

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

IVANTIS, INC., ALCON RESEARCH, LLC,
ALCON VISION, LLC, and ALCON INC.,
Petitioner,

v.

SIGHT SCIENCES, INC.,
Patent Owner.

IPR2022-01530
Patent 10,314,742 B2

Before ULRIKE W. JENKS, SUSAN L. C. MITCHELL, and
ZHENYU YANG, *Administrative Patent Judges*.

JENKS, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
35 U.S.C. § 325(d)

I. INTRODUCTION

A. *Background*

Ivantis, Inc., Alcon Research, LLC, Alcon Vision, LLC, and Alcon Inc. (collectively, “Petitioner”) filed a Petition for an *inter partes* review of claims 1–3, 6–9, 12, 13, 15, and 17–20 (“the challenged claims”) of U.S. Patent No. 10,314,742 B2 (Ex. 1003, “the ’742 patent”). Paper 2 (“Pet.”). Sight Sciences, Inc. (“Patent Owner”) filed a Preliminary Response to the Petition. Paper 6 (“Prelim. Resp.”).

With our authorization, the parties filed additional pre-institution briefing to address whether we should exercise our discretion under 35 U.S.C. §§ 314(a) or 325(d). Petitioner filed “Petitioner’s Reply to Patent Owner’s Preliminary Response” addressing these issues. Paper 11 (“Reply”). Patent Owner filed “Patent Owner Sur-Reply” in response. Paper 12 (“Sur-reply”).

B. *Summary of the Institution Decision*

We have authority to determine whether to institute an *inter partes* review. *See* 35 U.S.C. § 314 (2018); 37 C.F.R. § 42.4(a) (2020). For the reasons provided below, under 35 U.S.C. § 325(d), we deny institution of an *inter partes* review.

C. *Real Parties in Interest*

Petitioner identifies Ivantis, Inc., Alcon Research, LLC, Alcon Vision, LLC, and Alcon Inc. as the real parties-in-interest. Pet. 2. Patent Owner identifies itself, Sight Sciences, Inc., as real party-in-interest. Paper 6, 1.

D. *Related Matters*

The '742 patent is at issue in *Sight Sciences, Inc. v. Ivantis, Inc.*, C.A. No. 21-1317-GBW-SRF (D. Del.). Pet. 2; Paper 4, 1. Petitioner states that it is “concurrently filing IPR petitions for three other patents in the same family as the '742 patent, all of which are asserted in the Delaware Litigation: U.S. Patent Nos. 8,287,482; 9,370,443; and 9,486,361.” Pet. 2. These filed petitions are IPR2022-01533, IPR2022-01529, and IPR2022-01540, respectively. Paper 10, 1.

E. *Asserted Grounds of Unpatentability*

Petitioner challenges the patentability of claims 1–3, 6–9, 12, 13, 15, and 17–20 of the '742 patent on following grounds:

Claim(s) Challenged	35 U.S.C. §¹	Reference(s)/Basis
1–3, 6–9, 12, 15, 17–20	102	Gharib ²
13	103	Gharib, Bergheim ³
1–3, 9, 12, 15, 17–20	102	Grieshaber ⁴
6–8	103	Grieshaber
13	103	Grieshaber, Bergheim
1–3, 9, 12, 15, 17, 18	102	Lynch ⁵
13	103	Lynch, Bergheim

¹ The Leahy-Smith America Invents Act (“AIA”) included revisions to 35 U.S.C. § 103 that became effective on March 16, 2013. Because the '742 patent issued from an application that claims priority from an application filed before March 16, 2013, we apply the pre-AIA versions of the statutory bases for unpatentability.

² U.S. Patent Application Publication No. 2002/0165478 A1, published November 7, 2002 (Ex. 1005).

³ U.S. Patent Application Publication No. 2003/0060752 A1, published March 27, 2003 (Ex. 1006).

⁴ Canadian Patent Publication No. CA 02244646 A1, published August 11, 1998 (Ex. 1012).

⁵ U.S. Patent Application Publication No. 2005/0038334 A1, published Feb. 17, 2005 (Ex. 1008).

6-8	103	Lynch, Gharib
9	103	Lynch, Burns ⁶

Pet. 3. In support of its patentability challenge, Petitioner relies on, *inter alia*, the Declaration of Dr. Michael Reynard. Ex. 1001.

F. *The '742 patent (Ex. 1003)*

The '742 patent is titled "Intraocular Implants and Methods and Kits Therefor." Ex. 1003, (54). The '742 patent relates to devices implanted into the eye "for reducing intraocular pressure" by using "the natural drainage process of the eye." *Id.*, (57).

Figure 2 of the '742 patent is reproduced below.

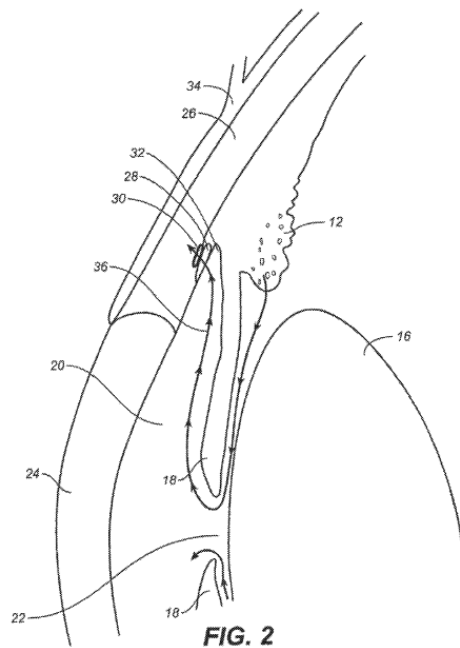


Figure 2, above, is a partial cross-sectional side view of a normal fluid drainage path from the eye. *Id.* at 5:20-21. Figure 2 depicts the general flow of aqueous humor from ciliary body 12, between lens 16 and iris 18, through

⁶ U.S. Patent Application Publication No. 2004/0147870 A1, published July 29, 2004 (Ex. 1007).

pupil 22 into the anterior chamber 20, across the trabecular meshwork 28, across Schlemm's canal 30, and into aqueous veins or collector channels (not shown). *Id.* at 6:53–56. Schlemm's canal 30 extends 360° circumferentially around trabecular meshwork 28. *Id.* at 6:42–44; Fig. 3.

