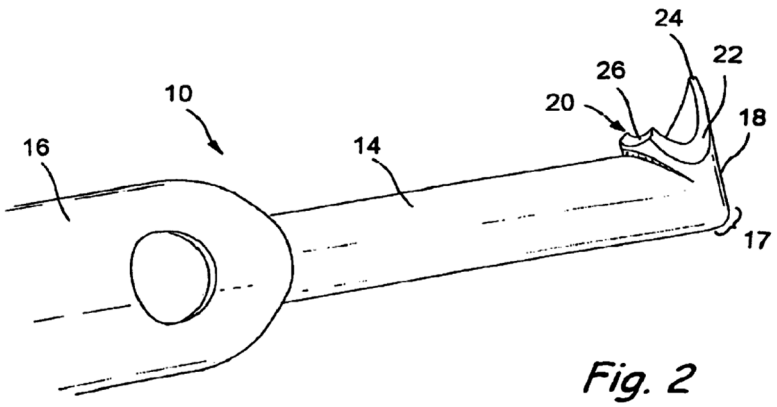


Fig. 2

Figure 2 shows a portion of needle cutter device 10 having cutting tube 14 at an end of outer tube 16. *Id.* at 3:3–7, 3:56–58. “First and second cutting edges 20, 22 are formed on generally opposite edges of the distal end of the cutting tube 14.” *Id.* at 3:7–9. “[F]irst and second cutting edges 20, 22 are located on opposite lateral sides of the distal end of the cutting tube 14,” “a blunt, protruding tip 24 is located on the bottom of the distal end of the cutting tube,” and “blunt edge 26 is located at the top of the distal end of the cutting tube 14.” *Id.* at 3:10–16. According to the ’155 patent, “only the lateral cutting edges 20, 22 are sharp and intended to cut tissue.” *Id.* at 3:16–17. Cutting tube 14 has bend 17 of approximately 90 degrees at a point proximal to these features. *Id.* at 3:27–29. The ’155 patent explains that “[o]ne or more bends or curves may optionally be formed in the cutting tube 14 to facilitate its use for its intended purpose.” *Id.* at 3:25–27.

D. Illustrative Claims of the ’155 Patent

Petitioner challenges claims 1–7 (all claims) of the ’155 patent. Pet. 2. Claim 1 is independent and claims 2–7 depend from claim 1. Ex. 1001, 6:41–7:30.

Claim 1, below, is illustrative of the claimed subject matter.[4]

1. A dual blade device useable for performing an ab intern[o] procedure within a human eye to remove a strip of trabecular meshwork tissue, said device comprising:

a handle configured to be grasped by an operator's hand;

an elongate probe comprising a shaft that extends from the handle along a longitudinal axis;

a blunt protruding tip that extends in a lateral direction from a distal end of the shaft to form a bend or curve of approximately 30 degrees to approximately 90 degrees relative to the adjacent longitudinal axis of the shaft;

first and second lateral cutting edges formed at stationary side-by-side locations on the shaft, said first and second lateral cutting edges facing in the same lateral direction as the blunt protruding tip and being spaced apart such that an area exists between the first and second lateral cutting edges; and

a blunt top edge that extends transversely from a top end of the first lateral cutting edge to a top end of the second lateral cutting edge and traverses above the area between the first and second lateral cutting edges;

the blunt protruding tip having a transverse width, a top surface, a bottom surface and a terminal end, the transverse width being narrowest at the terminal end;

the blunt protruding tip being below the area between the first and second lateral cutting edges and protruding in the lateral direction beyond the first and second lateral cutting edges such that tissue may pass over the top surface of the blunt protruding tip before coming into contact with the first and second lateral cutting edges;

a distal portion of the shaft and the blunt protruding tip being sized to pass through an incision formed in the eye by a 1.5 mm slit knife; and

[4] Claim 1 of the '155 patent recites "ab intern," which we understand to be a typographical error intended to be "ab interno." *See* Ex. 1001 code (57) (stating in the Abstract that the described device is "useable for performing an ab interno procedure").

> the blunt protruding tip being further sized to fit within Schlemm's Canal of the human eye and, when so positioned, to be advanceable through Schlemm's Canal with trabecular meshwork tissue passing over its top surface and into contact with the first and second lateral cutting edges.

Ex. 1001, 6:41–7:1.

E. References and Testimony

Below we provide an abbreviated summary of the qualifications of Dr. Peter Netland, who provides testimony in support of Petitioner, and Garry P. Condon, M.D., who provides testimony in support of Patent Owner.[5] We also provide a table identifying the primary references relied

[5] During the trial Patent Owner also sought to introduce the "Sworn Affidavit of Manuel Quintana, M.D." as Exhibit 2020. We granted Petitioner's Motion to Strike Exhibit 2020 (Paper 22) because Patent Owner was unable to make Dr. Quintana available for cross examination and Petitioner maintained "that the refusal of cross-examination is 'extremely prejudicial' because the Quintana Affidavit 'contradicts and attempts to rewrite portions of" the 1985 reference authored by Dr. Quintana and relied upon by Petitioner (Ex. 1004, cited in full below). Paper 33, 4; *see also id.* at 5 (explaining that "[w]e will not consider the affidavit of Dr. Quintana without Patent Owner making the witness available for the desired cross-examination by Petitioner" (citing 37 C.F.R. § 42.12(a) and (b)). We further stated that "to the extent that Patent Owner relies on Exhibit 2020 in its briefing, wholly or in-part, as evidence to support its argument, we give no weight to that reliance on the evidence." *Id.* at 6. Even if we had considered Exhibit 2020, we find that it would not have altered the outcome of this Decision because it does not persuasively address what Quintana (the reference) would have disclosed to a person of ordinary skill in the art at the time of the invention, as opposed to the purported personal views of Dr. Quintana when the Affidavit was purportedly signed by him in Spain in 2021, and, in the absence of cross-examination, the Affidavit would have been given little, if any, weight.

upon by Petitioner, as well as the exhibits corresponding to the declarations and deposition testimony in the record for Dr. Netland and Dr. Condon.

Dr. Netland states that he is currently a Professor and Chairman of the Department of Ophthalmology at the University of Virginia School of Medicine and earned his Doctor of Philosophy in Physiology and Biophysics in 1985 from Harvard University and his Medical Doctor degree in 1987 from the University of California School of Medicine in San Francisco. Ex. 1003 ¶¶ 7, 12. During the time from 1997 to 2009, Dr. Netland states that he was Assistant Professor and Professor at the University of Tennessee and served as the Director of Glaucoma Fellowship and Director of Glaucoma Services. *Id.* ¶ 11. Dr. Netland further states that his "research interests have focused primarily on pharmacological effects and surgical techniques in glaucoma" and that his "publications have covered a wide array of glaucoma-related topics including screening for glaucoma, evolution of glaucoma, management of glaucoma, glaucoma filtration devices, glaucoma drainage, effects of therapy on glaucoma, and therapy of pediatric glaucoma." *Id.* ¶ 13. Considering the record before us, we determine that Dr. Netland is qualified to offer testimony on the knowledge of one of ordinary skill in the art at the time of the invention. *See id.* ¶¶ 1–17, 25, 33–60, (Dr. Netland's statements as to his background and qualifications, definition of the person of ordinary skill in the art, background on the relevant technology, and professional history), App'x A (*curriculum vitae*).

Dr. Condon did not summarize his qualifications in his declaration, however, according to his *curriculum vitae*, he is currently a Professor in the Department of Ophthalmology at Drexel University and received his Medical Doctor degree in 1981 from the Memorial University of

Newfoundland. Ex. 2019 ¶ 2, App'x A, 1, 4. Dr. Condon lists, for example, the American Board of Ophthalmology as a Specialty Certification since 1987. *Id.* ¶ 2. From 1991 to 2003 Dr. Condon indicates he was the Adjunct Clinical Instructor in Ophthalmology at the University of Pittsburgh. *Id.* ¶ 3.

Dr. Condon's testimony was the subject of a motion to exclude by Petitioner (Paper 39, "Pet. Mot.") and, although that motion was denied (Paper 49, "Order"), it did highlight certain cross-examination testimony by Dr. Condon 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 with this understanding that we consider and analyze Dr. Condon's testimony here. Considering the record before us, we determine that Dr. Condon is qualified to offer testimony on the knowledge of one of ordinary skill in the art at the time of the invention. *See* Ex. 2019, App'x A (*curriculum vitae*).

References and Witness Testimony[6]	**Date**	**Ex. No.**
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) ("Quintana")	1985	1004
U.S. Patent 4,900,300 ("Lee")	Feb. 13, 1990	1006

[6] The table identifies only a select number of documents particularly pertinent to this Decision. *See, e.g.*, Paper 44 (Patent Owner Exhibit List); Paper 45 (Petitioner's Updated Exhibit List). A complete identification of the papers and exhibits that form the record of this case is available in the docket of this proceeding.

References and Witness Testimony[6]	Date	Ex. No.
Philipp C. Jacobi et al., *Technique of goniocurettage: a potential treatment for advanced chronic open angle glaucoma*, 81 BRIT. J. OPHTHALMOLOGY 302–07 (1997) ("Jacobi")	1997	1007
Declaration of Dr. Peter Netland	Oct. 1, 2020	1003
Reply Declaration of Dr. Peter Netland	Sep. 23, 2021	1030
Transcript of Deposition of Dr. Peter Netland	May 27, 2021	2021
Transcript of Deposition of Dr. Peter Netland	May 28, 2021	2022
Transcript of Deposition of Dr. Peter Netland	Sep. 30, 2021	2032
Declaration of Garry P. Condon, M.D.	July 7, 2021	2019
Transcript of Deposition of Garry Condon, M.D.	Aug. 17, 2021	1041
Transcript of Deposition of Garry Condon, M.D.	Aug. 18, 2021	1042

F. Asserted Grounds of Unpatentability

Petitioner asserts that the Challenged Claims are unpatentable based on the following grounds:

Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis[7]
1–7	103	Quintana, Lee
1–3, 6, 7	102	Quintana
4, 5	103	Quintana
1–7	103	Jacobi

Pet. 4.

[7] Petitioner expressly refers to the knowledge of a person of ordinary skill in the art in its table identifying "References" relied upon. Pet. 4. When analyzing whether claims would have been obvious and whether it would have been obvious to combine or modify prior art, it must always be from the perspective of a skilled artisan and one must consider knowledge generally available to one of ordinary skill in the art. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007) (one must often consider "the background knowledge possessed by a person having ordinary skill in the art"). Thus, the "knowledge of a person of ordinary skill in the art" is always a consideration and is not a basis for a separate challenge for obviousness. Therefore, we do not separately analyze a challenge where "knowledge" is the only basis for it being separately presented, and consider obviousness over the cited prior art from the perspective of the skilled artisan.

II. ANALYSIS[8]

A. Legal Standards of Anticipation and Obviousness

Petitioner contends under one ground that certain of the Challenged Claims are anticipated. Pet. 4. A claim is anticipated if a single prior art reference either expressly or inherently discloses every limitation of the claim. *Orion IP, LLC v. Hyundai Motor Am.*, 605 F.3d 967, 975 (Fed. Cir. 2010). "A single prior art reference may anticipate without disclosing a feature of the claimed invention if such feature is necessarily present, or inherent, in that reference." *Allergan, Inc. v. Apotex Inc.*, 754 F.3d 952, 958 (Fed. Cir. 2014) (citing *Schering Corp. v. Geneva Pharm.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003)).

Petitioner contends under three grounds that the Challenged Claims are unpatentable based on obviousness. Pet. 4. As set forth in 35 U.S.C. § 103(a),

> [a] patent may not be obtained . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

The question of obviousness is resolved on the basis of underlying factual determinations including (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level

[8] The Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112-29, 125 Stat. 284, 287–88 (2011), amended 35 U.S.C. § 103, effective March 16, 2013. Because the application from which the '155 patent issued has an effective filing date prior to March 16, 2013, the pre-AIA version of §§ 102 and 103 apply. This Decision, however, would not change regardless of which version of the statute applies.

of ordinary skill in the art; and (4) when in evidence, objective evidence of nonobviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

An obviousness analysis "need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007). However, Petitioner cannot satisfy its burden of proving obviousness by employing "mere conclusory statements." *In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1380 (Fed. Cir. 2016). Instead, Petitioner must articulate a reason why a person of ordinary skill in the art would have combined the prior art references. *In re NuVasive*, 842 F.3d 1376, 1382 (Fed. Cir. 2016); *see also Pers. Web Tech., LLC, v. Apple, Inc.*, 848 F.3d 987, 993–94 (Fed. Cir. 2017) ("[O]bviousness concerns whether a skilled artisan not only *could have made* but *would have been motivated to make* the combinations or modifications of prior art to arrive at the claimed invention") (quoting *Belden Inc. v. Berk-Tek LLC*, 805 F.3d 1064, 1073 (Fed. Cir. 2015)).

B. Person of Ordinary Skill in the Art

The level of skill in the art is a factual determination that provides a primary guarantee of objectivity in an obviousness analysis. *Al-Site Corp. v. VSI Int'l Inc.*, 174 F.3d 1308, 1324 (Fed. Cir. 1999) (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966); *Ryko Mfg. Co. v. Nu-Star, Inc.*, 950 F.2d 714, 718 (Fed. Cir. 1991)). In determining the level of ordinary skill in the art, various factors may be considered, including the "type of problems encountered in the art; prior art solutions to those problems; rapidity with which innovations are made; sophistication of the technology;

and educational level of active workers in the field." *In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995) (citation omitted).

Petitioner contends that a person of ordinary skill in the art would have had either "a medical degree and at least two years' experience with treating glaucoma and performing glaucoma surgery," or "an undergraduate or graduate degree in biomedical or mechanical engineering and at least five years of work experience in the area of ophthalmology, including familiarity with ophthalmic anatomy and glaucoma surgery." Pet. 25 (citing Ex.1003 ¶ 26). Patent Owner does not dispute Petitioner's proposed level of ordinary skill in the art. Resp. 12 n.6.

We adopt Petitioner's definition as we find it is undisputed and consistent with the level of skill in the art at the time of the invention, as reflected by the prior art and the '155 patent. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (explaining that specific findings regarding ordinary skill level are not required "where the prior art itself reflects an appropriate level and a need for testimony is not shown" (quoting *Litton Indus. Prods., Inc. v. Solid State Sys. Corp.*, 755 F.2d 158, 163 (Fed. Cir. 1985))).

C. Claim Construction

We apply the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. § 282(b). 37 C.F.R. § 42.100(b). Under that standard, claim terms "are generally given their ordinary and customary meaning" as understood by a person of ordinary skill in the art at the time of the invention. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc). "In determining the meaning of the disputed claim limitation, we look principally to the intrinsic evidence of record, examining the claim language itself, the written description, and the

prosecution history, if in evidence." *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 469 F.3d 1005, 1014 (Fed. Cir. 2006) (citing *Phillips*, 415 F.3d at 1312–17). Extrinsic evidence is "less significant than the intrinsic record in determining 'the legally operative meaning of claim language.'" *Phillips*, 415 F.3d at 1317.

