

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ASCENTCARE DENTAL PRODUCTS, INC.,
Petitioner

v.

SOLMETEX, LLC
Patent Owner

Patent No. 11,589,969

Case No. IPR2025-01020

PATENT OWNER'S DISCRETIONARY DENIAL BRIEF

TABLE OF CONTENTS

I. INTRODUCTION1

II. THE BOARD SHOULD DENY INSTITUTION PURSUANT TO 35 U.S.C. § 325(D)6

 A. Petitioner’s References Were Previously Considered or Cumulative ..7

 B. Petitioner Has Not Shown Any Material Error21

 1. Petitioner’s Argument That the Examiner Did Not “Appreciate” the Scope of the Term “Connecting Wall” Ignores the Facts from the File History22

 2. Petitioner Mischaracterizes the Examiner’s Findings with Respect to the “Bridge Structure”25

 3. Petitioner Presents No Meaningful Additional Evidence or Facts that Warrant Reconsideration.....28

III. THE PARALLEL LITIGATION WILL MOST EFFICIENTLY RESOLVE THE PARTIES’ ENTIRE DISPUTE29

IV. THE BOARD SHOULD DENY INSTITUTION PURSUANT TO *FINTIV* 31

 A. Factor 1 Weighs Against Institution or is Neutral32

 B. Factor 2 Weighs Against Institution or is Neutral34

 C. Factor 3 Weighs Against Institution36

 D. Factor 4 Weighs Against Institution38

 E. Factor 5 Weighs Against Institution39

V. SETTLED EXPECTATIONS FAVOR DISCRETIONARY DENIAL39

VI. PETITIONER’S FAILURE TO PROFFER EXPERT TESTIMONY FROM A POSITA FAVORS DISCRETIONARY DENIAL.....42

VII. CONCLUSION.....45

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>Advanced Bionics, LLC v. Med-EL Elektromedizinische Gerate GmbH,</i> IPR2019-01469, Paper 6 (PTAB Feb. 13, 2020).....	9, 24, 31
<i>Apple Inc. v. Fintiv, Inc.,</i> IPR2020-00019, Paper 11 (PTAB Mar. 20, 2020).....	<i>passim</i>
<i>Apple Inc. v. Fintiv, Inc.,</i> IPR2020-00019, Paper 15 (PTAB May 13, 2020)	34
<i>Becton, Dickinson & Co. v. B. Braun Melsungen AG,</i> IPR2017-01586, Paper 8 (PTAB Dec. 15, 2017)	10, 18, 31
<i>Bell & Howell Document Mgmt. Prods. Co. v. Altek Sys.,</i> 132 F.3d 701 (Fed. Cir. 1997)	49
<i>Bd. of Regents of the Univ. of Tex. Sys. v. BENQ Am. Corp.,</i> 533 F.3d 1362 (Fed. Cir. 2008)	22
<i>Cuozzo Speed Techs., LLC v. Lee,</i> 136 S.Ct. 2131 (2016).....	1
<i>DeJule v. MillerKnoll, Inc.,</i> No. 1:23-CV-969, 2024 WL 5680071 (W.D. Mich. Feb. 2, 2024).....	36, 37
<i>Ecto World, LLC v. RAI Strategic Holdings, Inc.,</i> IPR2024-01280, Paper 13 (PTAB May 19, 2025)	11, 14, 18, 24
<i>Extreme Networks, Inc. v. Enterasys Networks, Inc.,</i> 395 F. App'x 709 (Fed. Cir. 2010).....	47
<i>Gen. Plastic Indus. Co. v. Canon Kabushiki Kaisha,</i> IPR2016-01357, Paper 19 (PTAB Sept. 6, 2017).....	33

<i>Harmonic Inc. v. Avid Tech., Inc.</i> , 815 F.3d 1356 (Fed. Cir. 2016)	1
<i>Helena Labs. Corp. v. Sebia</i> , IPR2024-00801, Paper 10 (PTAB Oct. 23, 2024).....	18
<i>IOENGINE, LLC v. PayPal Holdings, Inc.</i> , No. CV 18-452-WCB, 2019 WL 3943058 (D. Del. Aug. 21, 2019)	37
<i>Intel Corp. v. InterDigital, Inc.</i> , IPR2024-01441, Paper 13 (PTAB Apr. 1, 2025)	18
<i>iRhythm Techs., Inc. v. Welch Allyn, Inc.</i> , IPR2025-00363, Paper 10 (PTAB Jun. 6, 2025)	45
<i>Kyocera Senco Indus. Tools Inc. v. ITC</i> , 22 F.4th 1369, 1376 (Fed. Cir. 2022)	47
<i>Markman v. Westview Instruments, Inc.</i> , 52 F.3d 967 (Fed. Cir. 1995)	49
<i>Motorola Sols., Inc. v. Stellar, LLC</i> , IPR2024-01205, Paper 19 (PTAB Mar. 28, 2025).....	43
<i>Roton Barrier, Inc. v. Stanley Works</i> , 79 F.3d 1112 (Fed. Cir. 1996)	48
<i>Samsung Bioepis Co, Ltd. v. Regeneron Pharmas., Inc.</i> , IPR2025-00176, Paper 12 (PTAB Jun. 2, 2025)	39
<i>Shenzen Tuozhu Tech. Co., Ltd. v. Stratasys, Inc.</i> , IPR2025-000354, Paper 11 (PTAB Jun. 12, 2025)	43
<i>Trover Grp., Inc. v. Dedicated Micros USA</i> , No. 2:13-CV-1047-WCB, 2015 WL 1069179 (E.D. Tex. Mar. 11, 2015)	36
Statutes	
35 U.S.C. § 314.....	1, 9

35 U.S.C. § 316.....38
35 U.S.C. § 325.....*passim*

LISTING OF EXHIBITS

Exhibit No.	Description
2001	U.S. Patent Publication No. 2009/0274991 to Black
2002	U.S. Patent No. 1,731,322 to Riddle ("Riddle")
2003	U.S. Patent No. 4,083,115 to McKelvey ("McKelvey")
2004	International Publication No. WO 2011/014952 to Maycher ("Maycher")
2005	U.S. Patent Publication No. 2006/0063129 to Hirsch ("Hirsch '129")
2006	Patent Owner's May 17, 2023 Infringement Notice Letter to Petitioner
2007	First Case Management Order, <i>Solmetex, LLC v. Ascentcare Dental Products, Inc.</i> , Case No. 1:24-cv-00954-RJJ-MV, ECF No. 20 (Apr. 22, 2025)
2008	Defendant/Counter-Plaintiff Ascentcare Dental Products, Inc.'s Brief in Support of Motion to Stay, <i>Solmetex, LLC v. Ascentcare Dental Products, Inc.</i> , Case No. 1:24-cv-00954-RJJ-MV, ECF No. 38 (Jul. 11, 2025)
2009	Declaration of Nathan P. Sportel in Support of Defendant/Counter-Plaintiff's Motion to Stay, <i>Solmetex, LLC v. Ascentcare Dental Products, Inc.</i> , Case No. 1:24-cv-00954-RJJ-MV, ECF No. 39 (Jul. 11, 2025)
2010	Plaintiff/Counter-Defendant Solmetex, LLC's Opposition to Ascentcare's Motion to Stay, <i>Solmetex, LLC v. Ascentcare Dental Products, Inc.</i> , Case No. 1:24-cv-00954-RJJ-MV, ECF No. 41 (Jul. 25, 2025)
2011	Defendant/Counter-Plaintiff Ascentcare Dental Products,

	Inc.'s Invalidity Contentions Cover Pleading, <i>Solmetex, LLC v. Ascentcare Dental Products, Inc.</i> , Case No. 1:24-cv-00954-RJJ-MV, served July 18, 2025
2012	Defendant/Counter-Plaintiff Ascentcare Dental Products, Inc.'s Invalidity Contentions Claim Chart for the '969 Patent, <i>Solmetex, LLC v. Ascentcare Dental Products, Inc.</i> , Case No. 1:24-cv-00954-RJJ-MV, served July 18, 2025
2013	DocketNavigator Statistics, Western District of Michigan
2014	Email dated June 3, 2025 from Counsel for Solmetex to Counsel for Ascentcare
2015	Defendant/Counter-Plaintiff Ascentcare Dental Products, Inc.'s Non-Infringement Contentions, <i>Solmetex, LLC v. Ascentcare Dental Products, Inc.</i> , Case No. 1:24-cv-00954-RJJ-MV, served July 18, 2025

Pursuant to the Interim Processes for PTAB Workload Memorandum (“Memo”) dated March 26, 2025, Patent Owner Solmetex, LLC (“Patent Owner”) hereby submits its discretionary denial brief for Director review.

