Paper 14 Date: March 27, 2023

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.

IPR2022-01533 Patent 8,287,482 B2

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

 ${\tt JENKS}, Administrative \ Patent \ Judge.$

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, 2, 5, 7, 8, 10, 11, 15, 18, 21, 23, 32, 33, 36, 38, 39, 41, 42, 46, 49, 52, 54, 63, 65, 68–70, 73, 77, 79, and 80 ("the challenged claims") of U.S. Patent No. 8,287,482 B2 (Ex. 1003, "the '482 patent"). Paper 2 ("Pet."). Sight Sciences, Inc. ("Patent Owner") filed a Preliminary Response to the Petition. Paper 7 ("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 4, 1.

D. Related Matters

The '482 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 '482 patent, all of which are asserted in the Delaware Litigation: U.S. Patent Nos. 9,370,443; 9,486,361; and 10,314,742." Pet. 2. These filed petitions are IPR2022-01529, IPR2022-01540, and IP2022-01530. respectively. Paper 10, 1.

E. Asserted Grounds of Unpatentability

Petitioner challenges the patentability of claims 1, 2, 5, 7, 8, 10, 11, 15, 18, 21, 23, 32, 33, 36, 38, 39, 41, 42, 46, 49, 52, 54, 63, 65, 68–70, 73, 77, 79, and 80 of the '482 patent on following grounds:

Claim(s) Challenged	35 U.S.C. § ¹	Reference(s)/Basis
1, 2, 5, 7-8, 10,11, 15,		
18, 21, 23, 32, 33, 36, 38-39, 41, 42, 46, 49,	103	Grieshaber ²
52, 54, 63, 65, 68-70,		
73, 77, 79, 80		
1, 2, 5, 7-8, 10, 11, 15,		
18, 21, 23, 32, 33, 36,		
38-39, 41, 42, 46, 49,	103	Grieshaber, Bergheim ³
52, 54, 63, 65, 68-70,		_
73, 77, 79, 80		

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 Canadian Patent Publication No. CA 02244646 A1, published August 11, 1998 (Ex. 1012) ("Grieshaber" or "Grieshaber '646").

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

1, 2, 5, 7, 8, 15, 18, 21, 23, 32, 33, 36, 38, 39, 46, 49, 52, 54, 63, 65, 68-70, 73, 77	102	Lynch ⁴
1, 2, 5, 7, 8, 15, 18, 21, 23, 32, 33, 36, 38, 39, 46, 49, 52, 54, 63, 65, 68-70, 73, 77	103	Lynch, Bergheim
8, 10, 11, 39, 41, 42, 77, 79, 80	103	Lynch, Bergheim, Gharib ⁵

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

F. The '482 patent (Ex. 1003)

The '482 patent is titled "Intraocular Implants and Methods and Kits Therefor." Ex. 1003, (54). The '482 patent relates to devices implanted into the eye "for reducing intraocular pressure" by using "the natural drainage process of the eye." *Id.* (57).

⁴ U.S. Patent Application Publication No. 2005/0038334 A1, published Feb. 17, 2005 (Ex. 1008).

⁵ U.S. Patent Application Publication No. 2002/0165478 A1, published Nov. 7, 2002 (Ex. 1005).

Figure 2 of the '482 patent is reproduced below.

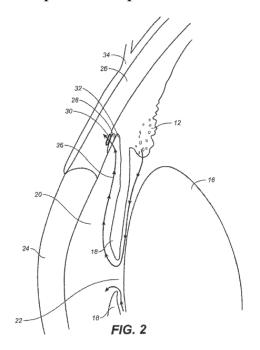


Figure 2, above, is a partial cross-sectional side view of a normal fluid drainage path from the eye. *Id.* at 5:13–14. Figure 2 depicts the general flow of aqueous humor from ciliary body 12, between lens 16 and iris 18, through pupil 22 into the anterior chamber 20, across the trabecular meshwork 28, across Schlemm's canal 30, and into aqueous veins or collector channels (not shown). *Id.* at 6:43–48. Schlemm's canal 30 extends 360° circumferentially around trabecular meshwork 28. *Id.* at 6:34–35; 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 '482 patent explains that the standard surgical treatment of "trabeculectomy, or filtration surgery . . . creat[es] a new drainage site for aqueous humor." *Id.* at 2:5–7.