Glaucoma is characterized by an increase in intraocular pressure, which may lead to blindness if left untreated. *Id.* at 1:27–30. To treat glaucoma, pre-glaucoma, and ocular hypertension, the '742 patent explains that the standard surgical treatment of “trabeculectomy, or filtration surgery. . . creat[es] a new drainage site for aqueous humor.” *Id.* at 2:7–9. Trabeculectomy, however, introduces the risk of, *inter alia*, “blockage of the surgically-created opening through scarring or other mechanisms, hypotony or abnormally low intraocular pressure.” *Id.* at 2:18–23.

As an alternative to trabeculectomy, “stents can be inserted between the anterior chamber of the eye and Schlemm's canal, bypassing the trabecular meshwork.” *Id.* at 2:26–28. Another alternative to trabeculectomy inserts “tubular elongated cylindrical hollow stents longitudinally into Schlemm's canal,” which measures approximately 190–370 μM in cross-sectional diameter. *Id.* at 2:38–39. A negative aspect of bypass stents is that they “can lose functionality over time as a result of occlusion or scarring.” *Id.* at 2:35–37. Further, because “Schlemm's canal is small,” stents are said to be “difficult or expensive to design and manufacture.” *Id.* at 2:38–40. According to the '742 patent, the walls of tubular stents “can have significant surface area contact with the trabecular meshwork and/or the collector channels, which can result in blockage of the meshwork or collector channels, substantially interfering with transmural flow across Schlemm's canal and into the eye's collector channel.” *Id.* at 2:46–52.

The '742 patent purports to resolve these problems with “devices for reducing pressure within the eye” comprising “a support implantable circumferentially within Schlemm’s canal that is configured to maintain the patency of at least a portion of the canal.” *Id.* at 2:61–67. The '742 patent explains that “[b]y ‘maintain the patency’ of at least a portion of the canal, it is meant that the support operates to keep the canal at least partially unobstructed to transmural flow, such that fluid can 1) exit through the trabecular meshwork; 2) traverse the canal; and 3) drain via the collector channels.” *Id.* at 7:36–41.

Figure 10B of the '742 patent is reproduced below.

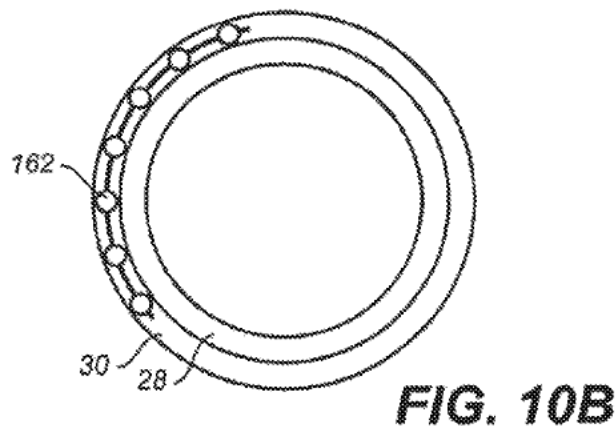


Figure 10B, above, is a configuration of support 162 implanted into and extending less than half way around Schlemm’s canal 30. *Id.* at 5:58–59; 12:1–2. Figure 10B also shows trabecular meshwork 28 adjacent to canal 30. *Id.* at 5:58–59; 12:52–53.

The '742 patent describes supports having a bowed or arcuate shape smaller or larger than the radius of curvature of Schlemm’s canal. *Id.* at 12:9–39. Figure 11D of the '742 patent is reproduced below.

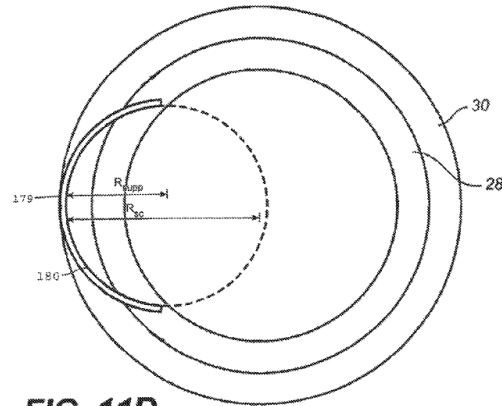


FIG. 11D

Figure 11D, above, illustrates a configuration of support 179 having a smaller radius of curvature than Schlemm's canal 30. *Id.* at 5:60–61. The '742 patent discloses that support 179 comprises arcuate member 180 having a radius of curvature R_{supp} that is less than the radius of curvature R_{sc} of canal 30. *Id.* at 12:20–22. The stiffness of arcuate member 180 is said to urge canal 30 open. *Id.* at 12:22–23. Figure 11D illustrates that support 179 extends out of Schlemm's canal 30 into adjacent trabecular meshwork 28. *Id.* at 12:52–53.

1. Illustrative Claim

Claim 1 is the sole independent claim challenged by Petitioner in this proceeding. Independent claim 1, reproduced below, is illustrative of the subject matter:

1. A method for treating an eye condition, comprising:
implanting a support within Schlemm's canal, wherein the support comprises an arcuate member, wherein at least a portion of the arcuate member has a radius of curvature smaller than the radius of curvature of Schlemm's canal such that at least a portion of the arcuate member extends out of Schlemm's canal.

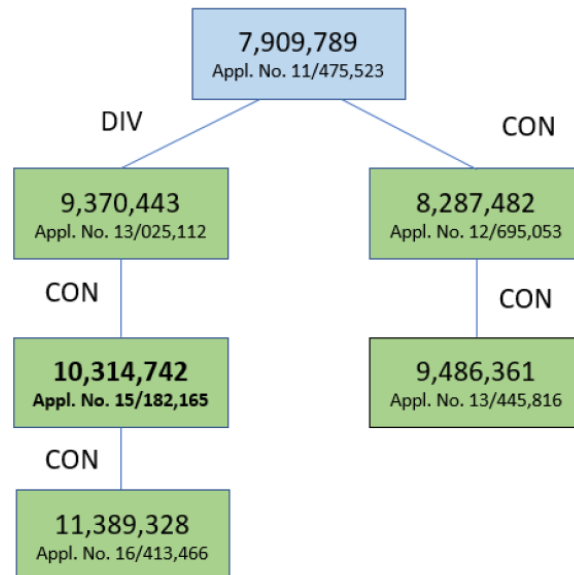
Id. at 18:37–7:43.