I. INTRODUCTION

The Board has discretion to decline to institute an IPR. 35 U.S.C. § 314(a); *Cuozzo Speed Techs., LLC v. Lee*, 136 S.Ct. 2131, 2140 (2016) (“[T]he agency’s decision to deny a petition is a matter committed to the Patent Office’s discretion”); *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1367 (Fed. Cir. 2016) (The Board is “permitted, but never compelled, to institute an IPR proceeding”). In this case, there are five independent reasons why the Director should exercise her discretion and deny institution.

First, the Petition presents a classic case for discretionary denial pursuant to 35 U.S.C. § 325(d). All but one of the references Petitioner relies on were considered by the Office during prosecution of the ‘969 Patent and/or one of its counterparts. Park—the only “new” reference in the Petition—is substantially similar to and entirely cumulative of the references that were expressly considered and that are also relied upon in the Petition. Petitioner’s suggestion that Patent Owner somehow misled the Examiner when amending the claims to recite a “connecting wall” rather than a “sidewall” is a red herring and does not demonstrate any error by the Office.

In the parallel litigation concerning the '969 Patent styled as *Solmetex, LLC v. Ascentcare Dental Products, Inc.*, Case No. 1:24-cv-00954, which is currently pending in the Western District of Michigan (“the Parallel Litigation”), Petitioner admitted to the Court that its petition is based on the same prior art that the Examiner applied during prosecution:

Also, [Petitioner] ***applied the prior art cited during the prosecution in the exact same manner in the IPRs as the Examiner did during prosecution***, so the previously considered art is still very relevant.

EX2008, 10 (emphasis added). Thus, by Petitioner's own admission, denial under 35 U.S.C. § 325(d) is warranted. Petitioner also represented that it did not begin conducting prior art searches and considering validity challenges until February 2025 (nearly 2 years after receiving Patent Owner's notice of infringement):

I began searching for prior art and considering grounds for invalidity in February 2025. After searches were run and I evaluated the prior art, I began drafting the IPR petitions in April 2025.

EX2009, ¶14. Considering that Petitioner's searching apparently located only a single “new” reference (Park) for this IPR that is entirely cumulative to other prior art already used in rejections by the Office (as explained below), it is clear that the Office had already located and applied the most pertinent art for the '969 Patent. On this record, Petitioner cannot show any material error by the Office.

Second, the Parallel Litigation currently involves not just the ‘969 Patent but also six other utility patents, three design patents asserted by Patent Owner, and a Lanham Act counterclaim asserted by Petitioner. As set forth below, Petitioner is seeking to initiate seven proceedings in the Office:

Patent No.¹	Case No.	Discretionary Denial Brief Deadline	Institution Deadline
11,589,969 (2013 Family)	IPR2025-01020	Aug. 18, 2025	Dec. 18, 2025
11,589,970 (2013 Family)	IPR2025-01057	Aug. 23, 2025	Dec. 23, 2025
11,744,686 (2013 Family)	IPR2025-01059	Aug. 24, 2025	Dec. 24, 2025
11,826,217 (2019 Family)	IPR2025-01065	Sept. 1, 2026	Jan. 1, 2026
12,011,329 (2013 Family)	IPR2025-01104	Sept. 1, 2026	Jan. 1, 2026
12,167,948 (2019 Family)	PGR2025-00058	Sept. 8, 2026	Jan. 8, 2026
12,290,418 (2013 Family)	IPR2025-01175	Sept. 8, 2026	Jan. 8, 2026

Like this Petition, all of Petitioner’s challenges in its other IPRs and PGR rely on the same or substantially similar prior art that was already considered by the Office.

The Director should exercise her discretion to deny all seven petitions (including this one) because even if the Board instituted and issued final written

¹ The seven patents include five related patents in one patent family (the “2013 Family”) and two related patents in a second patent family (the “2019 Family”).

decisions in Petitioner's favor in all of them, this would not resolve all of the parties' disputes, including the design patent claims and the Petitioner's Lanham Act claim. It would be far more efficient for the Government to conduct one proceeding—the Parallel Litigation—to resolve *all* of the parties' disputes, rather than seven separate proceedings in the Office which cannot afford such relief to either party.

Third, each of the factors in the Board's precedential *Fintiv* decision weigh in favor of denying institution in view of the Parallel Litigation. As of this brief, the parties have already exchanged infringement and invalidity contentions and are engaged in fact discovery. By the time the Board decides whether to institute an IPR in mid-December 2025, the parties will have already completed claim construction briefing, conducted a *Markman* hearing, and will be just weeks away from the fact discovery cutoff. While the court has not set a trial date yet, it is exceedingly likely that the Parallel Litigation will proceed to trial before the Board would issue a final written decision concerning the '969 Patent in December 2026.

Fourth, the settled expectations of the parties warrant denial. Petitioner has known about the '969 Patent for years but never challenged its validity, even after being expressly accused of infringement more than two years ago. Instead, Petitioner opted to argue non-infringement and pursued an alleged design around. This led Patent Owner to reasonably expect that Petitioner would not challenge the validity of the '969 Patent. Moreover, as Petitioner points out, prosecution of the '969 Patent

lasted *almost 9 years*. The Examiner issued at least eleven Office Actions and considered upwards of a hundred references. Patentees who have invested years of time and resources prosecuting an application before the Office should have a reasonable expectation that the issued patent is valid and will not be brought back before the Office for even more proceedings.

Fifth, the Director's Memo indicates that the extent to which the Petition relies on expert testimony is a relevant consideration for discretionary denial. Director Memo at 2. Here, Petitioner proffers testimony from Dr. Brian Black, but his testimony is facially flawed because Dr. Black is not a person of ordinary skill in the art ("POSITA") under the definition proposed in the Petition (the same POSITA definition that Petitioner advanced in the Parallel Litigation), which requires a mechanical engineering degree. The Federal Circuit has held that an expert must meet the definition for a POSITA, and Dr. Black does not meet Petitioner's definition. Moreover, Dr. Black improperly attempts to fill gaps in the Black reference by testifying regarding his own subjective thoughts and beliefs as its named inventor more than fifteen years ago. This testimony cannot support Petitioner's unpatentability arguments as a matter of law.

Each of these issues independently supports discretionary denial given that they raise issues of duplicative proceedings, inefficiency, and the risk of conflicting

outcomes. Considered together, they present a compelling case for the Director to exercise her discretion and deny institution pursuant to 35 U.S.C. § 314(a).

II. THE BOARD SHOULD DENY INSTITUTION PURSUANT TO 35 U.S.C. § 325(D)

Discretionary denial is warranted when “the same or substantially same prior art or arguments previously were presented to the Office.” 35 U.S.C. § 325(d). The Board applies a two-part test when considering whether to deny institution based on § 325(d): (1) whether the same or substantially the same art or arguments were previously presented to the Office; and (2) if part one satisfied, “whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of challenged claims.” *Advanced Bionics, LLC v. Med-EL Elektromedizinische Gerate GmbH*, IPR2019-01469, Paper 6 at 7 (PTAB Feb. 13, 2020) (precedential). The Board has enumerated the following factors to consider in exercising discretion pursuant to § 325(d):

- (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 the prior art or arguments.

Becton, Dickinson & Co. v. B. Braun Melsungen AG, IPR2017-01586, Paper 8 at 17–18 (PTAB Dec. 15, 2017) (precedential as to § III.C.5, first paragraph).

The Petition should be denied under § 325(d). Two of the key references in the Petition—Black and Hirsch—were not only cited and considered by the Examiner but were used to reject the claims in *multiple* Office Actions. Johnson and Baughan were also considered. The Petition's only remaining reference, Park, is entirely cumulative to the prior art the Examiner considered. Further, Petitioner's attempts to identify a material error by the Office are based on misdirection and a selective reading of the prosecution history.

A. Petitioner's References Were Previously Considered or Cumulative

The Petition relies on five references: Black, Park, Baughan, Johnson, and Hirsch. *See* Petition, 31-35. Each was previously considered by the Office or is cumulative of references that were considered.

