

UNITED STATES PATENT AND TRADEMARK OFFICE

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**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

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IVANTIS, INC., ALCON RESEARCH, LLC, ALCON VISION, LLC,  
AND ALCON INC.

Petitioners

v.

SIGHT SCIENCES, INC.

Patent Owner

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Case IPR2022-01530

**U.S. PATENT NO. 10,314,742**

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**PETITIONERS' REPLY  
TO PATENT OWNER'S PRELIMINARY RESPONSE**

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<b>Exhibit No.</b>	<b>Description</b>
1001	Declaration of Dr. Michael Reynard
1002	Curriculum Vitae of Dr. Michael Reynard
1003	U.S. Patent No. 10,314,742
1004	File History of U.S. Patent No. 9,370,443
1005	U.S. Pub. No. 2002/0165478 ("Gharib")
1006	U.S. Pub. No. 2003/0060752 ("Bergheim")
1007	U.S. Pub. No. 2004/0147870 ("Burns")
1008	U.S. Pub. No. 2005/0038334 ("Lynch '334")
1009	U.S. Patent No. 6,494,857 ("Neuhann")
1010	U.S. Pub. No. 2004/0260228 ("Lynch '228")
1011	U.S. Pub. No. 2006/0195187 ("Stegmann")
1012	CA 2244646 ("Grieshaber")
1013	"A History of the Surgical Management of Glaucoma," Razeghinejad & Spaeth (2011)
1014	"An Operation for Glaucoma," Stefansson (1925)
1015	"How Does Nonpenetrating Glaucoma Surgery Work? Aqueous Outflow Resistance and Glaucoma Surgery," Johnson & Johnson (2001)
1016	U.S. Patent No. 7,192,412 ("Zhou")
1017	WO 2006/066103 ("Stegmann")
1018	RESERVED

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Exhibit No.	Description
1019	Sight Sciences Inc.'s Second Amended Complaint (D.I. 59), <i>Sight Sciences, Inc. v. Ivantis, Inc.</i> , C.A. No. 21-1317-GBW (D. Del.)
1020	Exhibits A-P for Sight Sciences Inc.'s Second Amended Complaint (D.I. 59-1), <i>Sight Sciences, Inc. v. Ivantis, Inc.</i> , C.A. No. 21-1317-GBW (D. Del.)
1021	2022-03-28 ORAL ORDER Case assigned to District of Delaware's VAC (D.I. 27), <i>Sight Sciences, Inc. v. Ivantis, Inc.</i> , C.A. No. 21-1317-GBW (D. Del.)
1022	2022-04-11 ORAL ORDER referring case to Magistrate Judge S. Fallon (D.I. 30), <i>Sight Sciences, Inc. v. Ivantis, Inc.</i> , C.A. No. 21-1317-GBW (D. Del.)
1023	LexMachina Statistics
1024	Tu WO 2002036052
1025	U.S. 2004/0254520 ("Porteous")
1026	"Glaucoma drainage implants: a critical comparison of types," Schwartz et al. (2006)
1027	"Glaucoma drainage implants," Sidoti & Baerveldt (1994)
1028	U.S. Pub. No. 2005/0266047 ("Tu")
1029	WO 2000064391 ("Lynch '391")
1030	WO 2001097727 ("Hosheng")
1031	US10,299,958 ("Badawi")
1032	Docket, <i>Sight Sciences, Inc. v. Ivantis, Inc.</i> , 1:21-cv-01317-GBW (D. Del)

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Exhibit No.	Description
1033	Sight Sciences, Inc.'s Answer to Ivantis, Inc.'s Counterclaims (D.I. 26), <i>Sight Sciences, Inc. v. Ivantis, Inc.</i> , C.A. No. 21-1317-GBW (D. Del.)
1034	Sight Sciences, Inc.'s Responses and Objections to Defendant Ivantis, Inc.'s First Set of Interrogatories (Nos. 1-7) (May 23, 2022), <i>Sight Sciences, Inc. v. Ivantis, Inc.</i> , C.A. No. 21-1317-GBW (D. Del.)
1035	Updated LexMachina Statistics

## **I. INTRODUCTION**

Petitioners Ivantis, Inc. et al. (“Petitioners”) file this reply to Sight Sciences, Inc.’s (“Patent Owner”) preliminary response (“POPR”), as authorized by the Board’s January 30, 2023 Order. Paper 10. Petitioners explain below why Patent Owner’s request for discretionary denial under both *Becton Dickinson* and *Fintiv* should fail and why the Board should institute review.

