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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MICROSURGICAL TECHNOLOGY, INC.,
Petitioner,

v.

THE REGENTS OF THE UNIVERSITY OF COLORADO,
Patent Owner.

U.S. Patent No. 10,786,391
Issued: September 29, 2020

PETITION FOR POST-GRANT REVIEW PURSUANT TO 35 U.S.C. §§ 321-329 AND 37 C.F.R. § 42.200 *et seq.*

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EXHIBIT LIST

Exhibit	Description
1001	Kahook, Malik Y., U.S. Patent No. 10,786,391, "Intraocular device for dual incisions" issued September 29, 2020
1002	Kahook, Malik Y., U.S. Patent Application No. 15/701,306, "Intraocular device for dual incisions" filed September 11, 2017
1003	Kahook, Malik Y., U.S. Patent No. 9,757,279, "Intraocular device for dual incisions" issued September 12, 2017
1004	Kahook, Malik Y., U.S. Patent No. 9,872,799, "Intraocular device for dual incisions" issued January 23, 2018
1005	Kahook, Malik Y., U.S. Patent No. 10,327,947, "Modified dual-blade cutting system" issued June 25, 2019
1006	Kahook, Malik Y., International Application Publication WO 2013/163034. "Modified dual-blade cutting system" published October 31, 2013
1007	Kahook, Malik Y., U.S. Provisional Application No. 61/637,611. "Modified dual-blade cutting system" filed April 24, 2012
1008	Patent Owner's Complaint filed November 4, 2020, in the U.S. District Court for the Western District of Washington (No. 2:20-cv-01621) alleging infringement by Petitioner of U.S. Patent No. 10,786,391
1009	Baerveldt, *et al.*, International Application Publication WO 2018/151808 A1. "Devices, systems and methods for minimally invasive glaucoma surgery" published August 23, 2018
1010	Prosecution history of U.S. Patent No. 10,786,391
1011	Sorensen, *et al.*, U.S. Patent No. 9,107,729 "Methods for forming an opening in the trabecular meshwork of the eye of a patient" issued August 18, 2015
1012	Declaration of Garry P. Condon, M.D.

I. INTRODUCTION

MicroSurgical Technology, Inc. ("Petitioner") respectfully requests institution of a post-grant review ("PGR"), pursuant to 35 U.S.C. §§ 321-329 and 37 C.F.R. § 42.200 *et seq.*, of Claims 1-20 of U.S. Patent No. 10,786,391 ("the '391 Patent"), Ex. 1001, which is assigned to The Regents Of The University Of Colorado ("Patent Owner"), *see* Reel/Frame No. 051880/0422. This Petition, supported by the accompanying Declaration of Garry P. Condon, M.D. ("Condon Declaration"), Ex. 1012, shows that, more likely than not, Claims 1-20 of the '391 Patent ("the Challenged Claims") are unpatentable.

The '391 Patent relates to a dual blade microsurgical device and methods of its use for treatment of various conditions including eye diseases using minimally invasive surgical techniques. *See* Ex. 1001, Abstract. The '391 Patent issued on September 29, 2020, from U.S. patent application No. 16/678,785 ("the '785 Application"), filed on November 8, 2019. The '785 Application purports to be a continuation application claiming priority to U.S. patent application No. 15/701,306 ("the '306 Application"), Ex. 1002. But for the reasons set forth in this Petition, none of the '391 Patent claims may be accorded priority to an earlier application. Because the effective filing date for the Challenged Claims must be November 8, 2019, the '391 Patent is eligible for PGR.

The Challenged Claims are unpatentable for lack of written description and indefiniteness under 35 U.S.C. § 112(a). The '391 Patent added two new paragraphs, Ex. 1001 at 3:54-4:25 ("New Matter"), essentially copied from ***Petitioner's*** patent disclosures,[1] including international patent application No. PCT/US2018/000018, published on August 23, 2018, as WO 2018/151808 A1("Baerveldt"), Ex. 1009. This Petition shows that the recited elements of the Challenged Claims are missing from, and conflict irreconcilably with, the '391 Patent and its purported priority applications, but that Baerveldt expressly teaches all these same elements. Accordingly, not only are the Challenged Claims unpatentable under 35 U.S.C. § 112(a), they are unpatentable for anticipation under 35 U.S.C. § 102, and/or obviousness under 35 U.S.C. § 103, in view of Baerveldt.

Petitioner, Patent Owner, and Patent Owner's exclusive licensee and commercial partner, New World Medical, Inc. ("NWM"), are engaged in ongoing legal disputes. On November 4, 2020, roughly a month after the '391 Patent issued,

[1] In 2019, Petitioner acquired certain assets from NeoMedix Corporation, which was the original assignee of Baerveldt. Petitioner now holds all right, title and interest in Baerveldt as well as other former NeoMedix patents and applications to which this Petition refers.

Patent Owner and NWM jointly sued Petitioner in the U.S. District Court for the Western District of Washington, *see* Ex. 1008, alleging infringement of the '391 Patent by products including Petitioner's TrabEx™ and TrabEx+™ ophthalmic surgery devices, which compete in the market with NWM's Kahook Dual Blade® ("KBD") device. This lawsuit follows one filed on June 4, 2020, by Petitioner and The Regents of the University of California against NWM in the U.S. District Court for the District of Delaware, alleging that the KDB infringes five patents owned or licensed by Petitioner. Patent Owner and NWM have a clear motive for seeking illegitimate patent claims, such as the Challenged Claims, as part of their litigation strategy.

The Patent Owner never disclosed to the Examiner during prosecution that the New Matter had been inserted into the '391 Patent specification, thereby hiding the fact that the New Matter copied Baerveldt and other of Petitioner's patent disclosures. Patent Owner cemented its lack of candor when it filed a substitute specification identifying only unrelated minor changes. Because the Challenged Claims are based solely on the New Matter, the materiality of Patent Owner's misconduct is heightened.

For the reasons set forth below, this Petition shows that, more likely than not, the Challenged Claims violate the written description requirement of 35 U.S.C. § 112(a) (Grounds 1 & 2), violate the definiteness requirement of 35 U.S.C.

§ 112(b) (Ground 3), and are anticipated and/or rendered obvious by Baerveldt (Grounds 4 & 5). Accordingly, Petitioner requests institution of a PGR and cancellation of Claims 1-20 of the '391 Patent.

II. MANDATORY NOTICES UNDER 37 C.F.R. § 42.8(A)(1)

A. Real Party-In-Interest Under 37 C.F.R. § 42.8(b)(1)

Pursuant to 37 C.F.R. § 42.8(b)(1), the real party-in-interest for this Petition is MicroSurgical Technology, Inc., a corporation organized under the laws of the State of Washington, with its principal place of business at 8415 154th Avenue NE, Redmond, WA 98052-3863 USA.

1. Related parties

Petitioner is a subsidiary of Halma plc, headquartered at Misbourne Court, Rectory Way, Amersham, Bucks, HP7 0DE, UK. In addition, Petitioner is the exclusive licensee of certain patents relating to the technology at issue in this PGR that are assigned to The Regents of the University of California, a California public corporation, authorized and empowered to administer a public trust known as the University of California, pursuant to Article IX, Section 9, subdivisions (a) and (f) of the California Constitution, with its principal place of business in Oakland, Alameda County, CA USA.

B. Related Matters Under 37 C.F.R. § 42.8(b)(2)

Pursuant to 37 C.F.R. § 42.8(b)(2), Petitioner identifies the following

judicial or administrative matters that could be affected by a decision in this proceeding:

On November 4, 2020, Patent Owner and its exclusive licensee and commercial partner New World Medical, Inc. ("NWM"), filed suit in the U.S. District Court for the Western District of Washington (No. 2:20-cv-01621) alleging infringement by Petitioner of the '391 Patent, which is the subject of this Petition. *See* Ex. 1008.

In addition, Petitioner and NWM are involved in several other litigations: *MicroSurgical Tech., Inc. & Regents of the Univ. of Cal. v. New World Med., Inc.*, C.A. No. 20-754-MN (D. Del. filed June 4, 2020) alleging infringement by NWM of U.S. Patents No. 9,107,729, No. 9,358,155, No. 9,820,885, No. 9,999,544, and No. 10,123,905; and separate *inter partes* reviews (pending institution decisions) of these five patents-in-suit, *see* IPR2020-01573, IPR2020-01711, IPR2021-00017, IPR2021-00065, and IPR2021-00066.

C. Lead and Back-up Counsel Under 37 C.F.R. § 42.8(b)(3)

Pursuant to 37 C.F.R. § 42.8(b)(3), lead counsel for this Petition is Lawrence M. Sung (Reg. No. 38,330), and back-up counsel for this Petition are Mary Sylvia (Reg. No. 37,156) and Teresa M. Summers (*pro hac vice* admission to be requested). Pursuant to 37 C.F.R. § 42.10(b), Petitioner has filed a power of attorney designating the above-identified counsel.

D. Service Information Under 37 C.F.R. § 42.8(b)(4)

Pursuant to 37 C.F.R. § 42.8(b)(4), service information for the Petition is as follows:

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III. ADDITIONAL REQUIREMENTS

A. Payment of Fees Under 37 C.F.R. § 42.15

Petitioner submits herewith the required fees in accordance with 37 C.F.R. §§ 42.203(a) and 42.15(b). If any additional fees are due during this proceeding, the Office is authorized to charge such fees to Deposit Account No. 50-1129.

B. Timing Under 37 C.F.R. § 42.202

The ’391 Patent issued on September 29, 2020. Pursuant to 37 C.F.R. § 42.202(a), a petition for PGR of a patent must be filed no later than nine months after the issue date of the patent. Accordingly, the deadline to file a petition for PGR of the ’391 Patent is June 29, 2021, and this Petition is timely.

C. Grounds for Standing Under 37 C.F.R. § 42.204(a)

Petitioner certifies that the ’391 Patent is available for PGR. The ’391 Patent issued on September 29, 2020 from an application filed on November 8, 2019. For

the reasons discussed below (Section VI), at least one claim of the '391 Patent has an effective filing date on or after March 16, 2013, making PGR available. *See* Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112-29, §§ 3(n)(1)(A), 6(f)(2), 125 Stat. 284, 293, 311 (2011). Petitioner is not barred or estopped from requesting post-grant review of any claims of the '391 Patent on the grounds identified herein.

IV. SUMMARY OF THE '391 PATENT

A. The '391 Patent Disclosure

The '391 Patent relates to a dual blade microsurgical device and methods of its use for treatment of various conditions including eye diseases using minimally invasive surgical techniques. Ex. 1001, Abstract. The '391 Patent includes FIG. 4 below and describes it as "one embodiment of the dual blade device for treatment of glaucoma" having "dual cutting blades (black arrows) as well as the distal point (asterisk) that is designed to pierce the trabecular meshwork ('TM') and enter into the Schlemm's canal. Once in the canal, the device is advanced so that the TM moves up the ramp from the distal point toward the dual cutting blades, which then cleanly incise the presented TM." Ex. 1001 at 7:32-39.

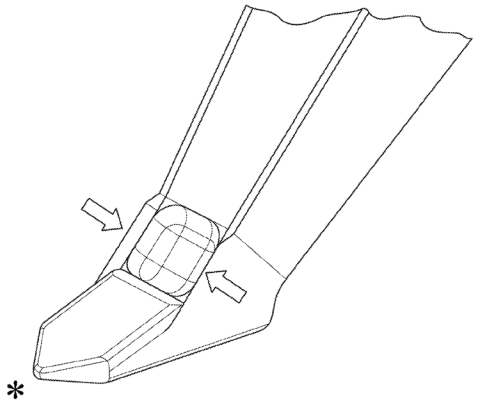


FIG. 4

The ’391 Patent issued from the ’785 Application filed November 8, 2019. Although the ’785 Application purports to be a continuation of the ’306 Application, *see* Ex. 1010 (Application Data Sheet filed Nov. 8, 2019), the specifications differ in a specific and crucial way. When compared with the ’306 Application, the ’391 Patent contains two brand new paragraphs (“New Matter”). Ex. 1001 at 3:54-4:25. Other than this material change, the respective disclosures are virtually identical. Furthermore, the ’306 Application is indistinguishable from its parent application, U.S. patent application No. 15/484,041, and its grandparent application, U.S. patent application No. 15/207,329.

Because the Challenged Claims are a verbatim recitation of the New Matter, the two-paragraph addition appears to be a calculated attempt to provide *ipsis verbis* written description support for these claims. But the New Matter and the Challenged Claims are completely divorced from the rest of the specification. As

the Declaration of Dr. Garry P. Condon, Ex. 1012, accompanying this Petition explains, a person having skill in the art ("POSA") would find that the New Matter and the Challenged Claims conflict irreconcilably with the rest of the '391 Patent and the purported priority applications. Moreover, the reason for this disconnect becomes apparent upon the revelation that the entirety of the New Matter essentially copied Petitioner's earlier Baerveldt application, Ex. 1009, as shown below.