1. Black was Considered (Grounds 1 and 4-5)

Black was cited in an IDS and was considered by the Examiner. EX1001, Cover; EX1002 at 70 (IDS filed on Sept. 2, 2014), 188 (showing examiner considered Black). This fact alone is sufficient to satisfy the first part of the *Advanced Bionics* test. *Ecto World, LLC v. RAI Strategic Holdings, Inc.*, IPR2024-01280, Paper 13 at 4 (PTAB May 19, 2025) (“Challenging the claims using the same prior art that was previously presented on an IDS is sufficient to satisfy the first part of the *Advanced Bionics* framework”). What is more, the Examiner applied Black in *five* rejections as either a primary or secondary reference and also explained what claim elements were lacking in Black before allowing the ‘969 Patent.

a) Black Was Used in Rejections During Prosecution of the ‘969 Patent

First, in a Final Office Action dated June 6, 2016, pending claim 1 was rejected as anticipated by Black.² EX1002, 245. Dependent claims 9-10, which recited a “bridge structure,” were rejected as obvious over Black and Riddle (EX2002). *Id.*, 247. The Examiner found that “Black et al. discloses the invention

² The Examiner applied the publication of Black (Pat. Pub. No. 2009/0274991) in these rejections, but there is no material difference between the publication and the issued patent. *Compare* EX1005 (Black) *with* EX2001 (Black publication).

substantially as claimed except for a bridge structure.” *Id.*

Second, in a Non-Final Office Action dated November 7, 2016, the Examiner rejected claim 1 as obvious over Black and McKelvey (EX2003). EX1002, 346-49. With respect to dependent claims 9-10, the Examiner stated that “Black et al in view of McKelvey discloses the invention substantially as claimed, except the bridge structure,” leading the Examiner to again apply Riddle for claims 9-10. *Id.*, 349-50. Following this Office Action, on February 8, 2017, claim 1 was canceled and dependent claims 9-10 were amended to depend from independent claim 21. EX1002, 372-75.

Third, in a Final Office Action dated January 16, 2018, independent claim 21 was rejected as obvious over Maycher (EX2004) in view of Black. EX1020, 15-18. With respect to claims 9-10, the Examiner found that “Maycher/Black discloses the invention substantially as claimed except for a bridge structure,” leading the Examiner to again apply Riddle for claims 9-10. *Id.*, 18.

Fourth, after an Amendment and RCE (EX1020, 109-19), in a Non-Final Office Action dated October 5, 2018, independent claim 21 was rejected for a second time as obvious based on Maycher in view of Black. EX1020, 123-27. For claims 9-10, the Examiner again found that Maycher and Black do not disclose the “bridge structure,” and applied Riddle again. *Id.*, 125-27.

Fifth, in a Final Office Action dated July 15, 2019, independent claim 21 was rejected as obvious for a third time based on Maycher in view of Black. EX1020, 169-70. Again, the Examiner found that Maycher and Black do not disclose the “bridge structure” in dependent claims 9-10. *Id.*, 170-72.

b) Black Was Used in Rejections During Prosecution of the Parent ‘232 Patent

The same Examiner (Hao D. Mai) considered and applied Black in multiple rejections during prosecution of U.S. Patent No. 8,911,232, which is the parent of the ‘969 Patent (hereinafter, “the Parent ‘232 Patent”). First, in a Non-Final Office Action dated May 6, 2014, the Examiner rejected (1) independent claim 1 and dependent 8 as anticipated by Rhoades and (2) dependent claims 9-10 as obvious over Rhoades and Black. EX1015, 49-52. Claims 9-10 are reproduced below:

9. The mouthpiece of claim 8, wherein the bridge structure protrudes from the interior surface of the posterior wall in a wave shape, and wherein the contact points are at crests of the wave shape.

10. The mouthpiece of claim 9, wherein troughs of the wave shape are configured to allow suction through the bridge structure.

Id., 25. This Office Action from the Parent ‘232 Patent’s file history was cited in an IDS and considered by the Examiner during prosecution of the ‘969 Patent. EX1002, 192.

Then, in a Final Office Action dated October 24, 2014, the Examiner rejected claims 1 and 8 as anticipated by Black, but found claims 9-10 allowable over Black because: “the prior arts fail to disclose or reasonably teach of a mouthpiece holding comprising, inter alia: a bridge structure protruding from an interior surface of the posterior wall in a wave shape, wherein the contact points are at crests of the wave shape.” EX1015, 109-11. This Office Action from the Parent ‘232 Patent was also cited in an IDS and considered by the Examiner during prosecution of the ‘969 Patent. EX1002, 189.

Importantly, each of the independent claims of the ‘969 Patent that are challenged in the Petition require the claimed bridge structure to have this “wave-shape,” which is not taught by Black as determined by the same Examiner during prosecution of the Parent ‘232 Patent.

2. Hirsch was Considered (Grounds 3 and 5)

Hirsch was cited in an IDS and was considered by the Examiner. EX1002, 387 (IDS filed on Feb. 8, 2017), 438 (showing examiner considered Hirsch); *Ecto World*, IPR2014-01280, Paper 13 at 4. Moreover, Hirsch or a substantially similar version of Hirsch were used by the Examiner in multiple rejections during prosecution.

For example, in a Non-Final Office Action dated June 5, 2017, the Examiner rejected independent claim 21 and dependent claims 9-10 (on the “bridge” feature)

as anticipated by Hirsch. EX1002, 428-30. Hirsch was then the subject of an Examiner Interview on June 30, 2017. EX1002, 444.

As another example, in a Non-Final Office Action dated January 10, 2020, the Examiner rejected pending claims as obvious over Maycher and U.S. Patent Publication No. 2006/0063129 to Hirsch (“Hirsch ‘129”). EX1020, 221-24. Hirsch ‘129 (EX2005) is a continuation-in-part of the version of Hirsch (Ex. 1012) Petitioner relies on. For purposes of this IPR, there are no material differences between Hirsch and Hirsch ‘129. For example, FIGS. 1-20 in Hirsch and Hirsch ‘129 are identical. *Compare* EX1012, FIGS. 1-20 *with* EX2005, FIGS. 1-20. The Examiner found that “Maycher/Hirsch discloses the invention substantially as claimed except for a bridge structure” and again applied Riddle for this feature of claims 9-10. EX1020, 225.

As yet another example, in a Final Office Action dated November 27, 2020, the Examiner rejected independent claim 21 again as obvious over Maycher and Hirsch ‘129. EX1020, 287-89. The Examiner again found that Maycher and Hirsch ‘129 do not disclose a “bridge structure” and applied Riddle. *Id.*, 289. Subsequently, on January 11, 2021, there was an Examiner Interview to discuss adding reciting “a bridge structure that includes a plurality of protrusions integral with and protruding from an interior surface of a second wall” to overcome the rejections based on Maycher and Hirsch ‘129. *Id.*, 306, 322-29.

As a further example, in a Non-Final Office Action dated October 6, 2021, pending claim 23 (which issued as claim 19 of the '969 Patent) was rejected as anticipated by Hirsch '129. EX1020, 479. In response, Applicant explained that Hirsch does not disclose a “bridge structure” with “a wave shape comprising one or more crests and one or more troughs.” EX1021, 120-24. The claims were subsequently allowed. *Id.*, 300.

3. Baughan was Considered (Grounds 2-4)

While Baughan is not listed on the face of the '969 Patent, the record is clear that it was expressly considered by the Examiner. In a response accompanying an RCE filed on June 17, 2021, the Applicant noted that “[d]uring the Examiner Interview on March 2, 2021, the Examiner had argued that Baughan (U.S. Patent 3,101,543A) teaches a first wall and a second wall comprising a bridge structure.” EX1020, 424. The Applicant explained that, among other things, Baughan “fails to disclose any ‘wave shape comprising one or more crests and one or more troughs’ as claimed.” *Id.*, 425.

To the extent Petitioner suggests Baughan was not fully considered, Petitioner admits that Baughan is cumulative of Black—which was considered at length during prosecution—in arguing that “the concept of using perpendicularly projecting structures to prevent collapse of parallel walls under suction was demonstrated by

Black and Baughan.” Petition, 62-63 (emphasis added). Thus, by Petitioner’s own admissions, Baughan is cumulative of Black on this point.

Further, Baughan, and the manner in which Petitioner relies on Baughan, is cumulative of Riddle, which was used in multiple rejections in combination with Black during prosecution. In at least three different Office Actions, the Examiner stated that:

Riddle discloses a saliva ejector tube having a bridge structure 5 protruding from an interior surface of a wall thereof and unattached to the opposite wall. The protruding bridge comprises a plurality of protrusions (waved wire) to keep the walls separated from one another during section (Fig. 1). It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate such bridge into Maycher/Black’s device in order to prevent collapse when under suction pressure as explicitly taught by Riddle.

EX1002, 247 (Jun. 6, 2016); EX1020, 127 (Oct. 5, 2018 Office Action); *id.*, 172-73 (Jul. 15, 2019 Office Action). Similarly, Petitioner relies on Baughan as teaching “a mechanical element that prevents collapse under suction” and argues that it would have obvious to incorporate this in Park “to prevent collapse of the posterior and anterior walls.” Petition, 61-62. Petitioner’s argument here is effectively the same as how the Examiner applied Riddle during prosecution of the ‘969 Patent, rendering Baughan and Petitioner’s obviousness theory cumulative of Riddle.

4. Johnson was Considered (Grounds 3-4)

Johnson is cited in an IDS filed on May 12, 2014 and was considered by the Examiner. EX1001, Cover; EX1002, 45 (citing in IDS), 190 (showing Examiner considered Johnson); *Ecto World*, IPR2014-01280, Paper 13 at 4.