Petitioner addresses the claim terms "ab interno," "dual blade device," "blunt protruding tip," and "blunt top edge." Pet. 26–30. Patent Owner states that "all of the terms in the Challenged Claims should be accorded their plain and ordinary meaning," and argues that the '155 patent "sets forth no particularized definitions" for the claim terms addressed by Petitioner. Resp. 12. We address each of the terms identified by Petitioner below and find that an express construction of any claim term is not necessary for purposes of rendering this Decision. *See Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1361 (Fed. Cir. 2011) ("[C]laim terms need only be construed 'to the extent necessary to resolve the controversy.'") (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)).

1. "ab interno"

Claim 1 recites a device "for performing an ab intern[o] procedure." Ex. 1001, 6:41–43. The Specification of the '155 patent states that "a goniectomy procedure is an ab interno surgical procedure," but does not otherwise explicitly provide a meaning for "ab interno." *Id.* at 5:19–25. Petitioner contends that a person of ordinary skill in the art would have understood "ab interno" to mean "from the inside." Pet. 26 (citing Ex. 1003 ¶ 76). Patent Owner agrees that "ab interno" generally means from the inside. Resp. 35. Accordingly, we discern no dispute over the meaning of "ab interno" that requires an express construction.

2. "dual blade device"

Claim 1 recites a "dual blade device" comprising "first and second lateral cutting edges." Ex. 1001, 6:41–43, 6:51–51. The Abstract of the '155 patent also refers to "[a] dual blade device comprising an elongate probe having first and lateral second cutting edges," but the Specification of the '155 patent does not otherwise explicitly provide a meaning for "dual blade device." *Id.* at code (57). Petitioner argues that "a 'dual blade device' has two edges capable of cutting tissue." Pet. 27–28 (citing Ex. 1001, 3:16–17, 3:44–45, Fig. 4, cls. 1,2; Ex. 1003 ¶¶ 84–86). Patent Owner states that "the dual blade device of the Challenged Claims must have two distinct cutting edges, no more and no less," but does not offer an express construction of the term beyond its plain and ordinary meaning. *See, e.g.,* Resp. 12–13.

The language "dual blade device" is readily understandable on its face; "dual" refers to two, and "blade," in context, refers to a cutting part. To the extent the parties dispute whether a particular reference teaches a "dual blade device," we address those arguments in our analysis below. *See, e.g.*, Resp. 26. Accordingly, we discern no dispute over the meaning of "dual blade device" that requires an express construction.

3. "blunt protruding tip"

Claim 1 recites a device comprising "a blunt protruding tip." Ex. 1001, 6:47–50. Claim 1 includes additional limitations directed to the recited "blunt protruding tip," as follows:

- the tip "extends in a lateral direction from a distal end of the shaft to form a bend or curve of approximately 30 degrees to approximately 90 degrees relative to the adjacent longitudinal axis of the shaft;"

- the tip has "a transverse width, a top surface, a bottom surface and a terminal end, the transverse width being narrowest at the terminal end;"
- the tip "being below the area between the first and second lateral cutting edges and protruding in the lateral direction beyond the first and second lateral cutting edges such that tissue may pass over the top surface of the blunt protruding tip before coming into contact with the first and second lateral cutting edges;"
- the tip "being sized to pass through an incision formed in the eye by a 1.5 mm slit knife;" and,
- the tip "being further sized to fit within Schlemm's Canal of the human eye and, when so positioned, to be advanceable through Schlemm's Canal with trabecular meshwork tissue passing over its top surface and into contact with the first and second lateral cutting edges."

Id. at 6:41–7:11; *see also id.* at cl. 3 (further requiring "the bottom surface of the blunt protruding tip extends at an angle of approximately 90 degrees relative to the adjacent longitudinal axis of the shaft). The '155 patent further states as follows:

> The blunt, protruding tip 24 can, in some applications, be configured and used to facilitate insertion of the device 10 to its intended location and/or the blunt protruding tip 24 may be placed in an anatomical or man made grove or channel (e.g., Schlemm's Canal of the eye) such that it will then advance through the channel or groove and guide the advancement and positioning of the remainder of the device 10.

Id. at 3:17–24. Thus, required features of a "blunt protruding tip" are expressly set forth in claims 1 and 3, as detailed above, but the Specification

of the '155 patent does not otherwise explicitly provide a meaning for "blunt protruding tip," or, more particularly, for "blunt." Figure 2 of the '155 patent, reproduced above, illustrates blunt protruding tip 24. *See supra* Section I.C; *see also* Ex. 1001, Fig. 3A (reproduced below, *infra* Section II.C.4).

Petitioner does not offer an express construction of "blunt protruding tip," but instead, regarding the scope of the term, asserts it "must encompass devices with tips that can pierce [trabecular meshwork] tissue, including needles and needle-like devices." Pet. 28 (citing Ex. 1003 ¶ 91). Petitioner further reasons as follows:

> The '155 patent describes a "needle cutter device 10" with a "blunt protruding tip 24" that is "located on the bottom of the distal end of the cutting tube" and is used to "facilitate insertion" of the device into its "intended location" in [Schlemm's Canal]. Ex.1001, 3:13–24, 6:9–11. A [person of ordinary skill in the art] would understand insertion of the device into [Schlemm's Canal] necessarily requires the "blunt protruding tip 24" penetrate [trabecular meshwork] tissue to reach the device's "intended location" in [Schlemm's Canal]. Ex.1003, ¶92. The patent fails to provide any other explanation as to what constitutes a "blunt" tip, like how sharp or dull the tip must be to be "blunt." While the ordinary meaning of "blunt" may be, for example, not sharp,[ ] the '155 patent requires that the claimed "blunt protruding tip" has at least some sharpness to allow the tip to pierce the [trabecular meshwork] to "facilitate insertion" of the device into [Schlemm's Canal]. *Id.*, ¶¶92–93.

Pet. 28 (footnote omitted). Petitioner further argues that "blunt protruding tip" may not exclude "needles and needle-like devices," because "the sole embodiment disclosed in the patent is 'needle cutter device 10.'" *Id.* at 29 (citing Ex. 1001, 3:3–24, 4:60–64, 6:9–11, Figs 3A, 3B, 4; Ex. 1003 ¶ 93; *SynQor, Inc. v. Artesyn Techs., Inc.*, 709 F.3d 1365, 1378–79 (Fed.

Cir. 2013) ("[a] claim construction that 'excludes the preferred embodiment is rarely, if ever, correct'").

Patent Owner does not offer an express construction of "blunt protruding tip," but maintains that the "ordinary and customary meaning" of "blunt" is "not sharp." *See, e.g.*, Resp. 12–13, 31 (citing Ex. 2025 (Dorland's Pocket Medial Dictionary, 28th Ed. 2009, defining "blunt" as "having a thick or dull edge or point; not sharp")).

As to Petitioner's assertion that "blunt protruding tip," "must encompass devices with tips that can pierce [trabecular meshwork] tissue," there is no dispute. *See* Pet. 28 (citing Ex. 1003 ¶ 91). Patent Owner acknowledges that "[w]ith the claimed devices in the challenged patents, the blunt protruding tip can penetrate tissue in order to insert the device but it does not cut a strip." Tr. 73:3–6; *see also* Ex. 1042, 279:9–20 (Dr. Condon stating "it could be a blunt tip and penetrate trabecular meshwork").

However, there is no description in the Specification of the '155 patent and no other evidence in the record to show how a person of ordinary skill in the art would have understood whether a protruding tip is "blunt," within the meaning of claim 1. For example, when Dr. Condon was asked whether the '155 patent provided "any indication how to determine or measure bluntness," he stated he did not recall "the '155 [patent] specifying how to measure bluntness," that he didn't know "what bluntness refers to in any of these documents, the 'ness,'" that "[b]lunt is just not sharp," and that "anything that's sharp is not blunt." Ex. 1042, 281:5–14, 282:2–9. Dr. Netland states that "the '155 patent does not provide a clear indication of what constitutes a 'blunt protruding tip,'" but that the '155 patent makes clear that the blunt protruding tip "must have at least some sharpness to allow the tip to pierce the trabecular meshwork overlaying Schlemm's

Canal." Ex. 1003 ¶¶ 91, 92. That, however, is insufficient evidence to persuade us that "blunt protruding tip" necessarily includes "needles and needle-like devices," as Petitioner asserts, even though the only embodiment disclosed in the '155 patent describes a "needle cutter device." *See*, *e.g.*, Ex. 1001, 3:3–24, 4:60–64, 6:9–11, Figs 3A, 3B, 4. Ideed, Patent Owner argues that "a standard hypodermic needle tip," like that used in Quintana, "is sharp and not blunt as a matter of fact." Resp. 32. Thus, there is no consensus among the parties that "blunt protruding tip" includes "needles and needle-like devices."

Patent Owner, however, does not dispute that Lee teaches a "blunt protruding tip," as asserted by Petitioner. *See generally* Resp; Pet. 68–6 (asserting that "the distal end 15 of the bowl-like tip of Lee's device protrudes 'for ease of tissue penetration and cutting' and is 'softly rounded' and 'generally parabolic in shape in order to avoid damage to the outer wall of Schlemm's Canal'" (citing Ex.1006, 4:38–48).

To the extent the claim language may raise an issue of indefiniteness, which is not before us in an *inter partes* review, we note that the Federal Circuit has stated that indefiniteness "does not necessarily preclude the Board from addressing the patentability of the claims on section 102 and 103 grounds." *Samsung Elecs. Am., Inc. v. Prisua Eng'g Corp.*, 948 F.3d 1342, 1353 (Fed. Cir. 2020). For the reasons provided below, we determine that the controversy presented in this proceeding may be resolved without determining an express construction for "blunt protruding tip." *See Wellman,* 642 F.3d at 1361.

4. "blunt top edge"

Claim 1 recites a "blunt top edge that extends transversely from a top end of the first lateral cutting edge to a top end of the second lateral cutting

edge and traverses above the area between the first and second lateral cutting edges." Ex. 1001, 6:57–60. The Specification of the '155 patent identifies blunt top edge 26 in Figures 3A–3D and states that "a blunt edge 26 is located at the top of the distal end of the cutting tube 14," and "[t]hus, only the lateral cutting edges 20, 22 are sharp and intended to cut tissue." *Id.* at 3:15–17, 4:60–64. Petitioner does not propose an express definition for "blunt top edge," but argues as follows:

> Like "blunt protruding tip," the patent provides little explanation for "blunt top edge." Other than stating the "blunt top edge" is located on "needle cutter device" (i.e., "at the top of the distal end of the cutting tube") and how "blunt top edge" is formed (i.e., cutting the end of "standard tubing"), the patent provides no explanation of what constitutes a "blunt" edge, including how sharp or dull the edge must be to be "blunt." *See* Ex.1001, 3:15-16, 4:60-64; Ex.1003, ¶¶94–95. Regardless, for the reasons discussed above, the term "blunt top edge" cannot exclude needles and needle-like devices because that is the sole embodiment disclosed by the patent. . . . The term must encompass the top edge of the cutting area of devices intended for penetrating [trabecular meshwork] tissue including needles and needle-like devices. Ex.1003, ¶96

Pet. 30; *see also* Ex. 1001 4:60–62 (identifying "stainless steel hypodermic tubing" as an example of "standard tubing"). The '155 patent further states that "the distal end of a tube is cut to form the lateral cutting edges 20, 22, the protruding tip 24 and the blunt top edge 26." Ex. 1001, 4:62–64.

Figure 3A of the ’155 patent is reproduced below.

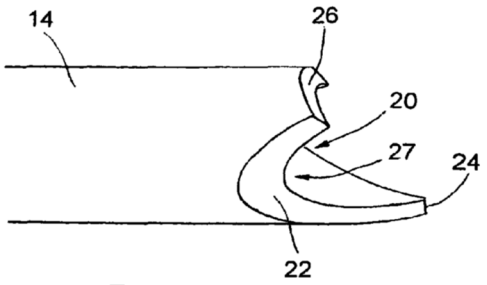


Fig. 3A

Figure 3A shows the first step in “an example of a method for manufacturing the cutting tube 14” in which “the end of a tube is cut to form the lateral cutting edges 20, 22, the protruding tip 24 and the blunt top edge 26.” *Id.* The ’155 patent does not describe any other steps in manufacturing cutting tube 14 to distinguish blunt top edge 26 (or protruding tip 24) from cutting edges 20, 22 with regard to sharpness or bluntness. Patent Owner’s assertion that the ’155 patent “clearly describes machining the sides of standard hypodermic needle tubing” is unsupported by the portions of the Specification cited by Patent Owner. *See* Sur-reply 5 (citing Ex. 1001, 3:7–9, 3:16–17). The ’155 patent states only that “the tube is cut *to form* the lateral cutting edges 20, 22” and discloses no additional machining, contrary to Patent Owner’s assertion. *See* Ex. 1001, 4:62–64 (emphasis added). Further, the ’155 patent likewise describes that the tube is “cut to form” the “blunt top edge 26.” *Id.*

Patent Owner argues that Petitioner’s construction disregards the “ordinary and customary” meaning of “blunt” as “not sharp,” “improperly imports a limitation from the [S]pecification,” and “wrongly seeks to define a structural element based on an unsupported and overbroad purported function that would render the claim term ‘blunt’ meaningless.” Resp. 34. Patent Owner does not explain how one of ordinary skill in the art would

have known whether a "top edge" made by cutting stainless steel hypodermic tubing at an angle, as taught by the '155 patent was "blunt" or "not blunt." *See* Ex. 1001 4:62–64.

Patent Owner, however, does not dispute that it would have been obvious to modify Quintana's needle to have a blunt top edge. *See generally* Resp; Pet. 70 (asserting a person of ordinary skill in the art "would have been motivated to modify Quintana's needle for safety reasons and would have known one way of doing so would be to round portions of the needle near the tip such as the top edge (citing Ex.1003 ¶ 189)).

To the extent the claim language may raise an issue of indefiniteness, which is not before us in an *inter partes* review, we note again that it "does not necessarily preclude the Board from addressing the patentability of the claims on section 102 and 103 grounds." *See Samsung Elecs.*, 948 F.3d at 1353. For the reasons provided below, we determine that the controversy presented in this proceeding may be resolved without determining an express construction for "blunt top edge." *See Wellman,* 642 F.3d at 1361.

5. Additional Claim Terms

We find that no other claim term requires an express construction for purposes of rendering this Decision. *See Wellman*, 642 F.3d at 1361.

D. Scope and Content of the Asserted Art

Petitioner contends the Challenged Claims are unpatentable on grounds based on Quintana, Lee, and Jacobi. Pet. 4. Each of these references is summarized in relevant part below.

1. Summary of Quintana[9]

Quintana is a paper from a glaucoma symposium published in 1985 that describes "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, 1–3. Quintana explains that "[i]ncreased resistance to the outflow of aqueous through the trabecular meshwork is the most accepted pathogenic mechanism in the majority of open angle glaucomas ('trabecular glaucomas'). Thus, the rational treatment of the trabecular glaucomas should consist in opening the trabecular meshwork." *Id.* at 3. To treat this type of glaucoma, Quintana "describe[s] a surgical method of goniotrabeculotomy which achieves a section of the trabecular meshwork without damage to the external wall of Schlemm's canal." *Id.*

Quintana describes that, with the assistance of a goniolens, a bent "needle penetrates the anterior chamber at 6 hours (right eye) or 12 hours (left eye) through the *scleral* side of the limbus; this is in order to run parallel to Schlemm's canal." *Id.* at 3–4. Figure 1 of Quintana, reproduced below, compares the application of the bent-needle device using this "tangential approach" (right-hand side), with "the perpendicular approach as in classic goniotomy or goniotrabeculotomy" (left-hand side). *Id.* at 4.

