

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NEW WORLD MEDICAL, INC.,
Petitioner,

v.

MICROSURGICAL TECHNOLOGY, INC.,
Patent Owner.

IPR2022-00684
Patent 10,888,460 B2

Before JAMES A. TARTAL, ROBERT A. POLLOCK, 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 1–18 (“the Challenged Claims”) of U.S. Patent No. 10,888,460 B2 (“the ’460 patent,” Ex. 1001). Paper 1 (“Pet.”). MicroSurgical Technology, Inc. (“Patent Owner”) filed Mandatory Notices (Paper 4), but did not file a preliminary response to the Petition.

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 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 ’460 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 ’460 Patent*

The ’460 patent issued on January 12, 2021, from U.S. Application No. 15/714,909, which was filed on September 25, 2017, 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 '460 patent is directed to a “dual blade device and method useable for performing an ab interno procedure within a human eye to remove a strip of trabecular meshwork tissue.” *Id.* at code (57).

As background, the '460 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 1:27–30. The '460 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 goniotomy. In a goniotomy 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 1:41–50. The '460 patent also states that “there remains a need in the art for the development of simple, inexpensive and accurate instruments useable to perform the goniotomy procedure as well as other procedures where it is desired to remove a strip of tissue from a larger mass of tissue.”

Id. at 2:3–7. The '460 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 goniotomy, to form an incision of a desired width or to remove a strip of tissue of a desired width. *Id.* at 4:35–37, 5:21–27.

¹ Petitioner acknowledges this priority claim to June 10, 2003, and does not challenge it as the effective date of the '460 patent. Pet. 23.

Figure 2 of the '460 patent is reproduced below.

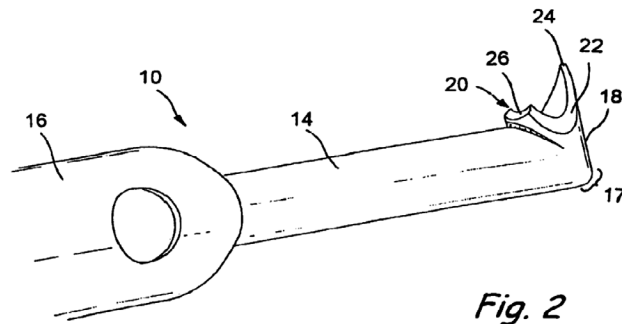


Figure 2 shows a portion of needle cutter device 10 having cutting tube 14 at an end of outer tube 16. *Id.* at 3:8–14, 3:63–65. “First and second cutting edges 20, 22 are formed on generally opposite edges of the distal end of the cutting tube 14.” *Id.* at 3:11–13. “[F]irst and second cutting edges 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 3:16–22. According to the '460 patent, “only the lateral cutting edges 20, 22 are sharp and intended to cut tissue.” *Id.* at 3:22–23. Cutting tube 14 has bend 17 of approximately 90 degrees at a point proximal to these features. *Id.* at 3:33–35. The '460 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 3:31–33.

B. Illustrative Claim

Petitioner challenges claims 1–18 (all claims) of the '460 patent. Pet. 4–5. Claims 1–7 are directed to a “dual blade device” and claims 8–18 are directed to a “method for using the device according to claim 1.” Ex. 1001, 6:51–8:46. Claim 1 is illustrative of the claimed subject matter and is reproduced below.

