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Paper 11
Date: April 21, 2021

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NEW WORLD MEDICAL, INC.,
Petitioner,

v.

MICROSURGICAL TECHNOLOGY, INC.,
Patent Owner.

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*.

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

New World Medical, Inc. ("Petitioner") filed a Petition pursuant to 35 U.S.C. §§ 311–319 requesting an *inter partes* review of claims 1–7 ("the Challenged Claims") of U.S. Patent No. 9,358,155 B2 ("the '155 patent," Ex. 1001). Paper 1 ("Pet."). MicroSurgical Technology, Inc. ("Patent Owner") filed a Preliminary Response. Paper 9 ("Prelim. Resp.").

We have authority to determine whether to institute an *inter partes* review. 35 U.S.C. § 314(b) (2018); 37 C.F.R. § 42.4(a) (2019). An *inter partes* review may not be instituted "unless . . . the information presented in the petition . . . shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a). Upon consideration of the Petition, the Preliminary Response, and the evidence of record, we conclude that the information presented shows a reasonable likelihood that Petitioner would prevail in showing the unpatentability of at least one of the Challenged Claims. Accordingly, we authorize an *inter partes* review to be instituted as to the Challenged Claims of the '155 patent on the grounds raised in the Petition. Our factual findings and conclusions at this stage of the proceeding are based on the evidentiary record developed thus far (prior to Patent Owner's Response). This is not a final decision as to patentability of claims for which *inter partes* review is instituted. Any final decision will be based on the record, as fully developed during trial.

II. BACKGROUND

A. 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.[1] 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.

[1] 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.

Figure 2 of the ’155 patent is reproduced below.

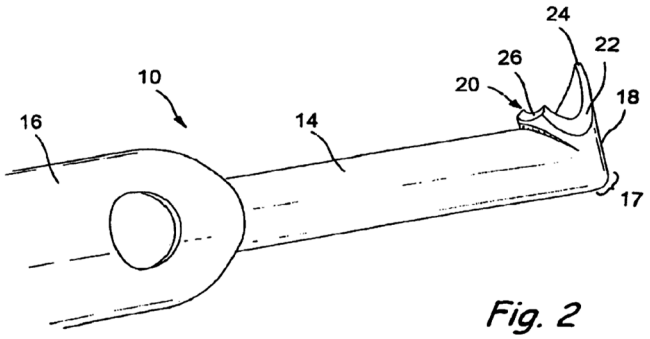


Fig. 2

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.

B. Illustrative Claim

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 is illustrative of the claimed subject matter and is reproduced below.

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

a handle configured to be grasped by an operators 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

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, 6:41–7:11.

C. Petitioner's Asserted Grounds for Unpatentability

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

Claims Challenged	35 U.S.C. §[2]	Reference(s)/Basis
1–3, 6, 7	102	Quintana[3]
4, 5	103	Quintana[4]
1–7	103	Quintana, Lee[5]

[2] 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 to which the '155 patent claims priority has an effective filing date prior to March 16, 2013, the pre-AIA version of §§ 102 and 103 apply.

[3] Manuel Quintana, *Gonioscopic Trabeculotomy. First Results* in DOCUMENTA OPHTHALMOLOGICA PROCEEDINGS SERIES 43, SECOND EUROPEAN GLAUCOMA SYMPOSIUM 265–71 (E.L. Greve et al. eds. 1985). Ex. 1004 ("Quintana"). Quintana has original pagination and also pagination at the lower right-hand corners of each page that appears to have been added. We reference the added pagination at the lower right corner of the document, as has Petitioner.

[4] 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.

[5] U.S. Patent 4,900,300 (issued Feb. 13, 1990). Ex. 1006 ("Lee").

Claims Challenged	35 U.S.C. §[2]	Reference(s)/Basis
1–4, 7, 8	103	Jacobi[6]

See Pet. 4. Petitioner relies on the supporting Declaration of Dr. Peter Netland, dated October 1, 2020. Ex. 1003.

D. Real Parties in Interest

Petitioner and Patent Owner each identifies itself and no others as a real party in interest. Pet. x; Paper 3, 1. Patent Owner also argues that, because Petitioner has not identified the Regents of the University of Colorado ("the University") as a real party in interest, "the Board should deny institution or order that Petitioner amend its mandatory disclosures to name the University as [a real party in interest]." Prelim. Resp. 2 (citing 35 U.S.C. § 312(a)(2)). Specifically, Patent Owner argues the University is an unnamed real party in interest "because (1) the University has voluntarily joined Petitioner's legal disputes with Patent Owner related to the technology at issue; (2) the University and Petitioner have a long-standing, symbiotic business relationship; and (3) the University has a strong financial motivation to invalidate" the '155 patent. *Id.* at 5. For the reasons below, we are not persuaded by Patent Owner's arguments.