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 2:15–18.

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 2:23–25. 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 2:34–35. A negative aspect of bypass stents is that they "can lose functionality over time as a result of occlusion or scarring." *Id.* at 2:33–34. Further, because "Schlemm's canal is small," stents are said to be "difficult or expensive to design and manufacture." *Id.* at 2:34–36. According to the '482 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 2:43–48.

The '482 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 2:57–59. The '482 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 7:28–33.

Figure 10B of the '482 patent is reproduced below.

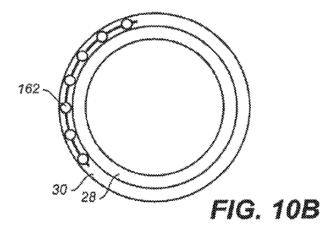


Figure 10B, above, is a configuration of support 162 implanted into and extending less than half way around Schlemm's canal 30. *Id.* at 5:51–52; 12:1–2. Figure 10B also shows trabecular meshwork 28 adjacent to canal 30. *Id.* at 5:58–59; 12:53–54.

The '482 patent describes supports having a bowed or arcuate shape smaller or larger than the radius of curvature of Schlemm's canal. *Id.* at 11:60–12:20. Figure 11B of the '482 patent is reproduced below.

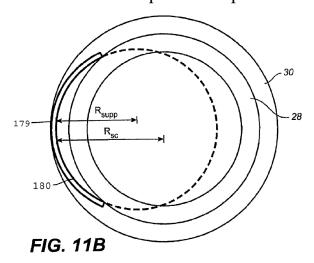


Figure 11B, above, illustrates a configuration of support 179 having a smaller radius of curvature than Schlemm's canal 30. *Id.* at 5:53–56; 12:3–5. The '482 patent discloses that support 179 comprises arcuate member 180 having a radius of curvature R_{supp} that is less than the radius of curvature R_{sc} of canal 30. *Id.* at 12:3–5. The stiffness of arcuate member 180 is said to urge canal 30 open. *Id.* at 12:5–6.

1. Illustrative Claim

Claims 1, 32, and 63 are independent claims challenged by Petitioner in this proceeding. Independent claim 1, reproduced below, is illustrative of the subject matter:

1. A device comprising:

a support having at least one fenestration that is longitudinally insertable into a lumen of Schlemm's canal, the support having a cross-sectional dimension Sufficient to at least partially prop open Schlemm's canal upon insertion into the canal, and to thereby maintain patency of at least a portion of the canal so that fluid may traverse the canal without Substantial interference from the Support,

wherein when the support is disposed within a lumen of Schlemm's canal, contact between the Support and a wall of the canal is discontinuous along a perimeter of the lumen of the canal, and wherein when the support is disposed within a cylindrical section of the lumen of the canal having an internal wall surface area C, the support contacts less than 30% of C.

Id. at 18:12–26. Claim 32, also a device claim, and claim 63, a method claim, similarly recite "wherein when the support is disposed within a cylindrical section of the lumen of the canal having an internal wall surface area C, the support contacts less than 30% of C."

II. ANALYSIS

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

We consider Patent Owner's request that we deny institution⁶ under 35 U.S.C. § 325(d). Prelim. Resp. 12–54; Sur-Reply 1–5. Patent Owner contends that Petitioner's alleged prior art was presented previously to Examiner during prosecution of the '482 patent and its parent applications. Prelim. Resp. 12.

The '482 patent is a continuation of the '789 patent. Prelim. Resp. 8. Patent Owner argues that the same "Primary Examiner . . . examined all patents in this family. (See '789; '482)." *Id*.