[9] Quintana has original pagination and also pagination at the lower right-hand corner of each page that appears to have been added. We reference the added pagination appearing at the lower right-hand corner of each page, as has Petitioner.

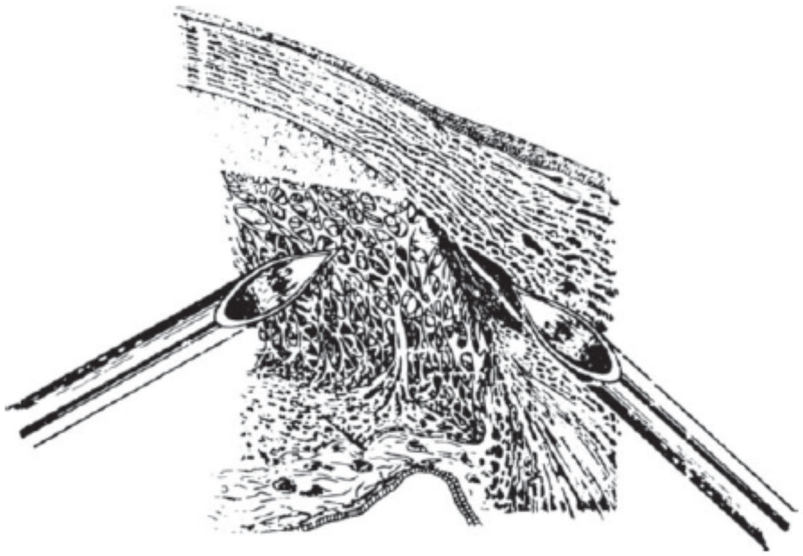


Fig. 1. Schematic drawing comparing the tangential approach to the perpendicular approach as in classic goniotomy or goniotrabeculotomy.

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" (described by Quintana as "a good wetting agent between cornea and goniolens"). Ex. 1003 ¶ 98; Ex. 1004, 3–4. The right-hand side of Figure 1 shows this device penetrating the anterior chamber of an eye, running parallel to Schlemm's Canal, incising and stripping the trabecular meshwork with the tip of the needle, while the convex side of the bent tip is pointed towards the external wall so as to not cause damage. *Id.* at 4. With this procedure, "100-120° trabeculotomy can be achieved." *Id.* Quintana states that healon can be injected during the process at any time, particularly "if the surgeon wants to deepen the angle" or if there is "chamber loss," and that, after the procedure, the device is withdrawn. *Id*.

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

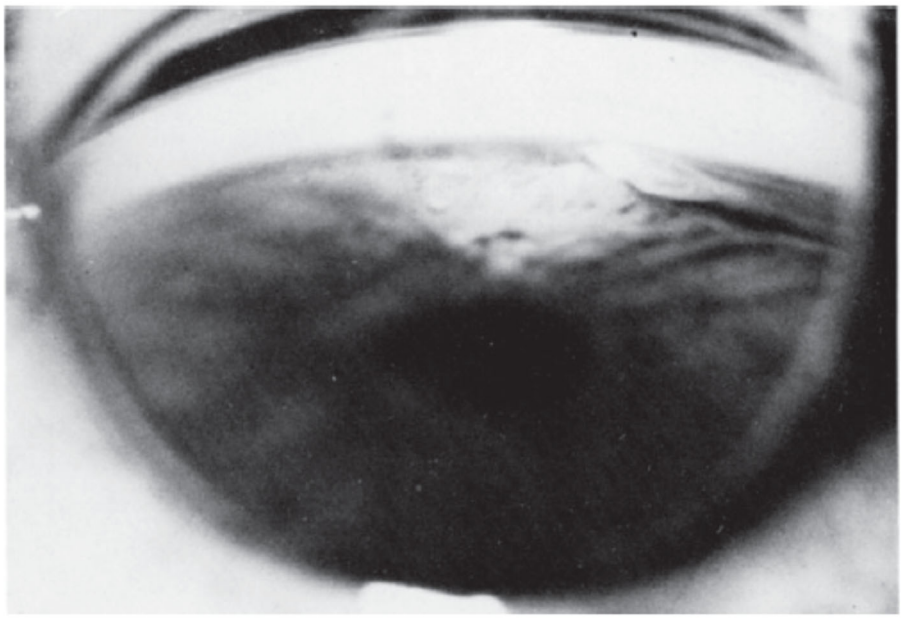


Fig. 2. Goniophotography at operation. The tip of the needle stripping the trabecular meshwork.

Id. at 5. Figure 2 shows the tip of the bent needle instrument introduced in the Schlemm's Canal of an eye (see upper right quadrant of image, needle's tip points toward center line of image and needle's shaft extends to the edge of the image) and the trabecular meshwork being stripped away "slowly, gently and easily from the canal's lumen towards the anterior chamber as the needle progresses." *Id.* at 4. Quintana concludes, "our results show that goniotrabeculotomy, although highly successful in the first postoperative month, is in the end a partially successful procedure. Further studies are necessary to disclose the 'in vivo' behaviour of the sectioned trabecular meshwork." *Id.* at 8.

2. Summary of Lee

Lee, titled "Surgical Instrument," issued February 13, 1990. Ex. 1006, codes [45], [54]. Lee is directed to "the design and application of a goniectomy instrument for the purpose of diagnostically and therapeutically removing tissue from the anterior chamber angle of the eye and for retrieving this tissue for further examination." *Id.* at code [57]. Lee's surgical instrument comprises "a hollow, tapered shaft having a cutting edge at one end as an integral part thereof; a retractable stylet contained within the hollow interior of the tapered shaft; and an irrigation port running along the outside of the tapered shaft." *Id.* Lee describes this instrument as "useful for excising tissue to relieve an obstruction blocking the outflow of aqueous humor from the eye as well as for providing specimens of the excised tissue for histopathological examination." *Id.*

Figures 1 and 2 of Lee are reproduced below:

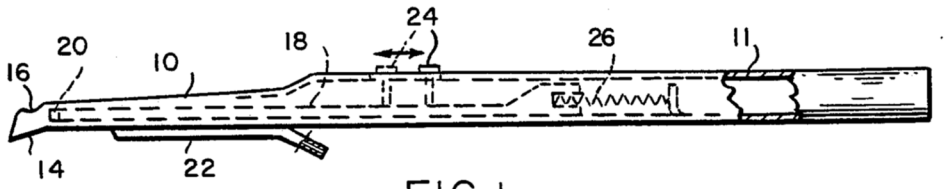


FIG. 1

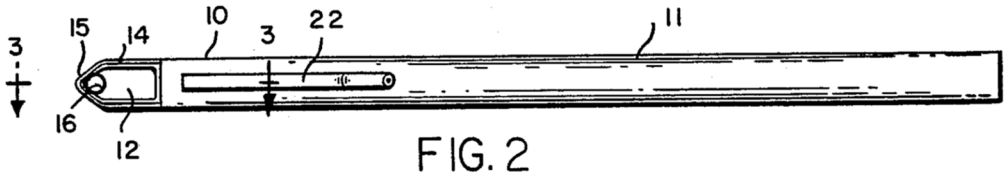


FIG. 2

"FIG. 1 is a schematic side view of the surgical instrument of [Lee's] invention" and "FIG. 2 is a schematic bottom view of the surgical instrument of [Lee's] invention." *Id.* at 3:62–65. Lee states that Figures 1 and 2 show "the surgical instrument" having "a more or less cylindrical hollow shaft 10[,] which is tapered from a larger diameter at the handle end 11 to

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

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

Figure 5 of Lee is reproduced below.

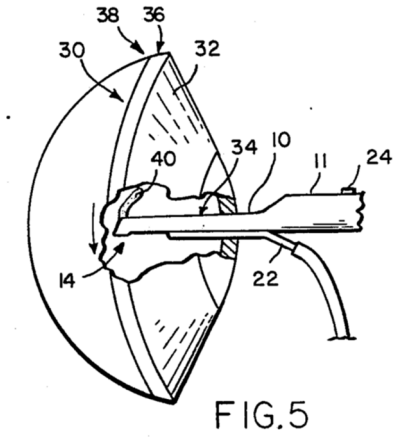


FIG.5

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 goniolens over the cornea, forming an incision into the anterior chamber through the cornea, introducing the goniectomy 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.

3. Summary of Jacobi[10]

Jacobi, an article titled "Technique of goniocurettage: a potential treatment for advanced chronic open angle glaucoma," was published in 1997. Ex. 1007, 1. Jacobi discloses a procedure for a "[g]onioscopically controlled ab interno abrasion of the trabecular meshwork" using an "instrument resembl[ing] a modified cyclodialysis spatula with a bowl-shaped tip, 300 μm in diameter, and with its edges sharpened." *Id.* The instrument described in Jacobi, identified as a "gonioscraper," is shown in 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 describes the gonioscraper shown in Figure 1 as follows:

> 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

[10] Jacobi has original pagination and also pagination at the lower right-hand corner of each page that appears to have been added. We reference the added pagination appearing at the lower right-hand corner of each page, as has Petitioner.

> 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.

According to Jacobi, the instrument is used "to abrade rather than incise uveal meshwork; this novel method, therefore, is termed goniocurettage." *Id.* Jacobi explains that the gonioscraper is inserted into the anterior chamber of an eye through a corneal incision, and then positioned against the trabecular meshwork and used to peel off trabecular meshwork by passing the device there-over. *Id.* This results in "strings of trabecular tissue" being removed from the eye. *Id.* A stage of this procedure is shown in Figure 2, reproduced below.

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

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

E. Alleged Obviousness over Quintana and Lee

Petitioner contends the Challenged Claims would have been obvious over Quintana in combination with Lee. *See*, *e.g.*, Pet. 62–74; Reply 26–28. Patent Owner disputes Petitioner's contentions as to the teachings of Quintana and Lee, as well as to the reasons asserted in support of their combination. *See*, *e.g.*, Resp. 13–50; Sur-reply 1–18, 22–23.

Below we first explain our determination, based on our review of the entire record developed at trial, that Petitioner shows by a preponderance of the evidence that the combination of Quintana and Lee teaches each limitation of the Challenged Claims. We then discuss our determination that Petitioner shows by a preponderance of the evidence that a person of ordinary skill in the art would have had sufficient reasons to modify Quintana in light of the teachings of Lee, as Petitioner asserts, and would have had a reasonable expectation of success. Finally, we consider all of the *Graham* factors and conclude that Petitioner has shown by a preponderance of the evidence that the Challenged Claims would have been obvious over the combination of Quintana and Lee.

1. Differences Between the Subject Matter of Independent Claim 1 and the Combination of Quintana and Lee[11]

The combination of Quintana and Lee teaches each limitation of claim 1, as shown by Petitioner, for the reasons below based on the supporting cited evidence of record. *See* Pet. 40–56, 64–71; Reply 7–23. 26–28. Patent Owner's arguments to the contrary are not persuasive because they are insufficiently supported by the cited evidence of record. Resp. 13–50; Sur-reply 5–18, 22–23.

> *A dual blade device useable for performing an ab intern[o] procedure within a human eye to remove a strip of trabecular meshwork tissue, said device comprising:*

Regarding the above quoted preamble of claim 1, Quintana teaches, as Petitioner shows, a needle with "two spaced-apart, lateral cutting edges on opposite sides of the needle tube," corresponding to a "dual blade device" useable to remove a strip of trabecular meshwork tissue." Pet. 40–43, 64; Ex. 1003 ¶¶ 119–120; Ex. 1004, 3, Fig. 1. In this regard, we credit the testimony of Dr. Netland who explains as follows:

> Quintana explicitly indicates that the cutting edges of the needle device are capable of cutting tissue. Quintana indicates that the device "achieves a section of the trabecular meshwork." Ex.1004 (Quintana), 3. More specifically, Quintana discloses that "the tip of the instrument" (i.e., as explained below, the "blunt protruding tip") "is introduced into Schlemm's canal, and

[11] Petitioner also contends that claim 1 is anticipated by Quintana and in explaining how claim 1 would have been obvious over the combination of Quintana and Lee, Petitioner refers, in part, back to its anticipation analysis. *See*, *e.g.*, Pet. 64–71. Likewise, Patent Owner refers back to its arguments made with regard to anticipation by Quintana in its opposition to the asserted obviousness of claim 1 over Quintana and Lee. *See* Resp. 43–44. Accordingly, in addressing obviousness over Quintana and Lee our analysis necessarily addresses arguments addressed by the parties in the context of the alleged anticipation of claim 1 by Quintana.

> the [trabecular meshwork] is stripped slowly, gently and easily from the canal's lumen towards the anterior chamber as the needle progresses in the angle." *Id.* [at] 4. The first and second cutting edges of Quintana's needle are thus capable of cutting trabecular meshwork tissue.
>
> . . .
>
> Quintana's disclosure of "stripping" the trabecular meshwork to "achieve[] a section of the trabecular meshwork" refers to excising or cutting a "strip of tissue" from the trabecular meshwork as claimed. In order to create such a "strip of tissue," both the first and second cutting edges of Quintana's needle must contact the trabecular meshwork and be concurrently cutting the trabecular meshwork (otherwise, Quintana's procedure would not have achieved a "section" of the trabecular meshwork, but instead would have merely created a slitlike opening in the trabecular meshwork).

Ex. 1003 ¶¶ 121, 128.

Patent Owner argues that Quintana does not teach a "dual blade device" because it uses a needle tip with "a single bevel including a sharp point that creates an incision to facilitate tissue penetration." Resp. 22–28 (citing, e.g., Ex. 2019 ¶ 22). According to Patent Owner, "the beveled sides of the Quintana device tip merely act alongside the sharp point as part of a single blade to allow the tip to create a slit-like incision in the [trabecular meshwork." *Id.* at 22–23 (citing Ex. 2019 ¶ 23).

In this regard, Patent Owner directs us to the testimony of Dr. Netland, who explains as follows:

> Quintana also specifies that the needle penetrates the anterior chamber at 6 or 12 o'clock to allow for a "tangential approach." *Id.* By this tangential approach, persons of ordinary skill in the art would have understood Quintana to mean that the tip of the needle with the 20-30° bend approaches and enters the trabecular meshwork at a very shallow angle. This would have allowed the opposing edges at the end of the needle to contact and to each separately cut the trabecular meshwork. In this orientation, the

> opposing edges would serve as separate cutting edges to allow the needle to excise a strip of tissue from the trabecular meshwork. By contrast, a perpendicular approach used in classic goniotomy techniques would have been understood to mean that the tip of a needle approaches and enters the trabecular meshwork at a roughly 90-degree angle. This would have allowed only the very tip of the needle to contact the trabecular meshwork. In this orientation, an unbent needle tip would have acted as a single blade to allow the needle to create a slit-like incision in the trabecular meshwork.

