

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.

IPR2022-01540
Patent 9,486,361 B2

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

YANG, *Administrative Patent Judge.*

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

I. INTRODUCTION

Ivantis, Inc., Alcon Research, LLC, Alcon Vision, LLC, and Alcon Inc. (collectively, “Petitioner”) filed a Petition (Paper 2, “Pet.”), seeking an *inter partes* review of claims 1–3 and 5–9 of U.S. Patent No. 9,486,361 B2 (Ex. 1003, “the ’361 Patent”). Sight Sciences, Inc. (“Patent Owner”) filed a Preliminary Response. Paper 6 (“Prelim. Resp.”). With our authorization (Paper 10), Petitioner filed a Reply (Paper 11), and Patent Owner filed a Sur-reply (Paper 12).

For the reasons provided below, we exercise our discretion under 35 U.S.C. § 325(d), and deny institution of an *inter partes* review.

A. *Related Matters*

According to the parties, Patent Owner asserted the ’361 patent against Petitioner in *Sight Sciences, Inc. v. Ivantis, Inc.*, No. 21-1317 (D. Del.). Pet. 1–2; Paper 4, 1.

Petitioner also filed IPR petitions “for three other patents in the same family as the ’361 patent, all of which are asserted in the Delaware Litigation.” Pet. 2.

B. *The ’361 Patent and Related Background*

The ’361 patent issued from Application No. 13/445,816 (“the ’816 application”). Ex. 1003, code (21). It relates to “intraocular implants implantable into Schlemm’s canal that can reduce intraocular pressure without substantially interfering with fluid flow across Schlemm’s canal.” *Id.* at 1:18–21.

Glaucoma, a potentially blinding disease, is characterized by an increase in intraocular pressure. *Id.* at 1:25–28. It can be treated by surgery.

Id. at 1:62–66. According to the '361 patent, trabeculectomy, or filtration surgery, is a standard surgical procedure, but carries risks, including “blockage of the surgically-created opening through scarring or other mechanisms, hypotony or abnormally low intraocular pressure.” *Id.* at 2:6–20.

As an alternative to trabeculectomy, “[s]tents can be inserted between the anterior chamber of the eye and Schlemm’s canal, bypassing the trabecular meshwork.” *Id.* at 2:26–28. In addition, tubular elongated cylindrical hollow stents can be inserted longitudinally into Schlemm’s canal. *Id.* at 2:32–34. These stents, however, also have various issues, including, for example, losing functionality over time, difficult or expensive to design and manufacture, and “interfering with transmural flow across Schlemm’s canal and into the eye’s collector channels.” *Id.* at 2:30–52.

The '361 patent states that “easily manufacturable, minimally invasive devices for effective, long-term reduction in intraocular pressure are desirable.” *Id.* at 2:53–55. According to the '361 patent,

[Its] devices for reducing pressure within the eye comprise a support implantable circumferentially within Schlemm’s canal that is configured to maintain the patency of at least a portion of the canal. The support occupies at least a portion of a central core of Schlemm’s canal. The support does not substantially interfere with transmural flow across Schlemm’s canal, and thereby utilizes the eye’s natural drainage pathways. The support can be implanted into Schlemm’s canal with minimal trauma to the eye.

Id. at 2:61–3:3.

The '361 patent explains that

By “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.

C. Illustrative Claim

Among the challenged claims, claim 1 is independent. It is illustrative of the claimed subject matter and is reproduced below.

1. A method for reducing intraocular pressure, comprising:
introducing a tubular cannula having a lumen at least partially within Schlemm’s canal;
delivering a high viscosity fluid into Schlemm’s canal; and
inserting a support into Schlemm’s canal by passing the support through the tubular cannula, wherein the support comprises an arcuate member, wherein at least a portion of the arcuate member has a radius of curvature smaller than a radius of curvature of Schlemm’s canal, and wherein the support comprises at least one fenestration.

Ex. 1001, 18:33–45.

D. Asserted Challenges to Patentability

Petitioner asserts the following challenges to patentability:

Claims Challenged	35 U.S.C. §¹	Reference(s)
1–3, 5–9	103	Tu ’047 ²

¹ The Leahy-Smith America Invents Act (“AIA”), Pub. L. No. 112-29, 125 Stat. 284, 287–88 (2011), amended 35 U.S.C. §§ 102, 103, effective March 16, 2013. As explained below, we deny institution under § 325(d), regardless of which version of the law applies.

² U.S. Patent Appln. Pub. No. 2005/0266047 A1, published December 1, 2005 (Ex. 1028, “Tu ’047”).