II. ANALYSIS

A. *Discretion Under 35 U.S.C. 325 (d)*

We first consider Patent Owner’s request that we deny institution⁷ under 35 U.S.C. § 325(d). Prelim. Resp. 9–52. Patent Owner contends that Petitioner’s alleged prior art was presented previously to Examiner during prosecution of the ’742 patent and its parent applications. *Id.*

In the Patent Owner Response, Patent Owner provides a patent family tree, reproduced below.



The patent family tree shows that “[t]he ’443 is a parent and the ’789 is a grandparent of the ’742” patent. Prelim. Resp. 8. Patent Owner argues that the same “Primary Examiner . . . examined all patents in this family. (*See*

⁷ Patent Owner presents an alternative basis for denying institution under 35 U.S.C. § 314(a) based on *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 (PTAB Mar. 20, 2020) (precedential) and the Director’s Memo re Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings with Parallel District Court Litigation (“Vidal Memo”), at 4 (June 21, 2022). Prelim Resp. 76–81. Because we deny institution based on 35 U.S.C. § 325(d) need not separately reach a conclusion based on *Fintiv* in this decision.

'789; '443; '742.).” *Id.* Patent Owner argues that discretionary denial is appropriate because

[a]ll Grounds in the Petition rely on one of three primary references: Gharib [(Ex. 1005)], Grieshaber [(Ex. 1012)] or U.S. Patent Application Publication 2005/0038334 (“Lynch ’334” or “Lynch”) (Ex.1008). These references are identical to or substantially the same as (and cumulative of) references that were considered during prosecution of the ’742 patent and related applications.

Prelim. Resp. 11. Additionally, Patent Owner contends that Petitioner makes “no attempt to establish that the Examiner ‘erred in evaluating the art or arguments’ previously presented.” *Id.*

Institution of *inter partes* review is discretionary. *See Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1367 (Fed. Cir. 2016) (“the PTO is permitted, but never compelled, to institute an IPR proceeding”). Section 325(d) provides that the Director may elect not to institute⁸ a proceeding if the challenge to the patent is based on matters previously presented to the Office. *Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH*, Case IPR2019-01469, Paper 6 (February 13, 2020) (precedential) (“*Advanced Bionics*”). “Previously presented art includes art made of record by the Examiner, and art provided to the Office by an applicant, such as on an Information Disclosure Statement (IDS), in the prosecution history of the challenged patent.” *Id.* at 7–8.

Advanced Bionics sets out a two-part framework for evaluating “whether the petition presents to the Office the same or substantially the same art previously presented to the Office.” *Advanced Bionics* at 7. *Advanced Bionics* two-part framework reads as follows:

⁸ The Board institutes trial on behalf of the Director. 37 C.F.R. § 42.4(a).

- (1) whether the same or substantially the same art previously was presented to the Office or whether the same or substantially the same arguments previously were presented to the Office; and
- (2) if either condition of first part of the framework is satisfied, whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of challenged claims.

Id. at 8.

In Part 1 of the *Advanced Bionics* two-part framework, we evaluate *Becton, Dickinson* factors (a), (c) and (d). *Advanced Bionics* at 10. (citing *Becton, Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8, 17–18 (PTAB Dec. 15, 2017) (precedential as to § III.C.5, first paragraph) (“*Becton Dickson*”). If it is determined that the same or substantially the same art or arguments previously were presented to the Office, we then turn to Part Two of *Advanced Bionics* framework. In Part 2 we evaluate *Becton, Dickinson* factors (c), (e) and (f).

Becton, Dickinson identifies the following non-exclusive factors:

- (a) the similarities and material differences between the asserted art and the prior art involved during examination;
- (b) the cumulative nature of the asserted art and the prior art evaluated during examination;
- (c) the extent to which the asserted art was evaluated during examination, including whether the prior art was the basis for rejection;
- (d) the extent of the overlap between the arguments made during examination and the manner in which Petitioner relies on the prior art or Patent Owner distinguishes the prior art;
- (e) whether Petitioner has pointed out sufficiently how the Examiner erred in its evaluation of the asserted prior art; and
- (f) the extent to which additional evidence and facts presented in the Petition warrant reconsideration of prior art or arguments.

We analyze these factors below as they apply to the record in this proceeding, and find that, on balance, the factors weigh in favor of exercising our discretion under 35 U.S.C. § 325(d).

1. Gharib

Petitioner contends that “[t]he grounds presented in the petition include anticipation and obviousness challenges applying Gharib, Grieshaber, and Lynch as base references, none of which was applied against the Challenged Claims or discussed by the Examiner during prosecution of the ’742 patent or its parent applications.” Pet. 16; *see* Reply 2. Petitioner contends that the Petition includes challenges applying Gharib that was not applied against the challenged claims or discussed by Examiner during prosecution of the ’742 patent or its parent applications, therefore, weighing against exercising our discretion under §325(d). Pet. 16 (citing *Fasteners for Retail, Inc. v. RTC Indus., Inc.*, IPR2019-00994, Paper 9 at 7–11 (PTAB Nov. 5, 2019)); *see* Reply 2. With respect to claim 13, Petitioner additionally presents challenges based on the combination of Gharib and Bergheim. Pet. 36–48.

According to Petitioner, during prosecution of the ’742 patent parent application Examiner rejected the claims over Neuhann. Because “Neuhann’s support resides entirely within Schlemm’s canal and therefore does not meet the limitation” of the ’742 patent claims. Pet. 17. Petitioner argues that Gharib’s “continuous structure does not detach and instead forms an arcuate shape that traverses the trabecular meshwork and resides in Schlemm’s canal when implanted,” and therefore is not cumulative to Neuhann. Reply 4; Pet. 17. Petitioner further contends that “Gharib ’478 and Lynch ’334 are not cumulative to Neuhann because each addresses the

deficiency Patent Owner argued Neuhann suffers from.” Reply 3.