1. A dual blade device useable for performing an ab interno 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 shaft that extends from the handle along a longitudinal axis to a distal end;

- a tip portion that extends along a second longitudinal axis from the distal end of the probe shaft to form an angle of approximately 30 degrees to approximately 90 degrees relative to the longitudinal axis of the shaft, the tip portion being configured to penetrate through the trabecular meshwork tissue and having a transverse width, a top surface, a bottom surface and a terminal end, the transverse width of the tip portion being narrowest at its terminal end;

- first and second spaced apart cutting edges configured to simultaneously cut tissue that passes over the top surface of the protruding tip and into contact with the first and second spaced apart cutting edges; and a top edge that traverses above an area between the first and second spaced apart cutting edges;

wherein;

- a) the top surface of the tip portion extends from the terminal end of the tip portion to the first and second spaced apart cutting edges;
- b) a distal portion of the probe, inclusive of the tip portion, is sized to pass through an incision formed in the eye;
- c) the tip portion is sized to fit within Schlemm's Canal of the human eye and, when so positioned, is advanceable through Schlemm's Canal with trabecular meshwork tissue passing over its top surface and into contact with the first and second spaced apart cutting edges;
- d) the first and second spaced apart cutting edges are formed on generally opposite edges of the distal end of the elongate probe shaft and are separated by a distance D; and
- e) the first and second spaced apart cutting edges face towards the second longitudinal axis of the tip portion.

Id. at 6:51–7:24.

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 ³
1–3, 6–10, 13–18	102	Quintana ⁴
4, 5, 11, 12	103	Quintana
1–18	103	Quintana, Lee ⁵
1–18	103	Jacobi ⁶

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 ’460 patent claims priority has an effective filing date prior to March 16, 2013, the pre-AIA version of §§ 102 and 103 apply.

³ Although Petitioner refers to the knowledge of a person of ordinary skill in the art in its table identifying “References” relied upon (Pet. 4–5), we do not consider that to be a basis for being a separate ground when analyzing whether claims would have been obvious and whether it would have been obvious to combine or modify prior art, because our analysis must always be from the perspective of a skilled artisan. *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”).

⁴ Manuel Quintana, *Gonioscopic Trabeculotomy. First Results* in DOCUMENTA OPHTHALMOLOGICA PROCEEDINGS SERIES 43, SECOND EUROPEAN GLAUCOMA SYMPOSIUM 265–71 (E.L. Greve et al. eds. 1985). Ex. 1004 (“Quintana”). We reference the pagination at the lower right-hand corners of each page that appears to have been added, as has Petitioner, and not the original pagination of Quintana.

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

⁶ Philipp C. Jacobi et al., *Technique of goniotomy: a potential treatment for advanced chronic open angle glaucoma*, 81 BRIT. J. OPHTHALMOLOGY 302–07 (1997). Ex. 1007 (“Jacobi”). We reference the pagination at the lower right-hand corners of each page that appears to have been added, as has Petitioner, and not the original pagination of Jacobi.

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See Pet. 4–5. Petitioner relies on the supporting Declaration of Dr. Peter Netland, dated March 9, 2022. Ex. 1003.

D. Real Parties in Interest

Petitioner and Patent Owner each identifies itself and no others as a real party in interest. Pet. xiv; Paper 4, 1.

E. Related Proceedings

The parties identify the '460 patent as a subject of *MicroSurgical Technology, Inc., et al. v. New World Medical*, Case No. 20-cv-00754 (D. Del.) following amendment of the complaint in that case on March 15, 2021. Pet. xiv; Paper 4, 1. The parties identify five additional patents at issue in that district court proceeding, each of which was challenged by Petitioner in the following *inter partes* review proceedings: IPR2020-01573 regarding U.S. Patent No. 9,107,729 B2; IPR2020-01711 regarding U.S. Patent No. 9,358,155; 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. xiv–xv; Paper 4, 1–2. On March 11, 2022, the Board issued final written decisions in IPR2020-01573, IPR2021-00065, and IPR2021-00066 finding in each proceeding all challenged claims unpatentable. Pet. xv; Paper 4, 2; Exs. 1056, 1057, 1058. On April 20, 2022, the Board issued final written decisions in IPR2020-01711 and IPR2021-00017 finding all challenged claims unpatentable. *New World Medical, Inc. v. Microsurgical Technology, Inc.*, IPR2020-01711, Paper 50 (PTAB April 20, 2022); *New World Medical, Inc. v. Microsurgical Technology, Inc.*, IPR2021-00017, Paper 49 (PTAB April 20, 2022).