'391 Patent New Matter Ex. 1001 at 3:54-4:25	**Baerveldt**[2]
According to some embodiments, disclosed is a device for incising a trabecular meshwork. The device includes	1. A device comprising:
a shaft, a distal member positioned at a distal end of the shaft, the distal member having a forward end and a rearward end, a tip disposed at the forward end of the distal member, a right edge and	a shaft; a distal member positioned at a distal end of the shaft, said distal member having a forward end and a rearward end; a forward tip formed at the forward end of the distal member; a right edge and
a left edge extending towards the rearward end from the tip,	a left edge progressing rearwardly from the forward tip;

[2] Exact language from Claims 1 and 17, where portions of Claims 1, 4, 17, and 37, and the Baerveldt specification are arranged for ease of comparison and the subscripts refer to: [a]Claim 4; [b]Ex. 1009 at ¶0061; [c]Claim 1; and [d]Claim 37.

wherein the right edge and the left edge increase in height as they extend rearward, a gap rearward of the tip and between the right edge and the left edge, wherein at least portions of the right and left edges are configured to cut trabecular meshwork tissue as the trabecular meshwork tissue advances in a rearward direction over the right and left edges, wherein as the trabecular meshwork tissue advances over the right and left edges, an incline of the right and left edges is configured to cause the trabecular meshwork tissue to be lifted away from a back wall of a Schlemm's canal.	[wherein the right edge and left edge increase in height as they progress rearward][a] a depression, trough, cavity or open area rearward of the forward tip and between the right edge and the left edge; wherein at least portions of the right and left side edges are configured to cut tissue as the tissue advances in the rearward direction over the right and left edges. As TM tissue advances over the edges 20, the incline of the edges will cause the TM tissue to be lifted away from the back wall of Schlemm's canal.[b]
According to some embodiments, disclosed is a method for incising a trabecular meshwork to form an opening in trabecular meshwork tissue of an eye having a Schlemm's Canal, an anterior chamber and a trabecular meshwork. The method includes inserting a distal portion of a device into the anterior chamber. The device includes a shaft, a distal member positioned at a distal end of the shaft, the distal member having a forward end and a rearward end, a tip disposed at the forward end of the distal member, a right edge and a left edge extending towards the rearward end from the tip,	17. A method for using a device according to any of claims 1 through 16 to form an opening in trabecular meshwork tissue of an eye having a Schlemm's Canal, an anterior chamber and a trabecular meshwork, said method comprising the steps of: inserting into the anterior chamber a distal portion of said device, [a shaft; a distal member positioned at a distal end of the shaft, said distal member having a forward end and a rearward end; a forward tip formed at the forward end of the distal member; a right edge and a left edge progressing rearwardly from the forward tip;][c]

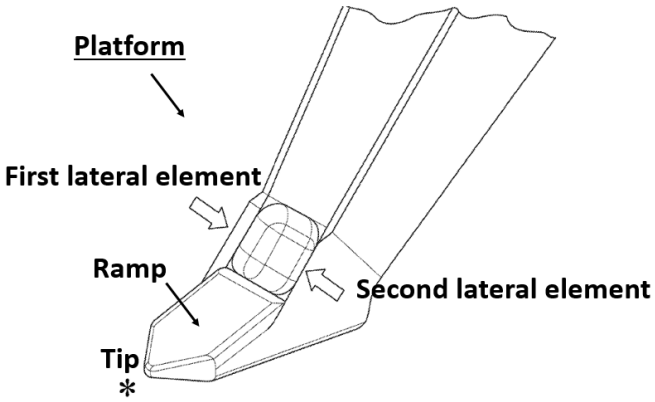
wherein the right edge and the left edge increase in height as they extend rearward, and wherein a width between the right and left edges increases as they extend rearward, and a gap rearward of the tip and between the right edge and the left edge, wherein the distal portion includes the distal member. The method also includes, advancing the distal member, tip first, through the trabecular meshwork and into the Schlemm's Canal, and advancing the distal member, tip first, through the Schlemm's Canal such that trabecular meshwork tissue contacts, is stretched between, and is severed by the right and left edges of the distal member.	[wherein the right edge and left edge increase in height as they progress rearward][a] [wherein the separation or width between the right edge and the left edge increases as they progress rearward][d] [a depression, trough, cavity or open area rearward of the forward tip and between the right edge and the left edge;][c] said distal portion including the distal member; advancing the distal member, front tip first, through the trabecular meshwork and into Schlemm's Canal; and advancing the distal member, front tip first, through Schlemm's Canal such that trabecular meshwork tissue contacts and is severed by the right and left edges of the distal member.

Because the New Matter and the Challenged Claims are copied from Baerveldt, several terms never before used in the purported priority applications are now found in the '391 Patent, including: a ***distal member***; a ***right edge***; a ***left edge***; and a ***width between the right and left edges***. The Condon Declaration, Ex. 1012, explains that these terms found in the New Matter and the Challenged Claims are incongruous with the rest of the '391 Patent, as well as the purported priority application specifications.

1. "distal member"

The New Matter describes a device having "a distal member positioned at a distal end of the shaft, the distal member having a forward end and a rearward end, a tip disposed at the forward end of the distal member." Ex. 1001 at 3:56-58, 4:9-12. But other than the New Matter and the Challenged Claims using terms copied from Baerveldt, there is no mention, much less any description, of a ***distal member*** anywhere else in the '391 Patent disclosure, or in any of the purported priority applications.

Instead, the '391 Patent teaches a "***platform*** comprising a tip at a distal side of the platform and a planar ***ramp*** extending from the distal side to a proximal side of the platform, opposite the distal side of the platform, wherein the ramp increases from a distal thickness at the distal side to a proximal thickness, greater than the distal thickness, at the proximal side; and first and second ***lateral elements*** for creating first and second incisions through the trabecular meshwork, the first and second lateral elements (i) being separated by a gap having a width and (ii) extending from the proximal side of the platform." Ex. 1001. 4:31-41 (formatting added). The '391 Patent provides FIG. 4 as a representative embodiment of its dual blade microsurgical device, shown below annotated here in Patent Owner's own words.



Annotated FIG. 4 of the '391 patent

The wholly different terms used in the New Matter and the Challenged Claims versus the rest of the '391 Patent and the purported priority applications to describe the distal end of the disclosed embodiment would certainly confuse a POSA regarding what constitutes a ***distal member*** as required by the Challenged Claims. Ex. 1012 at ¶41. Moreover, a POSA would find that the ***distal member*** recited in the New Matter and the Challenged Claims conflicts irreconcilably with the rest of the '391 Patent and the purported priority applications. *Id.*

For example, the right and left edges of the ***distal member*** described in the New Matter and the Challenged Claims cannot be reconciled with any of the configurations of a tip, ramp, gap, and first and second lateral elements that the rest of the '391 Patent discloses. If the right and left edges of the distal member must extend towards the rearward end from the tip, as the Challenged Claims require, then they must also incorporate the ***ramp***. But as shown in annotated FIG. 4 above,

there is no gap between the right and left edges of the ramp extending from the tip, which the Challenged Claims also require. And conversely, if the right and left edges of the ***distal member*** are meant to refer interchangeably to the first and second ***lateral elements***, then FIG. 4 clearly shows that they do not extend towards the rearward end from the tip, as the Challenged Claims also require.

Patent Owner's wholesale importation of the New Matter from Baerveldt creates this unresolvable paradox. Baerveldt teaches a ***distal member*** and makes clear how it relates to the other elements described in that disclosure. Ex. 1009 at ¶0039. As shown in FIG. 2 of Baerveldt, reproduced below, "distal member 14 [is disposed] on the distal end of the shaft 12, [and] in this example the distal member 14 has a bottom surface B, right and left upwardly extending side walls 22 and a cavity or open area 18 between the side walls 22 and rearward of the forward tip 16 [which] may be tapered to a blunt point[, and] edges 20 form the sides of the forward tip 16 and transition in orientation as they progress in the rearward direction to form spaced-apart, upwardly-sloping top surfaces of the sidewalls 22." *See id.*; FIG. 2.

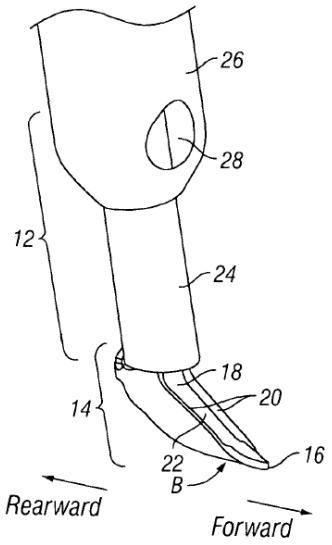


FIG. 2

Accordingly, the ***distal member*** recited in the New Matter and the Challenged Claims only makes sense in the proper context of ***Petitioner's*** invention in Baerveldt. But even if a POSA were unaware that Patent Owner copied Baerveldt, a POSA would necessarily conclude that (1) Patent Owner was not in possession of any invention having a ***distal member*** based on the '391 Patent, (2) the Challenged Claims are not entitled to the benefit of an earlier filing date from any of the purported priority applications; and (3) the '391 Patent fails to inform those skilled in the art what ***distal member*** as required by the Challenged Claims means with any clarity or reasonable certainty. Ex. 1012 at ¶44.

2. "right edge" and "left edge"

The New Matter describes a device having "a right edge and a left edge extending towards the rearward end from the tip, wherein the right edge and the

left edge increase in height as they extend rearward, a gap rearward of the tip and between the right edge and the left edge, wherein at least portions of the right and left edges are configured to cut trabecular meshwork tissue as the trabecular meshwork tissue advances in a rearward direction over the right and left edges." Ex. 1001 at 3:58-66. But other than the New Matter and the Challenged Claims using terms copied from Baerveldt, there is no mention, much less any description, of such a ***right edge*** or a ***left edge*** anywhere else in the '391 Patent disclosure, or in any of the purported priority applications.

Instead, the '391 Patent and the purported priority applications consistently use three interchangeable terms to refer to the same structural component of the disclosed device: *e.g.*, in the '391 Patent, first or second ***lateral element*** is used at least 30 times; first or second ***lateral blade*** is used at least 15 times; and first or second ***cutting edges*** are used at least 6 times. None of these terms provides adequate written description support for a ***right edge*** or a ***left edge*** as required in the Challenged Claims.

In fact, the '391 Patent consistently teaches the first and second ***lateral elements*** "extending from the proximal side of the platform," as opposed to from the tip at a "distal side of the platform." Ex. 1001 at 4:31-32; 4:38-41; 5:65-67; 6:1-2; 6:33-34. The '391 Patent also makes clear that the ***ramp*** must be located between the ***tip*** and first and second ***lateral elements***. For example, the

specification discloses that "the ***ramp*** 13 increases from a distal 10 width at the distal side (*e.g.*, at the ***tip*** 6) to a proximal width, greater than the distal width, at the proximal side (*e.g.*, adjacent to the ***lateral blades*** 10, 11)." *Id*. at 13:10-13. The specification also notes that "[b]etween the cutting ***tip*** and the first and second ***lateral blades*** 10, 11, the ***ramp*** 13 is shaped to avoid cutting tissue." *Id.* at 16:46-48 (emphasis added). Moreover, the '391 Patent figures all consistently show the tip, ramp and lateral elements sequentially adjoined along the lateral direction. *See id.* at FIGs. 4, 8-19. The New Matter disclosure of "a right edge and a left edge extending towards the rearward end from the tip" makes no sense in the context of the rest of the '391 Patent or any of the purported priority applications.

The wholly different terms used in the New Matter and the Challenged Claims versus the rest of the '391 Patent and the purported priority applications to describe the distal end of the disclosed embodiment would certainly confuse a POSA regarding what constitutes a ***right edge*** and a ***left edge*** as required by the Challenged Claims. Ex. 1012 at ¶48. Moreover, a POSA would find that the ***right edge*** and the ***left edge*** recited in the New Matter and the Challenged Claims conflicts irreconcilably with the rest of the '391 Patent and the purported priority applications. *Id.*

Once again, Patent Owner's wholesale importation of the New Matter from Baerveldt creates this unresolvable paradox. Baerveldt teaches a ***right edge*** and a

left edge and makes clear how they relate to the other elements described in that disclosure. Ex. 1009 at ¶0039. As shown in FIG. 2 of Baerveldt, reproduced at Section IV.A.1., *supra*, "edges 20 form the sides of the forward tip 16 and transition in orientation as they progress in the rearward direction to form spaced-apart, upwardly-sloping top surfaces of the sidewalls 22." *See id.*; FIG. 2.

Accordingly, the ***right edge*** and the ***left edge*** recited in the New Matter and the Challenged Claims only makes sense in the proper context of ***Petitioner's*** invention in Baerveldt. But even if a POSA were unaware that Patent Owner copied Baerveldt, a POSA would necessarily conclude that (1) Patent Owner was not in possession of any invention having a ***right edge*** and a ***left edge*** based on the '391 Patent, (2) the Challenged Claims are not entitled to the benefit of an earlier filing date from any of the purported priority applications; and (3) the '391 Patent fails to inform those skilled in the art what a ***right edge*** and a ***left edge*** as required by the Challenged Claims mean with any clarity or reasonable certainty. Ex. 1012 at ¶50.