Ex. 1003 ¶ 100; *see also* Resp. 22 (citing Ex. 1003 ¶ 100). We credit Dr. Netland's testimony, and it does not support Patent Owner's argument. Dr. Netland persuasively explains that when the tip of a needle was used in a "perpendicular approach" it created a "slit-like incision" where the "tip acted as a single blade." *Id.* By contrast, when used in a "tangential approach," as taught by Quintana, the "opposing edges" of the needle "each separately cut the trabecular meshwork," corresponding to the recited "dual blade device." *Id.* We agree with Patent Owner that "apparatus claims cover what a device is, not what a device does." Resp. 27–28 (quoting *Hewlett–Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1468 (Fed. Cir. 1990)). Patent Owner, however, misrepresents Dr. Netland's testimony in asserting that he "testified that depending on its use at any moment, the Quintana device may be a one-blade, two-blade, or multiple-blade device." *Id.* at 27 n.9 (citing Ex. 2021, 185:10–21). As explained above, the device of Quintana has dual blades, regardless of whether both blades are used for a particular procedure or only the tip is used for insertion. Dr. Netland testified to this as follows:

> Q. And so is it your testimony that because it can act as two cutting blades, it makes it a dual blade device?
>
> A. That it has functionally two cutting edges, is the area.

> Q. But I thought you had said earlier that functionally the tip of this device can also cut tissue; is that correct?
>
> A. Correct.
>
> Q. So when the tool is being used for its intended purpose, how do you know when it is a one-blade device or two-blade device or multiple-blade device?
>
> THE WITNESS: It can have multiple functions. So to initiate the procedure, for example, in Quintana, the tip is used to enter the trabecular meshwork. And then the dual blade function comes -- the dual blades come into play as the tip is advanced through the tissue. They cut.

Ex. 2021, 185:1–21 (objection omitted).

We also find not persuasive Patent Owner's argument that defining a "cutting edge to include anything sharp and intended to cut tissue" is a "demonstratively false premise." Resp. 24 (citing Ex. 1001, 3:10–17; Ex. 2019 ¶ 27). Patent Owner argues that "the proper context" of the '155 patent somehow conveys some other meaning, but the portion cited by Patent Owner expressly says "only the lateral cutting edges 20, 22 are sharp and intended to cut tissue." Ex. 1001, 3:10–17. We fail to discern any "false premise" in Petitioner equating a "cutting edge" to an edge that is "sharp and intended to cut tissue." *See* Resp. 24–25. Nor are we persuaded by Patent Owner's argument that because both cutting edges in Quintana are part of a single bevel, it is not a dual blade device. Resp. 25–26 (citing Ex. 2019 ¶ 28). As discussed above, the language "dual blade device" is readily understandable on its face; "dual" refers to two, and "blade," in context, refers to a cutting part. *See* supra Section II.C.2. As further explained below, Petitioner shows that each side of the needle tip of Quintana separately and distinctly cuts the trabecular meshwork, which

necessarily requires a "dual blade device," i.e. a device with two cutting parts, even if the two cutting parts are associated with a single bevel.

Relatedly, Patent Owner argues that "Quintana never mentions creating or removing a strip of [trabecular meshwork]," and does not "describe a device that creates or removes a strip of [trabecular meshwork]." Resp. 1, 14–21, 23, 25 n.8, 30; Sur-reply 10. According to Patent Owner, when Quintana expressly describes "a surgical method of goniotrabeculotomy which achieves a section of the trabecular meshwork without damage to the external wall of Schlemm's canal," the term "section" means "incising or opening" and not "creating and removing a strip of [trabecular meshwork]." Resp. 15–16 (citing Ex. 1004, 3; Ex. 2023, 605; Ex. 2024, 519). Patent Owner argues that Quintana "otherwise refers only to 'incising' or 'opening the [trabecular meshwork]" and does not mention "the study of any [trabecular meshwork] samples by microscopic examination," which Patent Owner suggests would have supported "alternative definitions" of "section." *Id.* at 16 (citing Ex. 1004, 3, 4). Patent Owner also argues that "Quintana only ever uses the terms 'goniotrabeculotomy,' 'trabeculotomy,' and 'goniotomy,' while referring to incising, cutting, sectioning, opening, or stripping" trabecular meshwork, and that "excising or removing tissue would have been described as 'goniotrabeculectomy,' 'trabeculectomy,' and 'goniectomy.'" Resp. 17 (citing Ex. 2019 ¶ 35); *see also id.* at 21 (arguing that Petitioner "coins the term 'excisional goniotomy'" and applies this "biased hindsight perspective") (citing Ex. 1003 ¶¶ 55–56; Ex. 2019 ¶ 81).

With regard to the meaning of "section," as used in Quintana, Petitioner shows that Patent Owner neglects alternate meanings in the dictionary definition that it relies upon that are more appropriate. Reply 9; *see also* Ex. 2023, 605 (defining "section" as "a segment or subdivision of

an organ"); Ex. 2024, 519 (defining "section" as "[a] thin slice of a tissue specimen taken for examination under a microscope"). We agree with Petitioner that Quintana's disclosure that its procedure "achieves a section" makes no sense if Patent Owner's proposed construction is applied. *Id.*; *see also id*. (arguing that the author of Quintana knew how to use "incise" and 'opening' but chose 'section' and 'stripping' to describe his results").

We also do not agree that terms Quintana uses to label its procedure determine whether Quintana teaches a "device useable for performing an ab interno procedure within a human eye to remove a strip of trabecular meshwork tissue," as claimed. We credit the detailed and supported explanation provided by Dr. Netland over the conclusory arguments of Dr. Condon in this regard. *See* Ex. 1003 ¶¶ 45–57; Ex. 2019 ¶ 36. Dr. Netland explains that a "goniotomy" is an "ab interno" procedure to treat glaucoma first introduced in 1938 "in which an incision in the anterior chamber angle was believed to reduce obstruction to aqueous outflow caused by a membrane across the trabecular meshwork," and included passing the "goniotomy blade" across the anterior chamber "at a generally perpendicular angle," such that "only the very tip of the blade contacts the trabecular meshwork, resulting in a slit-like incision in the tissue." Ex. 1003 ¶¶ 52–54. A "trabeculotomy" is an "ab externo" procedure to treat glaucoma introduced in the early 1960's "for incising the trabecular meshwork" through the sclera. Ex. 1003 ¶¶ 49–50 (citing Ex. 1011, 49). A "trabeculectomy" is a procedure to treat glaucoma first describe in 1968, which "*excised* (or removed) a portion of the trabeculum and Schlemm's Canal." *Id.* ¶ 51 (citing Ex. 1011, 61–63).

Dr. Netland further explains that "decades before the filing of the '155 patent . . . surgical approaches were developed that, rather than simply

incising or disrupting the trabecular meshwork, created larger openings that removed strips of tissue to 'avoid early reclosure' of the trabecular meshwork."[12] *Id.* ¶ 55 (citing Ex. 1007, 4–5, 7; Ex. 1006, 1:39–47; Ex. 1014, 2). Dr. Netland directs us specifically to Lee, issued in 1990, as teaching "a surgical instrument for performing a goniectomy procedure 'to excise a piece of tissue from the anterior chamber angle . . . 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.* ¶ 57 (quoting Ex.1006, 3:50–57, 5:55–6:45). A "goniectomy," as taught by Lee, is an "ab interno" procedure that uses a device "to excise and remove pieces of trabecular meshwork tissue from the eye." *Id.* (citing Ex. 1006, 5:55–6:45).

Dr. Netland explains that Quintana, "discloses what it refers to as a goniotrabeculotomy procedure for 'stripping' and 'achiev[ing] a section' of trabecular meshwork tissue." *Id.* Ex. 1004, 3, 4. Quintana acknowledges the lack of effectiveness of prior techniques (noting, for example, "a slow rise in pressure occurs in most cases") and describes a technique "which eliminates most of the presumed causes of failure of previous methods." Ex. 1004, 3. Dr. Netland explains that Quintana "appreciated that prior approaches such as trabeculotomy that simply incised or disrupted the trabecular meshwork

[12] Patent Owner takes issue with Dr. Netland's statement that "for the purpose of [his] opinion" he would "generally refer" to approaches that removed "larger segments (e.g. strips) of tissue from the trabecular meshwork using an 'ab interno' approach" as "excisional goniotomy" approaches as reflecting a "biased hindsight perspective." PO Resp. 21; Ex. 1003 ¶ 56. We find Patent Owner's argument not persuasive because a term Dr. Netland states he is using in his opinion has no relevance to what was taught in the art or known to a person of ordinary skill at the relevant time, and is not relied upon for purposes of this Decision.

were not completely effective," and sought to improve the technique by "'stripping' trabecular meshwork tissue from the canal." Ex. 1003 ¶ 58 (citing Ex. 1004, 3). Thus, we find persuasive Dr. Netland's opinion that "despite using different terminology for the procedure, Quintana discloses a goniectomy procedure for excising and removing trabecular meshwork tissue from the eye." *Id.* In short, Dr. Netland's statement that "surgical approaches have been called various different names but generally share certain common features," is supported. Indeed, Petitioner shows that Dr. Condon could not define "goniectomy" and that Patent Owner offers no evidence to show "goniotrabeculotomy," the term used by Quintana, was a known term in the art (or, even were it, that its use indicates Quintana's express disclosure of "stripping" tissue would not have been understood on its face to mean cutting and removing strips of tissue). Reply 10 (citing Ex. 1041, 15:18–16:20 (Dr. Condon stating that he was "not entirely sure what the meaning of [goniectomy] in this – in this patent document is")).

Quintana's disclosure expressly states that "[o]nly the tip of the instrument is introduced into Schlemm's canal, and the [trabecular meshwork] is stripped slowly, gently and easily from the canal's lumen towards the anterior chamber as the needle progresses," which informs one of ordinary skill in the art that the beveled edges of the needle cut and remove a strip of trabecular meshwork tissue. *See* Ex. 1004, 4; *see also id.* at 8 ("[f]urther studies are necessary to disclose the 'in vivo' behaviour of the sectioned trabecular meshwork"), caption to Figure 2 ("[t]he tip of the needle stripping the trabecular meshwork"); *see also* Ex. 1030 ¶¶ 7–10 (Dr. Netland discussing Quintana from the perspective of one of ordinary skill in the art).

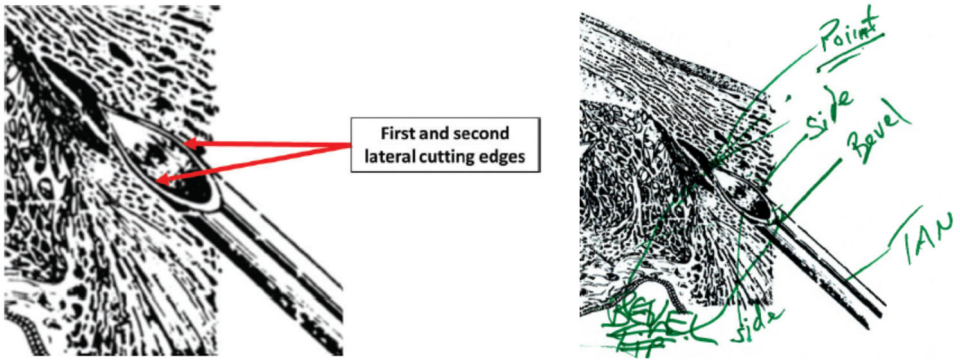
Patent Owner argues that in Quintana "stripped" and "stripping" means "cutting or tearing," but provides no evidence in support and instead argues Petitioner "substitutes the noun 'strip(s)'" to improperly argue that Quintana's procedure "would have resulted in cutting 'strips of tissue.'" Resp. 18–19; *see also id.* at 18 (arguing without any basis that a person of ordinary skill "would have" described removal of trabecular meshwork using "excise" or "excising" rather than "section" or "stripping"") Patent Owner offers no evidence in support of its arguments. In reply Petitioner shows, and we agree, that the commonly understood meaning of "strip," as a verb, would have related to "removal," not merely "cutting or tearing." Reply 10 (citing Ex. 1037, 2; Ex. 1038, 1). Likewise, we are unpersuaded by Patent Owner's argument is its Sur-reply that Quintana's reference to "opening" the trabecular meshwork and limited success suggests that Quintana's device is not "useable" to remove a strip of trabecular meshwork. *See* Sur-reply 10–11.

Patent Owner also argues that Quintana's reference to the "'in vivo' behaviour of the sectioned trabecular meshwork" "is better understood to refer merely to [trabecular meshwork' remaining in the patient's eye that had been incised or opened," not removed. Resp. 16–17 (citing Ex. 2019 ¶ 35). Petitioner argues in reply, and we agree, that the more logical reading of the disclosure in context teaches that "the sectioned trabecular meshwork" refers to the trabecular meshwork "left behind after excising a 'section' of [trabecular meshwork]." Reply 9. Petitioner argues that Quintana sought to eliminate scarring, and that "it is no surprise Quintana suggested studying [trabecular meshwork] remaining after excision to confirm it did not close up." Reply 9 (citing Ex. 1004, 3, 8). We find Petitioner's argument persuasive because it is supported by Quintana, which, as Petitioner notes,

states that "the trabecular meshwork cells are known not to reproduce; moreover, with this technique the scleral wall of Schlemm's canal is not damaged," "[b]ut the remaining cells can enlarge." Ex. 1005, 8; *see also* Reply 9 (stating that "Quintana's statement that 'remaining cells can enlarge' strongly implies removal"). Although Patent Owner disputes Petitioner's showing in its Sur-reply we find those arguments unsupported and, therefore, not persuasive. *See* Sur-reply 12–13.

The record further supports that the two sides of a hypodermic needle's end are sufficiently sharp so as to form "two stationary cutting edges," and remove a strip of trabecular meshwork tissue. In this respect, each party's witness appears to largely agree on how to classify the structural parts of Quintana's bent needle, which is used for "stripping" trabecular meshwork, according to Quintana. *See supra* Section II.D.1 (discussing Quintana); Ex. 1004, 4 ("Only the tip of the instrument is introduced into Schlemm's canal, and the TM is stripped slowly, gently and easily from the canal's lumen towards the anterior chamber as the needle progresses").

Two annotated versions of portions of Quintana's Figure 1 are reproduced below side-by-side.



Ex. 1003 ¶ 120; Ex. 1043, 192. The left panel above shows a portion of Quintana's Figure 1 annotated by Dr. Netland and includes two arrows in

red labeling first and second lateral cutting edges on Quintana's needle. *See* Ex. 1003 ¶ 107. The right panel above shows a portion of Quintana's Figure 1 annotated by Dr. Condon during his deposition and identifies in green the needle's point, its bevel and two sides of the beveled end, and also identifies 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. Netland and Dr. Condon agree that Quintana's needle is used, in some fashion, to surgically treat trabecular meshwork, with Dr. Netland opining that it is used to remove a strip of the trabecular meshwork and Dr. Condon characterizing the procedure as creating a slit and "producing some spreading effect" as the tip enters the meshwork. Ex. 1003 ¶ 104; Ex. 1041, 23:3–34:15. We find Dr. Netland's testimony more credible and persuasive than Dr. Condon's because it is supported by the disclosure of Quintana, as explained below.