There appears to be substantial similarity in certain claim language and prior art arguments asserted between this proceeding and the related

proceedings between the same parties identified above. Accordingly, the parties should address in subsequent briefing (i.e., in Patent Owner's response and Petitioner's reply) whether the Board has made determinations in the final written decisions in related proceedings identified above of issues raised in this proceeding, and whether any of those prior determinations has preclusive effect as to any issue raised in this proceeding, including discussion of any precedential support.

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. .

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. 22–23 (citing Ex.1003, ¶ 26). In the absence of any preliminary response, Patent Owner, at this stage of the proceeding, takes no position on the definition of the person of ordinary skill in the art.

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 ’460 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 suggests, generally, that “all terms should be given their plain and ordinary meaning” and notes that in the related proceedings the Board “gave the term ‘dual blade device’ its ordinary meaning, noting ‘dual refers to two, and blade, in context, refers to a cutting part,’ and construed ‘ab interno’ as generally meaning ‘from the inside or from within the eye.’” Pet. 23, 27, 30–31 (citing Ex. 1056, 22–23). 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, 6–10, and 13–18 are anticipated by Quintana. Pet. 23–58. Petitioner’s contentions are supported by the declaration testimony of Dr. Netland. Ex. 1003 ¶¶ 118–192. At this stage of the proceeding, Patent Owner has not disputed Petitioner’s unpatentability contentions. 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.

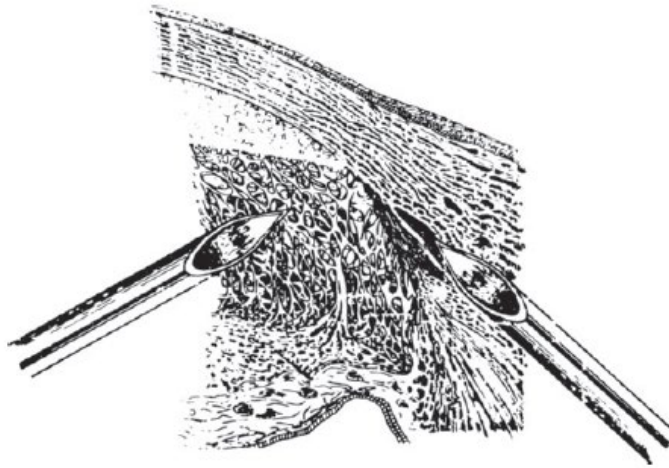


Fig. 1. Schematic drawing comparing the tangential approach to the perpendicular approach as in classic goniotomy or goniotrabeculotomy.

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 ¶ 82; 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.

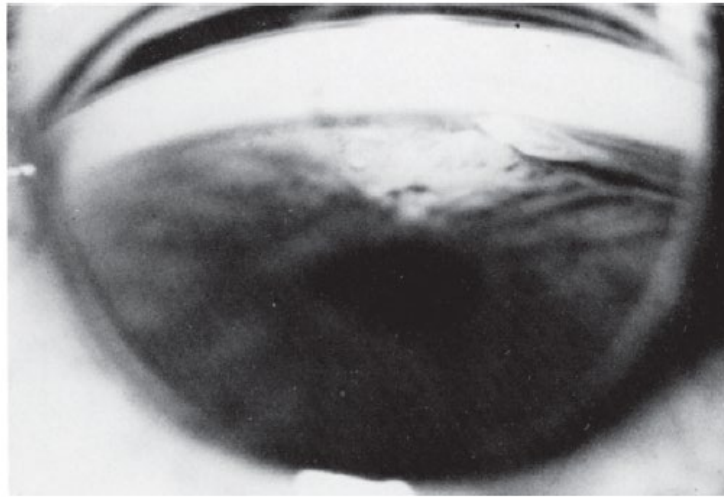


Fig. 2. Goniophotography at operation. The tip of the needle stripping the trabecular meshwork.