There is no dispute that the Petition’s grounds and the prior art the Office previously applied are different, so Patent Owner’s arguments that the Petition’s grounds are cumulative of the art and arguments considered during the original examination miss the mark. Patent Owner’s *Fintiv* arguments fare no better because Patent Owner ignores the guidance provided in the Director’s Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings with Parallel District Court Litigation (June 21, 2022) (“Vidal Memo”). The Vidal Memo instructs parties to apply median time to trial data in lieu of a scheduling order when considering *Fintiv* factor 2. Here, based on the median time from filing to trial data for the District of Delaware, trial should not be expected until July 2024, over three months after the March 29, 2024 Final Written Decision (“FWD”) due date for this IPR.

## **II. *BECTON DICKINSON* DOES NOT SUPPORT DENIAL**

Grounds 1 and 2 in the Petition apply Gharib ’478, which was not considered or applied by the Examiner during examination. And, Gharib ’841, the patent that

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issued from Gharib '478, was merely considered but never applied or discussed by the Examiner.<sup>1</sup> The same is true for each of Petitioners' remaining Grounds—none of Grieshaber (Grounds 3-5), Lynch '334<sup>2</sup> (Grounds 6-9), Bergheim (Grounds 2, 5, 7) or Burns (Ground 9) or any reference Patent Owner alleges is cumulative of these references were applied or discussed either. As stated in the Petition, the Board has consistently “held that a reference that ‘was neither applied against the claims nor discussed by the Examiner’ does not weigh in favor of exercising [] discretion under §325(d).” *Fasteners for Retail, Inc. v. RTC Indus., Inc.*, IPR2019-00994, Paper 9 at 7-11 (PTAB Nov. 5, 2019). This remains true even after *Advanced Bionics* set forth

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<sup>1</sup> Regardless of the similarities or differences between Gharib '478 and Gharib '841 or Grieshaber '646 and '546 for which Patent Owner provides a redline (Ex. 2009), none of these references were discussed or applied during prosecution.

<sup>2</sup> Patent Owner notes Lynch '197, allegedly cumulative of Lynch '334, was cited as a Category X reference during '742 prosecution. POPR 38. This ignores Lynch '197 was relevant only to claims that required the support be “configured to ***completely traverse*** a central core of Schlemm's canal,” a limitation not found in the '742. *See* Ex. 2007 at 277-78. Petitioner also relies on teachings in Lynch '334 (*e.g.*, Figs. 8B-C and 10) missing from Lynch '197. (Ex.1001 at ¶¶66-68).



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the two-part framework in February 2020 for resolving §325(d) issues under *Becton Dickinson*. See e.g., *Whitewater West Indus., LTD v. Am. Wave Machs.*, IPR2022-01033, Paper 8 at 16 (PTAB Nov. 22, 2022) (concluding that “the criteria adopted by the Board for denying the petition in *Advanced Bionics* included not only the fact the art was made of record, but also the fact it was applied and discussed during prosecution. Anything less disregards the express reasoning behind the Board’s exercise of discretion in that case.”).