3. "width between the right and left edges"

As further explained in the Condon Declaration, Ex. 1012, the incongruity between the New Matter and the Challenged Claims versus the rest of the '391 Patent and the purported priority applications, does not end with the ***right edge*** and the ***left edge*** alone. The Challenged Claims also require that "a width between the

right and left edges increases as they extend rearward." Ex. 1001 at 4:15-17. But other than the New Matter and the Challenged Claims using terms copied from Baerveldt, there is no mention, much less any description, of a ***width between the right and left edges*** anywhere else in the '391 Patent disclosure, or in any of the purported priority applications. Claim 13 (and, by dependency, Claims 14-20) recites this element from the New Matter *ipsis verbis*. Claim 8 similarly recites "a width between the right and left edges increases from a first width at a forwardmost portion of the distal member to a second width, greater than the first width, at a rearward portion of the distal member."

If the right and left edges recited in the Challenged Claims are interchangeable with the first and second lateral elements (or blades or cutting edges) taught in the '391 Patent, then the specification excludes the claimed (non-parallel) embodiment. The '391 Patent states consistently that the lateral elements must be parallel to each other. *Id*. at 13:8-9 ("the first and second lateral blades are parallel to each other."); *id.* at 14:53-54 ("said first blade 10 and said second blade 11 are parallel (shown in FIG. 15)"). Moreover, all the '391 Patent figures exclusively depict the first and second lateral elements in parallel configuration. *See id.* at FIGs. 4, 8-19. And conversely, if the right and left edges must be different than the first and second lateral elements, then the required "gap rearward of the tip and between the right edge and the left edge" is missing. The

only "gap" described in the '391 Patent outside the New Matter is located between the first and second lateral elements. *Id.* at FIG. 4.

The wholly different terms used in the New Matter and the Challenged Claims versus the rest of the '391 Patent and the purported priority applications to describe the distal end of the disclosed embodiment would certainly confuse a POSA regarding what constitutes a ***width between the right and left edges*** as required by the Challenged Claims. Ex. 1012 at ¶53. Moreover, a POSA would find that the ***width between the right and left edges*** recited in the New Matter and the Challenged Claims conflicts irreconcilably with the rest of the '391 Patent and the purported priority applications. *Id.*

For a third time, Patent Owner's wholesale importation of the New Matter from Baerveldt creates this unresolvable paradox. Baerveldt teaches a ***width between the right and left edges*** and makes clear how it relates to the other elements described in that disclosure. Ex. 1009 at ¶0039. As shown in FIG. 2 of Baerveldt, reproduced at Section IV.A.1., *supra*, "in embodiments where the width between the edges (e.g., W1, W2, W3) becomes wider, such widening may also transversely pull or stretch the TM tissue as it advanced over edges 20. This separation between the TM and the back wall of Schlemm's Canal, as well as transverse widening between edges in embodiments where the width between the edges becomes wider, stretches the TM as it advances over the top surface of the

tip and up the inclined tissue-severing blades 20, causing the TM to be opened by the two tissue-severing blades 20, thus creating a strip of TM." *See id.* at ¶0061; FIG. 2.

Accordingly, the ***width between the right and left edges*** recited in the New Matter and the Challenged Claims only makes sense in the proper context of ***Petitioner's*** invention in Baerveldt. But even if a POSA were unaware that Patent Owner copied Baerveldt, a POSA would necessarily conclude that (1) Patent Owner was not in possession of any invention having a ***width between the right and left edges*** based on the '391 Patent, (2) the Challenged Claims are not entitled to the benefit of an earlier filing date from any of the purported priority applications; and (3) the '391 Patent fails to inform those skilled in the art what a ***width between the right and left edges*** as required by the Challenged Claims mean with any clarity or reasonable certainty. Ex. 1012 at ¶55.

B. The Purported Priority Application Disclosures

The '391 Patent issued on September 29, 2020, from U.S. patent application No. 16/678,785 ("the '785 Application"), filed on November 8, 2019. The '785 Application purports to be a continuation application claiming priority to U.S. patent application No. 15/701,306 ("the '306 Application"), Ex. 1002, which is a continuation of U.S. patent application No. 15/484,041, filed on April 10, 2017, that issued on September 12, 2017, as U.S. Patent No. 9,757,279, Ex. 1003, which

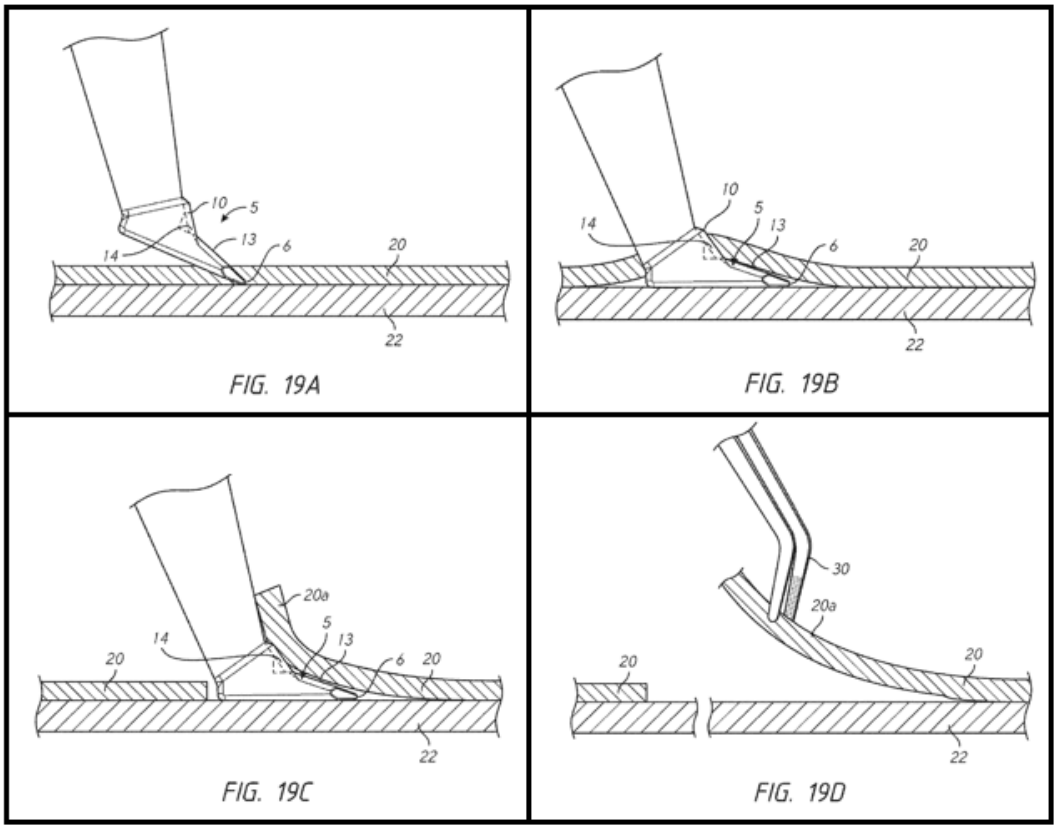
is a division of U.S. patent application No. 15/207,329, filed on July 11, 2016, that issued on January 23, 2018, as U.S. Patent No. 9,872,799, Ex. 1004, which is a continuation-in-part of U.S. patent application No. 14/375,350, filed on July 29, 2014, that issued on June 25, 2019, as U.S. Patent No. 10,327,947, Ex. 1005, which is the U.S. national stage entry from international patent application No. PCT/US13/37374, filed on April 19, 2013, and published on October 31, 2013, as Publication No. WO 2013/163034, Ex. 1006, which claims priority to U.S. patent application No. 61/637,611, filed on April 24, 2012 ("the '611 Provisional"), Ex. 1007. Except for the New Matter, the '391 Patent is indistinguishable from its parent application, U.S. patent application No. 15/701,306, its grandparent application, U.S. patent application No. 15/484,041 and its great-grandparent application, U.S. patent application No. 15/207,329.

According to Patent Owner, the '329 Application is a continuation-in-part ("CIP") of the '350 Application (now the '947 Patent, Ex. 1005). As compared with the parent '350 Application, the CIP '329 Application had a revised specification including a new set of figures (FIGs. 19A-19D). The Challenged Claims also include subject matter that was newly introduced in the CIP '329 Application.

For example, the ’799 Patent that issued from the CIP ’329 Application discloses that “[t]he ***bottom surface*** 15 can be planar, convex, concave, or combinations thereof.” Ex. 1004 at 12:47-48. Claims 3 and 15 of the ’391 Patent recite a distal member having a “concave bottom surface.” Claims 10 and 18 of the ’391 Patent further recite that a “bottom surface of the distal member has a maximum width that is less than a maximum width of the distal member.”

By contrast, the earlier ’350 Application is completely silent as to the shape or the maximum width of the bottom surface. Therefore, Claims 3, 10, 15 and 18 of the ’391 Patent, which recite subject matter not disclosed in the earlier ’350 Application, are not entitled to priority earlier than July 11, 2016, the effective filing date of the CIP ’329 Application. In any event, because Claims 3 and 10 depend from Claim 1, and Claims 15 and 18 depend from Claim 13, these claims are not entitled to a priority date earlier than November 8, 2019, for the reasons set forth Section IV.A., *supra*.

The figures (FIGs. 19A-19D) newly introduced in the CIP ’329 Application illustrate a method for incising a trabecular meshwork (“TM”) using a dual blade device, as shown below.



The specification of the '799 Patent, which issued from the CIP '329 Application, teaches the following method steps: (1) use the ***tip*** to enter into Schlemm's canal, Ex. 1004 at 15:17-19 ("once the target tissue 20 (e.g., TM) is reached, the tip 6 of the device may be then used to enter into Schlemm's canal ('SC') 22."); (2) use the ***ramp*** to elevate the TM, *id.* at 15:21-22 ("as shown in FIG. 19A, the ramp 13 may be used to elevate the TM 20 away from the outer wall of the Schlemm's canal 22."); (3) advancement of the ***platform*** to stretch the TM, *id.* at 15:23-25 ("as shown in FIG. 19B, the advancement of the platform 5 can stretch the TM 20 as it travels up the ramp 13 without tearing a strip 20a of the TM

20 that is on the ramp 13."); (4) the TM contacts the ***first and second lateral blades***, *id.* at 15:34-37 ("as shown in FIG. 19C, the TM 20 contacts the first and second lateral blades 10, 11 while the TM 20 is elevated (e.g., stretched and/or under tension)."); (5) use the ***first and second lateral blades*** to incise the TM, *id.* at 15:38-40 ("the first and second lateral blades 10, 11 incise first and second incisions into the TM 20 to form the strip 20a of the TM 20."); (6) a portion of the strip is received within the ***gap***, *id*. at 15:41-44 ("During advancement of the platform 5, at least a portion of the strip 20a can be received within the gap 14 between the first and second lateral blades 10, 11."); and (7) separate and remove the TM strip, *id*. at 15:53-56 ("as shown in FIG. 19D, the strip 20a that has been separated from a remainder of the TM 20 can be removed by a device 30 (e.g., forceps) or by aspiration.").

By contrast, none of the purported priority applications to the CIP '329 Application, specifically, the '350 Application (now the '947 Patent, Ex. 1005), the '374 PCT Application (Ex. 1006), and the '611 Provisional (Ex. 1007) disclose the method described in FIGs. 19A-19D of the '799 Patent, certainly not with the same detail. For example, the '611 Provisional teaches a three-step process for cutting a strip of tissue of width W from a tissue mass and the method comprises the steps of a) "providing a device"; b) "advancing the anterior insertion blade tip of the beveled platform through tissue such that the first and second cutting edges are

positioned adjacent to tissue to be cut"; and c) "advancing the distal end such that the cutting edges cut a strip of tissue of approximate width W and the cut strip of tissue remains substantially intact." Ex. 1007 at 45:15-25, 46:1-2. The '611 Provisional further discloses that "the device provided in step a of the method further comprises an anterior insertion blade tip of the beveled platform and wherein the anterior insertion blade ***tip*** of the beveled platform is advanced through the trabecular meshwork and into Schlemm's canal and, thereafter, the anterior insertion blade tip of the beveled platform is advanced through Schlemm's canal as the cutting tube is advanced to cut the strip of tissue. In one embodiment, the device provided in step a further comprises a apparatus for severing the strip of tissue after the strip of tissue has reached a desired length and wherein the method further comprises the step of: severing the strip of tissue after the strip of tissue has reached a desired length" *Id* at 46:12-19. The '611 Provisional also discloses that "the invention further comprises the step of: c) removing the strip of tissue." *Id*. at 46:23-24.