First, Patent Owner states that it "competes directly, and arguably solely, with Petitioner in the market for its pioneering surgical devices."

[6] Philipp C. Jacobi et al., *Technique of goniocurettage: a potential treatment for advanced chronic open angle glaucoma*, 81 BRIT. J. OPHTHALMOLOGY 302–07 (1997). Ex. 1007 ("Jacobi"). Jacobi has original pagination and pagination at the lower right-hand corners of each page that appears to have been added by Petitioner. We reference the added pagination at the lower right corner of the document, as has Petitioner.

Id. at 6. Patent Owner also states that after it filed an infringement action against Petitioner in district court, Petitioner then filed an infringement action against Patent Owner in district court, which the University, as licensor of the underlying patents, joined as co-plaintiff. *Id.* According to Patent Owner, the agreement license makes "clear that the University controlled the decision to sue Patent Owner," and, therefore, it is "entirely reasonable to believe the University is doing so likewise in this proceeding." *Id.* at 6–7. Patent Owner reasons that because "the proceedings against Patent Owner in this forum and in the district court are aimed at bringing financial gain to Petitioner and the University alike," the University "should be listed" as a real party in interest in this proceeding. *Id.* at 8. Second, Patent Owner argues that Petitioner and the University have a symbiotic partnership with the respect to the technology at issue, wherein Dr. Kahook and others at the University assist Petitioner in promoting and marketing Petitioner's KBD products. *Id.* at 8–10. Third, Patent Owner argues patents owned by the University and allegedly covering certain competing products are exclusively licensed by Petitioner, and "[t]he terms of this license agreement . . . provide the University with a strong financial motivation to invalidate" the '155 patent. *Id.* at 11–12.

Patent Owner concedes that "there is no time bar issue to this proceeding regardless of whether the University" is a real party in interest. *Id.* at 13. Patent Owner argues, however, that "[t]he estoppel concern is especially grave here." *Id.* But by "here" Patent Owner does not argue that there could be any estoppel in *this* proceeding, but rather argues that *under the circumstances* there are grave concerns that the University "remains armed with a 'collective' second bite at the apple" in the form of potential

future *inter partes* review petitions over the '155 patent should Petitioner not prevail in this trial. *Id.* at 2, 13. Patent Owner does not allege that either Petitioner or the University would be estopped from presenting a challenge in *this* proceeding, were both real parties in interest.

Section 312(a)(2) requires that the "petition identif[y] all real parties in interest." "This provision serves important notice functions to patent owners, to identify whether the petitioner is barred from bringing an [*inter partes* review] due to [a real party in interest] that is time-barred or otherwise estopped, and to the Board, to identify conflicts of interests that are not readily apparent from the identity of the petitioner." *SharkNinja Operating LLC v. iRobot Corp.*, IPR2020-00734, Paper 11, 17 (PTAB Oct. 6, 2020) (precedential) (footnote omitted) (citations omitted) ("*SharkNinja*").

Whether a non-party is a real party in interest is a highly fact-dependent question and must be considered on a case-by-case basis. *RPX Corp. v. Applications in Internet Time, LLC*, IPR2015-01750, Paper 128, 7–9 (Oct. 2, 2020) (precedential); *Ventex Co. v. Columbia Sportswear N. Am., Inc.*, IPR2017-00651, Paper 148 at 6 (PTAB Jan. 24, 2019) (Paper 148) (precedential). However, the question need not always be considered. The circumstance here is like that in *SharkNinja*, which is precedential authority for the Board.

Here, as in *SharkNinja*, the only argument asserted by Patent Owner against institution of trial is that Petitioner failed to name a third party as a real party-in-interest. *See SharkNinja* at 18. Here, as in *SharkNinja*, there is no time-bar or estoppel implication for any party, named a real party in interest or not. *See id.* at 18–19. Here, as in *SharkNinja*, Patent Owner does

not identify any immediate advantage gained by Petitioner in this trial in purposefully omitting the University as a real party in interest. *See id.* at 19.