In addition to being newly applied references, Gharib '478 and Lynch '334 are not cumulative to Neuhaus because each addresses the deficiency Patent Owner argued Neuhaus suffers from. Patent Owner argued that Neuhaus “fails to teach or suggest ‘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 so that at least a portion of the arcuate member is configured to extend out of Schlemm’s canal and into the trabecular meshwork.’” Ex. 1004 at 932. Patent Owner also argued that “Neuhaus’s description makes clear that its ‘tubular element’ is intended to reside *entirely within Schlemm’s canal*.” *Id.* at 932-33 (emphasis added). Patent Owner also argued that the Examiner incorrectly found that Neuhaus’s disclosed “remove[able]” “wire loop,” Ex. 1009, 5:10-23, taught the radius of curvature limitation because, according to Patent Owner, the “wire loop” is “distinct from the tubular element” and therefore “not a portion of the arcuate member.” Ex.1004 at

933. The Examiner subsequently allowed the claims based on this distinction.

The same cannot be said of Gharib '478 or Lynch '334. Even accepting Patent Owner's argument that Neuhann's "wire loop" is an entirely separate structure, removeable from the tubular support, and intended to help guide the support into place, Gharib '478 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. Ex. 1005 at ¶ 55, Fig. 5A, 7B, 8. Patent Owner incorrectly asserts that Gharib '478's support lacks an arcuate shape. POPR at 55-56. A POSITA would have understood Gharib '478's support is a continuous structure that unfolds like a zipper when deployed in the eye and comprises an "arcuate member." Ex. 1005, Fig. 7A. Indeed, Gharib '478's outlet section is connected to the inlet section by "at least one lumen 36 for transporting aqueous from the anterior chamber 20 of an eye to the Schlemm's canal 22." *Id.* ¶ 55. In contrast to Patent Owner's characterization of Neuhann, 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. Therefore, Gharib '478 is not cumulative of Neuhann.

Similarly, Lynch '334 discloses supports that are one continuous structure and therefore is not cumulative of Neuhann either. For example, Lynch '334's support has "a distal portion ... shaped to be circumferentially received within a portion of

Schlemm's canal, and a proximal portion... to be received within the anterior chamber of the eye." Ex.1008 ¶51, Fig. 6C.

### III. *FINTIV* DOES NOT SUPPORT DENIAL

The Vidal Memo reflects why the Board should reject Patent Owner's *Fintiv* arguments. The petition presents compelling evidence of unpatentability. And, applying the guidance provided by the Vidal Memo, the median time from filing to trial data (1,032 days<sup>3</sup>) for the District of Delaware reflects that trial should not be expected until July 2024, three to four months after the March 29, 2024 FWD due date for this IPR. For at least this reason, the *Fintiv* factors do not support denial.

**Factor 1 (Stay):** Petitioners will move to stay the parallel district court case if the Board institutes IPR, and the presiding judge has granted such motions under similar circumstances. *See Int'l Bus. Machs. Corp. v. Rakuten, Inc.*, 21-cv-00461-GBW, D.I. 230, at \*23 (D. Del. Dec. 22, 2022) (granting a stay on two of four asserted patents where the case had not reached "the most burdensome stages of the case[]," and the stay would "reduce the burden of litigation").

Much like in *Rakuten*, the Board's institution decisions are expected months before "completing fact discovery, preparing expert reports, filing and responding

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<sup>3</sup> Updated LexMachina Statistics indicate that the median time to trial in Delaware has increased to 1,032 days. Ex. 1035.

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to pretrial motions, preparing for trial, going through the trial process, and engaging in post-trial motions practice.” *Id.* Moreover, a stay following institution on four of five Asserted Patents here would reduce the litigation burden even more than *Rakuten*’s partial stay of two of four asserted patents. *Id.* And when eligible under 35 U.S.C. § 311(c)(1), Petitioners intend to challenge the fifth and final Asserted Patent that issued 10 months after Patent Owner sued Ivantis. Thus, with a stay likely to be granted, Factor 1 weighs against exercising discretion to deny institution.

**Factor 2 (Proximity of Trial Dates):** Patent Owner acknowledges that trial is scheduled after a FWD is due. Applying the guidance in the Vidal Memo, the expected trial date would be no earlier than July 2024, months after a FWD will have been entered. Thus, Factor 2 weighs against exercising discretion to deny institution.