Patent Owner argues that discretionary denial is appropriate because [a]ll Grounds in the Petition are based on primary references Grieshaber '646 (Ex.1016) or Lynch '334 (Ex.1008), which are identical or substantially the same as, and cumulative of, references that were considered during prosecution of the '482 patent. Petitioners' art and arguments, including secondary references, are also cumulative of the Examiner's arguments made during prosecution.

Prelim. Resp. 14. Additionally, Patent Owner contends that Petitioner makes "no attempt to establish that the Examiner 'erred in evaluating the art or arguments' previously presented." *Id*.

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⁶ 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.

Institution of *inter partes* review is discretionary. *See Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1367 (Fed. Cir. 2016) ("[T]he PTO is permitted, but never compelled, to institute an IPR proceeding"). Section 325(d) provides that the Director may elect not to institute⁷ 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:

- (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). *Id.* 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,

⁷ The Board institutes trial on behalf of the Director. 37 C.F.R. § 42.4(a).

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

Petitioner contends that neither Grieshaber (Ex. 1012) nor Lynch (Ex. 1008) was applied against the challenged claims or discussed by Examiner during prosecution of the '482 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 1–4.

Patent Owner disagrees. According to Patent Owner, "[a]ll Grounds in the Petition are based on primary references Grieshaber '646 (Ex.1016) or Lynch '334 (Ex.1008), which are identical or substantially the same as, and cumulative of, references that were considered during prosecution of the '482 patent." Prelim. Resp. 14. Patent Owner provides detailed analyses to support its argument. *Id.* at 14–54. Based on this record, and for reasons explained below, we find Patent Owner's arguments persuasive.

a) Grieshaber

As set forth above, Petitioner contends that Grieshaber was not applied against the challenged claims or discussed by Examiner during prosecution of the '482 patent or its parent applications, therefore, weighing against exercising our discretion under §325(d). Pet. 16 (citing *Fasteners for Retail*, Paper 9 at 7–11); Reply 1–4.

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. 15–33. 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 34–35.

Patent Owner contends that "Grieshaber '546 is substantially similar to the Grieshaber '646 reference cited in the Petition. Both references are in the same patent family, share the same priority application CH 1923/97, and list the same inventors. The specifications are also largely overlapping with identical figures, descriptions of figures, and embodiments." Prelim

Resp. 18; see also id. at 19–28 (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. 28; compare Grieshaber (Ex. 1012), with Grieshaber '546 (Ex. 2008); Ex. 2009; see Pet. 21 (citing Ex. 1012, 50 (Fig. 4)), see also id. at 22, 23, 26, 28, 31 (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],	Grieshaber, Figure 4 (Pet., 50-	Ex.2008, Figure 4:
2, 13, 18	52, 55):	
	36 35 35 35 35 35 35 35 35 35 35 35 35 35	22 29 29 29 29 29 29 29 29 29 29 29 29 2

Prelim Resp. 20. 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. 15–35; *see also id.* at 18 ("[T]he portions of Grieshaber '646 that Petitioners rely on in Ground 1 for all claim limitations are also present in Grieshaber '546."). On this record, we are persuaded that the disclosures of Grieshaber are substantially the same as that of Grieshaber '546.

We recognize that Examiner did not expressly rely on Grieshaber during prosecution of the '482 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 '482 patent. *See, e.g.*, Ex. 2009 ((Redline comparison of text) (*compare* Ex. 1012, *with* Ex. 2008)).

Patent Owner contends that Grieshaber '646 (Ex. 1012) is cumulative to Grieshaber '546 (Ex. 2008), "and overlaps with, the arguments previously discussed by and presented to the Office." Prelim. Resp. 29. Specifically, "the portions of Grieshaber '646 that Petitioners rely on in Ground 1 for all claim limitations are also present in Grieshaber '546." *Id.* at 18, *see also id.* at 19–28; *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. On this record, we are persuaded that the disclosures of Grieshaber are cumulative to that of Grieshaber '546.