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. 23–47; Ex. 1003 ¶¶ 118–154.

A dual blade device useable for performing an ab interno 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 shaft that extends from the handle along a longitudinal axis to a distal end;

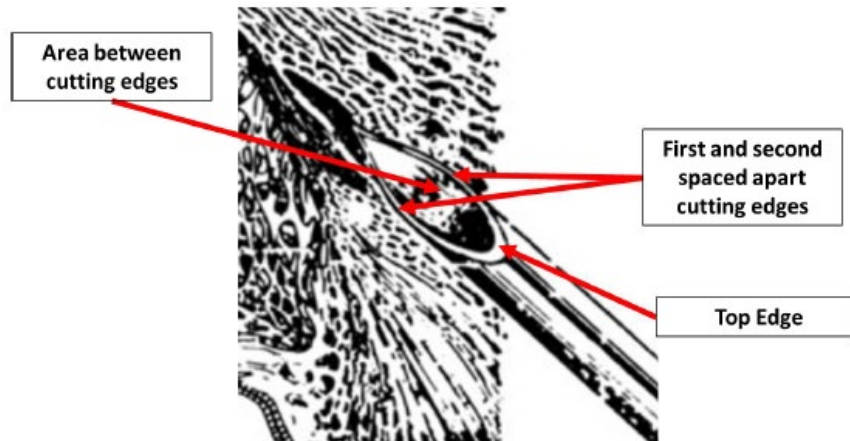
a tip portion that extends along a second longitudinal axis from the distal end of the probe shaft to form an angle of approximately 30 degrees to approximately 90 degrees relative to the longitudinal axis of the shaft, the tip portion being configured to penetrate through the trabecular meshwork tissue and having a transverse width, a top surface, a bottom surface and a terminal end, the transverse width of the tip portion being narrowest at its terminal end;

Petitioner contends that Figure 1 of Quintana discloses a “dual blade device” as a needle with “two cutting parts” with “spaced-apart cutting edges” that is used in *ab interno* procedure because “[t]he needle penetrates the anterior chamber . . . through the scleral side of the limbus” to “achieve a section” of trabecular meshwork tissue. Pet. 27–31 (citing, e.g., Ex. 1004, 3–4, 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 34 (quoting Ex. 1004, 3). Petitioner contends that the shaft of the needle of Quintana corresponds to the recited “elongate probe shaft.” *Id.* at 34–35 (citing Ex. 1003 ¶ 134; Ex. 1004, 3, Fig. 1). Petitioner also contends that “[t]he portion of Quintana’s needle extending from the distal end of the shaft is a ‘tip portion,’” and that Quintana discloses the tip is bent 20–30°. *Id.* at 35–39 (citing Ex. 1003 ¶¶ 135–139; Ex. 1004, 3–4, Fig 1) (emphasis omitted).

first and second spaced apart cutting edges configured to simultaneously cut tissue that passes over the top surface of the protruding tip and into contact with the first and second spaced apart cutting edges; and a top edge that traverses above an area between the first and second spaced apart cutting edges;

Petitioner contends that Quintana’s needle corresponds to a “dual blade device” with “first and second spaced apart cutting edges” on opposite

sides of a tube. *Id.* at 39–42. Petitioner includes annotated versions of Figures 1 and 2 of Quintana showing how Quintana allegedly discloses each of the above limitations. *Id.* (citing Ex. 1003 ¶¶ 141–144, 170–172; Ex. 1004, 3–4, Figs. 1, 2). For example, reproduced below is an annotated version of Figure 1 of Quintana provided by Petitioner.