Thus, consistent with the Board's reasoning in *SharkNinja*, we find under the circumstances presented in this case that the interests of cost and efficiency are best served by not engaging in a lengthy exercise to determine whether the University should have been named a real party in interest, because, regardless of the result of such an analysis, nothing would foreclose this trial from proceeding. *See id.* at 18–20. Accordingly, we need not, and do not, presently determine whether Petitioner has named all real parties in interest.

E. Related Proceedings

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 U.S. Patent No. 9,107,729 B2; IPR2021-00017 regarding U.S. Patent No. 9,820,885 B2; 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. Patent Owner also states that "U.S. Patent No. 9,358,155 is related to U.S. Patent Nos. 9,107,729 and 9,820,885." Paper 3, 1.

III. ANALYSIS

A. Legal Standards of Anticipation and Obviousness

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)).

A patent claim is unpatentable for obviousness if the differences between the claimed subject matter 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. *KSR*, 550 U.S. at 406. In *Graham v. John Deere Co.*, 383 U.S. 1 (1966), the Supreme Court set out a framework for assessing obviousness that requires consideration of four factors: (1) the "level of ordinary skill in the pertinent art," (2) the "scope and content of the prior art," (3) the "differences between the prior art and the claims at issue," and (4) "secondary considerations" of nonobviousness such as "commercial success, long felt but unsolved needs, failure of others, etc." *Id.* at 17–18; *KSR*, 550 U.S. at 407. At this stage of the proceeding there is no dispute as to the level of ordinary skill in the art and neither party addresses evidence directed to secondary considerations. *See generally* Pet.; Prelim. Resp.

B. Level of Ordinary Skill in the Art

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, at this stage of the proceeding, takes no position on the definition of the person of ordinary skill in the art. *See generally* Prelim. Resp.

For purposes of this Decision, at this stage of the proceeding, we accept Petitioner's proposed definition of the person of ordinary skill in the art, or skilled artisan, which is not opposed by Patent Owner and appears to be consistent with the level of skill in the art reflected in the prior art of record and the disclosure of the '155 patent. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) ("the prior art itself [may] reflect[] an appropriate level" as evidence of the ordinary level of skill in the art) (quoting *Litton Indus. Prods., Inc. v. Solid State Sys. Corp*., 755 F.2d 158, 163 (Fed. Cir. 1985)).

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 would have been 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,"[7] "dual blade device," "blunt protruding tip," and "blunt top edge." Pet. 26–30. Patent Owner does not dispute Petitioner's proposed constructions at this time and has not offered any other proposed claim constructions. *See generally* Prelim. Resp. We 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)).

D. Alleged Anticipation by Quintana

Petitioner contends that claims 1–3, 6, and 7 are anticipated by Quintana. Pet. 31–59. Petitioner's contentions are supported by the declaration testimony of Dr. Netland. Ex. 1003 ¶¶ 118–161. At this stage of the proceeding, Patent Owner has not yet disputed Petitioner's

[7] 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").

unpatentability contentions. *See generally* Prelim. Resp. Below we briefly summarize Quintana and consider whether the information presented by Petitioner is sufficient to support institution of *inter partes* review.

1. Summary of Quintana

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. Quintana's Figure 1 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.

Figure 1 of Quintana is reproduced below.

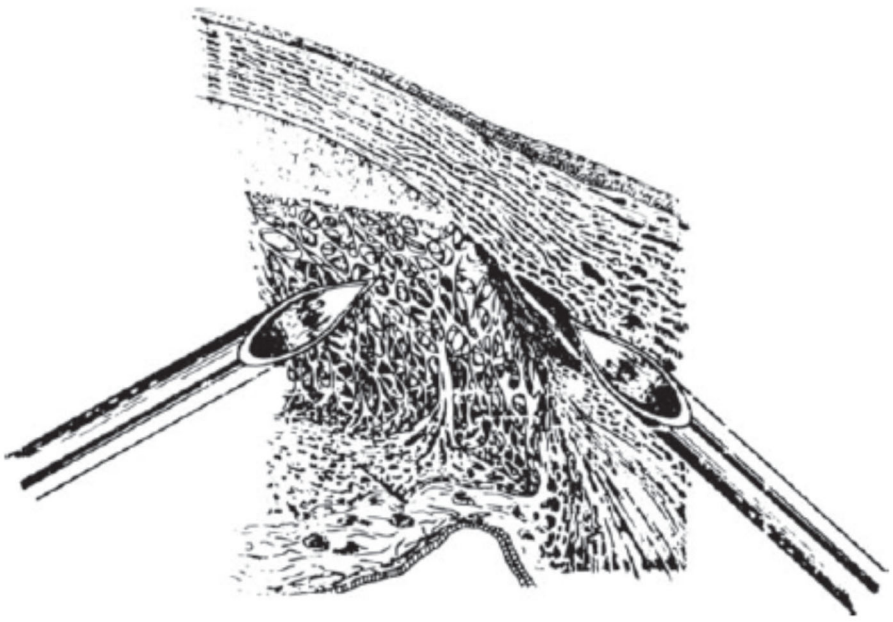


Fig. 1. Schematic drawing comparing the tangential approach to the perpendicular approach as in classic goniotomy or goniotrabeculotomy.