Finally, Patent Owner contends that "Petitioners arguments based on the Grieshaber '646 reference 'are essentially the same as the Examiner's reliance' on references discussed during '482 prosecution. For example, the Petitioners' and Examiner's arguments regarding the surface area contact limitation are similar." Prelim Resp. 29. During prosecution, Examiner asserted that "that a person of ordinary skill in the art ('POSA') would have modified Shadduck's stent to 'provide the desired level of contact with the walls of the Schlemm's canal." *Id.* at 30 (citing Ex. 1004, 106–107).

"During prosecution, the Patent Owner successfully overcame the Examiner's rejection over Shadduck for the following reason: '[T]here is no mention of the amount of contact of any one of Shadduck's implants with the internal wall surface area of Schlemm's canal." *Id.* (emphasis omitted); (citing Ex. 1004, 125).

[E]xaminer's statement of reasons for allowance: The cited prior art fails to disclose or suggest a device for reducing intraocular pressure comprising an apparatus that props open Schlemm's canal with discontinuous contact with the internal surface of the canal, wherein the support contacts less than a certain percentage of the interior surface, along with the other steps and limitations of the claims.

Ex. 1004, 159.

b) Bergheim

Petitioner asserts that Bergheim was not considered, applied, or discussed by Examiner. Pet. 17 (stating "none of the references applied by the examiner in either the '482 patent or its parent applications is cumulative of the references cited here"); Reply 1–2.

Patent Owner argues that Bergheim (Ex. 1006) "is cumulative of the art and arguments considered and discussed by the Examiner during prosecution for the Shadduck reference." Prelim. Resp. 31. Specifically, Patent Owner argues that Petitioner's reliance on Bergheim to argue that the '482 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" and "mimics the Examiner's argument based on Shadduck that a POSA would have modified Shadduck's stent to 'provide the desired level of contact with the walls of the Schlemm's canal." Prelim Resp. 32. (citing Ex. 1004, 107).

Patent Owner contends 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)).

Although Examiner did not discuss the specific Greishaber and Bergheim combination presented in the Petition, we agree with Patent Owner that during prosecution of the '482 patent that Examiner made similar arguments that Petitioner asserts here. Prelim. Resp. 32 (compare Pet. 38 ("Bergheim, for example, teaches including grooves or troughs on the surface of an ophthalmic support to 'allow the flow of aqueous humor' and 'provid[e] efficient aqueous transmission"), with Ex. 1004, 105 ("The porosity of the material [as disclosed in Shadduck]... creates fluted, or uneven edges around which fluid may flow")).

c) Lynch

Petitioner contends that Lynch was not applied against the challenge claims or discussed by Examiner during prosecution of the '482 patent or its parent applications, therefore, weighing against exercising our discretion under §325(d). Pet. 16 (citing *Fasteners for Retail*, Paper 9 at 7–11); Reply 4.

Patent Owner disagrees. Patent Owner argues that "Lynch' 334 is substantially similar to and cumulative of Lynch' 197, which was considered during prosecution." Prelim. Resp. 37 (Ex. 1004, 162 (Cite No. 37)). Lynch' 197 was also listed on the Written Opinion of the International Authority "that identified Lynch' 197 as Document' D2' for challenging the novelty of

similar pending claims." *Id.* (Ex. 1004, 138–39 (Cite No. 48), 142–147, 162–163 (Cite No. 48)).

Patent Owner contends that Lynch '197 is substantially similar to Lynch cited in the Petition. Prelim. Resp. 38. Patent Owner provides a table comparing the relevant portions of Lynch relied on by Petitioner in the Petition with Lynch '197. See id. at 38–50 (compare Lynch (Ex. 1008), with Lynch '197 (Ex. 2013)). Furthermore, Patent Owner during prosecution of the '482 patent listed "a Written Opinion of the International Searching Authority that identified Lynch '197 as Document 'D2' for challenging the novelty of similar pending claims." Id. at 37 (citing Ex.1004, 138–139 (Cite No. 48), 142–147, 162-63 (Cite No. 48)). On this record, we are persuaded that the disclosure of Lynch is substantially similar to Lynch '197.