Specifically, Petitioner contends that

Gharib ’478 [(Ex. 1005)] discloses a device comprising a bifurcatable outlet section that partly resides inside Schlemm’s canal and extends out into the trabecular meshwork through a continuous connection to the inlet section. . . . Gharib ’478’s continuous structure does not detach and instead forms an arcuate shape that traverses the trabecular meshwork and resides in Schlemm’s canal when implanted.

Reply 4.

Patent Owner disagrees. Patent Owner argues that Gharib (Ex. 1005) asserted against the claims here is identical to issued patent Gharib ’841 (Ex. 2005; *see also* Ex. 2006 (Redline comparison of text)) that was before Examiner. Prelim. Resp. 12. Patent Owner argues that Petitioner is presenting art and arguments that are the same or substantially the same art as considered by Examiner during prosecution of the application leading to the ’742 patent. *Id.* “Gharib ’841 contains identical text and figures as Gharib cited in the Petition.” *Id.* at 14 (Ex. 2006 (Redline comparison of text)); *see* Sur-reply 2–4. Patent Owner argues that Petitioner presents an improper new argument in their Reply regarding Gharib that is not supported by Petitioner’s declarant, Gharib, or the Petition. Sur-reply 4. Finally, Patent Owner argues that “Gharib and Bergheim are substantially the same and cumulative of the art and arguments previously considered by the Office.” Prelim Resp. 14.

- a) *Part 1 (Becton, Dickinson Factors (a), (b), (d)): Examiner considered substantially the same art and/or arguments during prosecution*

We begin by considering *Becton, Dickinson* Factor (a): The similarities and material differences between the asserted art and the prior art involved during examination.

Patent Owner contends that Gharib's patent application publication (Ex. 1005) is identical and cumulative to the issued patent Gharib '841 (Ex. 2005). Prelim. Resp. 12. Specifically, "Gharib '841 contains identical text and figures as Gharib cited in the Petition." Prelim. Resp. 13 (*Compare Ex. 2005, with Ex. 1005; see also Ex. 2006 (Redline comparison of text)*).

According to Patent Owner, Gharib '841 was listed in an IDS and acknowledged by Examiner. Prelim. Resp. 12 (Ex. 2007, 668-76 (Cite No. 118)). Patent Owner argues that "the Board has held that an IDS citation alone is deemed previously presented to, and considered by, the Office." Prelim. Resp. 13 (citing *Advanced Bionics*, IPR2019-01469, Paper 6 at 7-8 (PTAB Feb. 13, 2020); *Microsoft Corp. v. Koninklijke Philips N.V.*, IPR2018-00279, Paper 11 at 12, 14-15 (PTAB June 8, 2018); *Eyenovia, Inc. v. Sydnexis*, IPR2022-00963, Paper 7 at 10-11 (PTAB Nov. 8, 2022); *Fellowes, Inc. v. Treefrog Devs., Inc.*, IPR2020-01509, Paper 11 at 7-8, 17 (PTAB Feb. 22, 2021); *Ocado Grp. PLC v. Autostore Tech. AS*, IPR2021-00412, Paper 9 at 34-35 (PTAB July 21, 2021)); *see* Sur-reply 2 (citing additional Board decisions to support the position that there is no requirement for Examiner to have applied a reference in a rejection for the reference to be considered previously presented to the Office).

We recognize that Examiner did not expressly rely on Gharib '841 during prosecution of the '742 patent. Nonetheless, Patent Owner presents

persuasive arguments and supporting evidence that the disclosures in Gharib '841 was previously presented to Examiner. Thus, Patent Owner argues persuasively that Examiner considered many similar prior art references, including references containing the same figures that Petitioner asserts here, during the prosecution leading to the '742 patent. *See, e.g.*, Ex. 2006 ((Redline comparison of text) (*Compare* Ex. 1005, *with* Ex. 2005)). Accordingly, we find that, with respect to Gharib, this factor weighs in Patent Owner's favor.

We next consider *Becton, Dickinson* Factor (b): The cumulative nature of the asserted art and the prior art evaluated during examination.

Patent Owner contends that Gharib's patent application publication (Ex. 1005) is identical and cumulative to the issued patent Gharib '841 (Ex. 2005). Prelim. Resp. 12. Specifically, "Gharib '841 contains identical text and figures as Gharib cited in the Petition." *Id.* at 13 (*Compare* Ex. 2005, *with* Ex. 1005; *see also* Ex. 2006 (Redline comparison of text)). We are persuaded by Patent Owner's arguments and supporting evidence that the disclosures of Gharib was previously presented to Examiner and that these disclosures are cumulative to the art considered during prosecution. Accordingly, we find that this factor weighs in Patent Owner's favor.

To complete Part 1 of the *Advanced Bionics* two-part framework we consider *Becton, Dickinson* Factor (d): The extent of the overlap between the arguments made during examination and the manner in which Petitioner relies on the prior art or Patent Owner distinguishes the prior art.

According to Patent Owner, Petitioner's "arguments based on Gharib overlap with arguments previously considered by the Office during prosecution of the '443 parent patent. . . . Petitioner[] offer[s] the same obviousness arguments based on Gharib that the Examiner raised for the

same limitations of the parent '443 patent based on Neuhann.” Prelim. Resp. 14; *see* Ex. 1004, 898–99. Patent Owner argues that “Examiner noted that Neuhann’s apparatus comprises ‘wires [that] may sever trabecular formations, necessarily extending out of Schlemm’s canal and into the trabecular meshwork,’ and ‘[t]he small radius of curvature allows the wire to penetrate the wall of Schlemm’s canal.” Prelim. Resp. 15 (emphasis omitted) (citing Ex. 1004, 899 (citations omitted)). This argument presented by Examiner is similar to Petitioner’s present argument that Gharib’s bifurcated apparatus forms an arcuate shape. *Id.* Patent Owner contends that Petitioner’s “arguments mimic Examiner’s argument for Neuhann’s wire stent that if a part extends into the trabecular meshwork, it has a smaller radius of curvature.” Prelim Resp. 15–16 (citing Ex. 1004, 899). “Patent Owner distinguished Neuhann during prosecution by requiring that ‘a portion of the arcuate member’ extends out of Schlemm’s canal” and into the trabecular meshwork. Prelim Resp. 16, n.4; *see* Ex. 1004, 1067. In other words, during prosecution Examiner accepted that the “arcuate member” limitation is referring to the shape of the entire support and not just a portion of the support. *See* Ex. 1004, 1067 (citing Fig. 11D); *see also id.* at Ex. 1003, Fig. 11D.