Claims Challenged	35 U.S.C. § ¹	Reference(s)
1–3, 5–9	103	Gharib '478, ³ Smedley ⁴
1–3, 5–9	103	Gharib '478, Haffner '729 ⁵

Petitioner relies on the declaration of Michael Reynard, M.D., as support for its Petition. Ex. 1001.

II. ANALYSIS

Institution of an *inter partes* review is discretionary. *See Cuozzo Speed Techs., LLC v. Lee*, 579 U.S. 261, 273 (2016) (explaining that because § 314 includes no mandate to institute review, “the agency’s decision to deny a petition is a matter committed to the Patent Office’s discretion”); *see also Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1367 (Fed. Cir. 2016) (stating that under § 314(a), “the PTO is permitted, but never compelled, to institute an IPR proceeding”).

Under § 325(d), in determining whether to institute an *inter partes* review, “the Director may take into account whether, and reject the petition or request because, the same or substantially the same prior art or arguments previously were presented to the Office.” Our § 325(d) analysis employs a two-prong framework: (1) whether the arguments presented in the petition are the same or substantially the same as those previously presented to the Office; and (2) if so, whether the petitioner has demonstrated a material error by the Office in its prior consideration of those arguments. *Advanced*

³ U.S. Patent Appl. Pub. No. 2002/0165478 A1, published November 7, 2002 (Ex. 1005, “Gharib ’478”).

⁴ U.S. Patent No. 7,186,232 B1, issued March 6, 2007 (Ex. 1036, “Smedley”).

⁵ U.S. Patent Appl. Pub. No. 2004/0102729 A1, published May 27, 2004 (Ex. 1035, “Haffner ’729”).

Bionics, LLC v. Med-El Electromedizinische Geräte GmbH, IPR2019-01469, Paper 6 (“*Advanced Bionics*”), 8 (PTAB Feb. 13, 2020) (precedential). “If a condition in the first part of the framework is satisfied and the petitioner fails to make a showing of material error, the Director generally will exercise discretion not to institute *inter partes* review.” *Id.* at 8–9. “At bottom, this framework reflects a commitment to defer to previous Office evaluations of the evidence of record unless material error is shown.” *Id.* at 9.

Petitioner contends that Tu ’047 renders obvious claims 1–3 and 5–9 of the ’361 patent. Pet. 21–57. Petitioner also contends that claims 1–3 and 5–9 would have been obvious over the combined teachings of Gharib ’478 and Smedley, or Gharib ’478 and Haffner ’729. *Id.* at 46–86. Patent Owner argues that we should deny institution under § 325(d) “because Petitioners’ asserted art and arguments have already been considered and overcome during examination.” Prelim. Resp. 12. For the reasons explained below, we find Patent Owner’s arguments persuasive.

A. Prosecution History of the ’816 Application

During the prosecution of the ’816 application, the applicant submitted several Information Disclosure Statements (“IDSs”) listing numerous references, including U.S. Patent No. 6,736,791 (Ex. 2009, “Tu ’791”), U.S. Patent Application Publication No. 2009/0036819 (Ex. 2008, “Tu ’819”), and U.S. Patent Application Publication No. 2006/0200113 (Ex. 2010, “Haffner ’113”). *See* Ex. 1004, 638, 883, 971. The applicant also submitted a Supplementary European Search Report that identified Tu ’819 as Category “X” prior art, a category of cited documents

which is deemed “particularly relevant if taken alone.” *See id.* at 883; Ex. 2004, 1, 6.

Patent Owner pointed out that (1) the examiner signed all the IDSs, and noted “ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH;” and (2) none of the references were lined through. Prelim. Resp. 9 (citing Ex. 1004, 865, 957, 983).

B. Same or Substantially the Same Arguments

Petitioner contends

Tu [’047], Gharib [’478], Smedley, and Haffner [’729] were not applied against the Challenged Claims or discussed by the Examiner during prosecution of the ’361 or its parent applications. In addition, none of the references applied by the examiner in either the ’361 or its parent applications is cumulative of the references cited here.

Pet. 17; *see also* Reply 1 (arguing Tu ’047 “was not considered or applied by the Examiner during examination”), 3 (arguing “none of [Gharib ’478, Smedley, and Haffner ’729] were considered, applied, or discussed by the Examiner during prosecution”).

Patent Owner disagrees. According to Patent Owner, “[a]ll these references are identical or substantially the same as, and cumulative of, references that were considered during prosecution of the ’361 patent and related applications.” Prelim. Resp. 12–13. Patent Owner provides detailed analyses to support its argument. *Id.* at 13–17, 21–41. Based on this record, and for reasons explained below, we find Patent Owner’s arguments persuasive.