5. Park is Cumulative (Grounds 2-4)

Park is the *only* reference Petitioner relies on that was not already considered by the Office. But that is immaterial because Petitioner has admitted that Park is substantially similar to, and cumulative of, references that were both considered and used in rejections during prosecution. *Becton*, Paper 8 at 17-18; *see also Intel Corp. v. InterDigital, Inc.*, IPR2024-01441, Paper 13 at 15-16 (PTAB Apr. 1, 2025) (finding reference was cumulative where it was “relied upon to teach the same limitations as” a considered reference and did “not add anything new”); *Helena Labs. Corp. v. Sebia*, IPR2024-00801, Paper 10 at 12 (PTAB Oct. 23, 2024) (finding reference was cumulative even though “there are some differences” because “those differences do not affect . . . [the] analysis of the independent claims”).

Petitioner and its expert admit to the cumulative nature of Park by noting that Park has “the same basic structure of conventional isolation mouthpieces,” including Black and Hirsch, which, as discussed above, were considered during prosecution. Petition, 20-21. For example, Petitioner’s expert testifies:

It must be noted that all four mouthpieces I considered for this report (the '969 Patent, Hirsch, Park, Black) have similar shapes and structures due to their function. All four mouthpieces have a main larger body portion that blocks the tongue, then a narrower connecting portion that ends in a smaller cheek retractor end. One each mouthpiece, the larger body portion has an extension to connect to a suction hose. All of these devices have an anterior (front or first wall) and a posterior (back or second wall), and all mouthpieces are longitudinally symmetrical. Hence, none of these features of the '969 Patent are novel or unique.

EX1003, ¶27. Petitioner and its expert show these similarities below:

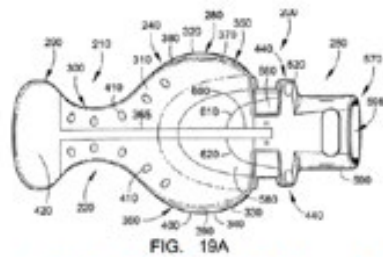


FIG. 19A of Hirsch

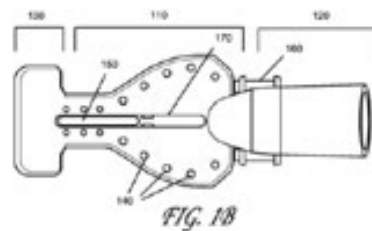


FIG. 1B of '969 Patent

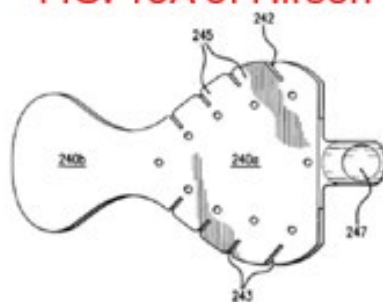


FIG. 4C of Black

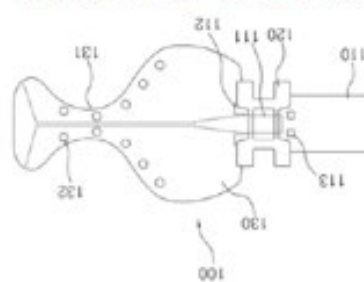


FIG. 3 of Park

Petition, 15 (annotations added)

Park is therefore substantially similar to and cumulative of references that were already considered during prosecution.

First, Park is cumulative of any portion of Black relied on by Petitioner. In Ground 1, Petitioner argues that Black anticipates independent claim 19 and discloses the claimed “bridge structure,” even though the Examiner expressly found multiple times that it does not. *See* Petition, 36-50; *supra*, § II.A.1.

In Ground 2, Petitioner admits that “Park is silent regarding whether any structures are formed inside the interior chamber of the main body.” Petition, 58. Petitioner’s expert goes further, admitting that “Park fails to expressly describe or illustrate whether the mouth prop 100 includes any internal features that assist with suction or preventing collapse under suction”. EX1003, ¶131. Because Park fails to disclose any internal features, Petitioner is forced to rely on Johnson and Baughan as allegedly teaching the claimed bridge structure having a plurality of protrusions in a wave shape comprising one or more crests and one or more troughs. Petitioner’s analyses of Black relative to claim 19 in Ground 1 and of Park relative to claim 19 in Ground 2 confirms the cumulative nature of Park because, according to Petitioner, Black teaches *more* of the claimed structures of independent claim 19 than Park.

To the extent Petitioner argues that Park is not cumulative of Black because Park discloses a “enclosed dental isolation mouthpiece with sidewalls” (Petition, 51) and Black does not, this distinction is immaterial. Claim 19 recites a “connecting wall,” not a “sidewall.” EX1001, 6:40-43. While claims 1-18 recite a “sidewall,” these claims do not require an entirely “enclosed” mouthpiece or multiple sidewalls.

See, e.g., id., 6:13-45 (claim 1). Petitioner proffers no claim construction for “sidewall” or “connecting wall,” let alone a reason why Park is not cumulative of Black with respect to patentability. *See* Petition, 29-30. Further, the Examiner found multiple times during prosecution that Black discloses a “sidewall.” EX1002, 247 (“Black et al. discloses the invention substantially as claimed except for a bridge structure”), 346-47 (finding Black discloses a sidewall); *see also* EX1015, 110 (finding that Black discloses “a side wall (peripheral side wall shown in Figures 1 and 6A-6C0 between the anterior wall and the posterior wall)”).

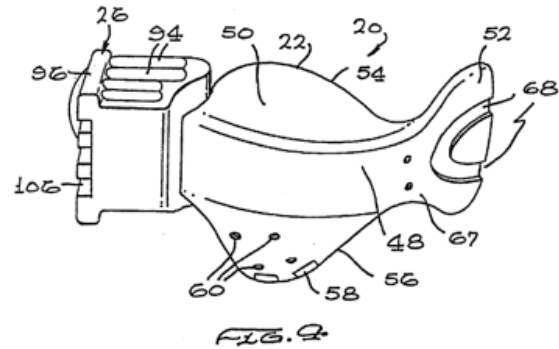
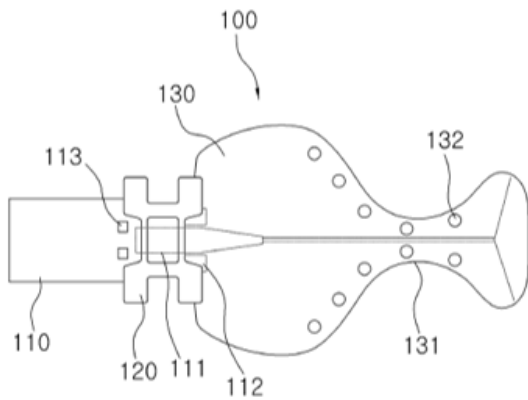
Similarly, to the extent Petitioner argues Park is not cumulative because Ground 1, which is based on Black, “addresses some of Patent owner’s broader construction [sic],” while Ground 2, which is based on Park, “addresses either Patent Owner’s or Petitioner’s construction of sidewall/connecting wall, ‘edge,’ ‘side,’ ‘end,’ ‘interior surface,’ and ‘corresponding shape,’” this is unavailing. Petition, 30. Petitioner does not explain what any of these purported constructions are, or the basis (if any) for Petitioner’s constructions. *Id.* Petitioner’s vague reference to unspecified claim constructions for a laundry list of claim terms does not render Park non-cumulative.

Second, Park is substantially similar to and cumulative of Hirsch, which was also considered at length during prosecution of the ‘969 Patent. *Supra*, § II.A.2. In addition to the admissions noted above from Petitioner’s expert about the substantial

similarity between Park and Hirsch, in Ground 3, Petitioner proposes combining Park and Hirsch and argues that “both mouthpieces perform the same function and have very similar designs (Hirsch simply lacks sidewalls).” Petition, 74. Thus, according to Petitioner, the only difference between Park and Hirsch is that Hirsch allegedly lacks “sidewalls.” *Id.* There are several problems with this assertion.