Notably, the '611 Provisional contains substantial disclosure identical to the language used in at least two of Petitioner's earlier filed applications, including Sorensen, Ex. 1011, and U.S. Patent No. 7,959,641.

C. The Challenged Claims of the ’391 Patent

The ’391 Patent contains twenty claims, including two independent claims, Claims 1 and 13. Petitioner challenges all claims of the ’391 Patent. The recited elements of Claims 1-20 are enumerated and set forth in Tables 1-20 below.

Table 1: Elements of Claim 1	
Ref. No.	*Element*
1.1	A method for incising a trabecular meshwork to form an opening in trabecular meshwork tissue of an eye having a Schlemm’s Canal, an anterior chamber and a trabecular meshwork, the method comprising:
1.2	providing a device comprising:
1.3	a shaft;
1.4	a distal member positioned at a distal end of the shaft, the distal member having a forward end and a rearward end;
1.5	a tip disposed at the forward end of the distal member;
1.6	a right edge and a left edge extending towards the rearward end from the tip,
1.7	wherein the right edge and the left edge increase in height as they extend rearward; and
1.8	a gap rearward of the tip and between the right edge and the left edge,
1.9	the gap defining an unoccupied space that is not part of a lumen,
1.10	wherein at least portions of the right and left edges are configured to cut trabecular meshwork tissue as the trabecular meshwork tissue advances in a rearward direction over the right and left edges;
1.11	inserting a distal portion of the device into the anterior chamber, the distal portion including the distal member;
1.12	advancing the distal member, the tip first, through the trabecular meshwork and into the Schlemm’s Canal; and

Table 1: Elements of Claim 1	
Ref. No.	*Element*
1.13	advancing the distal member, tip first, through the Schlemm's Canal such that trabecular meshwork tissue contacts and is severed by the right and left edges of the distal member.

Table 2: Elements of Claim 2	
Ref. No.	*Element*
2	The method according to claim 1, wherein when the distal member is advanced into the Schlemm's Canal, a bottom surface of the distal member is juxtaposed to a back wall of the Schlemm's Canal.

Table 3: Elements of Claim 3	
Ref. No.	*Element*
3	The method according to claim 1, wherein when the distal member is advanced through the Schlemm's Canal a transversely concave bottom surface of the distal member is configured to abut and be atraumatic to a back wall of the Schlemm's Canal.

Table 4: Elements of Claim 4	
Ref. No.	*Element*
4	The method according to claim 1, wherein when the distal member is advanced through the Schlemm's Canal, the trabecular meshwork tissue is lifted away from a back wall of the Schlemm's canal.

Table 5: Elements of Claim 5	
Ref. No.	*Element*
5	The method according to claim 1, wherein when the distal member is advanced through the Schlemm's Canal, the trabecular meshwork tissue is transversely stretched over the gap.

Table 6: Elements of Claim 6	
Ref. No.	*Element*
6	The method according to claim 1, further comprising removing the severed trabecular meshwork tissue by one of forceps and aspiration.

Table 7: Elements of Claim 7	
Ref. No.	*Element*
7	The method according to claim 1, wherein as the trabecular meshwork tissue advances over the right and left edges, an incline of the right and left edges is configured to cause the trabecular meshwork tissue to be lifted away from a back wall of a Schlemm's canal.

Table 8: Elements of Claim 8	
Ref. No.	*Element*
8	The method of claim 1, wherein a width between the right and left edges increases from a first width at a forward-most portion of the distal member to a second width, greater than the first width, at a rearward portion of the distal member.

Table 9: Elements of Claim 9	
Ref. No.	*Element*
9	The method of claim 8, wherein the first width is between 0.2 to 0.3 mm inclusive.

Table 10: Elements of Claim 10	
Ref. No.	*Element*
10	The method of claim 1, wherein a bottom surface of the distal member has a maximum width that is less than a maximum width of the distal member.

Table 11: Elements of Claim 11	
Ref. No.	*Element*
11	The method of claim 1, wherein, at a first location on the tip, the right edge and left edge are positioned at a first height and oriented at a first orientation that is substantially vertical.

Table 12: Elements of Claim 12	
Ref. No.	*Element*
12	The method of claim 1, wherein at least portions of the right and left edges are angled between 20 and 90 degrees with respect to a bottom surface of the distal member.

Table 13: Elements of Claim 13	
Ref. No.	*Element*
13.1	A method for incising a trabecular meshwork to form an opening in trabecular meshwork tissue of an eye having a Schlemm's Canal, an anterior chamber and a trabecular meshwork, the method comprising:
13.2	inserting a distal portion of a device into the anterior chamber, the device comprising:
13.3	a shaft;
13.4	a distal member positioned at a distal end of the shaft, the distal member having a forward end and a rearward end;
13.5	a tip disposed at the forward end of the distal member;
13.6	a right edge and a left edge extending towards the rearward end from the tip,

Table 13: Elements of Claim 13	
Ref. No.	*Element*
13.7	wherein the right edge and the left edge increase in height as they extend rearward; and
13.8	wherein a width between the right and left edges increases as they extend rearward; and
13.9	a gap rearward of the tip and between the right edge and the left edge,
13.10	the gap defining an unoccupied space that is not part of a lumen,
13.11	wherein the distal portion includes the distal member;
13.12	advancing the distal member, the tip first, through the trabecular meshwork and into the Schlemm's Canal; and
13.13	advancing the distal member, tip first, through the Schlemm's Canal such that trabecular meshwork tissue contacts, is stretched between, and is severed by the right and left edges of the distal member.

Table 14: Elements of Claim 14	
Ref. No.	*Element*
14	The method according to claim 13, wherein when the distal member is advanced into the Schlemm's Canal, a bottom surface of the distal member is juxtaposed to a back wall of the Schlemm's Canal.

Table 15: Elements of Claim 15	
Ref. No.	*Element*
15	The method according to claim 13, wherein when the distal member is advanced through the Schlemm's Canal a transversely concave bottom surface of the distal member is configured to abut and be atraumatic to a back wall of the Schlemm's Canal.

Table 16: Elements of Claim 16	
Ref. No.	*Element*
16	The method according to claim 13, wherein when the distal member is advanced through the Schlemm's Canal, the trabecular meshwork tissue is lifted away from a back wall of the Schlemm's canal.

Table 17: Elements of Claim 17	
Ref. No.	*Element*
17	The method according to claim 13, wherein when the distal member is advanced through the Schlemm's Canal, the trabecular meshwork tissue is transversely stretched over the gap.

Table 18: Elements of Claim 18	
Ref. No.	*Element*
18	The method of claim 13, wherein a bottom surface of the distal member has a maximum width that is less than a maximum width of the distal member.

Table 19: Elements of Claim 19	
Ref. No.	*Element*
19	The method of claim 13, wherein, at a first location on the tip, the right edge and left edge are positioned at a first height and oriented at a first orientation that is substantially vertical.

Table 20: Elements of Claim 20	
Ref. No.	*Element*
20	The method of claim 13, wherein at least portions of the right and left edges are angled between 20 and 90 degrees with respect to a bottom surface of the distal member.

D. Prosecution History of the ’391 Patent:

Patent Owner filed the ’785 Application on November 8, 2019, and represented this application to be a continuation of the ’306 Application. Ex. 1010 at 399. Patent Owner also filed a Request for Prioritized Examination of the ’785 Application. *Id*. at 356. Patent Owner later submitted a substitute specification on January 17, 2020, in response to the November 27, 2019 Notice to File Corrected Application Papers to replace the header and footer of Table 1 at page 31 of the specification. *Id*. at 341, 349. Patent Owner claimed that “[n]o new matter has been introduced by way of these amendments.” *Id*. at 341. But two new paragraphs appear in both the original and substitute specifications of the ’785 application. During prosecution, Patent Owner neither disclosed these additions to the Examiner, nor attested that the additions constituted new matter. There is no indication in the prosecution history that the Examiner was aware that the ’785 Application included two newly added paragraphs that none of the purported priority applications contained. *See id.*

The initial claims of the ’785 application filed November 8, 2019, included one set of apparatus claims (Claims 1-9) directed to a device for incising a trabecular meshwork and two sets of methods claims (Claims 10-15 and 16-20, respectively) using the device recited in the apparatus claims for incising a trabecular meshwork. *Id*. at 444-47. Claims 1, 10 and 16 recited the

limitation that "a right edge and a left edge extending towards the rearward end from the tip"; and Claims 2 and 16 recited the limitation that "a width between the right and left edges increases from a first width at a forward-most portion of the distal member to a second width, greater than the first width, at a rearward portion of the distal member." *Id*. at 446. As discussed at Section IV.A., *supra*, these limitations are recitations *ipsis verbis* of the New Matter in the '391 Patent.

On February 14, 2020, the Examiner issued a non-final office action rejecting Claims 1-2 and 4-8 under pre-AIA 35 U.S.C. § 102(e) as anticipated by US2012/0083727 (Barnett); rejecting Claims 3 and 9 under pre-AIA 35 U.S.C. § 103(a) as being unpatentable over Barnett; rejecting Claims 1-20 on the ground of nonstatutory double patenting as being unpatentable over Claims 1-16 of U.S. Patent No. 9,872,799, Ex. 1004; and rejecting Claims 1-9 on the ground of nonstatutory double patenting as being unpatentable over Claims 1-22 of U.S. Patent No. 10,327,947, Ex. 1005. *See* Ex. 1010 at 216-21.

In response to the February 14, 2020 office action, Patent Owner filed claim amendments on May 13, 2020, and, *inter alia*, amended Claim 1 to recite "the tip comprising[] a foremost portion having a vertical face; and right and left angled portions extending from opposing sides of the vertical face" and "a right edge and a left edge extending towards the rearward end from the right

and left angled portions of the tip." *Id*. at 202-205. Additionally, Patent Owner proposed to file terminal disclaimers with respect to the cited patents to overcome the double patenting rejections. *Id*. at 206.

On May 21, 2020, the Examiner issued a final office action rejecting Claims 1-15 under 35 U.S.C. § 112(a) or 35 U.S.C. § 112 (pre-AIA), first paragraph, as failing to comply with the written description requirement. The Examiner asserted that "[t]he limitation of claim 1 that the tip has 'a foremost portion having a vertical face' with the right and left angled portions extending from opposing sides of the vertical face was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the invention or a joint inventor, or for pre-AIA the inventor(s), at the time the application was filed has possession of the claimed invention." *Id*. at 153. The Examiner further rejected Claims 1-9 under pre-AIA 35 U.S.C. § 103(a) as being unpatentable over Barnett in view of U.S. Patent No. 5,258,002 (Jeffers). *Id*. at 154. The Examiner also maintained the double patent rejections raised in the February 14, 2020 office action because Patent Owner had not filed terminal disclaimers as proposed in its May 13, 2020 response to the previous office action.

On July 10, 2020, the Examiner conducted a telephonic interview with Patent Owner's Representative, Brad Wilson. They agreed on claim

amendments to overcome the rejections under 35 U.S.C. §§ 112 and 103 and double patenting. *Id*. at 130. Patent Owner then filed claim amendments on July 15, 2020, to cancel Claims 1-9 and rewrite dependent method Claim 10 in independent form reciting most of the limitations of the device in the original apparatus Claim 1 filed November 8, 2019, including the limitations reflected in the New Matter. Patent Owner further added new dependent method Claims 21-29 reciting the limitations of the original Claims 2-3 and 7-9 filed November 8, 2019. *Id*. at 140-144. Patent Owner also filed a terminal disclaimer with respect to the cited ’799 patent, but not the ’947 patent. *Id*. at 133-34.

On July 23, 2020, the Examiner issued a Notice of Allowance and proposed Examiner’s Amendment to correct minor formality errors. *Id*. at 75-81.

On July 31, 2020, Patent Owner filed a Request for Continued Examination and submitted an Information Disclosure Statement citing Sorensen, Ex. 1011, U.S. patent publication US2005/0245953, and several non-patent articles. Ex. 1010 at 62-74. As mentioned in Section II.B., *supra*, on June 4, 2020, Petitioner had sued Patent Owner’s exclusive licensee and commercial partner NWM in the U.S. District Court for the District of Delaware, alleging that NWM infringed five patents, including the ’729 patent (Sorensen).

On August 19, 2020, the Examiner issued the second Notice of Allowance. Ex. 1010 at 2. The Examiner initially rejected the pending claims in view of Sorensen. *Id.* at 7 ("[t]he indicated allowability of claims 10-29 is withdrawn in view of the newly discovered reference(s) to US 9,107,729 (Sorensen).").

On August 19, 2020, the Examiner spoke again with Mr. Wilson. Without any written explanation of reason or basis, the Examiner entered an Examiner's Amendment adding the negative limitation "the gap defining an unoccupied space that is not part of a lumen" to independent Claims 10 and 16, which presumably overcame the Examiner's own rejection over Sorensen. *Id*. at 8-9. Patent Owner immediately paid the issue fee the same day. *Id*. at 57. These amended claims issued as the Challenged Claims of the '391 Patent.