1. Tu '047

Patent Owner contends “Tu '047 is substantively identical to and cumulative of its related divisional patent Tu '819, which was considered during prosecution of the '361 patent.” Prelim. Resp. 13. Patent Owner points out that during prosecution, (1) Tu '819 was listed in an IDS, and (2) a Supplementary European Search Report, listed on the same IDS, identified Tu '819 as Category “X” prior art. *Id.* at 13–15.

Petitioner argues that Tu '819 “was merely considered by the Examiner, but never applied or discussed.” Reply 1–2. Although this argument is correct, it does not help Petitioner. Indeed, the statute authorizes us to “take into account whether, and reject the petition or request because, the same or substantially the same prior art or arguments previously were *presented* to the Office.” 35 U.S.C. § 325(d) (emphasis added). Under Board precedent, previously presented art includes art provided by an applicant on an IDS in the prosecution history of the challenged patent. *Advanced Bionics*, 7–8. Thus, we are persuaded that Tu '819 was previously presented to the Office.⁶

Patent Owner argues Tu '819 is “substantially identical” to Tu '047. Prelim. Resp. 16. As support, Patent Owner points out that “Tu '819 issued from a divisional of Application No. 11/083,713, which was published as Tu '047.” *Id.* Patent Owner submits a redline comparison of the written description of Tu '819 and Tu '047 (*see* Ex. 2013), showing “the specification disclosures are identical, except for differences in the Title,

⁶ We note Tu '819 appears on the face of the '361 patent. *See* Ex. 1003, code (56).

Abstract, Related Applications, and Claims Sections.” Prelim. Resp. 16. Patent Owner also argues that Tu ’819 and Tu ’047 have identical figures. *Id.*; compare Ex. 2008, 2–61, with Ex. 1028, 2–61. On this record, we are persuaded the disclosure of Tu ’819 is substantially the same as that of Tu ’047.

2. Gharib ’478

Patent Owner points out that, when prosecuting the grandparent application of the ’816 application, the examiner conducted a prior art search with Gharib ’478 as one of the queries. Prelim. Resp. 21 (citing Ex. 1004, 627). During the prosecution of the ’816 application, the examiner recorded the same prior art search. *Id.* According to Patent Owner, this demonstrates that the examiner “also considered the reference for examining the claims of the ’361 patent.” *Id.* We find Patent Owner’s argument reasonable.

Petitioner counters that the search Patent Owner relies on was conducted “almost two years before the [’816] application was even filed, for a *different patent application* that lists Gharib ’478 as one of 127 references in 1 of 29 searches conducted that day.” Reply 3. Although we agree with Petitioner’s observation, we are not persuaded that these facts would weigh against applying § 325(d).

Indeed, the Board previously addressed the application of § 325(d) in a case with similar facts. *See Becton, Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8 (PTAB Dec. 15, 2017) (precedential as to § III.C.5, first paragraph) (“*BD*”). In that case, the patent owner argued the Office had already considered the prior art asserted in the petition “in connection with prior art considered during prosecution of the

parent application.” *Id.* at 16. There, the application that issued as the challenged patent was filed on May 28, 2010. IPR2017-01586, Ex. 1001, code (22). The examiner considered the prior art-at-issue during prosecution of the parent application on May 29, 2007 (*see BD* at 18 (citing Ex. 2004, 121–24); Ex. 2004, 120 (showing the date of the office action)) and March 30, 2009 (*see BD* at 21 (citing Ex. 2004, 314–23); Ex. 2004, 314 (showing the date of the office action)). In other words, just like in the instant proceeding, in *BD*, the examiner considered the prior art-at-issue when prosecuting a different application and before the application that issued into the challenged patent was filed. Even so, the Board agreed with the patent owner that prior art considered during prosecution of the parent application constitutes prior art previously presented to the Office under § 325(d). *BD* at 23.

Petitioner also asserts “[t]here is no indication that the Examiner considered Gharib ’478 for the pending claims, it is not listed in any searches in the ’361’s file history, and it was not discussed or applied to any pending claims.” Reply 3. We are not persuaded by this argument either.

First, Petitioner’s argument that the examiner did not consider Gharib ’478 during the prosecution of the ’816 application is mere speculation. Second, the search with Gharib ’478 as a query is, in fact, listed in the prosecution history of the ’816 application. *See* Ex. 1004, 627 (listing Gharib ’478 as a query); Pet. iii (characterizing Ex. 1004 as “File History of U.S. Patent No. 9,486,361”). Under Board precedent, previously presented art “includes art made of record by the Examiner . . . in the prosecution history of the challenged patent.” *Advanced Bionics*, 7–8. Third, even

though Gharib '478 was not specifically discussed or applied to the pending claims, it was the examiner who identified the reference and used it as a query for the prior art search. In our view, that means the examiner did consider the reference. Arguably, this fact is stronger than when the applicant lists the reference in an IDS, which also satisfies the “previously presented” requirement.