Id. at 4. According to Quintana, Figure 1 shows a "trabeculotome," i.e., a tool for opening the trabecular meshwork of an eye to treat glaucoma, which consists of a 0.4 x 15 mm needle, or insulin-type needle, bent by 20–30° at the tip using a needle-holder, inserted into a syringe filed with "healon" (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. Healon can be injected at will at any time if the surgeon wants to deepen the angle. There is usually no chamber loss, but if this is the case, healon is injected." *Id*.

Quintana states that the healon can be injected during the process at any time and that, after the procedure, the device is withdrawn. *Id*.

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

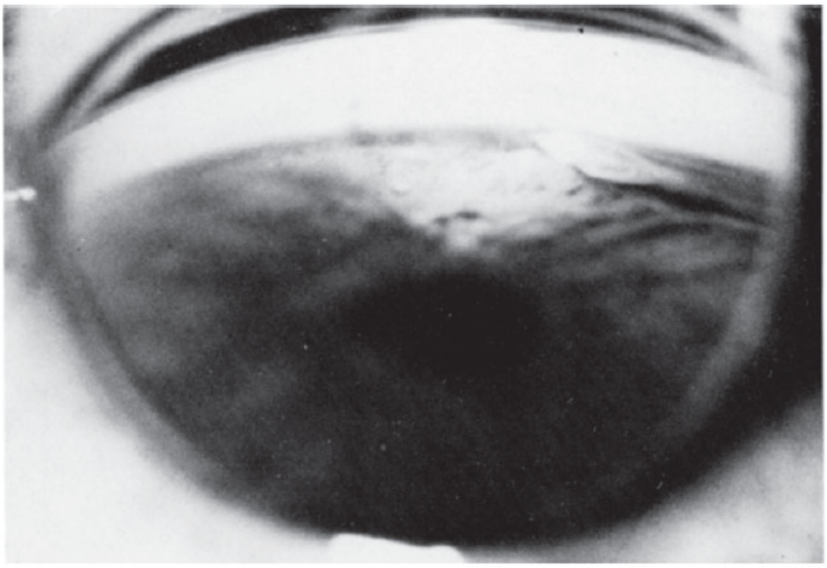


Fig. 2. Goniophotography at operation. The tip of the needle stripping the trabecular meshwork.

Id. at 5. Figure 2 shows the tip of the bent needle instrument introduced into the Schlemm's Canal of an eye (see upper right quadrant of image, needle's tip points toward center line of image and needle's shaft extends 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.

2. Independent Claim 1

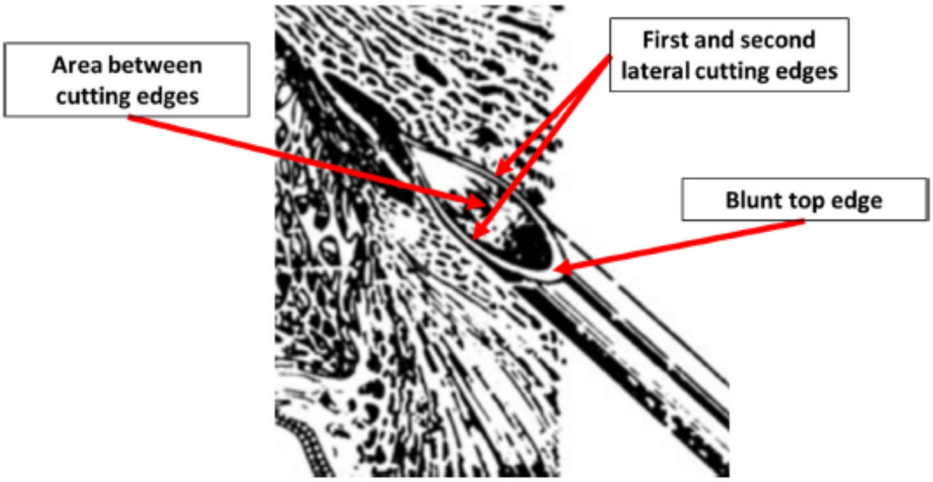
Petitioner provides a detailed explanation, supported by the declaration testimony of Dr. Netland, of how Quintana allegedly discloses each limitation of claim 1. Pet. 40–56; Ex. 1003 ¶¶ 118–150.