Petitioner relies on Bergheim for arriving at the limitation of dependent claim 13 that is directed to the amount of contact the device has with the internal wall surface of the Schlemm canal, specifically, the claim recites “the support contacts less than 30% of C.” *See* Pet. 45–48 (citing Ex. 1006 ¶¶ 3, 35, 73–76, 100–111, 116–119; Ex. 1001 ¶¶ 108–109).

Patent Owner argues that Bergheim (Ex. 1006) “is cumulative of the art and arguments considered and discussed by the Examiner related to U.S. Patent Application Publication 2004/0260228 (‘Lynch ’228’) (Ex.1010).”

Prelim. Resp. 18. Specifically, Patent Owner argues that Petitioner’s “reliance on Bergheim to argue that the ’742 surface area limitation is an ‘obvious step of optimizing the contact ratio between the support and the canal wall to achieve the desired aqueous fluid drainage’ is cumulative of Examiner’s argument—made thrice over—based on different prior art references.” Prelim. Resp. 18 (*see* Ex. 1004, 898–99, 719–20, 764).

During prosecution, Examiner cites Neuhann for disclosing an apparatus for retaining the patency of the Schlemm canal that does not interfere with flow across the canal. *See* Ex. 1004, 898. Examiner acknowledges that Neuhann does not discuss the ratio of contact between the stent and the wall of the Schlemm canal, concluding that “it would have been obvious to one having ordinary skill in the art at the time of invention to optimize the ratio of contact between the stent and Schlemm’s canal in order to achieve the desired aqueous fluid drainage.” Ex. 1004, 899.

Examiner during prosecution also references Lynch US 2004/0260228 (Ex. 1010) as disclosing an apparatus that “is approximately equal a portion of the radius, curvature, and diameter of Schlemm’s canal . . . [and concludes that] the ratio of contact between the stent and the internal lumen of Schlemm’s canal, such a limitation is a result-effective variable.”

Ex. 1004, 764, *see also id.* at 719 (“of the ratio of contact between the stent and the internal lumen of Schlemm’s canal, such a limitation is a result-effective variable”).

Although Examiner did not discuss the specific combination of Gharib and Bergheim presented in the Petition, we agree with Patent Owner that during prosecution of the ’742 patent and the ’443 parent patent that Examiner made similar arguments that Petitioner asserts here. *See, e.g.*, Ex. 1004, 898–99, 719–20, 764. Accordingly, we find that with respect to

Gharib and the combination of Gharib and Bergheim, this factor also weighs in Patent Owner's favor.

Having determined that Examiner during prosecution leading to the '742 patent considered substantially similar art and arguments as those presented in the Petition, we now turn to the question whether Petitioner has established that the Office materially erred.

b) Part 2 (Becton, Dickinson Factors (c), (e), (f)): Petitioner has not established that the Office materially erred

We continue our analysis by considering *Becton, Dickinson* Factor (c): The extent to which the asserted art was evaluated during examination, including whether the prior art was the basis for rejection.

Neither Gharib nor the combination of Gharib and Bergheim was cited in a rejection during the prosecution leading to the '742 patent. Although Examiner did not discuss the specific Gharib, or the Gharib and Bergheim combination presented in the Petition, we agree with Patent Owner that during prosecution of the '742 patent and the '443 parent patent that Examiner made findings similar to arguments that Petitioner asserts here. *See, e.g.*, Ex. 1004, 898–99, 719–20, 764, 1069; *see* Prelim Resp. 12–19. Patent Owner argues, and we agree, that there is no requirement that Examiner needs to rely on a reference in a rejection during prosecution in order for the reference to be “considered” during prosecution. *See* Prelim Resp. 20; *see, e.g.*, *Advanced Bionics*, Paper 6 at 7–8 (stating that previously presented art includes art cited in an IDS). Accordingly, we find that this factor weighs in Patent Owner's favor.

We next consider *Becton, Dickinson* Factor (e): Whether Petitioner has pointed out sufficiently how Examiner erred in its evaluation of the asserted prior art.

Here, Petitioner has not articulated how Examiner erred during the prosecution leading to the '742 patent. Therefore, we agree with Patent Owner that Petitioner did not meet their burden of showing material error. *See* Prelim Resp. 21; Pet. 16–17. Accordingly, we find that this factor weighs in Patent Owner's favor.

And finally, we consider *Becton, Dickinson* Factor (c): The extent to which additional evidence and facts presented in the Petition warrant reconsideration of prior art or arguments.

Patent Owner acknowledges that Petitioner presented a declaration by Dr. Michael Reynard. *See* Prelim Resp. 21; Ex. 1001. Here, Dr. Reynard looked at substantially the same references as the Examiner and comes to a different conclusion, but that is not compelling, especially when there is no explanation how the Examiner erred. Accordingly, we find that this factor also weighs in Patent Owner's favor.

2. *Grieshaber*

Petitioner contends that *Grieshaber* was not applied against the challenged claims or discussed by Examiner during prosecution of the '742 patent or its parent applications, and therefore, weighs against exercising our discretion under §325(d). Pet. 16 (citing *Fasteners for Retail*, Paper 9 at 7–11); Reply 2.

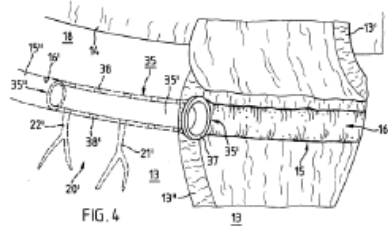
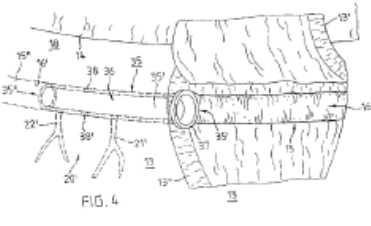
Patent Owner disagrees. Patent Owner argues that *Grieshaber* (Ex. 1012) is cumulative to *Grieshaber* '546 (Ex. 2008; *see also* Ex. 2009 (Redline comparison of text)) that was before Examiner. Prelim. Resp. 22–36. Additionally, Patent Owner argues that the combination of “*Grieshaber* and *Bergheim* are substantially the same and cumulative of the art and arguments previously considered by the Office.” *Id.* at 36.