On September 9, 2020, an Issue Notification was sent indicating that the '785 Application would be issued on September 29, 2020, as U.S. Patent No. 10,786,391. *Id*. at 1. About a month later, on November 4, 2020, Patent Owner and NWM jointly sued Petitioner in the U.S. District Court for the Western District of Washington alleging infringement of the '391 Patent. Ex. 1008.

V. STATEMENT OF THE RELIEF REQUESTED AND THE REASONS THEREFOR UNDER 37 C.F.R. § 42.22(A) AND 37 C.F.R. § 42.204(B)

MST respectfully requests post-grant review, and cancellation, of Claims 1-20 of the '391 Patent under 35 U.S.C. § 321 based on the following unpatentability grounds:

Ground	Statute	Challenge	Claims
1	35 U.S.C. § 112(a)	**Lack of written description** for "a distal member positioned at a distal end of the shaft, the distal member having a forward end and a rearward end" "a right edge and a left edge extending towards the rearward end from the tip" "wherein a width between the right and left edges increases as they extend rearward"	1-20
2	35 U.S.C. § 112(a)	**Lack of written description** for "the gap defining an unoccupied space that is not part of a lumen"	1-20
3	35 U.S.C. § 112(b)	**Indefiniteness** of "a distal member positioned at a distal end of the shaft, the distal member having a forward end and a rearward end" "a right edge and a left edge extending towards the rearward end from the tip, wherein the right edge and the left edge increase in height as they extend rearward" "wherein a width between the right and left edges increases as they extend rearward"	1-20
4	35 U.S.C. § 102	**Anticipation** by WO 2018/151808 A1("Baerveldt")	1-20

Ground	Statute	Challenge	Claims
5	35 U.S.C. § 103	**Obviousness** in view of WO 2018/151808 A1("Baerveldt")	1-20

A. Person of Ordinary Skill in the Art ("POSA")

A POSA would have: (1) a medical degree and at least two years' experience with treating glaucoma and performing glaucoma surgery; or (2) an undergraduate or graduate degree in biomedical or mechanical engineering and at least five years of work experience in the area of ophthalmology, including familiarity with ophthalmic anatomy and glaucoma surgery. Ex. 1012 at ¶11.

B. Claim Construction (37 C.F.R. § 42.204(b)(3))

Claims in PGR petitions filed after November 13, 2018, are construed using the same standard as in district court. *See* 83 Fed. Reg. 51340 (Oct. 11, 2018). Specifically, claims are construed in accordance with the ordinary and customary meaning of such claims as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent. 37 C.F.R. § 42.200(b). Claim terms are generally given their "ordinary and customary meaning," that is, "the meaning that the term would have to a [POSA] in question at the time of the invention, *i.e.*, as of the effective filing date of the patent application." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005) (*en banc*). Petitioner submits that any claim terms not

specifically discussed in this Section should be given their ordinary and customary meaning.

1. "Tip"

The term "tip" as used in the Challenged Claims should be interpreted to mean the point at the distal end of the device. *See* Ex. 1001 at FIG. 4 & 7:34-36 ("the distal point (asterisk) that is designed to pierce the trabecular meshwork ('TM') and enter into the Schlemm's canal"); *id.* at Abstract ("device tip provides entry into the Schlemm's canal"); *id.* at 4:31-32 ("a tip at a distal side of the platform"); *id.* at 6:44-45 ("distal segments of the first side and the second side [of the platform] intersect at the tip"). This definition is consistent with the ordinary meaning of "tip." *See* Merriam-Webster's Online Dictionary ("Tip: the usually pointed end of something.") (accessible at www.merriam-webster.com/dictionary/tip).

2. "Edge"

The term "edge" as used in the Challenged Claims should be interpreted to mean "a cutting structure" configured to sever the trabecular meshwork tissue. *See* Ex. 1001 at 3:63-66 ("at least portions of the right and left edges are configured to cut trabecular meshwork tissue as the trabecular meshwork tissue advances in a rearward direction over the right and left edges"). This definition is consistent with the ordinary meaning of "edge." *See* Merriam-Webster's Online Dictionary

("Edge: the cutting side of a blade.") (accessible at www.merriam-webster.com/dictionary/edge).

3. "Lumen"

The term "lumen" as used in the Challenged Claims should be interpreted to mean "the bore of a shaft." The '391 patent makes no mention of a lumen in relevant context. This definition is consistent with the ordinary meaning of "lumen." *See also* Merriam-Webster's Online Dictionary ("Lumen: the bore of a tube (as of a hollow needle or catheter)") (accessible at www.merriam-webster.com/dictionary/lumen).

VI. THE '391 PATENT IS PGR ELIGIBLE

Patent Owner bears the ultimate burden of demonstrating entitlement to an earlier application's filing date. *See In re NTP, Inc.,* 654 F.3d 1268, 1276-77 (Fed. Cir. 2011). This burden is not satisfied merely because the later application is a "continuation" of the earlier one. *See Research Corp. Techs. v. Microsoft Corp*., 627 F.3d 859, 865, 869-70 (Fed. Cir. 2010). Patent Owner must show that the claimed invention was "disclosed in the manner provided by the first paragraph of [35 U.S.C.] section 112 (a)" in the earlier application. 35 U.S.C. § 120; *see Anascape, Ltd. v. Nintendo of Am., Inc.*, 601 F.3d 1333, 1334-35 (Fed. Cir. 2010). If the earlier application is not an immediate parent, the invention must be disclosed in compliance with 35 U.S.C. § 112 in every intervening application.

Lockwood v. Am. Airlines, Inc., 107 F.3d 1565, 1571 (Fed. Cir. 1997). The earlier application(s) must "reasonably convey[] to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Ariad Pharms., Inc. v. Eli Lilly & Co*., 598 F.3d 1336, 1351 (Fed. Cir. 2010) (*en banc*). The claimed combination, not just its individual elements, must be described. *See Hyatt v. Dudas*, 492 F.3d 1365, 1369-71 (Fed. Cir. 2007).

If one or more claims of the '391 Patent is not entitled to an effective filing date earlier than March 16, 2013, then PGR is available. *See* AIA §§ 3(n)(1)(A), 6(f)(2), 125 Stat. at 293, 311.

The '391 Patent was filed after March 16, 2013—the effective date of the AIA—but claims priority to a U.S. provisional application filed prior to March 16, 2013 as shown below.

Patent Application	Filing Date	New Matter
U.S. patent application No. 61/637,611 (Ex. 1007)	April 24, 2012	
International patent application No. PCT/US13/37374 (Ex. 1006)	April 19, 2013	
U.S. patent application No. 14/375,350 (now U.S. Patent No. 10,327,947) (Ex. 1005)	July 29, 2014	

Patent Application	Filing Date	New Matter
U.S. patent application No. 15/207,329 (now U.S. Patent No. 9,872,799) (Ex. 1004) Continuation-in-Part	July 11, 2016	Ex. 1004 at FIGs. 19A-19D; 8:3-14; 12:47-48 (reflecting major revisions to the specification).
U.S. patent application No. 15/484,041 (now U.S. Patent No. 9,757,279) (Ex. 1003) Purported Division	April 10, 2017	
U.S. patent application No. 15/701,306 (Ex. 1002) Purported Continuation	September 11, 2017	
U.S. patent application No. 16/678,785 (now U.S. Patent No. 10,786,391) (Ex. 1001) Purported Continuation	November 8, 2019	Ex. 1001 at 3:54-4:25.

Petitioner identifies the following non-exhaustive reasons that demonstrate that Patent Owner will be unable to meet its burden of proving that the claims at issue are entitled to a filing date earlier than March 16, 2013. Thus, the PGR provisions of the AIA apply to the subject application. *See* AIA, § 3(n)(1).

A. No Written Description Support Can Be Found in Any of the Purported Priority Applications For the Challenged Claims Regarding Claim Element Nos. [1.4/13.4], [1.6/13.6], and [13.8]

None of the ’391 Patent claims may be accorded priority to an earlier application because there is no written description support in any of the purported priority applications for “a distal member positioned at a distal end of the shaft, the distal member having a forward end and a rearward end,” [Claim Element Nos.

1.4/13.4]; "a right edge and a left edge extending towards the rearward end from the tip," [Claim Element Nos. 1.6/13.6]; and "wherein a width between the right and left edges increases as they extend rearward," [Claim Element No. 13.8]. As set forth in Section IV.A., *supra*, Patent Owner filed the '391 Patent application on November 8, 2019, with the insertion of two new paragraphs never before seen in any of the purported priority applications. Ex. 1001 at 3:54-4:25 ("New Matter").

Not only do the claim terms ***distal member***, ***right edge***, and ***left edge*** not appear anywhere in the purported priority disclosures, but as the Condon Declaration, Ex. 1012, explains, a POSA would find the New Matter and the Challenged Claims to conflict irreconcilably with the rest of the '391 Patent and the purported priority applications. As explained in detail at Section IV.A., *supra*, in view of this conflict, a POSA would necessarily conclude that (1) Patent Owner was not in possession of any invention having a "a distal member positioned at a distal end of the shaft, the distal member having a forward end and a rearward end;" "a right edge and a left edge extending towards the rearward end from the tip;" and/or "wherein a width between the right and left edges increases as they extend rearward," based on the '391 Patent, and (2) the Challenged Claims are not entitled to the benefit of an earlier filing date from any of the purported priority applications. Accordingly, none of the Challenged Claims (Claims 1 and 13 and

their respective dependent claims) are entitled to an effective filing date earlier than November 8, 2019.

B. No Written Description Support Can Be Found in Any of the Purported Priority Applications For Challenged Claim 8 Regarding Claim Element No. [8]

In addition to the lack of written description basis explained in detail at Section VI.A., *supra*, regarding independent Claims 1 and 13, there is another, separate reason that challenged Claim 8 is not entitled to an effective filing date earlier than November 8, 2019. Claim 8 of the '391 Patent requires that "***a width between the right and left edges*** increases from a first width at a forwardmost portion of the distal member to a second width, greater than the first width, at a rearward portion of the distal member." For the same reasons articulated in Section VI.A., *supra*, regarding ***right edge*** and ***left edge***, this element in the New Matter and challenged Claim 8 is supported by neither anything in the rest of the '391 Patent, nor anything in any of the purported priority applications.

Not only does the claim term ***a width between the right and left edges*** not appear anywhere in the purported priority disclosures, but as the Condon Declaration, Ex. 1012, explains, a POSA would find the New Matter and the Challenged Claims to conflict irreconcilably with the rest of the '391 Patent and the purported priority applications. As explained in detail at Section IV.A., *supra*, in view of this conflict, a POSA would necessarily conclude that (1) Patent Owner

was not in possession of any invention having "a width between the right and left edges increases from a first width at a forwardmost portion of the distal member to a second width, greater than the first width, at a rearward portion of the distal member," based on the '391 Patent, and (2) the Challenged Claims are not entitled to the benefit of an earlier filing date from any of the purported priority applications. Accordingly, for this additional reason set forth in this section, Challenged Claim 8 is not entitled to an effective filing date earlier than November 8, 2019.

C. No Written Description Support Can Be Found In the '611 Provisional, the'374 PCT Application, And/Or the '350 Application For Challenged Claims 3 and 15 Regarding the Limitation of "transversely concave bottom surface" or For Challenged Claims 10 and 18 Regarding the Limitation of a "bottom surface of the distal member has a maximum width that is less than a maximum width of the distal member"

Claims 3 and 15 of the '391 Patent require that "a transversely concave bottom surface of the distal member is configured to abut and be atraumatic to a back wall of the Schlemm's Canal." In addition, Claims 10 and 18 of the '391 Patent require that a "bottom surface of the distal member has a maximum width that is less than a maximum width of the distal member." As set forth at Section IV.B., *supra*, Patent Owner introduced new matter when it filed the July 11, 2016 CIP '329 Application, which issued as the '799 Patent, that implicates the subject matter of Claims 3 and 15 as well as Claims 10 and 18 of the '391 Patent.

In none of the earlier purported priority applications was there any mention, much less description, of the shape of the bottom surface or the maximum width of the bottom surface being less than a maximum width of the distal member. Therefore, Claims 3, 10, 15, and 18 of the ’391 Patent, which recite subject matter not disclosed in the earlier ’350 Application, are not entitled to priority earlier than July 11, 2016, the effective filing date of the CIP ’329 Application. In any event, because Claims 3 and 10 depend from Claim 1 and Claims 15 and 18 depend from Claim 13, these claims are not entitled to a priority date earlier than November 8, 2019, for the reasons set forth in Section VI.A., *supra*.