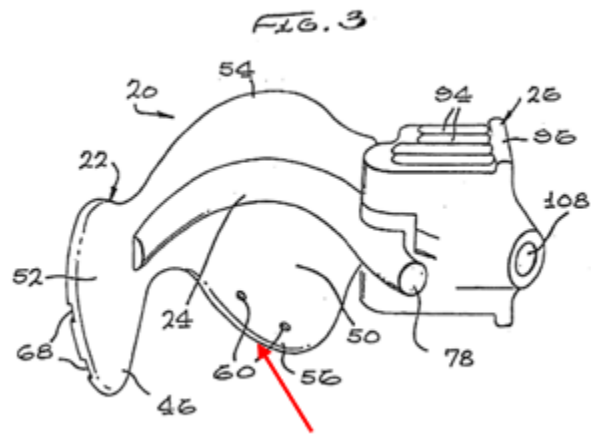
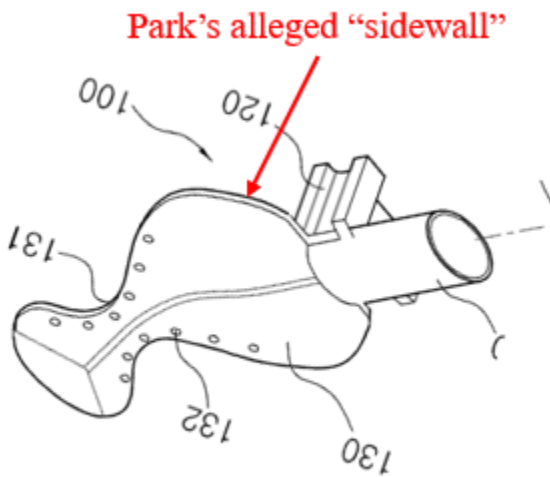
For starters, the alleged “sidewalls” distinction between Park and Hirsch is a red herring for independent claim 19, which recites a “connecting wall” rather than a “sidewall.” Indeed, Petitioner admits that the term “connecting wall” in claim 19 is broader than “sidewall” recited elsewhere. *See* Petition, 17-18, 23-28. This is consistent with the well-settled principle that “[d]ifferent claim terms are presumed to have different meanings.” *Bd. of Regents of the Univ. of Tex. Sys. v. BENQ Am. Corp.*, 533 F.3d 1362, 1371 (Fed. Cir. 2008).

Petitioner's suggestion that Hirsch does not disclose “sidewalls” is also wrong. As shown in the bottom views reproduced below, consistent with Petitioner's admission, Hirsch discloses a substantially similar mouthpiece as Park:



EX1006, FIG. 3 (Park); EX 1012, FIG. 9 (Hirsch)

Hirsch's "sidewall" and its substantial similarity to the alleged "sidewall" in Park is clearly shown in the perspective views reproduced below:



Hirsch's similar "sidewall"

Ex. 1006, FIG. 2 (Park) (rotated and annotated); Ex. 1012, FIG. 3 (Hirsch) (annotated)

Indeed, during prosecution, the Examiner specifically found that Hirsch '129 discloses a "sidewall." EX1002, 428 (finding that Hirsch '129 discloses "a side wall, i.e., any connecting material at edge 54"); see also EX1020, 479 (finding that in

Hirsch '129 discloses "a connect wall 62/64 that connects the first wall 50 and second wall 24 cross a span therebetween"). Petitioner's assertion that Park discloses a "sidewall" and Hirsch does not is incorrect.

Third, Park is cumulative of the Maycher/Hirsch '129 combination that was applied in multiple Office Actions. *Supra*, § II.A.2. The Examiner found that Maycher/Hirsch '129 "discloses the invention substantially as claimed," including a "sidewall," but does not disclose a bridge structure. EX1020, 211-25 (Non-Final Office Action dated Jan. 10, 2020), 287-89 (Final Office Action dated Nov. 27, 2020). Petitioner similarly contends that Park discloses everything in the independent claims except for the "bridge structure" limitation. *See* Petition, 50-67. Petitioner's obviousness arguments based on Park are thus substantially similar to the rejections based on Maycher, Hirsch '129, and Riddle during prosecution. *Supra*, §§ II.A.2-II.A.3; EX1020, 225, 289.

B. Petitioner Has Not Shown Any Material Error

Because the first part of the *Advanced Bionics* test is satisfied, Petitioner "must demonstrate that, for example, the previously presented art teaches the limitations of the challenged claims, and that no reasonable examiner could have found otherwise." *Ecto World*, Paper 13 at 5-6; *see also Advanced Bionics*, Paper 6 at 9 ("If reasonable minds can disagree regarding the purported treatment of the art or arguments, it cannot be said that the Office erred in a manner material to

patentability”). To the extent the Petition’s characterizations of the prosecution history are meant to address the second part of the *Advanced Bionics* test, Petitioner identifies no material error by the Office in issuing the ‘969 Patent.³

1. Petitioner’s Argument That the Examiner Did Not “Appreciate” the Scope of the Term “Connecting Wall” Ignores the Facts from the File History

In an attempt to identify an error by the Office, Petitioner makes much of the fact that independent claim 19 recites a “connecting wall” rather than a “sidewall” and characterizes this change as a “dramatic shift in claim scope” that the Examiner did not “appreciate.” Petition, 17-18, 23-28. Petitioner calls this change “problematic” because Patent Owner supposedly “went to great lengths to show and describe what was meant by the claimed sidewall” to overcome Black. Petition, 26. Petitioner then accuses Patent Owner of asserting that “the claimed ‘connecting wall’ reads on something Black . . . clearly discloses – namely a connecting wall formed at the first end of the mouthpiece near the suction connector.” *Id.*, 26-27. Based on the foregoing, Petitioner suggests that the Examiner should have rejected claim 19 based on Black because it is “broader than the claims that the Examiner had previously rejected in view of Black – presumably (and understandably) because

³ Patent Owner reserves the right to seek a reply brief should Petitioner identify an alleged material error for the first time in any opposition. *See* Memo at 2.

nearly 9 years has passed since the previous rejection in view of Black in a different patent application.” *Id.*, 28 (citing EX1015, 51-52, 109).

Petitioner's argument based on its perception of what might be a “connecting wall” versus a “sidewall” is a red herring. As discussed above, the Examiner found on no less than five separate occasions during prosecution of the '969 Patent that Black does not disclose a “bridge structure.” *Supra*, § II.A.1. Claim 19 recites “a bridge structure that includes a plurality of protrusions” that “protrude from the interior surface of the second wall toward the first wall in a wave shape comprising one or more crests and one or more troughs.” EX1001, 8:31-38. The difference between “connecting wall” and “sidewall” has no bearing on the Examiner's reasoning for allowing the claims over Black, which was based on Black's lack of a “bridge structure” having a “wave shape” and had nothing to do with whether or not Black discloses a “sidewall.” *Supra*, § II.A.1.

Even if, *arguendo*, the difference between “sidewall” and “connecting wall” was somehow relevant to the reasons for allowance (which is not the case), Petitioner's suggestion that the Examiner did not appreciate “the impact of Patent owner's broadening effort” ignores the file history. Petition, 17-18. The Examiner was acutely aware of this change yet still allowed the claims. In an amendment filed on January 21, 2021, pending claims 21 and 22 were amended to recite “a first wall” and a “second wall” while deleting the term “sidewall.” EX1020, 326-27. These

claims were also amended to recite a “bridge structure” that “is not attached to the first wall” and has protrusions “in a wave shape comprising or more crests and one or more troughs.” *Id.* Applicant also added new independent claim 23 (which eventually issued as claim 19) reciting, *inter alia*, “a first wall,” “a second wall,” and “a bridge structure” with protrusions “in a wave shape comprising one or more crests and one or more troughs.” *Id.*, 329.

In a Notice of Allowance dated March 17, 2021, the Examiner canceled new claim 23 and amended claims 21 and 22 to reintroduce the “sidewall” limitation. EX1020, 377-38. It was therefore clear to the Examiner that the Applicant had removed the “sidewall” limitations in its amendment because the Examiner specifically added that language back into the claims.

Later, Applicant filed an RCE amending claims 21 and 22 to recite a “connecting wall” and again added claim 23. *Id.*, 422-24. Claim 23 was subsequently rejected as anticipated by Hirsch in an Office Action dated October 6, 2021. *Id.*, 476-79. The Examiner expressly acknowledged the “connecting wall” language and stated that it was “broad.” *Id.*, 479. Despite clearly being aware of the change from “sidewall” to “connecting wall” during prosecution, the Examiner subsequently allowed the claims with minor amendments. EX1020, 298-300.

Consequently, Petitioner's argument that the Examiner did not appreciate the difference between the “connecting wall” and the “side wall” is belied by the

Examiner's treatment of these two claim terms in the prosecution history of the '969 Patent.

2. Petitioner Mischaracterizes the Examiner's Findings with Respect to the "Bridge Structure"

Petitioner also suggests that the Examiner erred by forgetting about a rejection based on Black that was issued during prosecution Parent '232 Patent, and that this same rejection should have been applied against claim 19 of the '969 Patent. *See* Petition, 23-28. However, Petitioner mischaracterizes the prosecution history and again ignores the Examiner's express reasoning for allowing the claims.

Petitioner is correct that during prosecution of the Parent '232 Patent, the Examiner originally found that "Black teaches a bridge structure." Petition, 24-25. However, the Examiner later withdrew this rejection because:

the prior art fail to disclose or reasonably teach of a mouthpiece holding comprising, inter alia: a bridge structure protruding from an interior surface of a posterior wall *in a wave shape*, wherein the contact points are at *crests of the wave shape*.