- a) Part 1 (Becton, Dickinson Factors (a), (b), (d)): Examiner considered substantially the same art and/or arguments during prosecution*

We begin by considering *Becton, Dickinson* Factor (a): The similarities and material differences between the asserted art and the prior art involved during examination.

Patent Owner contends that “Grieshaber . . . is substantially the same as, and cumulative of Grieshaber ’546, which was considered twice during prosecution of the ’742 patent.” Prelim Resp. 22–23. Patent Owner argues that “Grieshaber ’546 is substantially similar to the primary Grieshaber reference cited in this Petition. Both references are in the same family, share the same priority application CH 1923/97, and list the same inventors.” Prelim. Resp. 24, *see also id.* at 24–35 (providing a table of similarities between the two Grieshaber references). Patent Owner acknowledges that there are slight differences between Grieshaber and Grieshaber ’546, but argues that the disclosures relied on by Petitioner are found in both references. Prelim. Resp. 35; *compare* Grieshaber (Ex. 1012), *with* Grieshaber ’546 (Ex. 2008); Ex. 2009; *see* Pet. 50 (citing Ex. 1012, 50 (Fig. 4)), *see also id.* at 51, 53, 55, 59, 60 (each citing Ex. 1012, 50 (Fig. 4)).

Patent Owner provides a comparison between Grieshaber and Grieshaber ’546 and argues that all portions of Grieshaber relied on by Petitioner are present in Grieshaber ’546. Patent Owner’s comparison of Figure 4 from each of the Grieshaber references is reproduced below:

1[c], 1[d], 2, 13, 18	Grieshaber, Figure 4 (Pet., 50- 52, 55):  FIG. 4	Ex.2008, Figure 4:  FIG. 4
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Prelim Resp. 27. The figure above shows a side-by-side reproduction of Figure 4 from Grieshaber and Grieshaber '546. *Id.* We discern no differences between these figures and agree with Patent Owner that there are many additional similarities between these references. *See* Prelim Resp. 24–35; *see also id.* at 24 (“All portions of Grieshaber on which Petitioners rely are present in Grieshaber '546”).

We recognize that Examiner did not expressly rely on Grieshaber during prosecution of the '742 patent. Nonetheless, Patent Owner presents persuasive arguments and supporting evidence that the disclosure of Grieshaber was previously presented to Examiner. Thus, Patent Owner argues persuasively that Examiner considered many similar prior art references, including references containing the same figures that Petitioner asserts here, during the prosecution leading to the '742 patent. *See, e.g.,* Ex. 2009 ((Redline comparison of text) (*compare* Ex. 1012, *with* Ex. 2008)). Accordingly, we find that with respect to Grieshaber this factor weighs in Patent Owner's favor.

We next consider *Becton, Dickinson* Factor (b): The cumulative nature of the asserted art and the prior art evaluated during examination.

Patent Owner contends that Grieshaber's Canadian patent application (Ex. 1012) is cumulative to Grieshaber '546 (Ex. 2008). Prelim. Resp. 22. Specifically, "[a]ll portions of Grieshaber on which Petitioners rely are present in Grieshaber '546." *Id.* at 24, *see also id.* at 24–35; *compare* Ex. 2008, *with* Ex.1012; *see also* Ex.2009 (Redline comparison of text). We are persuaded by Patent Owner's arguments and supporting evidence that the disclosures of Grieshaber was previously presented to Examiner and that these disclosures are cumulative to the art considered during prosecution. Accordingly, we find that this factor weighs in Patent Owner's favor.

To complete Part 1 of *Advanced Bionics* two-part framework we consider *Becton, Dickinson* Factor (d): The extent of the overlap between the arguments made during examination and the manner in which Petitioner relies on the prior art or Patent Owner distinguishes the prior art.

For the same reasons discussed above (*see* Section II.A.1.a), we agree with Patent Owner that "Grieshaber and Bergheim are cumulative of the art and arguments made or considered by the Examiner." Prelim Resp. 36. Patent Owner contends that "[a]ll portions of Grieshaber on which Petitioners rely are present in Grieshaber '546." Prelim. Resp. 24; Ex. 2009 ((Redline comparison of text) (*Compare* Ex. 1012, *with* Ex. 2008)).

Patent Owner argues that Bergheim (Ex. 1006) "is cumulative of the art and arguments considered and discussed by the Examiner related to U.S. Patent Application Publication 2004/0260228 ("Lynch '228") (Ex.1010)." Prelim. Resp. 18. Specifically, Patent Owner argues that Petitioner's reliance on Bergheim to argue that the '742 surface area limitation is an "obvious step of optimizing the contact ratio between the support and the canal wall to achieve the desired aqueous fluid drainage' is cumulative of Examiner's

argument—made thrice over—based on different prior art references.”
Prelim. Resp. 19 (*see* Ex.1004, 898–99, 719–20, 764).

Although Examiner did not discuss the specific Grieshaber and Bergheim combination presented in the Petition, we agree with Patent Owner that during prosecution of the ’742 patent and the ’443 parent patent that Examiner made similar arguments that Petitioner asserts here. *See, e.g.*, Ex.1004, 898–99, 719–20, 764. Accordingly, we find that with respect to Grieshaber and Bergheim this factor also weighs in Patent Owner’s favor.

Having determined that Examiner during prosecution leading to the ’742 patent considered substantially similar art and arguments as those presented in the Petition, we now turn to the question whether Petitioner has established that the Office materially erred.

b) Part 2 (Becton, Dickinson Factors (c), (e), (f)): Petitioner has not established that the Office materially erred

We continue our analysis by considering *Becton, Dickinson* Factor (c): The extent to which the asserted art was evaluated during examination, including whether the prior art was the basis for rejection.