VII. THE CHALLENGED CLAIMS ARE UNPATENTABLE AND SHOULD BE CANCELLED

For the reasons detailed *infra*, all of the Challenged Claims are more likely than not unpatentable because they are unsupported by the specifications of the ’391 Patent and the purported priority applications with the exception of a recitation *ipsis verbis* contained in the New Matter added by Patent Owner on November 8, 2019, without any mention to the Examiner. Moreover, the *ipsis verbis* support for the Challenged Claims found in the New Matter is copied from ***Petitioner’s*** patent disclosures, including international patent application No. PCT/US2018/000018, published on August 23, 2018, as WO 2018/151808 A1(“Baerveldt”). When properly stripped of an undeserved

earlier priority date, the Challenged Claims are also anticipated and/or rendered obvious by Baerveldt.

A. The Challenged Claims Lack Written Description Under 35 U.S.C. § 112(A)

In order to satisfy the written description requirement, an application must "reasonably convey[] to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Ariad*, 598 F.3d at 1351. A lack of adequate written description may be found even though the issued claims were in the patent application as filed. The written description requirement is not necessarily met when the claim language appears *ipsis verbis* in the specification:

> Even if a claim is supported by the specification, the language of the specification, to the extent possible, must describe the claimed invention so that one skilled in the art can recognize what is claimed. The appearance of mere indistinct words in a specification or a claim, even an original claim, does not necessarily satisfy that requirement.

Enzo Biochem, Inc. v. Gen-Probe, Inc., 323 F.3d 956, 968 (Fed. Cir. 2002).

1. Ground 1: Lack of Written Description For the Challenged Claims Regarding Claim Element Nos. [1.4/13.4], [1.6/13.6], and [13.8]

To satisfy the written description requirement, "the specification must describe an invention understandable to [a person of ordinary skill in the art] and show that the inventor actually invented the invention claimed." *Ariad*, 598 F.3d at 1351. A "mere wish or plan" for obtaining the claimed invention is not adequate

written description. *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1566 (Fed. Cir. 1997).

The elements in the New Matter and the Challenged Claims of "a distal member positioned at a distal end of the shaft, the distal member having a forward end and a rearward end," [Claim Element Nos. 1.4/13.4]; "a right edge and a left edge extending towards the rearward end from the tip," [Claim Element Nos. 1.6/13.6]; and "wherein a width between the right and left edges increases as they extend rearward," [Claim Element No. 13.8], are supported by neither the rest of the '391 Patent, nor the purported priority applications. Not only do the claim terms ***distal member***, ***right edge***, ***left edge***, and ***a width between the right and left edges*** not appear in these disclosures, but as the Condon Declaration, Ex. 1012, explains, a POSA would find the New Matter and the Challenged Claims to conflict irreconcilably with the rest of the '391 Patent and the purported priority applications.

Patent Owner's wholesale importation of the New Matter from Baerveldt creates this unresolvable paradox. Baerveldt teaches Claim Element Nos. 1.4/13.4, 1.6/13.6, and 13.8, and makes clear how they relate to each other and the other elements described in that disclosure. Ex. 1009 at ¶0039; *see also* FIG. 2 of Baerveldt (reproduced at Section IV.A.1., *supra*). Accordingly, the elements recited in the New Matter and the Challenged Claims only make sense in the

proper context of ***Petitioner's*** invention in Baerveldt. But even if a POSA were unaware that Patent Owner copied Baerveldt, a POSA would necessarily conclude that Patent Owner was not in possession of any invention having Claim Element Nos. 1.4/13.4, 1.6/13.6, and/or 13.8, when the '391 Patent Application was filed. Ex. 1012 at ¶60. Accordingly, the Challenged Claims are more likely than not unpatentable for lack of written description.

2. Ground 2: Lack of Written Description For the Challenged Claims Regarding Claim Element Nos. [1.9/13.10]

As set forth in detail at Section IV.D., *supra*, the Examiner allowed the '391 Patent to issue only after entry of an Examiner's Amendment on August 19, 2020, adding the negative limitation "the gap defining an unoccupied space that is not part of a lumen" to pending independent Claims 10 and 16. During prosecution following Patent Owner's Request for Continued Examination to consider a newly-filed Information Disclosure Statement listing Petitioner's prior art Sorensen reference, the Examiner withdrew the allowability of the pending claims for lack of novelty. Presumably, but without any written explanation of reason or basis, the Examiner concluded that the negative limitation added by the Examiner's Amendment was sufficient to overcome the rejection based on Sorensen. This limitation, however, lacks written description support in the '391 Patent or any of the purported priority applications.

Any negative limitation or exclusionary proviso must have basis in the original disclosure. Any claim containing a negative limitation without support in the original disclosure fails to comply with the written description requirement. A lack of literal basis in the specification for a negative limitation may not be sufficient to establish a *prima facie* case for lack of descriptive support. *Ex parte Parks*, 30 USPQ2d 1234, 1236 (BPAI 1993). If alternative elements are positively recited in the specification, they may be explicitly excluded in the claims. *See In re Johnson*, 558 F.2d 1008, 1019 (CCPA 1977) ("[the] specification, having described the whole, necessarily described the part remaining"); *see also Ex parte Grasselli*, 231 USPQ 393 (BPAI 1983), *aff'd mem.*, 738 F.2d 453 (Fed. Cir. 1984). Additionally, if the "specification describes a reason to exclude the relevant limitation," the negative limitations are adequately supported. *Santarus, Inc. v. Par Pharm., Inc.*, 694 F.3d 1344, 1351 (Fed. Cir. 2012).

The term "lumen" is used only once in the specification of the '391 Patent, in a context wholly inapposite to the structural configuration of the claimed invention. Ex. 1001 at 18:25-30 ("it is believed that the device may be optimally designed to remove trabecular meshwork of the eye, unroofing small vessels (such as veins, arteries, lymphatic vessels, or other vessel with a ***lumen***,) and for creating a hole or opening in the tympanic membrane of the ear."). Neither the '391 Patent nor any of the purported priority applications ever describes a lumen. Not only are

the specifications completely silent regarding a lumen, there are no teachings or suggestions that any structural components of any of the disclosed embodiments could be considered a lumen.

Absent a particular definition in the ’391 Patent, a POSA would reasonably apply the customary and ordinary meaning to define the term “lumen.” As applied to the ’391 Patent, a POSA might consider a lumen as referring to the bore of the “shaft.” *See also* Merriam-Webster’s Online Dictionary (“Lumen: the bore of a tube (as of a hollow needle or catheter)”) (accessible at www.merriam-webster.com/dictionary/lumen). But because the specifications of the ’391 Patent and the purported priority applications never describe or depict any such structure, a POSA would be unable to define a “gap” associated with any lumen. Ex. 1012 at ¶62. Without an alternative element positively recited in the specification (*e.g.*, a gap defining an unoccupied space that ***is*** part of a lumen), let alone any reason to exclude such an alternative element even if it existed, the negative limitation “the gap defining an unoccupied space that ***is not*** part of a lumen” lacks written description support.

Accordingly, the Examiner erred in amending the pending claims to include this limitation and finding that the amended claims overcame the lack of novelty over Sorensen. The Challenged Claims, therefore, are more likely than not unpatentable for lack of written description on this ground.

B. The Challenged Claims Are Unpatentable as Indefinite Under 35 U.S.C. § 112(B)

Regardless whether the Board applies the standard set forth in *Nautilus, Inc. v. Biosig Instruments, Inc*., 572 U.S. 898 (2014) (requiring a patent's claims, viewed in light of the specification and prosecution history, to inform those skilled in the art about the scope of the invention with reasonable certainty) or *In re Packard*, 751 F.3d 1307, 1310 (Fed. Cir. 2014) (providing that "a claim is indefinite when it contains words or phrases whose meaning is unclear"), the Challenged Claims are indefinite under 35 U.S.C. § 112(b). A claim, although clear on its face, may be indefinite when a ***conflict or inconsistency*** between the claimed subject matter and the specification disclosure renders the scope of the claim uncertain as ***inconsistency*** with the specification disclosure or prior art teachings may make an otherwise definite claim take on an unreasonable degree of uncertainty. *In re Moore,* 439 F.2d 1232, 1235-36 (CCPA 1971); *In re Cohn,* 438 F.2d 989 (CCPA 1971); *In re Hammack,* 427 F.2d 1378 (CCPA 1970). For the reasons set forth in detail, *infra*, the Challenged Claims are more likely than not unpatentable for indefiniteness under 35 U.S.C. § 112(b).

1. Ground 3: Indefiniteness of the Challenged Claims Based on Claim Element Nos. [1.4/13.4], [1.6/13.6], and [13.8]

The elements recited in the New Matter and the Challenged Claims of "a distal member positioned at a distal end of the shaft, the distal member having a

forward end and a rearward end," [Claim Element Nos. 1.4/13.4]; "a right edge and a left edge extending towards the rearward end from the tip," [Claim Element Nos. 1.6/13.6]; and "wherein a width between the right and left edges increases as they extend rearward," [Claim Element No. 13.8], are supported by neither the rest of the '391 Patent, nor the purported priority applications. Not only do the claim terms ***distal member***, ***right edge***, ***left edge***, and ***a width between the right and left edges*** not appear in these disclosures, but as the Condon Declaration, Ex. 1012, explains, a POSA would find the New Matter and the Challenged Claims to conflict irreconcilably with the rest of the '391 Patent and the purported priority applications.

The internal inconsistency in the '391 Patent created by the New Matter is fatal to the Challenged Claims, the "objective boundaries" of which, therefore, are unclear and cannot be understood by a POSA with any reasonable certainty. *See Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364, 1371 (Fed. Cir. 2014) (citation omitted). In any event, the New Matter recitation *ipsis verbis* of the Challenged Claims notwithstanding, the '391 Patent provides no teaching – by way of drawings, examples, data, or otherwise – of any device having Claim Element Nos. 1.4/13.4, 1.6/13.6, or 13.8, or any methods using such a device for incising a trabecular meshwork (TM) to form an opening in the TM tissue of an eye.

Patent Owner's wholesale importation of the New Matter from Baerveldt creates this unresolvable paradox. Baerveldt teaches Claim Element Nos. 1.4/13.4, 1.6/13.6, and 13.8, and makes clear how they relate to each other and the other elements described in that disclosure. Ex. 1009 at ¶0039; *see also* FIG. 2 of Baerveldt (reproduced at Section IV.A.1., *supra*). Accordingly, the elements recited in the New Matter and the Challenged Claims only make sense in the proper context of ***Petitioner's*** invention in Baerveldt.

In sum, no claim may be read apart from and independent of the supporting disclosure on which it is based. *In re Cohn,* 438 F.2d at 993. Even if a POSA were unaware that Patent Owner copied Baerveldt, a POSA would necessarily conclude that Claim Element Nos. 1.4/13.4, 1.6/13.6, and 13.8 are unclear, and that the '391 Patent fails to inform those skilled in the art what the claim elements "a distal member positioned at a distal end of the shaft, the distal member having a forward end and a rearward end," [Claim Element Nos. 1.4/13.4]; "a right edge and a left edge extending towards the rearward end from the tip," [Claim Element Nos. 1.6/13.6]; and "wherein a width between the right and left edges increases as they extend rearward," [Claim Element No. 13.8], mean with any reasonable certainty as required under 35 U.S.C. § 112(b). Ex. 1012 at ¶63. Accordingly, the Challenged Claims are more likely than not unpatentable for indefiniteness under 35 U.S.C. § 112(b).

C. Grounds 4 & 5: The Challenged Claims Are Unpatentable as Anticipated Under 35 U.S.C. § 102 and/or Rendered Obvious Under 35 U.S.C. § 103 by International Patent Publication WO 2018/151808 A1("Baerveldt")

Because the Challenged Claims of the '391 Patent are not entitled to an effective filing date earlier than November 8, 2019 (*see supra* Section VI. A-C), Baerveldt is prior art under 35 U.S.C. § 102(a)(2).

Although Petitioner submits that the Challenged Claims are unpatentable because they violate 35 U.S.C. § 112 for lack of written description and indefiniteness, the Challenged Claims should also be found unpatentable because they are anticipated under 35 U.S.C. § 102 and/or rendered obvious under 35 U.S.C. § 103 by Baerveldt.

1. Prior Art Disclosure (Baerveldt)

Baerveldt teaches, *inter alia*, devices and methods useable for forming opening in the trabecular meshwork of eyes. Ex. 1009 at ¶0009. As depicted in annotated FIG. 2 below, Baerveldt teaches a device which "comprises a shaft and a distal member or foot on a distal end of the shaft. The distal member or foot may have a forward tip, a right edge, a left edge and a transversely concave depression, cavity or space between the right and left edges." *Id*. at ¶0010.