EX1015, 109-11 (emphases added); *see also* Petition, 25 (acknowledging same). Applicant subsequently amended the pending claims in the Parent '232 Patent, attempting to take this allowable subject matter but, notably, did not include the "wave shape" feature in those amended claims. EX1015, 124-31.

In the subsequent Notice of Allowance in the Parent '232 Patent, the Examiner entered an amendment adding the "wave shape" language to claim 1. *Id.*, 145-48. It

is therefore clear that the “wave shape” language was a key feature used to distinguish Black and the other references of record. Petitioner fails to acknowledge this portion of the file history of the Parent ‘232 Patent.

Turning back to the ‘969 Patent, Petitioner notes that at one point, the pending claims recited that the “bridge structure” was “unattached” and speculates that the Examiner did not issue a rejection based on Black because the claims “specifically recited that the bridge structure protruding from an interior surface of the posterior wall is also *unattached* to the anterior wall,” whereas in Black the alleged “bridge structure” is attached. Petition, 26 (citing EX1002, 225, 247) (emphasis in original). In other words, Petitioner suggests that the Examiner should have found that Black discloses the “bridge structure” in claim 19 because claim 19 does not include the word “unattached.”

Petitioner's argument again ignores the Examiner's repeated findings, including during prosecution of the Parent ‘232 Patent, that Black does not disclose the “bridge structure” with a “wave shape” having “crests” and “troughs.” Indeed, as shown below, claim 19 of the ‘969 Patent contains the same language that was allowable in the Parent ‘232 Patent:

Allowable Language in Parent ‘232 Patent	Claim 19 of the ‘969 Patent
<p>“a bridge structure protruding from an interior surface of the posterior wall in a wave shape, the protruding bridge structure comprising a plurality of spaced contact points that keep the anterior wall separated from the posterior wall during suction, wherein the spaced contact points are at crests of the wave shape and wherein a plurality of troughs of the wave shape between the spaced contact points allow for suction through the bridge structure.”</p>	<p>a bridge structure that includes a plurality of protrusions integral with and protruding from an interior surface of the second wall within the interior space of the pocket, wherein the protrusions of the bridge structure protrude from the interior surface of the second wall toward the first wall in a wave shape comprising one or more crests and one or more troughs</p>

Despite the fact that the Examiner consistently and repeatedly found that Black does not disclose a “bridge structure” as claimed, Petitioner nevertheless argues that it does. *See* Petition, 42-45. Aside from its misdirection regarding the “connecting wall” and mischaracterization of the Parent ‘232 Patent’s prosecution, Petitioner does not explain why the Examiner allegedly erred in this regard. *Advanced Bionics*, Paper 6 at 9 (“If reasonable minds can disagree regarding the

purported treatment of the art or arguments, it cannot be said that the Office erred in a manner material to patentability”). Petitioner would have the Board institute an IPR relitigating the exact same issue the Examiner already addressed multiple times.

Similarly, despite the fact that the Examiner consistently and repeatedly found during prosecution that it would not have been obvious to modify the various references applied during prosecution, including Black and Hirsch, to include a bridge structure, the Petition nevertheless advances substantially the same argument in Ground 2 based on the same or similar references. *See* Petition, 57-65. Again, the Petition makes no attempt to explain how the Examiner allegedly erred in allowing the claims. *Advanced Bionics*, Paper 6 at 9.

3. Petitioner Presents No Meaningful Additional Evidence or Facts that Warrant Reconsideration

Petitioner has not identified any “additional evidence and facts” that “warrant reconsideration of the prior art or arguments.” *Becton*, Paper 8 at 17-18. To the extent Petitioner argues that Dr. Black’s declaration (EX1003) is new evidence that warrants institution, that argument fails. The inclusion of an expert declaration with a petition, standing alone, cannot avoid the application of § 325(d). Moreover, as explained below, Dr. Black’s declaration is flawed, among other reasons, because he is not even a POSITA under Petitioner’s proposed definition and provides after-the-fact testimony about what his words and figures supposedly meant over a decade

ago when he filed his patent application (i.e., the Black reference discussed above).

Infra, § VI.

To the extent Petitioner argues Patent Owner's infringement allegations, for example, with respect to the "connecting wall" term, constitute new facts that should be considered, as discussed above, the "sidewall" and "connecting wall" distinction is a red herring. *Supra*, § II.B.1. To the extent Petitioner claims that Patent Owner is taking inconsistent positions for infringement and validity (which it is not), such a dispute would be better suited for the district court which can consider Patent Owner's infringement contentions and is fully equipped to consider the prosecution history.

III. THE PARALLEL LITIGATION WILL MOST EFFICIENTLY RESOLVE THE PARTIES' ENTIRE DISPUTE

As discussed above, this IPR is one of seven IPR/PGR challenges directed to the seven utility patents asserted by Patent Owner in the Parallel Litigation, along with three design patents asserted by Patent Owner and Petitioner's Lanham Act claims. If each of the seven petitions is instituted, the Board will need to issue seven final written decisions, which will only resolve the disputes for these patents if the Board finds that all 69 currently asserted claims in the Parallel Litigation are unpatentable.

By contrast, the Parallel Litigation will resolve not just the parties' dispute regarding the '969 Patent but *all* of the parties' disputes for all seven patents in a single proceeding. It will also resolve the parties' disputes regarding the three asserted design patents and Petitioner's Lanham Act claim. Congress designed IPRs "to provide an effective and efficient *alternative* to district court litigation." *Gen. Plastic Indus. Co. v. Canon Kabushiki Kaisha*, IPR2016-01357, Paper 19, 16-17 (PTAB Sept. 6, 2017) (precedential) (emphasis added). In this case, instituting an IPR of the '969 Patent would merely result in the creation of an *additional* proceeding given that the Parallel Litigation will continue even if Petitioner were successful in all of its petitions.

It would be far more efficient for the Government to conduct one proceeding (the Parallel Litigation) to resolve the parties' disputes rather than to strain the Offices' limited resources in conducting seven separate proceedings that would only potentially resolve *some* of the parties' disputes. Patent Owner submits that the Office should decline Petitioner's request to initiate piecemeal and duplicitous litigation. It would also be less burdensome for the parties to litigate all of their disputes in one proceeding rather than some of their disputes across seven separate proceedings. For these additional reasons, the Director should exercise her discretion to deny institution.

IV. THE BOARD SHOULD DENY INSTITUTION PURSUANT TO *FINTIV*

The Board considers six factors to determine whether to deny institution based on one or more parallel proceedings:

1. whether the court granted a stay or evidence exists that one may be granted if a proceeding is instituted;
2. proximity of the court's trial date to the Board's projected statutory deadline for a final written decision;
3. investment in the parallel proceeding by the court and the parties;
4. overlap between issues raised in the petition and in the parallel proceeding;
5. whether the petitioner and the defendant in the parallel proceeding are the same party; and
6. other circumstances that impact the Board's exercise of discretion, including the merits.

Apple Inc. v. Fintiv, Inc., IPR2020-00019, Paper 11 at 5-6 (PTAB Mar. 20, 2020) (precedential) (hereinafter, "*Fintiv*"); *see also Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 15 (PTAB May 13, 2020) (informative) (applying the *Fintiv* factors and denying institution) (hereinafter, "*Fintiv II*"). "[I]n evaluating the factors, the Board takes a holistic view of whether efficiency and integrity of the system are best served by denying or instituting review." *Fintiv*, Paper 11 at 6. Each of these factors weighs in favor of denying institution.

A. Factor 1 Weighs Against Institution or is Neutral

The first *Fintiv* factor weighs against institution because the district court has not granted a stay. On July 11, 2025, Petitioner moved to stay the Parallel Litigation based on its petitions challenging seven out of the ten asserted patents. EX2008; *supra*, § III.C. Patent Owner opposed. EX2010. The court has not yet ruled on the motion, which remains pending as of the filing of this brief.⁴ However, it is objectively unlikely that the court will grant a stay either pre-institution or post-institution.

When recently faced with a similar pre-institution stay request, the presiding judge in the Parallel Litigation, Judge Jonker, denied the motion because “the PTAB has not yet granted any re-examination on any of the four patents at issue and may never do so.” *DeJule v. MillerKnoll, Inc.*, No. 1:23-CV-969, 2024 WL 5680071, at *1 (W.D. Mich. Feb. 2, 2024) (J. Jonker). The same reasoning applies to this case. Indeed, most district courts routinely deny such motions as premature. *See, e.g., Trover Grp., Inc. v. Dedicated Micros USA*, No. 2:13-CV-1047-WCB, 2015 WL 1069179, at *5 (E.D. Tex. Mar. 11, 2015) (“the majority of courts that have ... postponed ruling on stay requests or have denied stay requests when the PTAB has

⁴ Patent Owner intends to seek authorization to supplement the record when the court rules on the motion.

not yet acted on the petition for review”); *IOENGINE, LLC v. PayPal Holdings, Inc.*, No. CV 18-452-WCB, 2019 WL 3943058, at *6 (D. Del. Aug. 21, 2019) (“courts almost invariably deny requests for stays pending IPR proceedings when the stay requests are filed before the IPR is instituted”)

A stay is also unlikely because there are additional claims in the Parallel Litigation that cannot be resolved by the Board, including Patent Owner's design patent claims and Petitioner's Lanham Act claim. *Supra*, § III. Petitioner's admission that the parties are direct competitors also makes a stay unlikely given the resulting prejudice to Patent Owner. EX2010, 11-13; *DeJule*, 2024 WL 5680071 at *2 (finding that patentee “would suffer significant unfair prejudice if forced to put all of [its] claims . . . on ice for a PTAB process that may or may not actually occur, and that cannot in any case address” all of the parties' disputes).