Id. at 42. Petitioner’s annotated Figure 1 of Quintana shows features allegedly corresponding to the recited “top edge,” “first and second spaced apart cutting edges,” and “an area between the first and second spaced apart cutting edges.”

wherein;

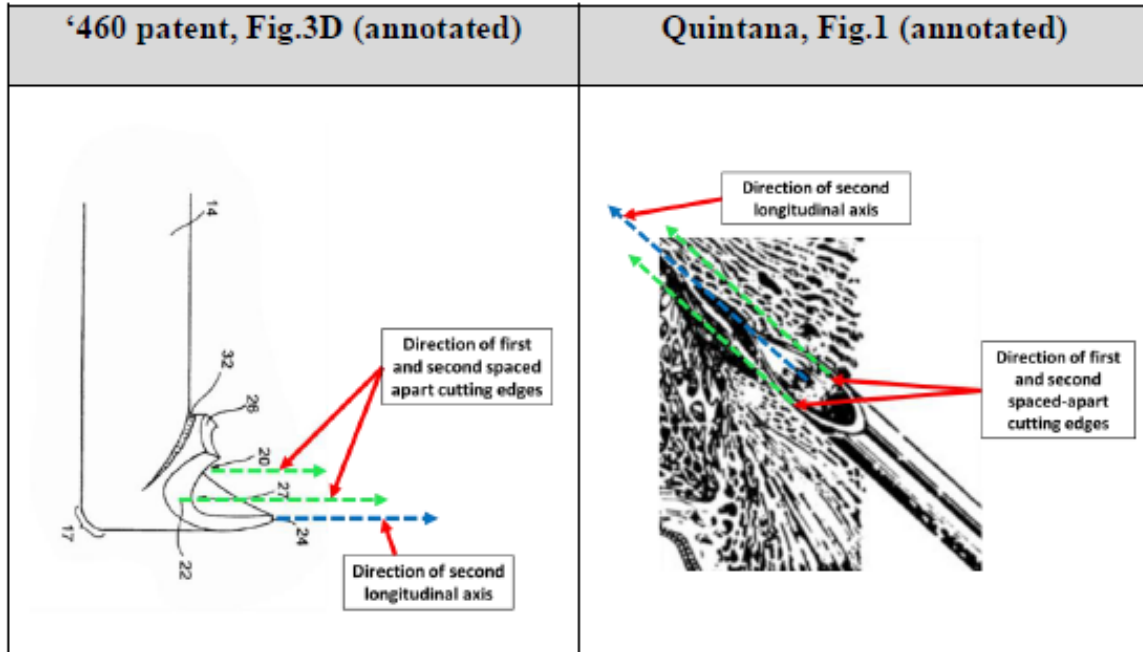
- a) the top surface of the tip portion extends from the terminal end of the tip portion to the first and second spaced apart cutting edges;*
- b) a distal portion of the probe, inclusive of the tip portion, is sized to pass through an incision formed in the eye;*
- c) the tip portion is sized to fit within Schlemm's Canal of the human eye and, when so positioned, is advanceable through Schlemm's Canal with trabecular meshwork tissue passing over its top surface and into contact with the first and second spaced apart cutting edges;*

Petitioner contends that Figure 1 of Quintana illustrates a needle with a “top surface” extending from the terminal end of the tip

portion to the first and second cutting edges. *Id.* at 43 (citing Ex. 1003 ¶ 147; Ex. 1004, Fig. 1). Petitioner further states that “Quintana’s needle penetrates and is inserted into the [anterior chamber] and progress through the angle,” such that it is sized to pass through “an incision formed in the eye” and fits within Schlemm’s Canal such that trabecular meshwork tissue “necessarily passes over the top surface of the tip and contacts the needle’s cutting edges as the needle advances through SC.” *Id.* at 43–45 (citing Ex. 1003 ¶¶ 148–150; Ex. 1004, 4, Figs. 1, 2).