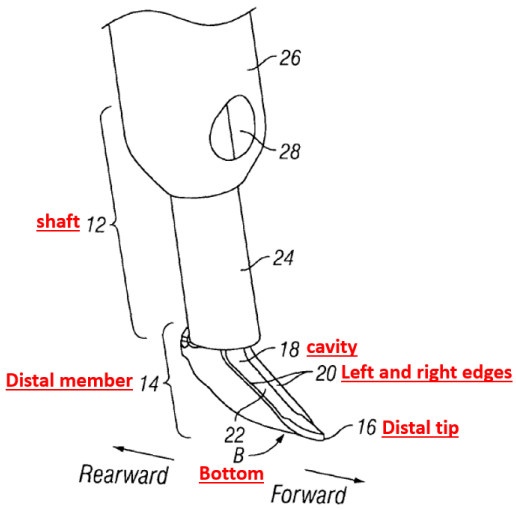


FIG. 2

As depicted in FIG. 7 below, Baerveldt also teaches a method useable for forming opening in the trabecular meshwork of eyes. *See id*. at ¶0063 ("In use, as shown in FIG. 7, as the distal member 14 advances through Schlemm's canal, TM tissue will ride over the non-planar, progressively rotating edges 20 and will bridge or be suspended across the open cavity 18 until the edges 20 (with or without optional cutting surfaces 21) have formed cuts or severances in the TM tissue. The resultant strip of laterally cut or severed TM tissue may then be aspirated from cavity 18 into the open distal end of tube 24, in embodiments which utilize aspiration.")

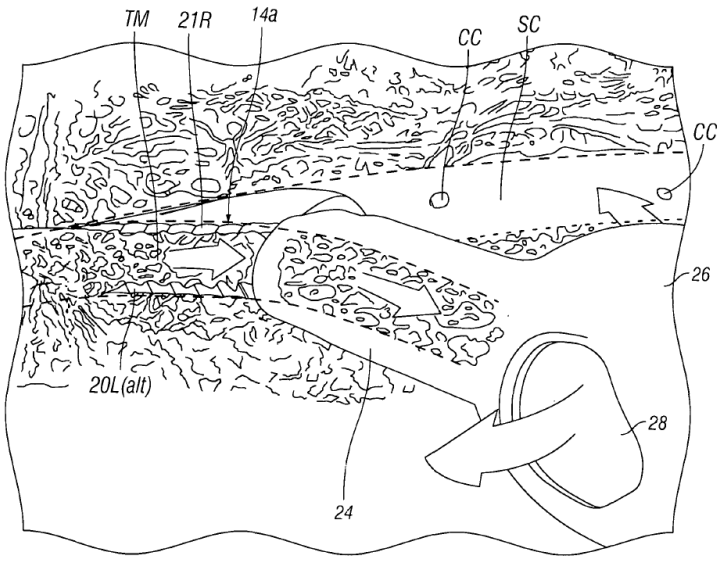


FIG. 7

As explained in detail at Section IV.A., *supra*, the New Matter and the Challenged Claims use terms not found in the rest of the ’391 Patent or any of the purported priority applications. Patent Owner’s wholesale importation of the New Matter from Baerveldt explains how and why each and every element of the Challenged Claims may be found expressly recited in Baerveldt.

2. Ground 4: The Challenged Claims Are Anticipated by Baerveldt

The table below summarizes how each and every element of the Challenged Claims are disclosed expressly or inherently in Baerveldt, which therefore anticipates Claims 1-20 of the ’391 Patent.

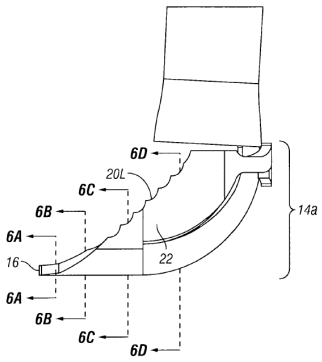
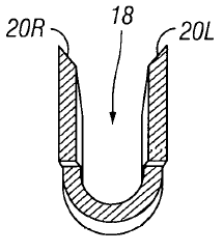
Ref. No.	Claim Element	Prior Art Disclosure (Baerveldt) Ex. 1009
1.1	A method for incising a trabecular meshwork to form an opening in trabecular meshwork tissue of an eye having a Schlemm's Canal, an anterior chamber and a trabecular meshwork, the method comprising:	Claim 17 of Baerveldt recites "[a] method for using a device according to any of claims 1 through 16 to form an opening in trabecular meshwork tissue of an eye having a Schlemm's Canal, an anterior chamber and a trabecular meshwork, said method comprising." Baerveldt teaches a "method useable for forming opening in the trabecular meshwork of eyes to facilitate drainage of aqueous humor and resultant lowering of intraocular pressure" *Id.* at ¶0009.
1.2	providing a device comprising:	Baerveldt teaches a device. *Id. at* ¶0010.
1.3	a shaft;	Claim 1 of Baerveldt recites "[a] device comprising: a shaft." Baerveldt teaches that the device comprises "a shaft." *Id.* at ¶0010.
1.4	a distal member positioned at a distal end of the shaft, the distal member having a forward end and a rearward end;	Claim 1 of Baerveldt recites "a distal member positioned at a distal end of the shaft, said distal member having a forward end and a rearward end." Baerveldt teaches that the device comprises "a distal member or foot on a distal end of the shaft." *Id*. at ¶0010.
1.5	a tip disposed at the forward end of the distal member;	Claim 1 of Baerveldt recites "a forward tip formed at the forward end of the distal member." *see also id.* at FIG. 2.
1.6	a right edge and a left edge extending towards the rearward end from the tip,	Claim 1 of Baerveldt recites "a right edge and a left edge progressing rearwardly from the forward tip." *See also id.* at FIG. 2.
1.7	wherein the right edge and the left edge increase in height as they extend rearward; and	Claim 4 of Baerveldt recites "the right edge and left edge increase in height as they progress rearward." Baerveldt teaches that "the edges 20 progress rearward, they progressively increase in height" *Id. at* ¶0062; *see also id.* at FIG. 2

Ref. No.	Claim Element	Prior Art Disclosure (Baerveldt) Ex. 1009
1.8	a gap rearward of the tip and between the right edge and the left edge,	Claim 1 of Baerveldt recites "a depression, trough, cavity or open area rearward of the forward tip and between the right edge and the left edge." Baerveldt teaches "a transversely concave depression, cavity or space between the right and left edges" *Id.* at ¶0010; and "a cavity or open area 18 between the side walls 22 and rearward of the forward tip 16." *Id.* at ¶0038; *see also id.* at FIG. 2. Furthermore, a gap between the right edge and the left edge is equivalent to a depression, trough, cavity or open area between the right edge and the left edge.
1.9	the gap defining an unoccupied space that is not part of a lumen,	Baerveldt teaches that a lumen is optional. *See Id. at* ¶0010 ("the device may ***optionally*** include lumens, opening or ports and associated connectors for infusing irrigation fluid and/or aspirating fluid and/or matter from the eye.")[3]

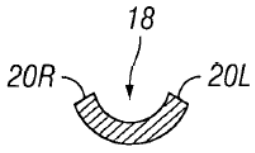
[3] A prior art teaching or suggestion that a claim element is ***optional or unnecessary*** applies to products and processes that embody, as well as those that do not embody, such an element. See *Upsher-Smith Lab'ys., Inc. v. Pamlab, LLC*, 412 F.3d 1319, 1322 (Fed. Cir. 2005).

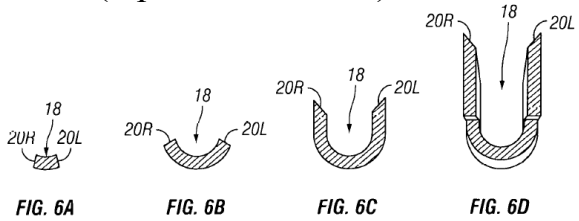
Ref. No.	Claim Element	Prior Art Disclosure (Baerveldt) Ex. 1009
1.10	wherein at least portions of the right and left edges are configured to cut trabecular meshwork tissue as the trabecular meshwork tissue advances in a rearward direction over the right and left edges;	Claim 1 of Baerveldt recites "wherein at least portions of the right and left side edges are configured to cut tissue as the tissue advances in the rearward direction over the right and left edges." *See also id.* at FIG. 7.
1.11	inserting a distal portion of the device into the anterior chamber, the distal portion including the distal member;	Claim 17 of Baerveldt recites "inserting into the anterior chamber a distal portion of said device, said distal portion including the distal member." Baerveldt teaches to "[i]nsert the shaft 12 and distal member 14 through the corneal incision and into the anterior chamber of the patient's eye." Ex. 1009 at 13 (Step 9).
1.12	advancing the distal member, the tip first, through the trabecular meshwork and into the Schlemm's Canal; and	Claim 17 of Baerveldt recites "advancing the distal member, front tip first, through the trabecular meshwork and into Schlemm's Canal." *See also id.* at FIG. 7.

Ref. No.	Claim Element	Prior Art Disclosure (Baerveldt) Ex. 1009
1.13	advancing the distal member, tip first, through the Schlemm's Canal such that trabecular meshwork tissue contacts and is severed by the right and left edges of the distal member	Claim 17 of Baerveldt recites "advancing the distal member, front tip first, through Schlemm's Canal such that trabecular meshwork tissue contacts and is severed by the right and left edges of the distal member." Baerveldt teaches that "[t]his optional widening or non-parallelism of the side walls 22 and/or edges 20 may serve to transverse stretch or transversely tighten tissue as it advances up the progressively-widening, upwardly-sloping regions of edges 20," *id.* at ¶0039; and "[t]he foot or distal member 14b or 14c is then advanced through Schlemm's Canal with the TM tissue being severed by edges 56R and 56L on the forward aspects of wing members 62," *id. at* ¶0073. *See also id.* at FIG. 7.
2	The method according to claim 1, wherein when the distal member is advanced into the Schlemm's Canal, a bottom surface of the distal member is juxtaposed to a back wall of the Schlemm's Canal.	Baerveldt teaches that "[w]hen the forward tip 16 pierces the TM and the distal member 14 is advanced into Schlemm's Canal, the back wall of Schlemm's canal will be juxtaposed to the bottom surface B." *Id.* at ¶0059; *see also id.* at FIG. 7.

Ref. No.	Claim Element	Prior Art Disclosure (Baerveldt) Ex. 1009
3	The method according to claim 1, wherein when the distal member is advanced through the Schlemm's Canal a transversely concave bottom surface of the distal member is configured to abut and be atraumatic to a back wall of the Schlemm's Canal.	Baerveldt teaches that "[t]he bottom B of the distal member 14 is preferably smooth and atraumatic to the outer wall of Schlemm's Canal. . . . The distal member 14 in this non-limiting example is transversely concave or U-shaped." *Id.* at ¶0045. *See also id.* at FIGs. 6 and 6D.  FIG. 6  FIG. 6D
4	The method according to claim 1, wherein when the distal member is advanced through the Schlemm's Canal, the trabecular meshwork tissue is lifted away from a back wall of the Schlemm's canal.	Baerveldt teaches that "[a]s TM tissue advances over the edges 20, the incline of the edges will cause the TM tissue to be lifted away from the back wall of Schlemm's canal." *Id.* at ¶0061.
5	The method according to claim 1, wherein when the distal member is advanced through the Schlemm's Canal, the trabecular meshwork tissue is transversely stretched over the gap.	Baerveldt teaches that "[t]his optional widening or non-parallelism of the side walls 22 and/or edges 20 may serve to transverse stretch or transversely tighten tissue as it advances up the progressively-widening, upwardly-sloping regions of edges 20." *Id.* at ¶0039. When the tissue advances up the progressively-widening, upwardly-sloping regions of edges, the tissue is over the gap and thus is transversely stretched over the gap. *See id.* at Fig. 7.

Ref. No.	Claim Element	Prior Art Disclosure (Baerveldt) Ex. 1009
6	The method according to claim 1, further comprising removing the severed trabecular meshwork tissue by one of forceps and aspiration.	Baerveldt teaches that "[o]nce a strip of TM tissue has been severed and detached, if it is not fully removed by aspiration through the inner tube 24 as described above, micro-forceps can be used to manually grasp and remove such tissue in accordance with operative techniques known in the field of Ophthalmology." Ex. 1009 at 12 (Step 13).
7	The method according to claim 1, wherein as the trabecular meshwork tissue advances over the right and left edges, an incline of the right and left edges is configured to cause the trabecular meshwork tissue to be lifted away from a back wall of a Schlemm's canal.	Baerveldt teaches that "[a]s TM tissue advances over the edges 20, the incline of the edges will cause the TM tissue to be lifted away from the back wall of Schlemm's canal." *Id.* at ¶0061.