It is also unlikely that the Parallel Litigation will be stayed if the Board institutes an IPR. As discussed below, by the time the Board issues an institution decision in mid-December 2025, the parties will have already completed claim construction, likely conducted a Markman hearing (scheduled for December 15, 2025), and will be just weeks away from the fact discovery cutoff. *Infra*, § IV.C. Accordingly, this factor weighs against institution or is at best neutral.

B. Factor 2 Weighs Against Institution or is Neutral

“If the court’s trial date is earlier than the projected statutory deadline, the Board generally has weighed this [second] factor in favor of exercising authority to deny institution.” *Fintiv*, Paper 11 at 9. There is no set trial date in the Parallel Litigation, but the court has set the following deadlines:

Parties exchange terms for constructions	Aug. 29, 2025
Parties exchange proposed claim constructions and extrinsic evidence	Sept. 12, 2025
Opening claim construction briefs	Oct. 3, 2025
Responsive claim construction briefs	Oct. 30, 2025
Substantial completion of document production, deadline to exchange privilege logs, and deadline to disclose reliance on opinion of counsel	Dec. 3, 2025
<i>Markman</i> hearing	Dec. 15, 2025
Close of fact discovery	Jan. 21, 2026
Second Rule 16 Scheduling Conference	Feb. 23, 2026

EX2007, 2-3.

If an IPR is instituted, the Board would need to issue its final written decision by December 18, 2026. 35 U.S.C. § 316(a)(11). While a trial date is not scheduled yet in the Parallel Litigation, with fact discovery set to close in January 2026, trial will likely occur before the Board’s final written decision deadline in December 2026. Patent Owner anticipates that the court will set deadlines for expert

disclosures, expert discovery, and dispositive motion briefing during the Second Rule 16 Conference in February 2026. Given that the fact discovery period is 9 months (between April 2025 and January 2026), it is likely that the case will go to trial before December 2026.

According to Docket Navigator, the median time to trial in the Western District of Michigan in patent cases is 48 months. EX2013. However, this figure is based on a small sample size of only four cases. *Id.* Notably, two of the four cases reached a jury trial within 2 years of their filing date. *Id.* Based on the January 2026 fact discovery cutoff in the Parallel Litigation, it is likely that trial in the Parallel Litigation will similarly occur within approximately two years of the filing of Patent Owner's complaint in September 2024, i.e., by the mid-December 2026 final written decision deadline.

While Petitioner may argue that *Fintiv* does not apply because there is no set trial date, the Board has denied petitions under *Fintiv* even where there was no firm trial date. *See, e.g., Samsung Bioepis Co, Ltd. v. Regeneron Pharmas., Inc.*, IPR2025-00176, Paper 12 at 13-14 (PTAB Jun. 2, 2025) (rejecting argument that the lack of a set trial deadline is dispositive under *Fintiv* and denying institution). Thus, this factor weighs against institution or is at best neutral.

C. Factor 3 Weighs Against Institution

The third factor concerns “the amount and type of work already completed in the parallel litigation by the court and the parties and the time of the institution decision.” *Fintiv*, Paper 11 at 9. In particular, substantive orders in the parallel litigation regarding the challenged patent, such as claim construction orders, favor denying institution. *Id.* at 9-10. Here, both the district court and the parties have invested substantial time and resources in the Parallel Litigation and will continue to do so before any institution decision.

As of this brief, the parties have negotiated a schedule, attended a scheduling conference, engaged in motion practice, and have commenced fact discovery, including serving and responding to dozens of interrogatories and hundreds of requests for production and serving several third-party subpoenas. EX2010, 1-2. The parties have also already exchanged thousands of pages of initial infringement contentions, invalidity contentions, and non-infringement contentions. *Id.*, EX2011; EX2012.

By the time the Board would decide whether to institute an IPR in mid-December 2025, even more work will have been done: the parties will have completed *Markman* briefing in October 2025 and the court will have held a *Markman* hearing on December 15, 2025. EX2007, 2-3. The parties will also have already substantially completed their respective document productions, exchanged

privilege logs, and disclosed any opinions of counsel. *Id.*, 3. At bottom, the case will be at a very advanced stage by the time the Board issues any institution decision.

The timing of the Petition is also considered under the third *Fintiv* factor: if “the petitioner did not file the petition expeditiously, such as at or around the same time that the patent owner responds to the petitioner’s invalidity contentions, or even if the petitioner cannot explain the delay in filing its petition, these facts have favored denial.” *Fintiv*, Paper 11 at 11-12. Here, Petitioner waited more than two years to challenge the ‘969 Patent after being accused of infringement. EX2006. Indeed, the supposed “infringement contentions” Petitioner included as Exhibit 1011 were provided by Patent Owner in its cease-and-desist letter more than two years ago (they are not infringement contentions from the Parallel Litigation). After receiving the cease-and-desist letter, Petitioner attempted to design-around the ‘969 Patent with a new version of its infringing product, rather than challenging its validity. *See* EX2008, 3-4 (admitting that Petitioner redesigned its product to attempt to avoid infringement).

To the extent Petitioner argues that it was justified in waiting to challenge the ‘969 Patent until it was sued for infringement, Petitioner still waited more than ***eight months*** after the filing of the Complaint to file its Petition. EX1009. As discussed above, Petitioner’s counsel represented under oath in the Parallel Litigation that Petition did not commence prior art searching until February 2025. EX2009, ¶14.

Petitioner's delay in filing the Petition is especially unwarranted because all but one of the references relied upon in the Petition were already cited and considered during prosecution of the '969 Patent, and the only "new" reference (Park) that Petitioner's searching located is entirely cumulative to the prior art the Examiner already considered and applied before granting the '969 Patent. *Supra*, § II.A. Accordingly, this factor weighs against institution.

D. Factor 4 Weighs Against Institution

Under factor 4, "concerns of inefficiency and the possibility of conflicting decisions [are] particularly strong" where a petition "includes the same or substantially the same claims, grounds arguments, and evidence as presented in the parallel proceeding." *Fintiv* at 12. That this precisely the case here.

In connection with Petitioner's pending motion to stay, Patent Owner inquired whether Petitioner intended to offer a *Sotera* stipulation to avoid duplicative efforts should the Board institute an IPR, but Petitioner declined to do so. EX2014, 1. Petitioner's refusal to agree to limit the scope of its invalidity case in the Parallel Litigation in light of its IPR strategy, let alone offer a full *Sotera* stipulation, weighs against institution because this demonstrates Petitioner's intent to assert the exact same grounds as the Petition in the Parallel Litigation, including the Black, Hirsch, Baughan, Johnson, and Park references. EX2011, 12-19, 62-66; EX2012.

Indeed, Petitioner's invalidity contentions in the Parallel Litigation are far more expansive than the Petition and assert (1) alleged prior art products called "Isolite Mouthpiece," "AirBug Mouthpiece," and "Mr. Thirsty"; (2) indefiniteness; (3) lack of enablement; and (4) lack of written description. EX2011, 12-19, 62-66, 92-98 (Invalidity Contentions Cover Pleading); EX2012 ('969 Patent Claim Chart). These facts weigh heavily in favor of denying institution. *See, e.g., Motorola Sols., Inc. v. Stellar, LLC*, IPR2024-01205, Paper 19 at 3-4 (PTAB Mar. 28, 2025) (vacating institution decision despite *Sotera* stipulation because "Petitioner's invalidity arguments in the district court are more expansive and include combinations of prior art asserted in these proceedings with unpublished system prior art"); *Shenzen Tuozhu Tech. Co., Ltd. v. Stratasy, Inc.*, IPR2025-000354, Paper 11 at 2-3 (PTAB Jun. 12, 2025) (denying institution despite *Sotera* stipulation based on petitioner's broad invalidity contentions in district court).

E. Factor 5 Weighs Against Institution

This factor weighs against institution because Petitioner is the defendant and counter-plaintiff in the Parallel Litigation. EX1009; *Fintiv*, Paper 11 at 13-14.