Quintana discloses a needle, "bent by 20–30° at the tip," having a distal end sufficiently sharp to penetrate and incise trabecular meshwork and strip it away as the device is moved along Schlemm's canal. *See* Ex. 1004, 3–4. We further understand the beveled ends of hypodermic needles, as disclosed by Quintana, are sharp and intended to cut tissue. Dr. Netland provides support for this view in his Reply Declaration, which includes experimental evidence that a hypodermic needle, bent by 30° at the tip and used in a surgical procedure as disclosed by Quintana, has sharp sides and cuts strips of trabecular meshwork having a generally regular width that generally matches the distance between the needle's beveled sides (on either side of the needle's opening, as shown in the figures above). Ex. 1030 ¶¶ 7–26; Exs. 1031–1033 (videos of procedure); *see also* Reply 7–13 (discussing Dr. Netland's Reply Declaration).

Dr. Netland performed these experimental procedures seeking to demonstrate the results of Quintana's procedure, as it would have been understood by the ordinarily skilled artisan. Ex. 1030 ¶¶ 7–26. Dr. Netland testified to the similarities and necessary differences between his experimental procedures and the procedure taught by Quintana, including, for example, his use of portions of cadaver eyes rather than live patients' eyes. *Id.* ¶¶ 13–16. We find that, considering these similarities and differences, Dr. Netland's experiments are useful to show how a person of ordinary skill in the art would have understood how a bent hypodermic needle's beveled end interacts with trabecular meshwork when used in a method as disclosed by Quintana.

Dr. Netland video recorded these procedures and the videos are a part of the record. Exs. 1031–1033; Ex. 1030 ¶ 19; *see also* Reply 4–5, 11–13 (discussing this evidence).[13] Dr. Netland provided annotated still screen shots of the videos of these procedures, which we reproduce below:

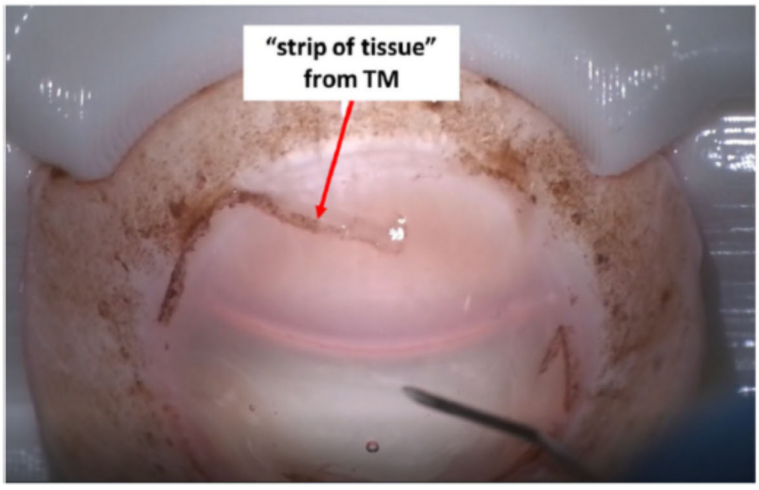


Figure 1

[13] Patent Owner filed a motion to strike directed, in part, to Exhibits 1031–1033 (Paper 38), which we found not persuasive for the reasons provided in our order denying the motion. Paper 49, 3–9.

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.

Dr. Netland's Figure 2 is reproduced below.

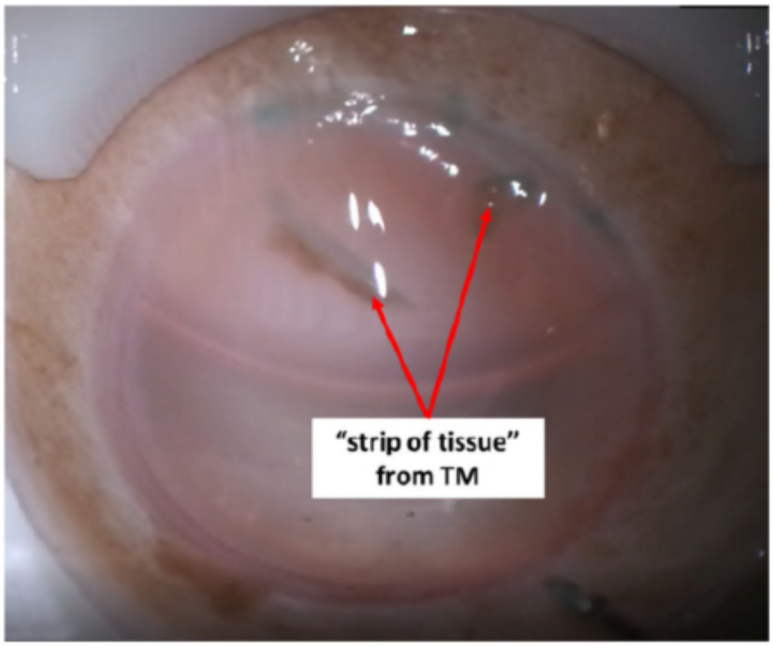


Figure 2

Figure 2 above shows a second still image from another video recording of Dr. Netland's Experiment 3. Ex. 1030 ¶ 21; Ex. 1032. As in Figure 1, Figure 2 shows the tip of a bent needle in the lower right quadrant; its sides and width are discernable. Figure 2 also shows a strip of trabecular meshwork tissue cut away, i.e., stripped, using the needle. Ex. 1030 ¶¶ 21, 23–26. The tissue strip has approximately the same width as the needle.

Dr. Netland's Figure 3 is reproduced below.

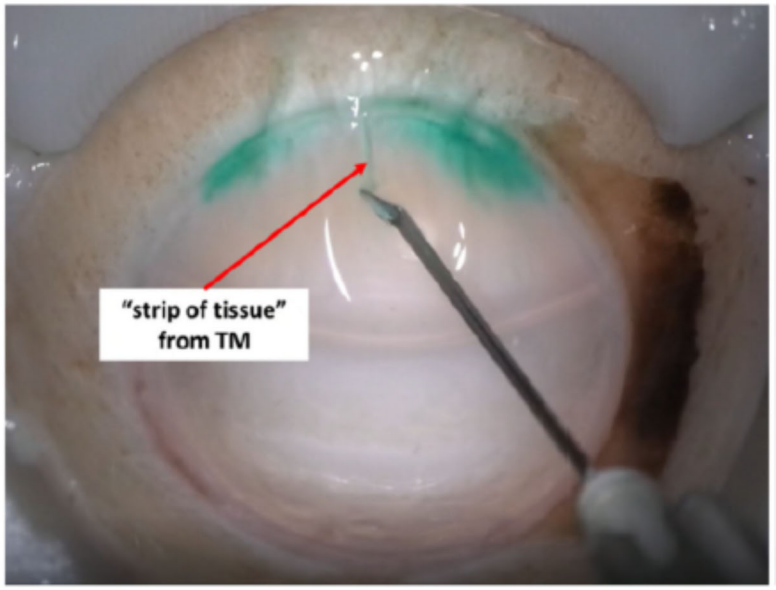


Figure 3

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

We further find Petitioner shows by a preponderance of the evidence that Quintana teaches an ab interno procedure. Pet. 41–42 (citing Ex. 1003 ¶¶ 122–126; Ex. 1004, 4, Fig. 2. We credit the testimony of Dr. Netland who explains as follows:

> Quintana discloses an "ab interno" method because Quintana's procedure approaches the trabecular meshwork from inside the eye within the anterior chamber. In particular, Quintana states "[t]he needle penetrates the anterior chamber at 6 hours (right eye) or 12 hours (left eye) through the scleral side of the limbus; this is in order to run parallel to Schlemm's canal." *Id.* [at] 4 (emphasis added). The needle is then introduced into the angle and is used to strip away the trabecular meshwork. *Id.* Thus, Quintana states explicitly that the needle is inserted into the anterior chamber, and from within the anterior

> chamber approaches and contacts the trabecular meshwork. Again, this is an ab interno procedure.

Ex. 1003 ¶ 122 (emphases omitted). Dr. Netland's testimony is persuasive because it is supported by the express disclosure of Quintana. *See id.* ¶ 123 (explaining that Quintana Figure 2 "shows the needle stripping trabecular meshwork tissue from within the anterior chamber of the eye" (citing Ex. 1004, 5). Dr. Netland further explains as follows:

> Importantly, the fact that Quintana uses a goniolens to visualize the chamber angle further demonstrates that the procedure is "ab interno." Quintana states that "[o]nce the needle is in the anterior chamber, the goniolens is inserted, held with the surgeon's left hand." *Id.*, 4 (emphasis added). Not only does this statement explicitly indicate that Quintana's needle is within the anterior chamber, a person of ordinary skill in the art would appreciate that a "goniolens" is only used in an "ab interno" procedure because it is used to visualize the angle within the anterior chamber. A goniolens would be unnecessary in an "ab externo" procedure because there is no need to visualize the chamber angle in an "ab externo" procedure and Schlemm's canal would be visible through the incision on the exterior of the eye. Accordingly, in my opinion that Quintana's recitation of use of a goniolens further demonstrates that the described procedure is "ab interno."

Id. ¶ 124.

Patent Owner agrees that "ab interno" generally means "from the inside," but argues that a person of ordinary skill in the art "would be unable to conclude with certainty that Quintana's surgical procedure must be ab interno." Resp. 35–38 (citing, e.g., Ex. 2019 ¶ 47). Patent Owner's argument, however, is directed to anticipation by Quintana, not obviousness. *See id.* at 38. To the extent it also applies to obviousness, for the reasons provided above we find Petitioner shows by a preponderance of the evidence that a person of ordinary skill in the art would have understood Quintana

teaches 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.

In sum, "[g]enerally, 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 an "ab interno procedure" 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 of claim 1 is limiting, because Petitioner's contentions are supported by the cited evidence of record, which we adopt as our own findings, we are persuaded that a preponderance of the evidence shows that Quintana teaches a "dual blade device useable for performing an ab intern[o] procedure within a human eye to remove a strip of trabecular meshwork tissue," as recited by claim 1. *See*, *e.g.*, Ex. 1003 ¶¶ 97–103, 173–182.

In the alternative, Petitioner contends that Lee teaches a "dual blade device" with dual cutting edges 14 used in an "ab interno" procedure to excise trabecular meshwork tissue, resulting in a "strip of angle tissue 40" that is removed for histopathological examination. Pet. 64–675 (citing Ex. 1006, 3:50–57, 6:28–40, Fig. 5); Ex. 1003 ¶¶ 57, 108, 109, 175; *see also id.* at 22 (stating that during prosecution of the '155 patent the Examiner found that Lee teaches a dual blade device) (citing Ex. 1022, 320–321). Patent Owner argues the Examiner was wrong and that Lee does not disclose a "dual blade device" because Lee describes a "single, more or less U-

shaped cutting edge 14," which is a "singular element." Resp. 44–47 (citing, *e.g.*, Ex. 1006, 4:38–48, 6:28–30). Having determined that Quintana teaches a "dual blade device useable for performing an ab interno procedure," we do not reach Petitioner's contentions based on Lee with respect to these limitations.

> *a handle configured to be grasped by an operator's hand;*
> *an elongate probe comprising a shaft that extends from the handle along a longitudinal axis;*

Regarding the above-quoted limitation of claim 1, Quintana teaches, as Petitioner shows, that the "needle is inserted into a syringe" such that the syringe, corresponding to the recited "handle," is grasped by the operator's hand. Pet. 43, 68 (quoting Ex. 1004, 3); *see also* Ex. 1003 ¶¶ 129, 183 (Dr. Netland explaining that "syringes are intended to be grasped by a hand of a human operator," and that "the syringe portion of Quintana's needle device acts as a 'handle' as claimed"). Petitioner also shows that the shaft of the needle of Quintana corresponds to the recited "elongate probe." Pet. 43 (citing Ex. 1003 ¶¶ 130, 184; Ex. 1004, 3, Fig. 1). Because Petitioner's contentions are supported by the cited evidence of record, which we adopt as our own findings, we are persuaded that a preponderance of the evidence shows that Quintana teaches a "handle" and an "elongate probe" corresponding to the limitations of claim 1 above.

> *a blunt protruding tip that extends in a lateral direction from a distal end of the shaft to form a bend or curve of approximately 30 degrees to approximately 90 degrees relative to the adjacent longitudinal axis of the shaft;*

Regarding the above-quoted limitation of claim 1, Quintana teaches, as Petitioner shows, a protruding tip that is bent 20 to 30 degrees, corresponding to the recite "protruding tip that extends in a lateral direction from a distal end of the shaft to form a bend or curve of approximately 30

degrees to approximately 90 degrees relative to the adjacent longitudinal axis of the shaft." Pet. 45–46, 68–69 (citing Ex. 1003 ¶ 134; Ex. 1004, 3–4. Dr. Netland explains that "[t]he 20-30° angle referred to by Quintana is relative to the longitudinal axis of the shaft—an unbent tip would be at 0° relative to the longitudinal axis of the shaft and the angle would increase to 20–30° relative to the shaft's longitudinal axis as the tip is bent from its original position." Ex. 1003 ¶ 134; *see also id.* (noting that "Quintana's specified 20-30° angle range overlaps" with the "30 degrees to approximately 90 degrees" recited in claim 1).

To the extent Patent Owner argues Quintana "does not necessarily disclose" a "tip that extends in a lateral direction from a distal end of the shaft to form a bend or curve of approximately 30 degrees to approximately 90 degrees relative to the adjacent longitudinal axis of the shaft," because the bend is "most likely done by the surgeon by hand," we understand the argument to be directed to anticipation, not obviousness, and further find it insufficiently supported and contrary to the express disclosure of Quintana. Resp. 33 (citing Ex. 2019 ¶ 99); Ex. 1004, 3–4.

Likewise, we find not persuasive Patent Owner's argument that "Quintana does not describe or depict precisely where at the needle tip, or along what axis of the needle, the bend is made." Resp. 33; Sur-reply 16. Quintana's express disclosure that the needle tip is bent 20 to 30 degrees corresponds to the recited "protruding tip that extends in a lateral direction from a distal end of the shaft to form a bend or curve" because the tip is at the distal end of the shaft. Ex. 1003 ¶ 134; Ex. 1004, 3.