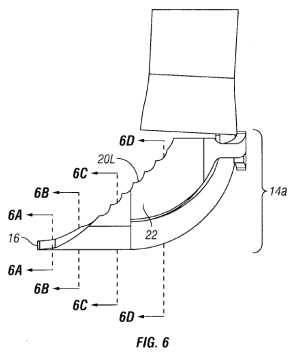
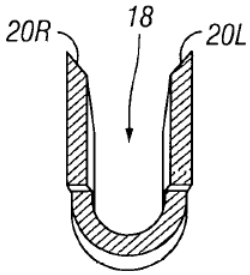
Ref. No.	Claim Element	Prior Art Disclosure (Baerveldt) Ex. 1009
8	The method of claim 1, wherein a width between the right and left edges increases from a first width at a forward-most portion of the distal member to a second width, greater than the first width, at a rearward portion of the distal member.	Baerveldt teaches that "the width between the edges may become wider as it progresses rearwardly." *Id. at* ¶0010. "At the same time, in embodiments where the width between the edges (e.g., W1, W2, W3) becomes wider." *Id.* at ¶0061. Because the width between the right and left edges may become wider as it progresses rearwardly, the first width W1 at the forward-most portion of the distal member would be less than the second width W2 at a rearward portion of the distal member. Because the width between the right and left edges may become wider as it progresses rearwardly, the width at a rearward portion of the distal member would be greater than the width at a forward-most portion of the distal member, *i.e.*, the tip.
9	The method of claim 8, wherein the first width is between 0.2 to 0.3 mm inclusive.	Baerveldt teaches that "the forward-most portion of the distal member 14 may have a first width W1. Width W1 may be about 230 microns (0.009 inches). For good clinical utility, given the elasticity and deformity of Schlemm's canal, this width W1 may vary between about 150–300 microns (0.006-.012 inches)" *Id.* at ¶0058. The width of the distal member is equivalent to the width between the right and left edges (20R & 20L). *See id.* at FIG. 6B (reproduced below).  FIG. 6B

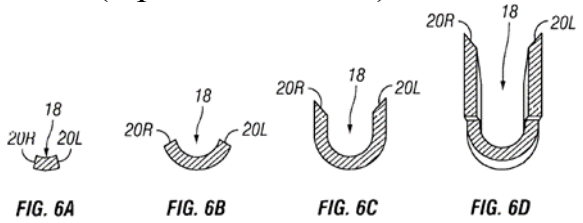
Ref. No.	Claim Element	Prior Art Disclosure (Baerveldt) Ex. 1009
10	The method of claim 1, wherein a bottom surface of the distal member has a maximum width that is less than a maximum width of the distal member.	A bottom surface of the distal member has a maximum width that is less than a maximum width of the distal member. *See id.* at FIGs. 6A-6D (reproduced below).  FIG. 6A FIG. 6B FIG. 6C FIG. 6D
11	The method of claim 1, wherein, at a first location on the tip, the right edge and left edge are positioned at a first height and oriented at a first orientation that is substantially vertical.	Claim 6 of Baerveldt recites "at a first location on the front tip, the right edge and left edge are positioned at a first height and oriented at a first orientation that is vertical or near vertical." Baerveldt teaches that "[a]t a location near the forward tip 16 the edges may be vertical or nearly vertical and converge at the forward end to form a pointed or blunt point on the forward tip 16 that is capable of penetrating through TM tissue." *Id.* at ¶0062.
12	The method of claim 1, wherein at least portions of the right and left edges are angled between 20 and 90 degrees with respect to a bottom surface of the distal member.	Claim 23 of Baerveldt recites "the first and second side edges incline at angles of from approximately 20 degrees to approximately 70 degrees relative to a linear axis that extends tangentially to the bottom surface at the tip."

Ref. No.	Claim Element	Prior Art Disclosure (Baerveldt) Ex. 1009
13.1	A method for incising a trabecular meshwork to form an opening in trabecular meshwork tissue of an eye having a Schlemm's Canal, an anterior chamber and a trabecular meshwork, the method comprising:	Baerveldt teaches "method useable for forming opening in the trabecular meshwork of eyes to facilitate drainage of aqueous humor and resultant lowering of intraocular pressure" *Id.* at ¶0009.
13.2	inserting a distal portion of a device into the anterior chamber, the device comprising:	Claim 17 of Baerveldt recites "inserting into the anterior chamber a distal portion of said device, said distal portion including the distal member." Baerveldt teaches that "[i]nsert the shaft 12 and distal member 14 through the corneal incision and into the anterior chamber of the patient's eye." Ex. 1009 at 13 (Step 9).
13.3	a shaft;	Claim 1 of Baerveldt recites "[a] device comprising: a shaft." Baerveldt teaches that the device comprises "a shaft." *Id.* at ¶0010.
13.4	a distal member positioned at a distal end of the shaft, the distal member having a forward end and a rearward end;	Claim 1 of Baerveldt recites "a distal member positioned at a distal end of the shaft, said distal member having a forward end and a rearward end." Baerveldt teaches that the device comprises "a distal member or foot on a distal end of the shaft." *Id.* at ¶0010.
13.5	a tip disposed at the forward end of the distal member;	Claim 1 of Baerveldt recites "a forward tip formed at the forward end of the distal member." *See also id.* at FIG. 2.
13.6	a right edge and a left edge extending towards the rearward end from the tip,	Claim 1 of Baerveldt recites "a right edge and a left edge progressing rearwardly from the forward tip." *See also id.* at FIG. 2.

Ref. No.	Claim Element	Prior Art Disclosure (Baerveldt) Ex. 1009
13.7	wherein the right edge and the left edge increase in height as they extend rearward; and	Claim 4 of Baerveldt recites "the right edge and left edge increase in height as they progress rearward." Baerveldt teaches that "the edges 20 progress rearward, they progressively increase in height" *Id.* at ¶0062; *see also id.* at FIG. 2.
13.8	wherein a width between the right and left edges increases as they extend rearward; and	Claim 37 of Baerveldt recites "wherein the separation or width between the right edge and the left edge increases as they progress rearward." Baerveldt teaches that "the width between the edges may become wider as it progresses rearwardly." *Id.* at ¶0010.
13.9	a gap rearward of the tip and between the right edge and the left edge,	Claim 1 of Baerveldt recites "a depression, trough, cavity or open area rearward of the forward tip and between the right edge and the left edge." Baerveldt teaches that "a transversely concave depression, cavity or space between the right and left edges," *id.* at ¶0010; and "a cavity or open area 18 between the side walls 22 and rearward of the forward tip 16," *id.* at ¶0039. *See also id.* at FIG. 2. Furthermore, a gap between the right edge and the left edge is equivalent to a depression, trough, cavity or open area between the right edge and the left edge.
13.10	the gap defining an unoccupied space that is not part of a lumen,	Baerveldt teaches that a lumen is optional. *See id.* at ¶0010 ("the device may ***optionally*** include lumens, opening or ports and associated connectors for infusing irrigation fluid and/or aspirating fluid and/or matter from the eye."); *see also* n.2, *supra*.
13.11	wherein the distal portion includes the distal member;	Claim 17 of Baerveldt recites "said distal portion including the distal member."

Ref. No.	Claim Element	Prior Art Disclosure (Baerveldt) Ex. 1009
13.12	advancing the distal member, the tip first, through the trabecular meshwork and into the Schlemm's Canal; and	Claim 17 of Baerveldt recites "advancing the distal member, front tip first, through the trabecular meshwork and into Schlemm's Canal." *See also id.* at FIG. 7.
13.13	advancing the distal member, tip first, through the Schlemm's Canal such that trabecular meshwork tissue contacts, is stretched between, and is severed by the right and left edges of the distal member.	Claim 17 of Baerveldt recites "advancing the distal member, front tip first, through Schlemm's Canal such that trabecular meshwork tissue contacts and is severed by the right and left edges of the distal member." Baerveldt teaches that "[t]his optional widening or non-parallelism of the side walls 22 and/or edges 20 may serve to transverse stretch or transversely tighten tissue as it advances up the progressively-widening, upwardly-sloping regions of edges 20." *Id.* at ¶0039. "The foot or distal member 14b or 14c is then advanced through Schlemm's Canal with the TM tissue being severed by edges 56R and 56L on the forward aspects of wing members 62." *Id.* at ¶0073; *see also id.* at FIG. 7.
14	The method according to claim 13, wherein when the distal member is advanced into the Schlemm's Canal, a bottom surface of the distal member is juxtaposed to a back wall of the Schlemm's Canal.	Baerveldt teaches that "[w]hen the forward tip 16 pierces the TM and the distal member 14 is advanced into Schlemm's Canal, the back wall of Schlemm's canal will be juxtaposed to the bottom surface B." *Id.* at ¶0059; *see also id.* at FIG. 7.

Ref. No.	Claim Element	Prior Art Disclosure (Baerveldt) Ex. 1009
15	The method according to claim 13, wherein when the distal member is advanced through the Schlemm's Canal a transversely concave bottom surface of the distal member is configured to abut and be atraumatic to a back wall of the Schlemm's Canal.	Baerveldt teaches that "[t]he bottom B of the distal member 14 is preferably smooth and atraumatic to the outer wall of Schlemm's Canal. . . . The distal member 14 in this non-limiting example is transversely concave or U-shaped." *Id.* at ¶0045; *see also id.* at FIGs. 6 and 6D (reproduced below).  FIG. 6  FIG. 6D
16	The method according to claim 13, wherein when the distal member is advanced through the Schlemm's Canal, the trabecular meshwork tissue is lifted away from a back wall of the Schlemm's canal.	Baerveldt teaches that "[a]s TM tissue advances over the edges 20, the incline of the edges will cause the TM tissue to be lifted away from the back wall of Schlemm's canal." *Id.* at ¶0061.
17	The method according to claim 13, wherein when the distal member is advanced through the Schlemm's Canal, the trabecular meshwork tissue is transversely stretched over the gap.	Baerveldt teaches that "[t]his optional widening or non-parallelism of the side walls 22 and/or edges 20 may serve to transverse stretch or transversely tighten tissue as it advances up the progressively-widening, upwardly-sloping regions of edges 20." *Id.* at ¶0039. When the tissue advances up the progressively-widening, upwardly-sloping regions of edges, the tissue is over the gap and thus is transversely stretched over the gap. *See id.* at FIG. 7.

Ref. No.	Claim Element	Prior Art Disclosure (Baerveldt) Ex. 1009
18	The method of claim 13, wherein a bottom surface of the distal member has a maximum width that is less than a maximum width of the distal member.	A bottom surface of the distal member has a maximum width that is less than a maximum width of the distal member. *See id.* at FIGs. 6A-6D (reproduced below). 
19	The method of claim 13, wherein, at a first location on the tip, the right edge and left edge are positioned at a first height and oriented at a first orientation that is substantially vertical.	Claim 6 of Baerveldt recites "at a first location on the front tip, the right edge and left edge are positioned at a first height and oriented at a first orientation that is vertical or near vertical." Baerveldt teaches that "[a]t a location near the forward tip 16 the edges may be vertical or nearly vertical and converge at the forward end to form a pointed or blunt point on the forward tip 16 that is capable of penetrating through TM tissue." *Id.* at ¶0062.
20	The method of claim 13, wherein at least portions of the right and left edges are angled between 20 and 90 degrees with respect to a bottom surface of the distal member.	Claim 23 of Baerveldt recites "the first and second side edges incline at angles of from approximately 20 degrees to approximately 70 degrees relative to a linear axis that extends tangentially to the bottom surface at the tip."

As shown in the summary table above, each and every element of the '391 Patent claims is disclosed expressly or inherently in Baerveldt in the same arrangement as the '391 Patent. Accordingly, it is more likely than not that Claims

1-20 of the ’391 Patent are unpatentable as anticipated under 35 U.S.C. § 102 by Baerveldt.

3. Ground 5: The Challenged Claims Are Obvious in View of Baerveldt

For the reasons set forth in Section VII.C.2., *supra*, a POSA would find that Baerveldt teaches each and every element of the Challenged Claims expressly or inherently in the same arrangement. In any event, a POSA also would find that the general knowledge of one skilled in the art suffices to bridge any gaps between Baerveldt and the Challenged Claims. Ex. 1012 at ¶65. Accordingly, it is more likely than not that Claims 1-20 of the ’391 Patent are unpatentable as obvious under 35 U.S.C. § 103 in view of Baerveldt.

VIII. CONCLUSION

For all the foregoing reasons, it is more likely than not that Claims 1-20 of the ’391 Patent are unpatentable. Accordingly, the Board should institute post-grant review of Claims 1-20 of the ’391 Patent on all of the grounds presented herein.

Respectfully submitted,

/s/ Lawrence M. Sung

Dated: December 17, 2020

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CERTIFICATE OF COMPLIANCE WITH TYPE VOLUME LIMITATION

Pursuant to 37 C.F.R. § 42.24(d), I hereby certify that this Petition complies with the type-volume limitation of 37 C.F.R. § 42.24(a)(1)(ii) because, based upon the word count of the word-processing system used to prepare this petition, the number of words in this petition is 16,017. Pursuant to 37 C.F.R. § 42.24(a), this word count does not include "a table of contents, a table of authorities, mandatory notices under § 42.8, a certificate of service or word count, or appendix of exhibits or claim listing."

By: *[illegible]*

Dated: December 17, 2020

/s/ Lawrence M. Sung

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CERTIFICATE OF SERVICE

The undersigned certifies that the foregoing PETITION FOR POST-GRANT REVIEW OF U.S. PATENT NO. 10,786,391 was served on the following individuals today via Federal Express:

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