

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. 11,589,970

Case No. IPR2025-01057

PATENT OWNER'S DISCRETIONARY DENIAL BRIEF

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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	RESERVED
2004	U.S. Patent No. 3,758,950 ("Krouzian")
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</i>

	<i>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	Docket Navigator 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
2016	Excerpts of the Prosecution History of U.S. Patent No. 11,589,969 (Ex. 1002 in IPR2025-01020)
2017	Excerpts of the Prosecution History of U.S. Patent No. 11,589,969 (Ex. 1020 in IPR2025-01020)
2018	Excerpts of the Prosecution History of U.S. Patent No. 11,589,969 (Ex. 1021 in IPR2025-01020)
2019	Excerpts of the Prosecution History of U.S. Patent No. 11,744,686 (Ex. 1002 in IPR2025-01059)
2020	Excerpts of the Prosecution History of U.S. Patent No. 11,744,686 (Ex. 1020 in IPR2025-01059)
2021	Excerpts of the Prosecution History of U.S. Patent No. 11,744,686 (Ex. 1021 in IPR2025-01059)
2022	Petition for <i>Inter Partes</i> Review of U.S. Patent No. 11,589,969, IPR2025-01020, Paper No. 2 (May 20, 2025)

2023	Defendant/Counter-Plaintiff Ascentcare Dental Products, Inc.'s Stipulation of Invalidity Contentions, <i>Solmetex, LLC v. Ascentcare Dental Products, Inc.</i> , Case No. 1:24-cv-00954-RJJ-MV (W.D. Mich. Aug. 20, 2025)
2024	Zyris, Inc. Virtual Patent Marking, https://www.zyris.com/patents/ (last accessed Aug. 25, 2025)
2025	U.S. Patent No. 4,802,851 ("Rhoades")

Pursuant to the Interim Processes for PTAB Workload Memorandum (“Director 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”). There are five independent reasons why the Director should 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 ‘970 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 ‘970 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:

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 consider by the Office (as explained below), it is clear that the Office had already located and applied the most pertinent art for the ‘970 Patent. On this record, Petitioner cannot show any material error by the Office.

Second, the Parallel Litigation currently involves not just the ‘970 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. 25, 2025	Dec. 23, 2025
11,744,686 (2013 Family)	IPR2025-01059	Aug. 25, 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

Patent Owner has already submitted its discretionary denial brief for IPR2025-01020 and is concurrently filing its brief for IPR2025-01059. Like this Petition, all of Petitioner's challenges rely on the same or substantially similar prior art that was already considered by the Office during prosecution.

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 seven proceedings, this would not resolve all of the parties' disputes, including the design patent claims and the parties' respective Lanham Act claims. 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.

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 late 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 '970 Patent in December 2026.

Fourth, the settled expectations of the parties warrant denial. Petitioner has known about the '970 Patent for years but never challenged its validity, even after being expressly accused of infringement almost 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 '970 Patent. Moreover, as Petitioner points out, prosecution of the '970 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 – especially a proceeding based on references that were already considered.

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 POSITA under the definition proposed in the Petition (and 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.

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 Elktromedizinische 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

1. Johnson was Considered (Grounds 1-3)

Johnson was cited in an IDS filed on May 12, 2014 and was considered by the Examiner. EX1002, 45 (citing in IDS), 190 (showing Examiner considered Johnson); This 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").