Petitioner argues that the protruding tip of Quintana is "blunt" because it is "located on the bottom of the distal end of the needle tube" and "is used to facilitate insertion of the tip through the [trabecular meshwork] into

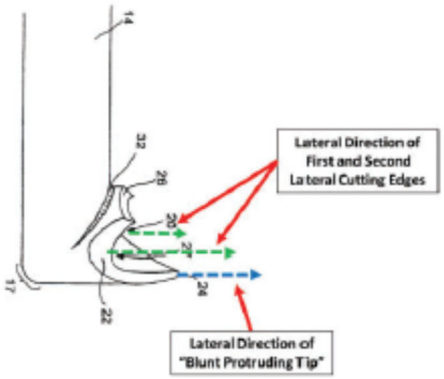
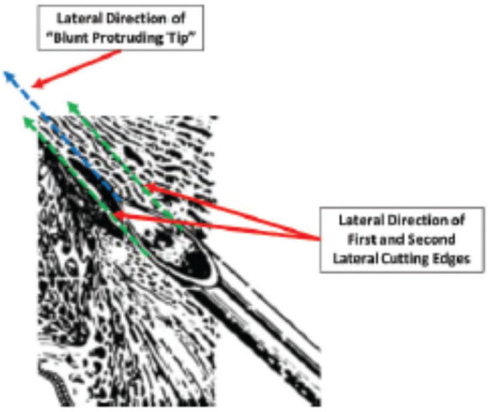
[Schlemm's Canal], and guides the needle through [Schlemm's Canal]." *Id.* at 45 (citing Ex. 1001, 3:10–24; Ex. 1003 ¶ 132; Ex. 1004, 4, Fig. 1. Patent Owner argues that Quintana does not teach a "blunt protruding tip" because Quintana's tip "is sharp and not blunt." Resp. 31–35. For the reasons addressed above, we do not reach whether Quintana teaches a protruding tip that is "blunt" as required by claim 1. *See supra* Section II.C.3.

In the alternative, Petitioner argues, and Patent Owner does not dispute, that Lee teaches a protruding tip that is "blunt." Pet. 68–69; *see generally* Resp. Specificaly, as explained by Petitioner, Lee teaches "the distal end 15 of the bowl-like tip of Lee's device protrudes 'for ease of tissue penetration and cutting' and is 'softly rounded' and 'generally parabolic in shape in order to avoid damage to the outer wall of Schlemm's Canal.'" Pet. 69 (quoting Ex. 1006, 4:38–48). In the absence of any dispute between the parties, Petitioner has shown by a preponderance of the evidence that Lee teaches a protruding tip that is "blunt." Because Petitioner's contentions are supported by the cited evidence of record, which we adopt as our own findings, we are persuaded that a preponderance of the evidence shows that the combination of Quintana and Lee teaches "a blunt protruding tip" corresponding to the limitations of claim 1 above.

> *first and second lateral cutting edges formed at stationary side-by-side locations on the shaft, said first and second lateral cutting edges facing in the same lateral direction as the blunt protruding tip and being spaced apart such that an area exists between the first and second lateral cutting edges; and*

Regarding the above-quoted limitation of claim 1, Quintana teaches, as Petitioner shows, a needle with "two spaced-apart, lateral cutting edges on opposite sides of the needle tube," corresponding to a "dual blade device"

with "first and second lateral cutting edges," as recited by claim 1. Pet. 40–43, 64; Ex. 1003 ¶ 119; Ex. 1004, Fig. 1. Petitioner includes in the Petition annotated versions of Figure 3D of the '155 patent and Figure 1 of Quintana, reproduced below.

'155 patent, Fig.3D (annotated)	Quintana, Fig.1 (annotated)
	

Pet. 48. The annotated figures above show first and second lateral cutting edges of a preferred device in the '155 patent on the left and in the bent-tip needle taught by Quintana on the right. Dr. Netland explains that "Quintana's needle is nearly identical to the 'needle cutter device' disclosed in the '155 patent," as shown in the comparison above. Ex. 1003 ¶ 120. As shown in Figure 1 of Quintana, the first and second cutting edges are "formed at stationary side-by-side locations on the shaft," face "in the same lateral direction" as the protruding tip, and are "spaced apart such that an area exists between the first and second lateral cutting edges," as required by claim 1. Pet. 45–49 (citing Ex. 1003 ¶¶ 133–137, 139; Ex. 1004, Fig. 1). Dr. Netland further explains that, as shown in Figure 3D of the '155 patent above, "at points near the terminal end of the blunt protruding tip 24, cutting edges 20 and 22 face in a nearly perpendicular direction to the lateral

direction of the blunt protruding tip 24," such that "the claim requirement that the cutting edges face in the same lateral direction as the blunt protruding tip must simply mean that some point along the cutting edges face in that direction," as also shown in Quintana Figure 1 above. Ex. 1003 ¶ 93.

Patent Owner first argues that "Petitioner has failed to prove that the Quintana device as used for its intended purpose meets the limitation that 'first and second lateral cutting edges are contacting the trabecular meshwork' as required by the Challenged Claims." Resp. 28–29; Sur-reply 13–15. Patent Owner's argument is not persuasive because, contrary to Patent Owner's assertion, none of the Challenged Claims, which are directed to a device, recite "first and second lateral cutting edges are contacting the trabecular meshwork." Next, Patent Owner argues again that "Quintana never mentions or suggests removing a strip of TM or a device for doing so," and that "nothing in Quintana would teach a [person of ordinary skill in the art] that the beveled sides of the Quintana device tip *concurrently* cut the [trabecular meshwork] to create and remove a strip of [trabecular meshwork] tissue of defined width. Resp. 30–31 (citing Ex. 2019 ¶ 43).

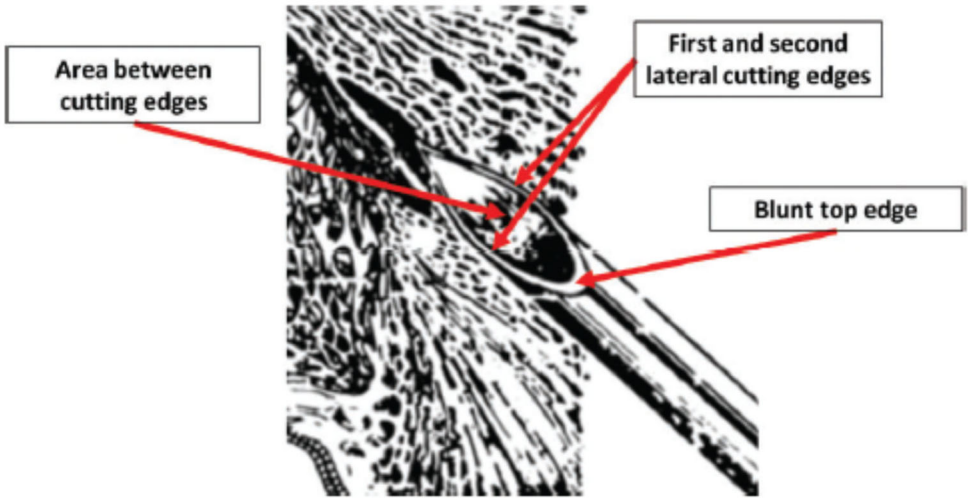
We find Patent Owner's arguments not persuasive for the same reasons provided above with respect to claim 1's recitation of "dual blades." Additionally, we note that claim 1 is directed to a device and does not expressly recite "concurrently" cutting trabecular meshwork. Patent Owner's argument that the Challenged Claims "require concurrent cutting" from the trabecular meshwork is not accurate. Presumably, Patent Owner intends to refer to claim 1's recitation of a "dual blade device useable . . . to

remove a strip of trabecular meshwork tissue" and the requirement that the cutting edges are "lateral . . . at stationary side-by-side locations."

Because Petitioner's contentions are supported by the cited evidence of record, which we adopt as our own findings, we are persuaded that a preponderance of the evidence shows that Quintana teaches a dual blade device with "first and second cutting edges," corresponding to the limitations of claim 1 above. Pet. 46–49; Ex. 1003 ¶¶ 135–139.

> *a blunt top edge that extends transversely from a top end of the first lateral cutting edge to a top end of the second lateral cutting edge and traverses above the area between the first and second lateral cutting edges;*

Regarding the above-quoted limitation of claim 1, Quintana teaches, as Petitioner shows, a "blunt top edge" as required by claim 1. Pet. 49–50, 70; Ex. 1003 ¶¶ 140–141, 189; *see also supra* Section II.C.4 (addressing the construction of "blunt top edge"). Reproduced below is an annotated version of Figure 1 of Quintana provided by Petitioner.



Pet. 49–50; Ex. 1003 ¶ 140. Petitioner's annotated Figure 1 of Quintana shows features taught by Quintana corresponding to the recited "first and second lateral cutting edges," an "area" between the cutting edges, and a

"blunt top edge." Like blunt top edge 26 of Figure 3D of the '155 patent shown above, the portion of Quintana's device relied on by Petitioner as the corresponding feature includes a sloped surface. We credit the testimony of Dr. Netland in this regard, who explains that "Quintana's needle has a 'blunt top edge' because, like the 'blunt top edge' of the '155 patent's 'needle cutter device,' it is located at the top of the distal end of the needle tube." Ex. 1003 ¶ 140 (citing Ex. 1001, 3:10–24; Ex. 1004, 4). Petitioner further explains that the blunt top edge "of Quintana's needle 'extends transversely from a top end of the first lateral cutting edge to a top end of the second lateral cutting edge,'" "extends between the top end of one cutting edge to the other, the same as the blunt top edge of the patent's 'needle cutter device,'" and is "'above the area between' the cutting edges, as it is on the top of the needle tube above the space between the cutting edges when in an operative position." Pet. 50 (citing Ex. 1003 ¶ 141).

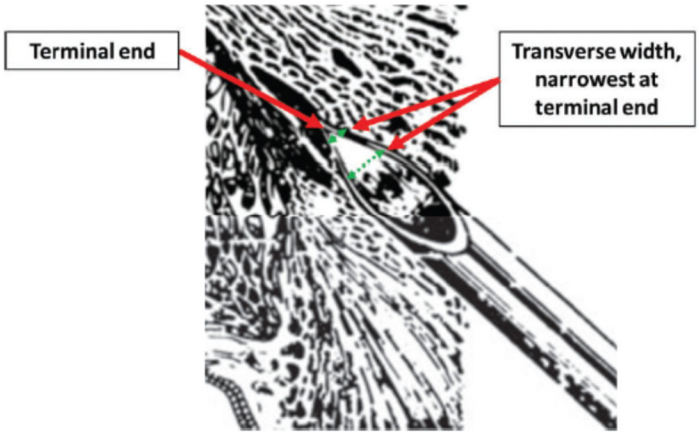
Patent Owner purports to argue that Quintana "does not disclose a blunt top edge," but the focus of Patent Owner's argument is on the dispute over the meaning of "blunt," not on what Petition identifies as a "blunt top edge" in Quintana. Resp. 34–35 (arguing that "the distal point of a standard hypodermic needle tip (like the Quintana device tip) is sharp and not blunt"); Sur-reply 17–18. Patent Owner's argument broadly directed to the "distal point" is not responsive to Petitioner's showing that the top edge of Quintana's needle is sloped in manner indistinguishable from the sloped top edge the '155 patent describes as a "blunt top edge." *See* Reply 21–22.

Because Petitioner's contentions are supported by the cited evidence of record, which we adopt as our own findings, we are persuaded that a preponderance of the evidence shows that Quintana teaches a "blunt top edge" corresponding to the limitations of claim 1 above. Alternatively,

Petitioner argues that "[i]f it is determined Quintana's needle does not have a blunt top edge, it would have been obvious to modify Quintana's needle to have a blunt top edge." Pet. 70. We address this contention in our discussion of reasons supporting obviousness below. *See infra* Section II.E.8.b.

> *the blunt protruding tip having a transverse width, a top surface, a bottom surface and a terminal end, the transverse width being narrowest at the terminal end;*

Regarding the above-quoted limitation of claim 1, Quintana teaches, as Petitioner shows, a protruding tip with a top surface, a bottom surface, and a terminal end.[14] Pet. 51–52, 71 (citing Ex. 1002, 199; Ex. 1003 ¶¶ 142, 143, 190; Ex. 1004, Fig. 1). Petitioner provides an annotated version of Figure 1 of Quintana, reproduced below, identifying the terminal end of the protruding tip and indicating it is the location of the narrowest transverse width, as required by claim 1.



[14] To the extent claim 1 refers repeatedly to a "blunt protruding tip," it is to be understood that we rely on Lee as teaching the "blunt" feature of the recited "blunt protruding tip" and on Quintana as teaching a "protruding tip" modified to be "blunt" in light of Lee. We do not repeat our analysis of the "blunt" feature of the protruding tip every time the claim refers to a "blunt protruding tip."

Pet. 52; Ex. 1003 ¶ 143. Dr. Netland explains that the protruding tip of Quintana's needle device "has a 'transverse width,' which becomes increasingly narrower moving toward the terminal end and is narrowest at the terminal end." Ex. 1003 ¶ 143.

Patent Owner argues that Quintana "would not necessarily have a transverse width being narrowest at the terminal end" because a person of ordinary skill in the art "could reasonably have viewed the transverse width narrowest at the proximal portion of the single bevel of the Quintana device tip." Resp. 33–34 (citing Ex. 2019 ¶ 108); Sur-reply 17 (citing Ex. 2019 ¶108). Patent Owner's argument is otherwise undeveloped and unexplained. Dr. Condon merely asserts without support that "one could reasonably view the transverse width as narrowest at the proximal portion of the single bevel of the Quintana trabeculotome that Dr. Netland otherwise depicts as the blunt top edge." Ex. 2019 ¶ 108. Were we to speculate, Dr. Condon's reference to the "single bevel" suggests that he may be referring to the transverse width of the lumen of the needle. The claim language, however, is not directed to the width of the lumen, but instead recites "the blunt protruding tip having a transverse width . . . being narrowest at the terminal end."

We discern no basis a person of ordinary skill in the art would have understood the recited "the blunt protruding tip having a transverse width . . . being narrowest at the terminal end" to correspond to the proximal portion of the single bevel of the Quintana trabeculotome as Patent Owner asserts. Moreover, to the extent Patent Owner maintains that "transverse width" refers to the lumen, Patent Owner fails to show how that interpretation is supported by what is described in the '155 patent. *See*, *e.g.* Ex. 1001, Figs. 3A, 3B (illustrating cutting tube 14 with a circular lumen).

See also Reply (arguing that Patent Owner's "assertion Quintana's needle would not have a transverse width narrowest at the terminal end makes little sense," and that the "transverse width" at the proximal end of the bevel in Quintana "is equivalent to the diameter of the needle tubing").

Because Petitioner's contentions are supported by the cited evidence of record, which we adopt as our own findings, we are persuaded that a preponderance of the evidence shows that the combination of Quintana and Lee teaches a "blunt protruding tip" corresponding to the corresponding to the limitations of claim 1 above.

> *the blunt protruding tip being below the area between the first and second lateral cutting edges and protruding in the lateral direction beyond the first and second lateral cutting edges such that tissue may pass over the top surface of the blunt protruding tip before coming into contact with the first and second lateral cutting edges;*

Regarding the above-quoted limitation of claim 1, Quintana teaches, as Petitioner shows, a protruding tip "below the area between the first and second lateral cutting edges and protruding in the lateral direction beyond the first and second lateral cutting edges such that tissue may pass over the top surface of the blunt protruding tip before coming into contact with the first and second lateral cutting edges." Pet. 53–55, 71 (citing Ex. 1003 ¶¶ 144–146, 191; Ex. 1004, 4, Fig. 2). Dr. Netland further explains that Figure 2 of Quintana shows that "tissue may pass over the top surface of the blunt protruding tip before coming into contact with the first and second lateral cutting edges," as required by claim 1. Ex. 1003 ¶¶ 144–146.

Patent Owner does not raise any additional arguments in opposition to Petitioner's contentions on these particular limitations. *See generally* Resp. Because Petitioner's contentions are supported by the cited evidence of

record, which we adopt as our own findings, we are persuaded that a preponderance of the evidence shows that the combination of Quintana and Lee teaches a "blunt protruding tip" corresponding to the limitations of claim 1 above.