Grieshaber ’546 was cited during prosecution leading to the ’742 patent but was not relied as a basis for a rejection by Examiner. Although Examiner did not discuss the specific Grieshaber, or the Grieshaber and Bergheim combination presented in the Petition, we agree with Patent Owner that during prosecution of the ’742 patent and the ’443 parent patent that Examiner made similar arguments that Petitioner asserts here. *See, e.g.*, Ex. 1004, 898–99, 719–20, 764, 1069; *see* Prelim Resp. 12–19. Patent Owner argues, and we agree, that there is no requirement that Examiner needs to rely on a reference in a rejection during prosecution in order for the reference to be “considered” during prosecution. *See* Prelim Resp. 36, *see*

also id. at 20; *see, e.g., Advanced Bionics*, Paper 6 at 7–8 (stating that previously presented art includes art cited in an IDS). Accordingly, we find that with respect to Grieshaber and Bergheim this factor weighs in Patent Owner’s favor.

We next consider *Becton, Dickinson* Factor (e): Whether Petitioner has pointed out sufficiently how Examiner erred in its evaluation of the asserted prior art.

Here, Petitioner has not articulated how Examiner erred during the prosecution leading to the ’742 patent. *See* Pet. 16–17. Therefore, we agree with Patent Owner that Petitioner did not meet their burden of showing material error. *See* Prelim Resp. 37. Accordingly, we find that this factor weighs in Patent Owner’s favor.

And finally, we consider *Becton, Dickinson* Factor (c): The extent to which additional evidence and facts presented in the Petition warrant reconsideration of prior art or arguments.

Patent Owner acknowledges that Petitioner presented a declaration by Dr. Michael Reynard. *See* Prelim Resp. 21; Ex. 1001.

Here, Dr. Reynard looked at substantially the same references as the Examiner and comes to a different conclusion, but that is not compelling, especially when there is no explanation how the Examiner erred. Accordingly, we find that this factor also weighs in Patent Owner’s favor.

3. *Lynch*

Petitioner contends that *Lynch* was not applied against the challenge claims or discussed by Examiner during prosecution of the ’742 patent or its parent applications, and therefore, weighs against exercising our discretion

under § 325(d). Pet. 16 (citing *Fasteners for Retail*, Paper 9 at 7–11). According to Petitioner, “Lynch ’334 discloses supports that are one continuous structure and therefore is not cumulative of Neuhann either.”

Reply 4.

Patent Owner disagrees. Patent Owner argues that Lynch (Ex. 1008) is highly similar and cumulative to Lynch ’197 which was considered during the prosecution of the ’742 patent. Prelim. Resp. 38 (Ex. 2007, 411 (Cite No. 101)). Lynch ’197 was also considered during prosecution of the parent ’443 patent and grandparent ’789 patent. *Id.* at 39 (Ex. 2010, 006–65; Ex. 1004, 377–436). In addition, Lynch ’197 was also listed on International and European Search Reports submitted during prosecution of the ’789 patent. *Id.* (citing Ex. 2010, 067; Ex. 1004, 689–90, 695–700 (cited reference D2), 950–52; Ex. 2004.).

a) Part I (Becton, Dickinson Factors (a), (b), (d)): Examiner considered substantially the same art and/or arguments during prosecution

We begin by considering *Becton, Dickinson* Factor (a): The similarities and material differences between the asserted art and the prior art involved during examination.

Patent Owner contends that Lynch ’197 is substantially similar to Lynch cited in the Petition. Prelim. Resp. 39. Patent Owner provides a table comparing the relevant portions of Lynch relied on by Petitioner in the Petition with Lynch ’197. *See id.* at 39–49 (*compare* Lynch (Ex. 1008), *with* Lynch ’197 (Ex. 2013)).

We recognize that Examiner did not expressly rely on Lynch (Ex. 1008) during prosecution of the ’742 patent. Nonetheless, Patent Owner presents persuasive arguments and supporting evidence that the disclosure of

Lynch was previously presented to Examiner. Thus, Patent Owner argues persuasively that Examiner considered many similar prior art references, including references containing the same figures that Petitioner asserts here, during the prosecution leading to the '742 patent. Prelim Resp. 39–49 (providing a table highlighting the similarities between Lynch (Ex. 1008) and Lynch '197 (Ex. 2013)). Accordingly, we find that with respect to Lynch this factor weighs in Patent Owner's favor.

We next consider *Becton, Dickinson* Factor (b): The cumulative nature of the asserted art and the prior art evaluated during examination.

Patent Owner contends that “Lynch is highly similar to and cumulative of Lynch '197, which was considered during prosecution of the '742 patent and its related applications.” Prelim Resp. 38. Patent Owner during prosecution of the '742 patent “submitted European Search Reports discussing novelty challenges in view of Lynch '197, and identifying Lynch '197 as Category “X” prior art.” Prelim Resp. 38 (citing Ex. 2007, 277–78, 280).

Patent Owner contends that Petitioner's citation to Lynch for teaching shape memory material is similar to Examiner's reliance on Lynch '228 for this disclosure in the parent '443 patent and grandparent '789 patent. *See* Prelim Resp. 38 (citing Ex. 2010, 6–65, 67; Ex. 1004, 377–436), *see also id.* at 51 (citing Ex. 1004, 901). Accordingly, we find that with respect to Lynch this factor weighs in Patent Owner's favor.

Patent Owner contends that Bergheim is cumulative of art and arguments considered during prosecution. Prelim Resp. 50; *see above II.A.1.a.*

We are persuaded by Patent Owner's arguments and supporting evidence that the disclosures of Lynch was previously presented to

Examiner and that these disclosures are cumulative to the art considered during prosecution. Accordingly, we find that this factor weighs in Patent Owner's favor.

To complete Part 1 of *Advanced Bionics* two-part framework we consider *Becton, Dickinson* Factor (d): The extent of the overlap between the arguments made during examination and the manner in which Petitioner relies on the prior art or Patent Owner distinguishes the prior art.

Petitioner contends that Lynch's support would meet the limitation of an "arcuate member has a radius of curvature smaller than the radius of curvature of Schlemm's canal" once implanted, and that it has a portion (the proximal portion) that extends out of Schlemm's canal. Pet. 67–70. Therefore, Petitioner contends that Lynch's support "necessarily has an overall radius of curvature smaller than Schlemm's canal." *Id.* at 69.