- d) the first and second spaced apart cutting edges are formed on generally opposite edges of the distal end of the elongate probe shaft and are separated by a distance D; and*
- e) the first and second spaced apart cutting edges face towards the second longitudinal axis of the tip portion.*

Petitioner contends that Figure 1 of Quintana discloses the recited “first and second spaced apart cutting edges” on “opposite edges of the elongate probe shaft” and “separated by a distance D.” *Id.* at 45 (citing Ex. 1004, Fig. 1). Petitioner further contends, as shown in Petitioner’s annotated version of Figure 3D of the ’460 patent and Figure 1 of Quintana, reproduced below, that both figures depict first and second spaced apart cutting edges that “face towards the second longitudinal axis of the tip portion,” as required by claim 1. *Id.* at 45–47.



Id. at 47. Above on the left, Figure 3D of the '460 patent is annotated to show the direction of the second longitudinal axis as a blue error parallel to green arrows showing the direction of first and second spaced apart cutting edges. Above on the right, Figure 1 of Quintana is annotated to show the direction of the second longitudinal axis as a blue error parallel to green arrows showing the direction of first and second spaced apart cutting edges, according to Petitioner.

3. *Claims 2, 3, 6–10, and 13–18*

Petitioner asserts that claims 2, 3, 6–10, and 13–18 are anticipated by Quintana. Pet. 47–58 (citing, e.g., 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 ¶¶ 156, 157, 159–161, 163, 165–172, 174, 175, 177, 179 181–183, 185, 186, 188, 190, 192). At this stage of the proceeding, Patent Owner has not disputed Petitioner's unpatentability contentions.

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, 6–10, and 13–18 as anticipated by Quintana.

E. *Alleged Obviousness over Quintana*

Petitioner contends that claims 4, 5, 11 and 12 would have been obvious over Quintana. Pet. 58–62. Petitioner's contentions are supported by the declaration testimony of Dr. Netland. Ex. 1003 ¶¶ 193–208. At this stage of the proceeding, Patent Owner has not disputed Petitioner's unpatentability contentions.

1. *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, 7:32–35. Petitioner contends that Quintana discloses a needle with a tip bent 20–30°, but concedes it does not disclose a 90 degree bend. Pet. 58–59 (citing Ex. 1003 ¶ 195–197, Ex. 1004, 3). Petitioner contends that “using devices having tips, points, or shafts bent at various angles to meet the needs of a given surgery was well-known.” *Id.* at 58 (citing Ex. 1003 ¶ 196; 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 58–59 (citing Ex. 1003 ¶ 197). Petitioner argues that a person of ordinary skill in the art “would have been

motivated to try variations, such as an angle of 90°, to expand or improve on Quintana’s results.” *Id.* at 59 (citing Ex. 1003 ¶¶ 198).

2. *Claim 5*

Claim 5 refers to 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, 7:36–38. 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. 60 (citing Ex. 1003 ¶ 201). Petitioner contends that at the time of the invention “forming incisions in the eye with different knives and blades with sizes depending on the procedure and surgical instrument that would subsequently be inserted through the incision, was well-known.” *Id.* (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 needle) for another (*e.g.*, incising via slit knife).” *Id.* at 62 (citing Ex. 1003 ¶ 201).

3. *Claims 11 and 12*

Claim 11 depends from claim 8 and further recites “wherein the eye is a left eye and the incision is formed at approximately a 3 o’clock position of the eye.” Ex. 1001, 8:21–23. Claim 12 depends from claim 8 and further recites “wherein the eye is a right eye and the incision is formed at approximately a 9 o’clock position of the eye.” *Id.* at 8:24–26.

Petitioner states that Quintana teaches a method whereby the needle “penetrates the anterior chamber at 6 hours (right eye) or 12 hours (left eye),” which “allows a tangential approach (Fig.1) to the angle.” Pet. 61 (quoting Ex. 1004, 4). According to Petitioner, Quintana also teaches “the perpendicular approach, in which the incision is formed at approximately a 3 o’clock position in the left eye and a 9 o’clock position in a right eye.” *Id.* (citing Ex. 1003 ¶ 204; Ex. 1004 Fig. 1). Petitioner reasons that “[t]he number of incision positions in the eye is finite, and a [person of ordinary skill in the art] would have been motivated to try variations to expand or improve the method with an expectation of success given the successful employment of different incision positions in the art.” *Id.* at 61–62 (citing Ex. 1003 ¶ 205; Ex. 1011, 51; Ex. 1053, 2).