> *a distal portion of the shaft and the blunt protruding tip being sized to pass through an incision formed in the eye by a 1.5 mm slit knife; and*
> *the blunt protruding tip being further sized to fit within Schlemm's Canal of the human eye and, when so positioned, to be advanceable through Schlemm's Canal with trabecular meshwork tissue passing over its top surface and into contact with the first and second lateral cutting edges.*

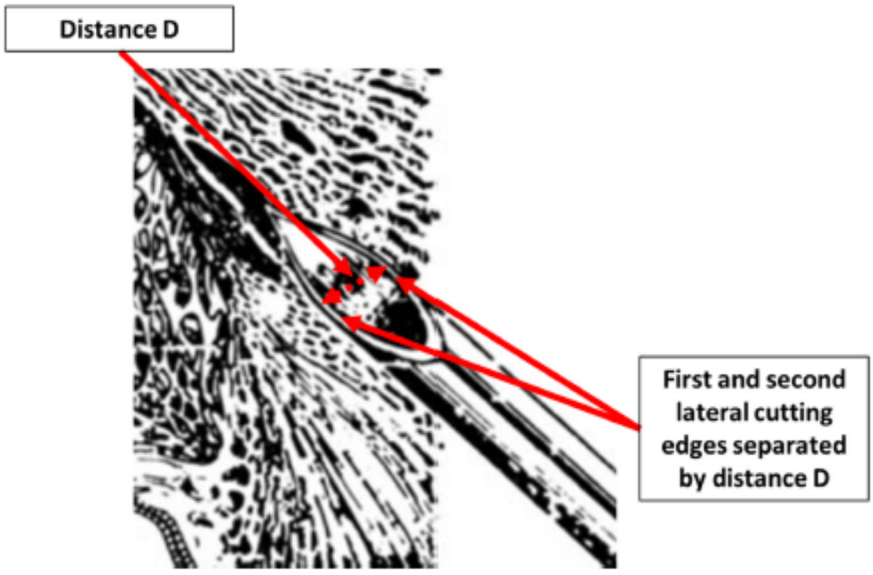
Regarding the above-quoted limitations of claim 1, Petitioner shows that Quintana teaches a "distal portion of the shaft" and a "protruding tip" that is "sized to pass through an incision formed in the eye by a 1.5 mm slit knife" because a "1.5mm slit knife is a knife with a generally flat blade having a width of 1.5mm, which would form an incision with a width of 1.5mm (or greater)" and Quintana's needle is a "0.4x15mm needle" with a diameter of 0.4mm and a length of 15mm." Pet. 54–55, 71 (citing Ex. 1003 ¶¶ 147, 148, 192, 193; Ex. 1004, 3, Figs. 1, 2). Further, as Petitioner shows, "Quintana's needle is 'progressively introduced' in the [anterior chamber] angle, the "tip of the instrument is introduced into [Schlemm's Canal]," and the "[trabecular meshwork] is stripped . . . from the canal's lumen' as the needle 'progresses in the angle.'" Pet. 54 (citing Ex. 1004, 4).

Patent Owner does not raise any additional arguments in opposition to Petitioner's contentions on these particular limitations. *See generally* Resp. Because Petitioner's contentions are supported by the cited evidence of record, which we adopt as our own findings, we are persuaded that a

preponderance of the evidence shows that Quintana teaches a "distal portion of the shaft" and the combination of Quintana and Lee teaches a "blunt protruding tip" corresponding to the limitations of claim 1 above.

2. *Differences Between the Subject Matter of Dependent Claim 2 and the Combination of Quintana and Lee*

Claim 2 depends from claim 1 and further recites that "the first and second lateral cutting edges are spaced apart by a distance D and cut a strip of trabecular meshwork tissue having a width W that is substantially equal to distance D." Ex. 1001, 7:12–15. Petitioner provides an annotated version of Figure 1 of Quintana, reproduced below, showing how it teaches the limitations of claim 2:



Pet. 57. As reflected in annotated Figure 1 above, Petitioner explains, and we agree, that "[t]he strip of tissue created when the cutting edges cut [trabecular meshwork] tissue would necessarily have a width W that is 'substantially equal to distance D' because the cutting edges of Quintana's needle concurrently cut the [trabecular meshwork] tissue, resulting in a strip

having a width corresponding to the distance between the cutting edges (i.e., 'distance D')." *Id.* (citing Ex. 1003 ¶ 153).

Patent Owner does not raise any additional arguments directed specifically to Petitioner's contentions with respect to claim 2. *See generally* Resp. We find Patent Owner's broader arguments that Quintana does not teach cutting a strip of trabecular meshwork "of defined width" not persuasive for the reasons provided above with regard to claim 1. Because Petitioner's contentions are supported by the cited evidence of record, which we adopt as our own findings, we are persuaded that a preponderance of the evidence shows that Quintana teaches the additional limitations of claim 2.

3. Differences Between the Subject Matter of Dependent Claim 3 and the Combination of Quintana and Lee

Claim 3 depends from claim 1 and further requires that the device be "useable for cutting a sector of trabecular meshwork tissue having a length of 2 to 10 millimeters." Ex. 1001, 7:16–18. Petitioner shows that the '155 patent acknowledges as background that the additional limitations of claim 3 were well-known in the art. Pet. 57 (citing Ex. 1:41–46). The cited portion of the '155 patent states that "[i]n a goniectomy 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 um in width is inserted into the anterior chamber of the eye and used to remove a full thickness strip of tissue from the trabecular meshwork." Petitioner further shows, as supported by Dr. Netland, that Quintana discloses a device "useable for cutting a sector of trabecular meshwork tissue having a length of 2 to 10 millimeters," as claimed. Pet. 57–58 (citing Ex. 1003 ¶¶ 156–157).

Dr. Netland explains as follows:

> Quintana explains that using the goniotrabeculotomy technique, "[a] 100-120° trabeculotomy can be achieved." Ex.1004 (Quintana), 4. . . . [A] "100-120° trabeculotomy" would correspond to a strip of tissue of about 2 to 10 mm as claimed. The circumference of Schlemm's canal (and thus, the trabecular meshwork) is approximately 36 mm. *See* Ex.1010 (Hogan), 5. A 100° section of trabecular meshwork corresponds to approximately 28% of the total length (100°/360° = 0.28). 28% of 36 mm equates to a section that is 10.08 mm in length, which is "about" 10 mm, as claimed. Given Quintana's statement that a "100-120° trabeculotomy can be achieved," persons of ordinary skill in the art would have understood that a shorter segment of trabecular meshwork tissue could also be achieved using Quintana's method as well. In other words, Quintana teaches that strips of trabecular meshwork tissue ranging anywhere from 0-10.08mm (or greater) could be achieved, which overlaps with the range specified in the claim.

Ex. 1003 ¶¶ 156–157. Because Petitioner's contentions are supported by the cited evidence of record, which we adopt as our own findings, we are persuaded that a preponderance of the evidence shows that Quintana teaches the additional limitations of claim 3.

4. *Differences Between the Subject Matter of Dependent Claim 4 and the Combination of Quintana and Lee*

Claim 4 depends from claim 1 and further requires that "the bottom surface of the blunt protruding tip extends at an angle of approximately 90 degrees relative to the adjacent longitudinal axis of the shaft." Ex. 1001, 7:19–22. Quintana teaches, as Petitioner shows, a protruding tip bent 20 to 30 degrees (and that the "bottom surface" of the protruding tip would "necessarily extend at the same angle" as the rest of the tip relative to the longitudinal axis), but does not teach a tip bent "approximately 90 degrees." Pet. 59–61, 73–74; Ex. 1004, 3. Petitioner relies on the knowledge of a person of ordinary skill in the art to show that

"[i]t was well-known in the art to use devices having tips, points, or shafts bent at various angles to meet the needs of a given surgery as taught in Quintana itself and various other references. *Id.* at 59–60, 71 (citing Ex. 1003 ¶¶ 164, 165, 207–211; Ex. 1005, 2). Petitioner explains that Johnstone, for example, "discloses a procedure using 'a cystotome with the point oriented at right angles to the shaft' inserted through the [trabecular meshwork] into [Schlemm's Canal]." *Id.* at 60 (quoting Ex. 1005, 2). Petitioner also specifically cites Lee as teaching angling the end of the device "depending on surgical requirements." *Id.* at 60 (citing Ex. 1006, 4:49–54).

Patent Owner does not dispute that the additional limitations of claim 4 would have been within the general knowledge of a person of ordinary skill in the art. *See generally* Resp. We address whether a person of ordinary skill in the art would have had reason to apply that knowledge to Quintana below. *See infra* Section II.E.8.c. Because Petitioner's contentions are supported by the cited evidence of record, which we adopt as our own findings, we are persuaded that a preponderance of the evidence shows that the additional limitations of claim 4 would have been within the knowledge of a person of ordinary skill in the art.

5. *Differences Between the Subject Matter of Dependent Claim 5 and the Combination of Quintana and Lee*

Claim 5 recites "[a] system comprising a device according to claim 1 in combination with a 1.5 mm slit knife for forming said incision in the human eye." Ex. 1001, 7:23–25. Petitioner recognizes that Quintana uses a needle to penetrate the anterior chamber of the eye. Pet. 61–62, 74. Petitioner further shows that at the time of the invention it was well-known to a person of ordinary skill in the art "to form incisions in the eye with

different types of knives and blades, including slit knives, the size of which depends on the type of procedure and surgical instrument that would subsequently be inserted through the incision." *Id.* at 61, 74 (citing Ex. 1003 ¶¶ 170, 171, 213, 214; Ex. 1006, 5:61–6:45; Ex. 1015 ¶¶ 76, 77, 121; Ex.1023 ¶ 4; Ex. 1024, 4:5–6). We credit Dr. Netland's testimony that "[i]n 2003, it was well-known in the art to form incisions in the eye with different types of knives and blades, including slit knives," because it is supported by the evidence he cites. Ex. 1003 ¶ 213 (citations omitted). Specifically, Dr. Netland explains that Lee teaches "a procedure involving making an incision into the anterior chamber with a sharp knife through clear cornea about 1mm. anterior to the limbus.'" *Id.* (quoting Ex. 1006, 5:61–6:45) (emphasis omitted).

Patent Owner does not dispute that the additional limitations of claim 5 would have been within the general knowledge of a person of ordinary skill in the art. *See generally* Resp. We address whether a person of ordinary skill in the art would have had reason to apply that knowledge to Quintana below. *See infra* Section II.E.8.d. Because Petitioner's contentions are supported by the cited evidence of record, which we adopt as our own findings, we are persuaded that a preponderance of the evidence shows that the additional limitations of claim 5 would have been within the knowledge of a person of ordinary skill in the art.

6. Differences Between the Subject Matter of Dependent Claim 6 and the Combination of Quintana and Lee

Claim 6 depends from claim 1 and recites that "the device is manually operable to remove a strip of trabecular meshwork tissue." Ex. 1001, 7:26–28. Petitioner shows, and we agree, that "Quintana's needle is inserted into a syringe and held in the surgeon's hand," such that a person of ordinary

skill in the art would have understood that "Quintana's needle is 'manually operable' because the device is operated by hand to remove strips of [trabecular meshwork] tissue." Pet. 58, 72–73 (citing Ex. 1003 ¶¶ 159, 202; Ex. 1004, 3–4). Patent Owner does not raise any additional arguments directed specifically to Petitioner's contentions with respect to claim 6. *See generally* Resp. We find Patent Owner's broader arguments that Quintana does not teach a device "operable to remove a strip of trabecular meshwork tissue" not persuasive for the reasons provided above with regard to claim 1.

Because Petitioner's contentions are supported by the cited evidence of record, which we adopt as our own findings, we are persuaded that a preponderance of the evidence shows that Quintana teaches the additional limitations of claim 6.

7. *Differences Between the Subject Matter of Dependent Claim 7 and the Combination of Quintana and Lee*

Claim 7 depends from claim 1 and further recites that "the shaft comprises a tube having at least one lumen." Ex. 1001, 7:29–30. Petitioner shows, as supported by Dr. Netland, that Quintana teaches the additional limitations of claim 7. Pet. 58–59, 73 (citing Ex. 1003 ¶¶ 161, 204; Ex. 1004, Fig. 1). Dr. Netland explains in this regard that "Quintana uses a needle device, which is a needle inserted into a syringe," that "[t]he needle of Quintana's device is an 'elongate probe,' which has a shaft," and that "[p]ersons of ordinary skill in the art would appreciate that needle shafts are made of tubing having at least one lumen, i.e., canal or cavity, inside the tubing." Ex. 1003 ¶ 204 (citing Ex. 1004, 3, Fig. 1). We further agree with Petitioner that Figure 1 of Quintana shows the needle, including the opening of the needle's inner lumen at the end of the needle shaft. Pet. 58–59 (providing an annotated version of Figure 1 of Quintana). Patent Owner

does not raise any additional arguments directed specifically to Petitioner's contentions with respect to claim 7. *See generally* Resp.

Because Petitioner's contentions are supported by the cited evidence of record, which we adopt as our own findings, we are persuaded that a preponderance of the evidence shows that Quintana teaches the additional limitations of claim 7.

8. Reasons Supporting Obviousness Over Quintana and Lee

We find for the reasons provided below that Petitioner has shown by a preponderance of the evidence persuasive reasons the subject matter of the Challenged Claims, as a whole, was taught by the combination of Quintana and Lee, in light of the knowledge of a person of ordinary skill in the art. We further find that, to the extent a feature of Quintana relied upon by Petitioner would have required modification to correspond to a feature of a Challenged Claim, Petitioner has shown by a preponderance of the evidence a person of ordinary skill not only could have made the modification, but would have had reason to do so in light of the teachings of Lee and the knowledge of a person of ordinary skill in the art. We focus our discussion below on the determinative issues in dispute.

a. "blunt protruding tip" (claim 1)

To the extent Quintana does not teach a protruding tip that is "blunt," there is no dispute that Lee teaches a "blunt protruding tip." *See supra* Section III.E.1. Moreover, Lee, as Petitioner shows, expressly explains that the reason the tip is "softly rounded" and "generally parabolic in shape" is "to avoid damage to the outer wall of Schlemm's Canal." Pet. 69 (quoting Ex. 1006, 4:3–48). In support of applying Lee's teaching of a blunt protruding tip to Quintana's protruding tip, we find Petitioner's reasoning, as follows, persuasive because it is expressly supported by Lee:

> Rounding the terminal end of the tip of Quintana's needle to create a "blunt protruding tip" would have been obvious for the exact reason expressed in the art, *i.e.*, avoiding damage to [Schlemm's Canal], and a [person of ordinary skill in the art] would have expected success as devices such as Lee's with a rounded tip were still successfully used to penetrate the [trabecular meshwork].