We recognize that Examiner did not expressly rely on Lynch (Ex. 1008) during prosecution of the '482 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 '482 patent. Prelim Resp. 38–40 (providing a table highlighting the similarities between Lynch (Ex. 1008) and Lynch '197 (Ex. 2013)).

Finally, Patent Owner contends that "Petitioners' arguments based on Lynch' 334 'are essentially the same as the' disclosures in Lynch' 197 and are therefore cumulative of the art considered during prosecution. . . . [and] do not include any overlooked disclosures in the prior art." Prelim Resp. 51.

d) Gharib

Petitioner asserts that Gharib was not considered, applied, or discussed by Examiner. Pet. 17 (stating "none of the references applied by the examiner in either the '482 patent or its parent applications is cumulative of the references cited here"); Reply 1–4.

Patent Owner disagrees. Patent Owner argues that Gharib is "cumulative of the references considered by the Examiner during prosecution." Prelim Resp. 52 (citing Ex. 1004, 106–108). On this record, we are persuaded that the disclosure of Gharib is cumulative to references considered by Examiner during prosecution.

e) Summary

In sum, Patent Owner has shown sufficiently that the disclosures of the asserted prior art are substantially the same and cumulative as those previously presented to the Office. Thus, we find the first part of *Advanced Bionics* two-prong framework is satisfied. We now turn to the question whether Petitioner has established that the Office materially erred.

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

Patent Owner argues that, despite "overlap" of disclosures between prior art asserted in the Petition and previously presented to the Office, Petitioner makes "no attempt to establish that the Examiner erred in evaluating the art or arguments previously presented to the Office, as has generally been required for such cumulative petitions to be instituted under § 325(d)." Prelim. Resp. 14. We agree.

Petitioner contends that none of the asserted prior art was applied or discussed during the prosecution of the '482 application or its parent

application, and none of the references considered are cumulative of those asserted in the Petition. Pet. 17 (stating "none of the references applied by the examiner in either the '482 patent or its parent applications is cumulative of the references cited here"); Reply 1–4. Petitioner, however, does not provide any analysis under the second prong of *Advanced Bionics* frame work. *Advanced Bionics*, Paper 6 at 8. Based on the current record, we determine Petitioner has not met its burden to show Examiner materially erred.

Even after we granted Petitioner's request to file a pre-institution Reply to address Patent Owner's arguments proposing discretionary denial (*see* Paper 11), Petitioner does not specifically address the material-error prong of the *Advanced Bionics* framework. Instead, Petitioner maintains its position that the asserted prior art and references cumulative thereto were not applied or discussed during the prosecution of the '482 patent. *See* Reply 1–5.

To the extent Petitioner equates Examiner's silence in discussing relevant prior art to a material error in these proceedings, we are not persuaded. Indeed, under Board precedent, Petitioner bears the burden to "demonstrate[] that the Office erred in a manner material to the patentability of challenged claims." *Advanced Bionics*, Paper 6 at 8. Petitioner does not point to competent evidence or present persuasive arguments to show that the disclosures in the prior art asserted in the Petition—but absent in the references considered during prosecution—would lead to a different conclusion on the patentability of the challenged claims. In other words, Petitioner does not sufficiently demonstrate or explain why a different conclusion should be reached based on the same disclosures in the same references that were cited during prosecution.

Finally, Patent Owner acknowledges that Petitioner presented a declaration by Dr. Michael Reynard. *See* Prelim Resp. 35; Ex. 1001. Here, Dr. Reynard looked at substantially the same references as Examiner and comes to a different conclusion, but that is not compelling, especially when there is no explanation how Examiner erred.

B. Summary

Taking account of the information presented in the Petition,
Preliminary Response, Reply, Sur-reply, and the evidence of record, we find
that the factors applying the *Advanced Bionic* framework 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 '482 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 '482 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, 2, 5, 7, 8, 10, 11, 15, 18, 21, 23, 32, 33, 36, 38, 39, 41, 42, 46, 49, 52, 54, 63, 65, 68–70, 73, 77, 79, and 80 of the '482 patent is *denied*, and no trial is instituted.

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