Patent Owner contends that this argument is the same as a finding made by Examiner during prosecution. "Patent Owner overcame the Examiner's similar rejection based on Neuhann." Prelim Resp. 49 (Ex. 1004, 933 ("Even if Neuhann's wire could be considered to extend out of Schlemm's canal and into the trabecular meshwork, it is not a portion of the arcuate member"). As Patent Owner explains, "[t]his radius of curvature is depicted in Figures 11A-D [of Ex. 1003], and refers to the longitudinal curvature along the length of the support relative to the curvature of Schlemm's canal, not the radius of a cross-section of the support." Prelim. Resp. 58 (citing Ex. 1003, 12:15–34, Fig. 11B, 11C). Examiner in the notice of allowance for the '433 parent patent explained that "the prior art [Neuhann] fails to disclose or suggest an ocular implant comprising an arcuate member configured for implantation in Schlemm's canal, wherein the arcuate member has a radius of curvature smaller than that of Schlemm's

canal, such that the arcuate member extends out of Schlemm's canal and into the trabecular meshwork, along with the other limitations of the claims.”

Ex. 1004, 1067. Thus, “Patent Owner distinguished Neuhann during prosecution by requiring that ‘a portion of the arcuate member’ extends out of Schlemm's canal” and into the trabecular meshwork. Prelim Resp. 16, n.4; *see* Ex. 1004, 1067. In other words, during prosecution Examiner accepted that the “arcuate member” limitation is referring to the shape of the entire support and not just a portion of the support. Ex. 1004, 1067 (citing Fig. 11D); *see also* Ex. 1003, Fig. 11D. Accordingly, we find that with respect to Lynch this factor also weighs in Patent Owner's favor.

Just like with the combination of Gharib and Bergheim discussed above (Section II.A.A.a), Petitioner with the combination of Lynch and Bergheim, relies on Bergheim for arriving at the limitation of dependent claim 13 – “the support contacts less than 30% of C.” Specifically, Petitioner relies on Bergheim to address the amount of contact the device has with the internal wall surface of the Schlemm canal. *See* Pet. 45–48 (citing Ex. 1006 ¶¶ 3, 35, 73–76, 100–111, 116–119; Ex. 1001 ¶¶ 108–109).

Patent Owner further contends that Petitioner's obviousness arguments with respect to the “surface area contact ratio limitation” mimic Examiner's findings during prosecution. Prelim Resp. 50 (compare Pet. 78–79 (increasing fenestrations to optimize contact ratio between support and the Schlemm canal wall), *with* Ex. 1004, 719–20, 764, 898–99).

Examiner during prosecution asserts that “recitation of the ratio of contact between the stent and the internal lumen of Schlemm's canal, such a limitation is a result-effective variable. That is, the amount of contact between the stent and the canal walls affects the canal's expansion and patency, which affects the resulting aqueous drainage.” Ex. 1004, 764, *see*

also id. at 899 (In reference to Neuhann, Examiner similarly asserts that “recitation of the ratio of contact between the stent and the internal lumen of Schlemm’s canal, such a limitation is a result-effective variable. That is, the amount of contact between the stent and the canal walls affects the canal’s expansion and patency, which affects the resulting aqueous drainage.”). For the same reasons discussed above (*II.A.1.a*), we agree with Patent Owner that during prosecution of the ’742 patent and the ’443 parent patent that Examiner made findings similar to the arguments that Petitioner asserts here. *See, e.g.*, Ex.1004, 898–99, 719–20, 764, 933. Accordingly, we find that with respect to the combination of Lynch and Bergheim this factor also weighs in Patent Owner’s favor.

Having determined that Examiner during prosecution leading to the ’742 patent considered substantially similar art and arguments as those presented in the Petition, we now turn to the question whether Petitioner has established that the Office materially erred.

b) Part 2 (Becton, Dickinson Factors (c), (e), (f)): Petitioner has not established that the Office materially erred

We continue our analysis by considering *Becton, Dickinson* Factor (c): The extent to which the asserted art was evaluated during examination, including whether the prior art was the basis for rejection.

Patent Owner contends that “Lynch is substantially the same art already considered by the Office” and that the additional references of Gharib, Burns, and Bergheim in conjunction with Lynch are cumulative of art and arguments made by Examiner during prosecution. Prelim Resp. 52. Accordingly, we find that this factor weighs in Patent Owner’s favor.

We next consider *Becton, Dickinson* Factor (e): Whether Petitioner has pointed out sufficiently how Examiner erred in its evaluation of the asserted prior art.

Patent Owner contends that Petitioner has “not met their burden of showing the Office erred in a manner material to patentability.” Prelim Resp. 52. We agree with Patent Owner, Petitioner has not sufficiently explained how Examiner’s interpretation of arcuate member during the prosecution of the ’742 patent and ’433 patent parent is erroneous based on the record. Accordingly, we find that this factor weighs in Patent Owner’s favor.

And finally, we consider *Becton, Dickinson* Factor (c): The extent to which additional evidence and facts presented in the Petition warrant reconsideration of prior art or arguments.

Patent Owner acknowledges that Petitioner presented a declaration by Dr. Michael Reynard. *See* Prelim Resp. 21; Ex. 1001.

Here, Dr. Reynard looked at substantially the same references as the Examiner and comes to a different conclusion, but that is not compelling, especially when there is no explanation how the Examiner erred. Accordingly, we find that this factor also weighs in Patent Owner’s favor.

4. Summary

Considering the above *Becton Dickson* factors as they are incorporated into the two-part *Advanced Bionic* framework, we find that the factors weigh in favor of exercising our discretion and denying institution under § 325(d). The asserted art is either the same as, or cumulative to, the prior art that Examiner has already considered during prosecution of the ’742 patent and its parent application. Further, the arguments Petitioner

advances in its Petition are substantially similar to information presented to Examiner during prosecution. Thus, we deny institution under § 325(d).

III. CONCLUSION

Because the same or substantially the same art previously were presented to the Office and Petitioner has not demonstrated that Examiner materially erred when considering the prior art, we exercise our discretion under § 325(d) and decline to institute *inter partes* review of the '742 patent.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that Petitioner's request for an *inter partes* review, pursuant to 35 U.S.C. § 314(a), of claims 1–3, 6–9, 12, 13, 15, and 17–20 of the '742 patent is *denied*, and no trial is instituted.

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Patent 10,314,742 B2

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