> *A dual blade device useable for performing an ab intern [sic] procedure within a human eye to remove a strip of trabecular meshwork tissue, said device comprising:*
> *a handle configured to be grasped by an operators 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;*

Petitioner contends that Figure 1 of Quintana shows a needle with "two spaced-apart, lateral cutting edges on opposite sides of the needle tube" that cuts tissue, corresponding to the recited "dual blade device." Pet. 40–41 (citing Ex. 1003 ¶ 119–121). Petitioner also asserts that the needle of Quintana is described as being used in a procedure within a human eye, corresponding to an "ab interno procedure within a human eye to remove a strip of trabecular meshwork tissue." *Id.* at 41–43 (citing Ex. 1003 ¶¶ 122–128; Ex. 1004, 3–5, Figs. 1, 2). Petitioner states that Quintana discloses that the "needle is inserted into a syringe," and contends that the syringe is grasped by the operator's hand, corresponding to the recited "handle." *Id.* at 43 (quoting Ex. 1004, 3). Petitioner contends that the shaft of the needle of Quintana corresponds to the recited "elongate probe." Pet. 43 (citing Ex. 1003 ¶ 130; Ex. 1004, 3, Fig. 1). Petitioner also contends that "the portion of Quintana's needle extending from the distal end of the shaft is a 'blunt protruding tip,'" and that Quintana discloses the tip is bent 20–30°. Pet. 44–46 (citing Ex. 1003 ¶¶ 131–134; Ex. 1004, 3, 4, Fig 1).

> *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;*

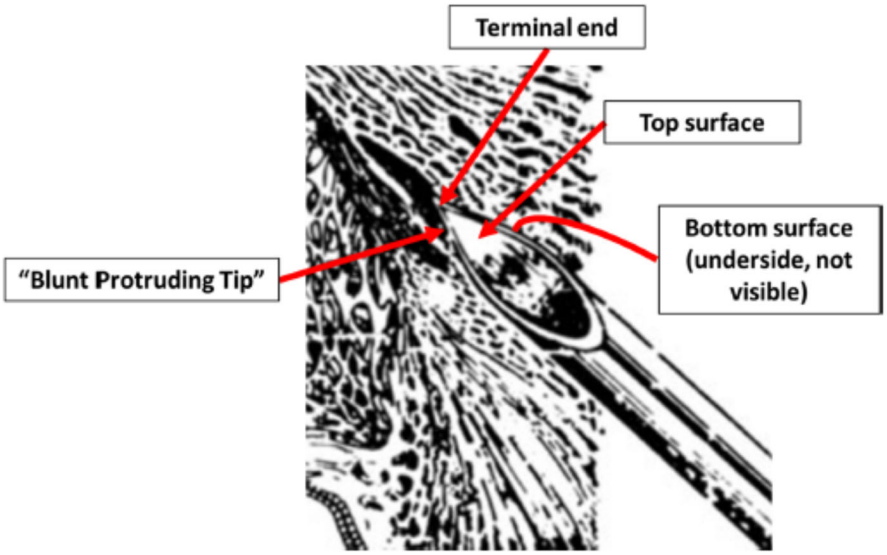
Petitioner contends that as a "dual blade device" Quintana's needle discloses the recited "first and second lateral cutting edges" with an area between them. Pet. 46–47. Petitioner includes annotated versions of Figure 1 of Quintana showing how Quintana allegedly discloses each of the above limitations. *Id.* at 47–50 (citing Ex. 1003 ¶¶ 135–137, 139–141; Ex. 1004 3–4, Fig. 1). For example, reproduced below is an annotated version of Figure 1 of Quintana provided by Petitioner.



Pet. 49–50. Petitioner's annotated Figure 1 of Quintana shows features allegedly corresponding to the recited "first and second lateral cutting edges," an "area" between the cutting edges, and a "blunt top edge."

> *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;*

Petitioner contends that Figure 1 of Quintana discloses the recited "blunt protruding tip," as identified in the annotated version provided by Petitioner and reproduced below.