4. *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, 5, 11, and 12 as obvious in view of Quintana.

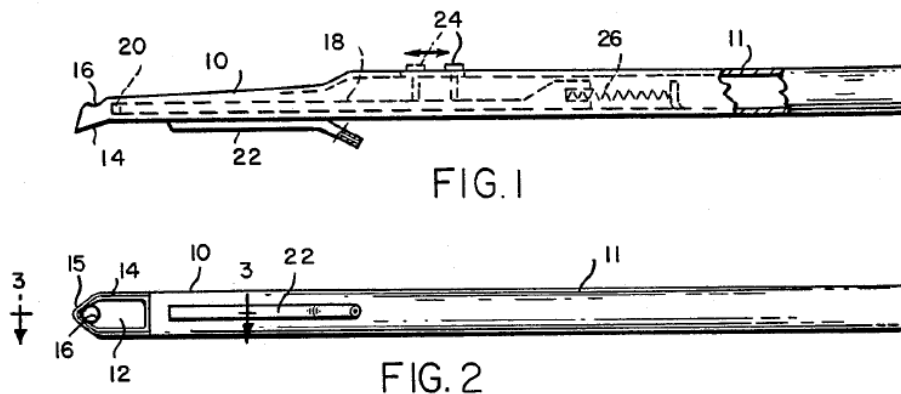
F. *Alleged Obviousness over the Combination of Quintana and Lee*

Petitioner contends that claims 1–18 would have been obvious over the combination of Quintana and Lee. Pet. 62–76. Petitioner’s contentions are supported by the declaration testimony of Dr. Netland. Ex. 1003 ¶¶ 209–280. At this stage of the proceeding, Patent Owner has not disputed Petitioner’s unpatentability contentions. 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 goniotomy instrument for the purpose of diagnostically and therapeutically removing tissue from the anterior chamber angle of the eye and for retrieving this tissue for further examination.” Ex. 1006, 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 edge 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 1–18

Petitioner contends that “[i]f the Board determines Quintana does not disclose an ‘ab interno’ procedure or a ‘dual blade device,’ as required by claim 1, it would have been obvious to modify Quintana with Lee.” Pet. 62–63. For example, Petitioner contends that Lee teaches “a dual blade device

for cutting and extracting large, intact segments” of trabecular meshwork tissue and that Lee explains an ab interno approach to the trabecular meshwork with a device through the anterior chamber. *Id.* at 64–67 (citing Ex. 1006, 1:39–47, 1:54–60, 3:39–42, 3:50–57, 5:61–6:45, Fig. 5).

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 refine Quintana’s procedure to further open the [trabecular meshwork], increase aqueous outflow, and prevent repair of the opened area.” *Id.* at 64–65 (citing Ex. 1003 ¶ 211). With regard to using an ab interno approach, according to Petitioner, “[m]odifying the entry site in Quintana requires nothing more than simple substitution of one known procedure (e.g., Quintana’s approach) for another (e.g., Lee’s clear cornea approach) and a [person of ordinary skill in the art] would have expected success.” *Id.* at 66 (citing Ex. 1003 ¶¶ 216–218).

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 1–18 as obvious in view of Quintana and Lee.

G. *Alleged Obviousness over Jacobi*

Petitioner contends that claims 1–18 would have been obvious over Jacobi. Pet. 76–103. Petitioner’s contentions are supported by the declaration testimony of Dr. Netland. Ex. 1003 ¶¶ 281–370. At this stage of the proceeding, Patent Owner has not disputed Petitioner’s unpatentability contentions. 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 gonioscurettage: 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 gonioscurettage.” *Id.* Jacobi explains that the gonioscraper is inserted into the anterior chamber of an eye through a corneal incision, and then positioned against the trabecular meshwork and used to peel off trabecular meshwork by passing the device there-over. *Id.* This results in “strings of trabecular tissue” being removed from the eye. *Id.* A stage of this procedure is shown in Figure 2, reproduced below.