Pet. 69 (citing Ex. 1003 ¶ 186). We further find persuasive in this regard Dr. Netland's supporting explanation, as follows:

> According to Quintana, "[s]ince the convexity of the tip is facing the external wall of the canal, this structure is not damaged. This is why we bend the tip and we point it towards the anterior chamber." [Ex, 1004, 4.] Thus, while Quintana takes measures to prevent the tip of the needle from damaging the external wall of Schlemm's Canal, persons of ordinary skill in the art would have recognized the possibility that the tip of the needle could damage Schlemm's Canal based on Quintana's explicit statements and been motivated to modify Quintana's needle to improve the safety of the device and procedure. One way of doing so would have been by modifying the terminal end of the tip of the needle, such as by rounding the tip or making the tip less sharp/duller. *Id.* It was known in the art well before 2003 that devices with tips for penetrating the trabecular meshwork and advancing through Schlemm's Canal could have rounded, duller portions for avoiding damage to Schlemm's Canal. For example, Lee's device has a bowl-like tip with sharpened cutting edges 14 and a distal end 15 of the cutting edges 14 that protrudes "for ease of tissue penetration and cutting" and is "softly rounded" and "generally parabolic in shape in order to avoid damage to the outer wall of Schlemm's Canal." Ex.1006 (Lee), 4:38–48. [Annotated figure omitted.]

Ex. 1003 ¶ 186 (further stating that "[p]ersons of ordinary skill in the art would have expected success given the fact that even with cutting edges having portions that are rounded, Lee's device was still successfully used to penetrate the [trabecular meshwork] and excise strips of tissue from Schlemm's Canal"). Patent Owner does not dispute Petitioner's asserted

rationale in support of applying Lee's teaching of a blunt protruding tip to the protruding tip of Quintana. *See generally* Resp.

b. "blunt top edge" (claim 1)

For the reasons provided above we are persuaded that Quintana teaches a "blunt top edge," as recited in claim 1. *See supra* Section II.E.1. In the alternative, Petitioner also shows that it would have been obvious to modify Quintana's needle to have a blunt top edge. Pet. 70. Petitioner reasons that a person of ordinary skill in the art "would have been motivated to modify Quintana's needle for safety reasons and would have known one way of doing so would be to round portions of the needle near the tip such as the top edge," and that such person "would have expected success as devices with rounded portions near the cutting area (e.g., Lee) were used safely and successfully." *Id.* (citing Ex. 1003 ¶ 189). We further find persuasive in this regard Dr. Netland's supporting explanation, as follows:

> [W]hile Quintana takes measures to prevent the tip of the needle from damaging the external wall of Schlemm's Canal, persons of ordinary skill in the art would have been motivated to modify Quintana's needle to improve the safety of the device and procedure. [citation omitted.] For the same reasons discussed above for blunt protruding tip, persons of ordinary skill in the art would likewise have found it obvious to round other portions near the cutting area (such as the top edge of Quintana's needle) or otherwise make these portions less sharp/duller to, for example, avoid damaging SC, and would have expected success given the successful use of devices in the prior art having cutting edges with rounded portions such as Lee. *Id.*

Ex. 1003 ¶ 189.

Patent Owner does not dispute Petitioner's asserted rationale in support of applying Lee's teaching of a blunt protruding tip to the protruding tip of Quintana.[15] *See generally* Resp.

c. "bottom surface of the blunt protruding tip extends at an angle of approximately 90 degrees" (claim 4)

Petitioner shows that, although Quintana teaches bending the tip of its needle 20 to 30 degrees, a person of ordinary skill in the art would have had various reasons to further bend the tip to approximately a right angle, as was well-known, to perform an *ab interno* procedure. Pet. 59–61, 73–74 (citing Ex. 1003 ¶¶ 164–168, 208–211; Ex. 1004, 3–4; Ex. 1005, 2; Ex. 1006, 4:49–54). Petitioner asserts, and we agree, that combining the teaching of Quintana's 20 to 30 degree bent tip with the well-knowledge in the art of a 90 degree bent tip would have been a combination of prior art elements

[15] Patent Owner's other arguments in opposition to Petitioner's asserted combination of Quintana and Lee with regard to claim 1 are not persuasive because they are directed to non-determinative issues for this Decision. Patent Owner argues that a person of ordinary skill "would not have been motivated by Lee to modify the Quintana device by sharpening the beveled sides of the Quintana device tip to make them into first and second lateral cutting edges." Resp. 48. As explained above, we find Quintana, even without modification, teaches "first and second lateral cutting edges." *See supra* Section II.E.1. Patent Owner also argues that "[n]o motivation exists in the art for modifying the Quintana method to include the step of removing a strip of [trabecular meshwork] tissue. Resp. 48–49. Patent Owner's argument is not persuasive because the Challenged Claims are directed to a device, not a method. Moreover, as explained above, Petitioner shows that Quintana teaches a device useable, without modification, "to remove a strip of trabecular meshwork tissue," as recited by claim 1. *See supra* Section II.E.1. In any event, we have discussed above why we agree with Petitioner that there would have been motivation to combine Lee with Quintana and that there would have been a reasonable expectation of success.

according to known methods, as well as a simple substitution to obtain predictable results. *Id.* at 60 (citing Ex. 1003 ¶¶ 166–167). Petitioner also shows that given the limited range of angles a tip could be bent, a person of ordinary skill in the art would have been motivated to try variations of Quintana's bent tip, including an angle of 90 degree, which was well-known in the art to work in ab interno procedures, and, therefore, would have been expected to be successful. *Id.* (citing Ex. 1003 ¶¶ 166–167). Petitioner also explains that although Quintana teaches a "tangential approach" to access the anterior chamber, Quintana acknowledges a "perpendicular approach" was used as well, and Petitioner shows that varying the angle of the tip "would have allowed for a number of different approaches" to achieve the same goal of stripping trabecular meshwork tissue. *Id.* (citing Ex. 1003 ¶ 168; Ex. 1004, 4).

We further find persuasive Petitioner's reliance on 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, which are disclosed as used for the same purpose. Ex. 1006, 4:49–54; *see also* Ex. 1003 ¶¶ 206–211 (reaching this conclusion on modifying the bend angle of Quintana's device).

Patent Owner's arguments to the contrary are not persuasive. Resp. 41–43, 49–50; Sur-reply 22–23. Patent Owner argues that a person of ordinary skill in the art "would have been taught away from modifying the Quintana device to change the angle of the tip bend beyond 20-30° for fear

of reducing the effectiveness of the device in working for its intended purpose in the tangential approach of the described surgical procedure, including increasing the risk of undesirable injury to the external wall of Schlemm's Canal." *Id.* at 49 (citing Ex. 2019 ¶¶ 85, 190). Patent Owner's argument, however, relies on Dr. Condon's testimony that Johnstone (not Quintana or Lee, upon which Petitioner relies) employed a tip bent at 90 degrees in a procedure that "damaged the external wall of Schlemm's Canal," but was "unconcerned with this result." Ex. 2019 ¶ 190 (citing Ex. 1005, 11); *see also* Resp. 49–50 (arguing that because Johnstone "did not share Quintana's concern about avoiding damage to the external wall of Schlemm's Canal," a person of ordinary skill in the art would not have been motivated to change the angle of Quintana's tip "to be approximately 90 degrees based on Johnstone").

Petitioner, however, does not propose a combination based on Quintana and Johnstone, but instead identifies Johnstone as support to show that a tip bent at 90 degrees was well-known in the art, which Patent Owner does not dispute (and which is supported by Lee when "surgical requirements" demand such a bend, as discussed above). *See* Pet. 59–60. Dr. Condon describes the results of Johnstone as "inconsistent" with Quintana. *Id.*; *see also* Resp 41 (citing *Meiresonne v. Google, Inc.*, 849 F.3d 1379, 1382 (Fed. Cir. 2017) ("A reference teaches away 'when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken' in the claim"). Dr. Condon does not suggest the procedures in Quintana and Johnstone are identical and does not explain why a person of ordinary skill in the art would have been led to believe that using a tip bent at 90 degrees would have increased the risk of

injury to Schlemm's Canal in Quintana's procedure. *See* Reply 28 (arguing that using a 90 degree bend with Quintana's tip "would have no effect on the risk of injury to [Schlemm's Canal]" because it would not have changed "that the convexity of the tip faces the external wall of [Schlemm's Canal])" (citing Ex. 1004, 4).

We find Petitioner's argument persuasive because it is supported by Quintana, which explains that "[s]ince the convexity of the tip is facing the external wall of the canal, this structure is not damaged," and that "this is why we bend the tip and we point it towards the anterior chamber"). Further, Patent Owner's arguments do not refute Petitioner's showing that a person of ordinary skill in the art would have known to bend the tip of a needle based upon the surgeon's desires and surgical requirements, as taught by Lee. *See, e.g.*, Ex. 1003 ¶ 165 (stating that "surgeons often bend their instruments at varying angles to meet the needs of the particular procedure being performed or the specific patient and a person of ordinary skill in the art would have known that, for example, a steeper approach angle would require increasing the angle of the needle bend up to 90 degrees); Ex. 1006, 4:49–54. For the same reasons, Patent Owner's arguments in its Sur-reply that a tangential approach with a 90 degree bend in the tip "would not achieve the same result" is misplaced because the claim 4 does not require a particular approach and Dr. Netland explains that the approach and the bend angle are co-dependent. Sur-reply 16; Ex. 1003 ¶ 165.

d. "in combination with a 1.5 mm slit knife" (claim 5)

Petitioner argues that "[a]lthough Quintana uses a needle to penetrate the [anterior chamber], the means for penetrating or incising the [anterior chamber] is not critical to Quintana's procedure." Pet. 61–62, 74 (citing Ex. 1003 ¶ 170–171, 213–214). Petitioner further shows that a 1.5 mm slit

knife would have been a well-known alternative to use "to create an incision" into the anterior chamber that would have simply involved "combining prior art elements according to known methods and/or simple substitution of one known way to enter the [anterior chamber] (e.g., penetrating via a needle) for another (e.g., incising the eye using a slit knife). *Id.* (citing Ex. 1003 ¶ 170). Petitioner further reasons that a person of ordinary skill in the art "modifying Quintana to form an incision with a 1.5mm slit knife" would have required both the slit knife and the needle of Quintana, "to perform the procedure," such that both devices would obviously have been included in "a system," as required by claim 5. *Id.* (citing Ex. 1003 ¶ 171).

We find Dr. Netland's explanation in this regard persuasive, as follows, because it is supported by the cited evidence:

> Forming incisions in the eye with different types of knives and blades of different sizes to perform surgical procedures within the eye was well-known in the art in 2003. For example, Lee discloses a procedure involving making an incision "into the anterior chamber with a sharp knife through clear cornea about 1mm. anterior to the limbus." Ex.1006 (Lee), 5:61–6:45 (emphasis added). . . . Persons of ordinary skill in the art would have expected success as it was routine at the time to use different types of knives, including 1.5 mm slit knives, to create incisions into a patient's eye, as evidenced by the prior art. . . . Indeed, persons of ordinary skill in the art modifying Quintana's procedure to form an incision into the eye with a 1.5mm slit knife, rather than Quintana's needle itself, would clearly need both the slit knife and the needle to perform the procedure.

Ex. 1003 ¶¶ 170–171.

Patent Owner's argues that "Petitioner offers no explanation why or how a [person of ordinary skill in the art] would have viewed combining

a 1.5 mm slit knife to have been advantageous with respect to Quintana, the asserted combination is the product of speculation, conjecture and hindsight." Resp. 43 (citing Ex. 2019 ¶195). We find Patent Owner's argument not persuasive because Petitioner shows, as explained above, that the use of a 1.5 mm slit knife with Quintana's device is merely a combination of known elements yielding predictable results. *See KSR*, 550 U.S. at 416 ("[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results"). Moreover, Petitioner shows that a person of ordinary skill in the art would have known to use a 1.5 mm slit knife as an alternative means of penetrating the anterior chamber, and that if a 1.5 mm slit knife is to be used in the procedure, it would be beneficial to include a 1.5 mm slit knife in a "system" for performing the procedure, as required by claim. *See* Ex. 1003 ¶¶ 170–171.

9. Collective Consideration of the Graham *Factors*

Based upon consideration of the entire record, and for the reasons discussed above, we determine Petitioner has shown by a preponderance of the evidence that the combination of Quintana and Lee teaches each limitation of the Challenged Claims and has also shown that an ordinarily skilled artisan would have had a reason to modify Quintana in light of Lee, as asserted by Petitioner, and would have had a reasonable expectation of success when doing so.[16] On the whole, we find that the information provided by Petitioner and Patent Owner in consideration of the *Graham* factors collectively demonstrates that Petitioner has shown by a

[16] The parties did not provide or discuss objective evidence of nonobviousness. *See generally* Pet.; Resp.

preponderance of the evidence that the Challenged Claims are unpatentable under 35 U.S.C. § 103(a) as obvious over Quintana and Lee.

F. Alleged Anticipation by, or Obviousness over, Quintana, Alone

Petitioner contends the claims 1–3, 6, and 7 are anticipated by Quintana, and that claims 4 and 5 would have been obvious over Quintana, alone. Pet. 4. We determined, as discussed above, that the Challenged Claims were shown to be unpatentable by a preponderance of the evidence based on obviousness over the combination of Quintana and Lee. *See supra* Sections II.E. As a result, we do not reach the merits of anticipation over Quintana or obviousness over Quintana, alone, and make no determination of whether Petitioner has shown the unpatentability of any of the Challenged Claims as anticipated by Quintana or obvious over Quintana, alone.

G. Alleged Obviousness over Jacobi

Petitioner contends the claims 1–7 would have been obvious over Jacobi. Pet. 4. We determined, as discussed above, that the Challenged Claims were shown to be unpatentable by a preponderance of the evidence based on obviousness over the combination of Quintana and Lee. *See supra* Sections II.E. As a result, we do not reach the merits of obviousness over Jacobi, and make no determination of whether Petitioner has shown the unpatentability of any of the Challenged Claims as obvious over Jacobi.

III. CONCLUSION

The outcome for the Challenged Claims in this proceeding is set forth in summary as follows:

Claim(s)	35 U.S.C. §	Reference(s)/Basis	Claim(s) Shown Unpatentable	Claim(s) Not Shown Unpatentable
1–7	103	Quintana, Lee	1–7	
1–3, 6, 7	102[17]	Quintana		
4, 5	103[18]	Quintana		
1–7	103[19]	Jacobi		
Overall Outcome			1–7	

[17] Because we determined all Challenged Claims were shown to be unpatentable over the combination of Quintana and Lee (*see supra* Section II.E), we do not reach Petitioner's contentions based on anticipation by Quintana (*see supra* Section II.F).
[18] Because we determined all Challenged Claims were shown to be unpatentable over the combination of Quintana and Lee (*see supra* Section II.E), we do not reach Petitioner's contentions based on obviousness over Quintana, alone (*see supra* Section II.F).
[19] Because we determined all Challenged Claims were shown to be unpatentable over the combination of Quintana and Lee (*see supra* Section II.E), we do not reach Petitioner's contentions based on obviousness over Jacobi (*see supra* Section II.G).

IV. ORDER[20]

Upon consideration of the record before us, it is:

ORDERED that claims 1–7 of U.S. Patent No. 9,358,155 B2 have been proven by a preponderance of the evidence to be unpatentable; and

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

[20] Should Patent Owner wish to pursue amendment of a Challenged Claim 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).

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