Pet. 51–52 (citing Ex. 1003 ¶¶ 142, 143). Petitioner explains that the features identified in the annotated figure correspond to the elements identified by Patent Owner during prosecution. *Id.* (citing Ex. 1002, 199). Petitioner also contends that the "blunt protruding tip of Quintana's needle is 'below the area between' the cutting edges, as it is on the bottom of the needle tube below the space between the cutting edges when in an operative position," and 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. *Id.* at 53–54 (citing Ex. 1003 ¶¶ 144–146).

> *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.*

Petitioner contends that "[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 that "[t]he distal portion of the shaft and blunt protruding tip of Quintana's needle are sized to pass through such an incision, as Quintana's needle is a "0.4x15mm needle" with a diameter of 0.4mm and a length of 15mm." Pet. 54–55 (citing Ex. 1003 ¶¶ 147, 148; Ex. 1004 3, Figs. 1, 2). Petitioner also contends that Quintana discloses a blunt protruding tip sized as further recited in claim 1 as shown in its use in Quintana Figure 2 to remove a strip of tissue. *Id.* at 55–56 (citing Ex. 1003 ¶¶ 149–150; Ex. 1004, 4, Fig. 2).

3. Dependent Claims 2, 3, 6, and 7

Petitioner asserts that dependent claims 2, 3, 6, and 7 are anticipated by Quintana. Pet. 56–58 (citing Ex. 1004, 3–4, Fig. 1). Petitioner details how it contends the recited features of the dependent claims are disclosed by Quintana, as supported by the declaration testimony of Dr. Netland. *Id.* (citing Ex. 1003 ¶¶ 152, 153, 156, 157, 159, 161).

4. Showing of a Reasonable Likelihood of Prevailing

We have reviewed Petitioner's contentions based on alleged anticipation by Quintana, which Patent Owner does not yet dispute, and determine that Petitioner has established a reasonable likelihood of prevailing in demonstrating the unpatentability of claims 1–3, 6, and 7 as anticipated by Quintana.

E. Alleged Obviousness over Quintana

Petitioner contends that claims 4 and 5 would have been obvious over Quintana. Pet. 59–62. Petitioner's contentions are supported by the declaration testimony of Dr. Netland. Ex. 1003 ¶¶ 162–171. At this stage of the proceeding, Patent Owner has not yet disputed Petitioner's unpatentability contentions. *See generally* Prelim. Resp.

1. Dependent Claim 4

Claim 4 depends from claim 1 and further recites "wherein 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. Petitioner contends that Quintana discloses a needle with a tip bent 20-30°, but concedes it does not disclose a 90 degree bend. Pet. 59–61 (citing Ex. 1003 ¶ 164, Ex. 1004, 3). Petitioner contends 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 (citing Ex. 1003 ¶ 165; Ex. 1005, 2; Ex, 1006, 4:49–54). Petitioner reasons that "bending the tip [of Quintana's needle] to 90 degrees would have involved combining prior art elements according to known methods or simple substitution to obtain predictable results—for example, combining Quintana's needle with known bends or

curves of 90 degrees." *Id.* at 60 (citing Ex. 1003 ¶¶ 166, 167). Petitioner argues that a person of ordinary skill in the art "would have motivated to try variations, such as an angle of 90 degrees, to expand or improve on Quintana's results." *Id.* at 60 (citing Ex. 1003 ¶¶ 166, 167).

2. Dependent Claim 5

Claim 5 depends from claim 1 and further 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 concedes that Quintana discloses the use of a needle to penetrate the anterior chamber of the eye, but contends that "the means for penetrating or incising the [anterior chamber] is not critical to Quintana's procedure." Pet. 61–62 (citing Ex.1003 ¶ 170). Petitioner contends that at the time of the invention "it was well-known 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 (citing Ex. 1006, 5:61–6:45; Ex. 1015 ¶¶ 76, 77, 121; Ex. 1023 ¶ 4; Ex. 1024, 4:5–6). Petitioner reasons that it would have been obvious to a person of ordinary skill in the art to use a 1.5mm slit knife to penetrate the eye in place of using the needle, and that such a substitution "would simply involve 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.* at 62 (citing Ex. 1003 ¶ 170).

3. Showing of a Reasonable Likelihood of Prevailing

We have reviewed Petitioner's contentions based on alleged obviousness over Quintana, which Patent Owner does not yet dispute, and determine that Petitioner has established a reasonable likelihood of prevailing in demonstrating the unpatentability of claims 4 and 5 as obvious in view of Quintana.