**Factor 3 (Investment in Parallel Proceedings):** The most burdensome parts of the district court case still remain. No fact depositions have occurred. Fact discovery is not scheduled to close until June 29, 2023, there has not been a claim construction ruling, and expert discovery has yet to begin. *See Sight Sciences, Inc. v. Ivantis, Inc.*, 21-cv-01317-GBW-SRF (“*Sight Sciences v. Ivantis*”), Second Amended Scheduling Order, D.I. 93, Ex. 2012; *see also Rakuten*, 21-cv-00461-GBW, D.I. 230, at \*23 (D. Del. Dec. 22, 2022) (“[T]he most burdensome stages of the cases—completing fact discovery, preparing expert reports, filing and responding to pretrial motions, preparing for trial, going through the trial process,

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and engaging in post-trial motions practice—all lie in the future.”) (quoting *IOENGINE, LLC v. PayPal Holdings, Inc.*, No. 18-452-WCB, 2019 WL 3943058, at \*5 (D. Del. Aug. 21, 2019)). Thus, Factor 3 weighs against exercising discretion to deny institution.

**Factor 4 (Overlap):** There should be no overlap of invalidity challenges. A FWD is likely to issue before the Delaware trial (see Factor 2) and Petitioners will be estopped from arguing grounds raised or that reasonably could have been raised in this IPR. Thus, Factor 4 weighs against exercising discretion to deny institution.

**Factor 5 (Parties):** This factor, which is met in nearly all IPRs, is of limited weight and Patent Owner fails to show how this factor could outweigh the others.

**Factor 6 (Other Circumstances):** The Petition presents compelling evidence that the '742 claims are met by the prior art such that, if unrebutted at trial, would plainly lead to a conclusion that one or more claims are unpatentable. *Illumina Inc. v. Trs. of Columbia Univ.*, IPR2020-00988, Paper 20 at 15 (PTAB Dec. 8, 2020) (declining to deny under *Fintiv* given strong evidence on the merits even though four factors weighed in favor of denial and remaining factor was neutral). The Patent Office did not apply or discuss the prior art in the Petition and could not have foreseen the breadth of claims Patent Owner would later assert in district court against Petitioners. Factor 6 weighs against exercising discretion to deny institution.

Petitioners' Reply to Patent Owner's Preliminary Response

Date: February 6, 2023

Respectfully submitted,

*/s/ W. Todd Baker*

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Gregg F. LoCascio, P.C. (Reg. No. 55,396)

W. Todd Baker (Reg. No. 45,265)

Justin Bova (Reg. No. 70,336)

gregg.locascio@kirkland.com

todd.baker@kirkland.com

justin.bova@kirkland.com

KIRKLAND & ELLIS LLP

1301 Pennsylvania Ave., N.W.

Washington, D.C. 20004

(202) 389-5000

Kat Li (Reg. No. 64,857)

kat.li@kirkland.com

KIRKLAND & ELLIS LLP

401 Congress Avenue

Austin, TX 78701

(512) 678-9100

*Attorneys for Petitioners Ivantis, Inc., Alcon  
Research, LLC, Alcon Vision, LLC, and  
Alcon Inc.*

**CERTIFICATE OF SERVICE**

The undersigned hereby certifies that a copy of the foregoing document and Exhibit 1035 were served on February 6, 2023, via electronic mail directed to counsel of record for the Patent Owner at the following:

Michelle S. Rhyu  
rhyums@cooley.com  
zSightSciencesIPR@cooley.com  
Orion Armon  
oarmon@cooley.com  
Mika Mayer  
mmayer@cooley.com  
Priya Arora  
parora@cooley.com

Cooley LLP  
ATTN: Patent Group  
1299 Pennsylvania Ave., NW, Suite 700  
Washington D.C. 20004

/s/ W. Todd Baker  
W. Todd Baker (Reg. No. 45,265)