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

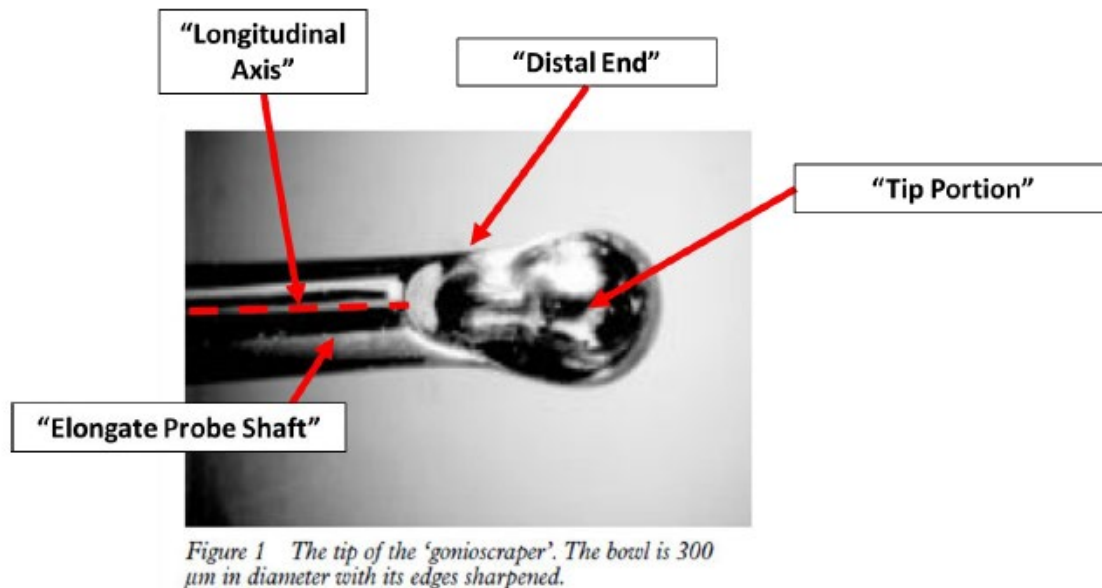
Id. Figure 2 shows the gonioscraper inserted into an eye, performing the gonioscurettage procedure. *Id.*

2. Claim 1

Petitioner asserts that Jacobi teaches a device called a “gonioscraper” used in an ab interno procedure called “gonioscurettage” to “peel” off “strings of trabecular tissue,” including a “tiny bowl” with “sharpened edges,” corresponding to a “dual blade device,” a handle, and an elongate probe shaft, as claimed. Pet. 76–81 (citing Ex. 1003 ¶¶ 94–98, 282–288; Ex. 1007, 1–2, Figs. 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. *Id.* at 76–94.

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



Pet. 81. 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 "elongate probe shaft," the "longitudinal axis," the "distal end" and the "tip portion." *Id.* (citing Ex. 1003 ¶ 289; Ex. 1007, 1–2).

Patent Owner does not, at this stage, dispute Petitioner's assertions.

3. Claims 2–18

Petitioner provides a detailed explanation of how it contends Jacobi teaches or suggests each limitation of claims 2–18. Pet. 94–103 (citing Ex. 1003 ¶¶ 316, 317, 319–321, 323–326, 328, 329, 331, 333–342, 344, 345,

347–349, 351, 353, 355, 357–359, 361, 362, 364, 366–368, 370; Ex. 1007, 1, 2, 4, 5, Figs. 1, 2).

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 1–18 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 ’460 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

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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 1–18 of U.S. Patent No. 10,888,460 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. 10,888,460 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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