F. Alleged Obviousness over the Combination of Quintana and Lee

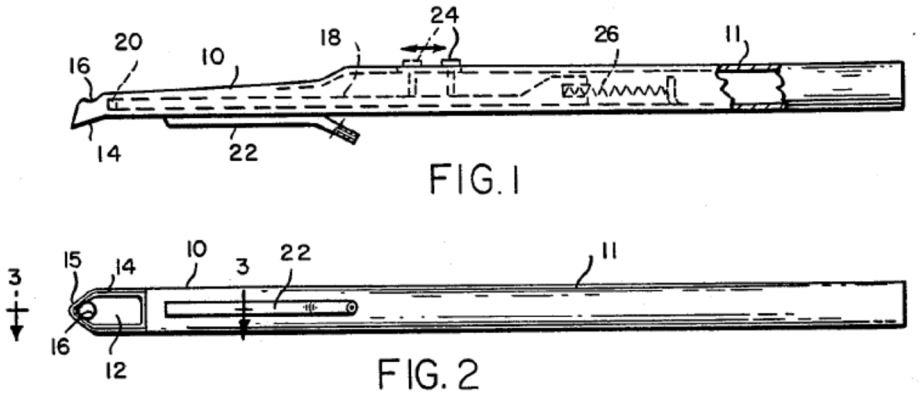
Petitioner contends that claims 1–7 would have been obvious over the combination of Quintana and Lee. Pet. 62–74. Petitioner's contentions are supported by the declaration testimony of Dr. Netland. Ex. 1003 ¶¶ 172–214. At this stage of the proceeding, Patent Owner has not yet disputed Petitioner's unpatentability contentions. *See generally* Prelim. Resp. Below we briefly summarize Lee and consider whether the information presented by Petitioner is sufficient to support institution of *inter partes* review.

1. 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." Ex. 1006, 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 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.

2. Claims 1–7

Petitioner contends that "[t]o the extent the Board determines Quintana does not disclose an "ab interno" procedure, a "dual blade device," or a "blunt protruding tip"/"blunt top edge" as required by claim 1, it would have been obvious to modify Quintana based on Lee." Pet. 62. For example, Petitioner contends that Lee teaches "a dual blade device for cutting and extracting large, intact segments" of trabecular meshwork tissue; that Lee explains an ab interno approach to the trabecular meshwork with a device through the anterior chamber, and 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," corresponding to the recited blunt protruding tip. Pet. 65–69 (citing Ex. 1006, 1:54–60, 3:39–42, 4:38–48, 5:61–6:45, Fig. 2). Petitioner also reasons, for example, that a person of ordinary skill would have been motivated to include dual blades taught by Lee in Quintana's

device to "improve the cutting edges' ability to strip [trabecular meshwork] tissue," "to modify Quintana by penetrating directly through the cornea to make the procedure safer and more convenient," and "to modify Quintana's needle [to] improve the safety of the device and procedure, such as by rounding the needle tip or making the tip less sharp/duller," as taught by Lee. Pet. 64–69 (citing Ex. 1003 ¶¶ 174–176, 180, 186).

3. Showing of a Reasonable Likelihood

We have reviewed Petitioner's contentions based on alleged obviousness over the combination of Quintana and Lee, which Patent Owner does not yet dispute, and determine that Petitioner has established a reasonable likelihood of prevailing in demonstrating the unpatentability of claims 1–7 as obvious in view of Quintana and Lee.

G. Alleged Obviousness over Jacobi

Petitioner contends that claims 1–7 would have been obvious over Jacobi. Pet. 75–102. Petitioner's contentions are supported by the declaration testimony of Dr. Netland. Ex. 1003 ¶¶ 215–267. At this stage of the proceeding, Patent Owner has not yet disputed Petitioner's unpatentability contentions. *See generally* Prelim. Resp. Below we briefly summarize the asserted art and consider whether the information presented by Petitioner is sufficient to support institution of *inter partes* review.

1. Summary of Jacobi

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.* at 1. 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 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.*

2. Independent Claim 1

Petitioner asserts that Jacobi teaches a device used in an ab interno procedure called a "gonioscraper" with "a handle, a convex-shaped arm, and a bowl-like tip with sharpened edges." Pet. 75 (citing Ex. 1003 ¶¶ 110, 111; Ex. 1007, 1–2). Petitioner asserts that Jacobi's gonioscraper corresponds to the dual blade device of claim 1 and provides a detailed explanation with annotated figures from Jacobi to show how each of the limitations was taught by, or would have been obvious in light of, Jacobi.