Thus, under *BD*, we are persuaded by Patent Owner’s argument that, during the prosecution of the '816 application, the examiner already considered Gharib '478.

3. Smedley

Patent Owner acknowledges Smedley was “not cited to the Examiner,” but contends it “is substantially similar to and cumulative of Haffner '113 that was considered during '361 prosecution.” Prelim. Resp. 28, 41. Patent Owner points out that (1) during prosecution, the examiner signed an IDS listing Haffner '113; and (2) Haffner '113 appears on the face of the '361 patent. *Id.* at 29 (citing Ex. 1003, cover; Ex. 1004, 983). Based on these facts, we are persuaded that Haffner '113 was previously presented to the Office. *See Advanced Bionics*, 7–8 (stating previously presented art includes art provided by an applicant on an IDS in the prosecution history of the challenged patent).

Patent Owner argues Haffner '113 is “substantially similar to” Smedley. Prelim. Resp. 29. As support, Patent Owner provides a side-by-side comparison to show “the portions of Smedley that Petitioner[] rel[ies] on for any given claim limitation in Ground 2 are also present in Haffner '113.” *Id.* at 29–34.

Petitioner does not dispute this assertion. On this record, we are persuaded the disclosure of Haffner '113 is substantially the same as that of Smedley.

4. Haffner '729

Patent Owner acknowledges Haffner '729 was “not cited to the Examiner,” but contends it “is substantially similar to and cumulative of Tu '819, which was considered during '361 prosecution.” Prelim. Resp. 35, 41. As explained above, we are persuaded that Tu '819 was previously presented to the Office. *See supra* Section II.B.1.

Patent Owner argues Haffner '729 is cumulative of Tu '819. Prelim. Resp. 35. As support, Patent Owner points out that “Tu '819 issued from an application that is a division of an application which is a continuation-in-part of application No. 10/634,213, that issued as Haffner '729.” *Id.* Patent Owner submits a redline comparison of the written description of Tu '819 and Haffner '729 (*see* Ex. 2015) to show that the two have “significant overlap” in their disclosures. Prelim. Resp. 35. Patent Owner also provides a side-by-side comparison to show “the portions of Haffner '729 that Petitioner[] rel[ies] on for any given limitation in Ground 3 are also present in Tu '819.” *Id.* at 35–40.

Petitioner does not dispute this assertion. On this record, we are persuaded the disclosure of Tu '819 is substantially the same as that of Haffner '729.

5. Summary

In sum, Patent Owner has shown sufficiently that the disclosures of the asserted prior art are substantially the same as those previously presented

to the Office. Thus, we find the first part of *Advanced Bionics* two-prong framework is satisfied.

C. Material Error

Having found that the condition in the first part of the two-prong framework is satisfied, we next evaluate whether Petitioner has demonstrated a material error by the Office in its prior consideration of the previously presented art. *Advanced Bionics*, 8. Based on the current record, we determine Petitioner has not met its burden to show the examiner materially erred.

Patent Owner argues that, despite “significant 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. 13 (quotation marks and brackets omitted). We agree.

Indeed, in the Petition, Petitioner contends that none of the asserted prior art was applied or discussed during the prosecution of the '816 application or its parent application, and none of the references considered are cumulative of those asserted in the Petition. Pet. 17. Petitioner does not provide any analysis under the second prong of *Advanced Bionics*.

Moreover, even after we granted Petitioner’s request to file a pre-institution Reply to address Patent Owner’s arguments proposing discretionary denial (*see* Paper 10), 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 '816 application. *See* Reply 1–5.

To the extent Petitioner equates the examiner's silence in discussing relevant prior art to a material error, 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*, 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 sum, Petitioner has not demonstrated that the examiner materially erred in considering the prior art previously presented to the Office.

III. CONCLUSION

Because the same or substantially the same art previously were presented to the Office and Petitioner has not demonstrated that the examiner materially erred when considering the prior art, we exercise our discretion under § 325(d) and decline to institute *inter partes* review of the '361 patent.⁷

⁷ Patent Owner also argues that we should deny review for other reasons. *See* Prelim. Resp. 43–65. We do not address those contentions because we deny the Petition for reasons explained above.

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IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that the Petition is denied, and no trial is instituted.

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