V. SETTLED EXPECTATIONS FAVOR DISCRETIONARY DENIAL

The "[s]ettled expectations of the parties" warrants discretionary denial. Memo at 2. The parties' patent disputes have been ongoing for *years* prior to the filing of this IPR. Specifically, Petitioner entered the market with its VacuLux dental

isolation mouthpieces while the patent application leading to the '969 Patent was still pending and marketed its mouthpieces as a replacement for Patent Owner's DryShield® mouthpiece. After the '969 Patent issued in 2023, Patent Owner notified Petitioner that its VacuLux mouthpieces infringe at least claim 19 of the '969 Patent. EX2006 (cease and desist letter dated May 17, 2023). Patent Owner provided an exemplary infringement claim chart⁵ showing how Petitioner's product infringes each and every limitation of at least claim 19 of the '969 Patent. *Id.*

In response, Petitioner did not identify any alleged prior art or challenge the validity of '969 Patent (or any of the related patents). Instead, Petitioner chose to redesign the accused product and argued non-infringement. EX2008, 3-4 (confirming the product was redesigned in response to the infringement allegations). In fact, in the Parallel Litigation, Petitioner admitted that it only "started searching for prior art and considering grounds for invalidity in February 2025." EX2009, ¶14. As discussed above, this "searching" apparently only led to a single "new" reference in the Petition (Park) that is entirely cumulative. *Supra*, § II.A.5. This confirms that the Patent Office already located and applied the most pertinent art during the lengthy prosecution history of the '969 Patent. Petitioner's failure to raise any

⁵ Exhibit 1011, which Petitioner refers to "Infringement Contentions," is a copy of the claim chart provided in May 2023.

substantive invalidity arguments and its focus on non-infringement—including redesigning its product—led Patent Owner to have a settled and reasonable expectation that Petitioner believed that the '969 Patent was valid.

The Director's recent discretionary denial in *iRhythm Techs., Inc. v. Welch Allyn, Inc.*, IPR2025-00363, Paper 10 (PTAB Jun. 6, 2025) is instructive in this regard. There, the Director found that “settled expectations favor denial of institution” based on the “Petitioner's awareness of Patent Owner's applications and failure to seek early review of the patents.” *Id.* at 3. Similarly, Petitioner received Patent Owner's cease-and-desist letter regarding the '969 Patent in May 2023, but failed to seek early review. Unlike in *iRhythm* where the petitioner's knowledge was shown through a citation in an IDS, Petitioner gained knowledge of the '969 Patent through an express charge of infringement (EX2006) and then waited two years before moving forward with an IPR. This makes Patent Owner's expectation that the validity of the '969 Patent would not be challenged more reasonable than in *iRhythm*.

Putting aside the parties' lengthy dispute, discretionary denial is appropriated based on settled expectations for another reason: as Petitioner acknowledges, the Office examined the application that led to the '969 Patent for *almost nine years*. Petition, 16, 23. The Examiner issued *eleven* Office Actions. *See* EX1002, 181-87 (Non-Final Office Action dated Nov. 6, 2015), 243-49 (Final

Office Action dated Jun. 6, 2016), 344-51 (Non-Final Office Action dated Nov. 7, 2016), 424-32 (Non-Final Office Action dated Jun. 5, 2017); EX1020, 11-20 (Final Office Action dated Jan. 16, 2018), 121-29 (Non-Final Office Action dated Oct. 5, 2018), 166-75 (Final Office Action dated Jul. 15, 2019), 219-27 (Non-Final Office Action dated Jan. 10, 2020), 283-92 (Final Office Action dated Nov. 17, 2020), 474-480 (Non-Final Office Action dated Oct. 6, 2021); EX2021, 25-54 (*Ex Parte* Quayle Action dated Nov. 25, 2022). At least **95 references** were considered by the Examiner. *See* EX1001, Cover.

After spending considerable time and resources for nearly nine years prosecuting the '969 Patent, Patent Owner should have a settled and reasonable expectation that its validity has been thoroughly and correctly determined by the Office. It would be an enormous waste of the Board's resources to institute an IPR for a patent that the Office has already devoted almost nine years to consider and allowed over the **same art** that Petitioner relies on. For this additional reason, the Patent Owner respectfully requests that the Director deny institution.

VI. PETITIONER'S FAILURE TO PROFFER EXPERT TESTIMONY FROM A POSITA FAVORS DISCRETIONARY DENIAL

"The extent of the petition's reliance on expert testimony" is a relevant consideration for discretionary denial. Memo at 2. Here, Petitioner proffers testimony from Dr. Brian Black, who is the named inventor of the Black reference Petitioner relies on in Grounds 1 and 4-5. *See* EX1003. But remarkably, Dr. Black

is *not* a POSITA under Petitioner's proposed definition,⁶ which is: "at least a B.S. degree in mechanical engineering or a related field with at least two years' experience designing medical devices." Petition, 29 (emphasis added). Petitioner has been consistent with its definition of the POSITA as it has proposed the same definition for a POSITA in the Parallel Litigation in its Invalidity Contentions (EX2011, 42) and Non-Infringement Contentions (EX2015, 7).

Dr. Black does not have an engineering degree and admits, consistent with Petitioner's definition, that "some knowledge of mechanical engineering is probably required." EX1004, p. 3; EX1003, ¶49. Petitioner does not contend that mechanical engineering and dentistry are "related field[s]." *See* Petition, 29. Consequently, Dr. Black's testimony does not support Petitioner's unpatentability arguments because it is well settled that an expert opining on patentability must possess the minimum level of skill in the art, which Dr. Black lacks under Petitioner's own definition. *See, e.g., Kyocera Senco Indus. Tools Inc. v. ITC*, 22 F.4th 1369, 1376 (Fed. Cir. 2022) (excluding expert who was "not at a minimum an ordinarily skilled artisan"); *Extreme Networks, Inc. v. Enterasys Networks, Inc.*, 395 F. App'x 709, 715 (Fed. Cir. 2010) (excluding expert that did not meet definition for a POSITA).

⁶ Tellingly, Dr. Black opines on and uses a different POSITA definition in his declaration that does not require a mechanical engineering degree. EX1003, ¶ 44.

Additionally, among other flaws in Dr. Black's opinions, he improperly attempts to fill gaps in Black by purporting to testify to his state of mind as the named inventor on his own patent, Black. For example, he admits that Black does not describe the circles depicted in FIG. 23B as perforations but claims "***I know*** these are perforations because ***I am the author*** of this reference." EX1003, ¶¶90-91 (emphases added). As another example, Dr. Black states that to the extent the claim phrase "corresponding edges along one or more corresponding sides' means a wall identical in size and shape, ***I foresaw*** such an embodiment before the priority date of the '969 Patent." *Id.*, ¶94 (emphasis added). As yet another example, for the "connecting wall" limitation in claim 19, Dr. Black states that "***I wrote Black and I know there is a connecting wall*** formed at that spot. I invented it." *Id.*, ¶104 (emphasis added).

Dr. Black's testimony about his subjective state of mind more than fifteen years ago is improper because his testimony is not framed from the perspective of what an objective POSITA would understand from Black. The Federal Circuit has made clear that an inventor's testimony about their own patent is entitled to little, if any, weight. *See Roton Barrier, Inc. v. Stanley Works*, 79 F.3d 1112, 1126 (Fed. Cir. 1996) (stating that "an inventor's after-the-fact testimony is of little weight compared to the clear import of the patent disclosure itself") (internal quotation marks omitted); *see also Bell & Howell Document Mgmt. Prods. Co. v. Altek Sys.*, 132 F.3d

701, 706 (Fed. Cir. 1997) (“the testimony of an inventor often is a self-serving, after-the-fact attempt to state what should have been part of his or her patent application”); *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 985 (Fed. Cir. 1995) (“The subjective intent of the inventor when he used a particular term is of little or no probative weight in determining the scope of a claim”).

Petitioner's reliance on Dr. Black's *ipse dixit* testimony about what he allegedly meant to disclose in Black is improper and should be disregarded. *See, e.g.*, Petition, 46 (“the inventor of Black testified that such a connecting wall is present in the tongue aspirator 340”), 76 (“the inventor of the patent, Dr. Brian P. Black, testified that the holes shown in those figures are perforations”). And even if this testimony is somehow admissible, Petitioner's reliance on it would be more appropriate in the Parallel Litigation where the judge and jury can receive live testimony from Dr. Black and assess his credibility firsthand.

Given the facial flaws in Dr. Black's testimony and the near certainty that at least some portions of Dr. Black's declaration—if not the entire declaration—will be excluded as inadmissible, the Director should deny institution.

VII. CONCLUSION

For the foregoing reasons, Patent Owner respectfully requests that the Director exercise her discretion and deny institution.

Patent No. 11,589,969
IPR2025-01020

Patent Owner's Discretionary Denial Brief

Respectfully submitted,

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CERTIFICATE OF SERVICE

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