Petitioner provides, for example, an annotated version of Figure 1 of Jacobi, reproduced below.

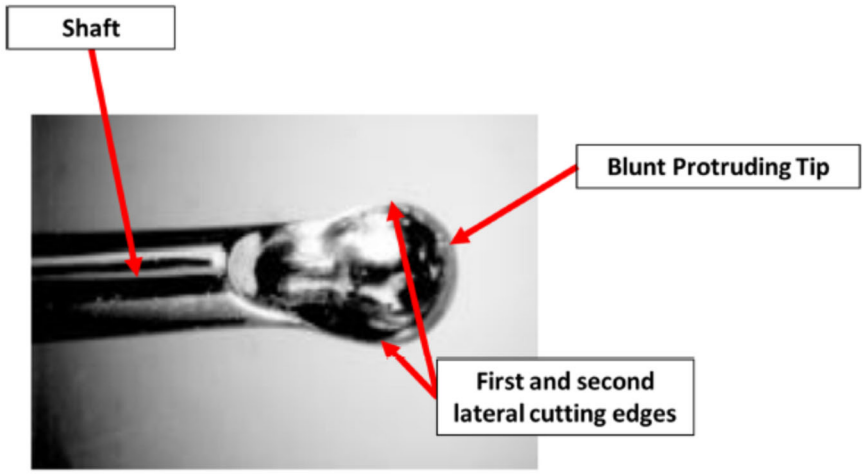


Figure 1 The tip of the 'gonioscraper'. The bowl is 300 μm in diameter with its edges sharpened.

Pet. 87. Petitioner identifies in the annotated version of Figure 1 of Jacobi above what Petitioner contends are features of Jacobi's gonioscraper that correspond to the shaft, blunt protruding tip, and first and second cutting edges. *Id.* (citing Ex. 1003 ¶ 231, 232). Patent Owner does not, at this stage, dispute Petitioner's assertions.

3. Dependent Claims 2–7

Petitioner provides a detailed explanation of how it contends Jacobi teaches or suggests each limitation of dependent claims 2–7. Pet. 97–102 (citing Ex. 1003 ¶¶ 250, 251, 254, 255, 257–260, 263, 265, 267; Ex. 1007, 1–3, Fig. 1).

4. Showing of a Reasonable Likelihood

We have reviewed Petitioner's contentions based on alleged obviousness over Jacobi, which Patent Owner does not yet dispute, and determine that Petitioner has established a reasonable likelihood of

prevailing in demonstrating the unpatentability of claims 1–7 as obvious in view Jacobi.

IV. CONCLUSION

Based on the evidence before us, we determine Petitioner demonstrates a reasonable likelihood of prevailing in its assertions that the Challenged Claims of the '155 patent are unpatentable. Accordingly, *inter partes* review shall proceed in this case on all of the grounds raised in the Petition. *See SAS Inst.*, 138 S. Ct. at 1359–60 (holding that a decision to institute under 35 U.S.C. § 314 may not institute on fewer than all claims challenged in the petition); *PGS Geophysical AS v. Iancu*, 891 F.3d 1354, 1360 (Fed. Cir. 2018) (stating the decision whether to institute *inter partes* review requires "a simple yes-or-no institution choice respecting a petition, embracing all challenges included in the petition").

Our determination in this Decision is not a final determination on either the patentability of any challenged claims or the construction of any claim term and, thus, leaves undecided any remaining fact issues necessary to determine whether sufficient evidence supports Petitioner's contentions by a preponderance of the evidence in the final written decision. *See TriVascular, Inc. v. Samuels*, 812 F.3d 1056, 1068 (Fed. Cir. 2016) (noting that "there is a significant difference between a petitioner's burden to establish a 'reasonable likelihood of success' at institution, and actually proving invalidity by a preponderance of the evidence at trial") (quoting 35 U.S.C. § 314(a) and comparing *id.* § 316(e)).

V. ORDER

Upon consideration of the record before us, it is:

ORDERED that, pursuant to 35 U.S.C. § 314, an *inter partes* review of claims 1–7 of U.S. Patent No. 9,358,155 B2 is instituted with respect to all grounds set forth in the Petition; and

FURTHER ORDERED that, pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4(b), *inter partes* review of U.S. Patent No. 9,358,155 B2 shall commence on the entry date of this Order, and notice is hereby given of the institution of a trial.

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