2. Black was Considered (Ground 2)

Black was cited in an IDS and was considered by the Examiner. Ex. 1001, Cover; EX1002, 70 (IDS filed on Nov. 12, 2014), 189 (showing examiner considered

Black); *Ecto World*, Paper 13 at 4. What is more, the Examiner applied Black² in several rejections during prosecution as either a primary or secondary reference during prosecution of the '970 Patent and during prosecution of related applications.

a) Black was Applied During Prosecution of the '970 Patent

In a Non-Final Office Action dated December 4, 2015, the Examiner rejected pending dependent claims 13-16 based on U.S. Patent No. 4,802,851 (EX2025, "Rhoades") and Black. EX1002, 186. The Examiner asserted:

Rhoades discloses the invention substantially as claimed except for a bridge structure comprising a plurality of protrusions and wave-shaped bridge structure. Black et al. discloses an intraoral suction device comprising a wave-shaped bridge structure 48c having formed therein the interior wall of the device 40 (Fig. 3B; paragraph 80). . . . It would have been obvious . . . to modify Rhoades by forming such bridge/transverse walls therein the interior of the intraoral device as taught by Black et al. in order to reinforce the device while still allowing effective suction.

Id. In a Final Office Action dated June 30, 2016, the Examiner applied the same rejection based on Rhoades and Black. *Id.*, 246.

Then, in a response dated September 30, 2016, the Applicant amended

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

pending independent claim 1 incorporate the “bridge structure” from previously pending claims 13-14. EX1002, 305-13. The Applicant argued “the walls of Black do not provide a wave shape as claimed in dependent claims 15 and 16.” *Id.*, 312. In an Office Action dated April 12, 2017, the examiner withdrew the prior rejections based on Black. *Id.*, 391. The Examiner instead rejected the amended claims based on Hirsch but found that claims 15-16, which recited that the bridge structure has a “wave shape” with “crests and “troughs” (*id.*, 309), were allowable over Hirsch and Black. *Id.*, 387-390.

Following a series of additional rejections, the Examiner issued a Final Office Action dated July 11, 2019 rejecting claims 15-16 based on Black in view of Hirsch. EX1020, 175-76. Here, the Examiner asserted:

As to claim 15-16, Hirsch et al. discloses the mouth piece 50 comprising bridge structure 24 having a wave shape defined by spaced protrusions (e.g. side walls of channel 80) at crests of the wave shape. It would have been obvious to one having ordinary skill in the art before the effective filing date of the claimed invention to modify Black et al. by including such bridge structure taught by Hirsch et al. in order to provide stability and reinforcement to the interior of the pocket.”

Id. The Examiner repeated the same rejection in a Final Office Action dated January 10, 2020. *Id.*, 226-27.

Later in prosecution, claims 15-16 were amended to depend from new

independent claim 21, which was broader the previously pending independent claim. *See* EX1020, 276-78. The claims that issued as part of the '970 Patent recite the "bridge structure" that "is not attached to the first wall" and has protrusions that "protrude from the interior surface of the second wall in a wave shape comprising one or more crests and one or more troughs" that the Examiner agreed was not disclosed in Black. EX1001, 6:31-36 (claim 1), 8:29-34 (claim 18).

**b) Black was Applied During Prosecution of
Counterpart Applications**

The prosecution of history of related applications in the same family as the '970 Patent further demonstrates that Black was thoroughly considered by the Office. Indeed, the same Examiner (Hao D. Mai) examined the applications leading to the '970 Patent, the parent '232 Patent, and the related '969 and '686 Patents.

The Examiner considered and applied Black during prosecution of U.S. Patent No. 8,911,232, which is the parent of the '970 Patent ("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. 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. Both of these Office Actions were cited during prosecution of the ‘970 Patent. EX1002, 199, 208.

Additionally, the Examiner applied Black in rejections in five Office Actions during prosecution of the related ‘969 Patent. EX2016, 247, 346-49, EX2017, 15-18, 123-27, 169-72. The Examiner also applied Black in multiple Office Actions during prosecution of the related ‘686 Patent. EX2019, 186-87; EX2020, 309-10.

3. Hirsch was Considered (Ground 3)

Hirsch was cited in an IDS and was considered by the Examiner. EX1002 at 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) was used in multiple rejections during prosecution of the ‘970 Patent and counterpart applications.

a) Hirsch was Applied During Prosecution of the '970 Patent

Hirsch was applied to reject the claims in six Office Actions during prosecution of the '970 Patent. In a Non-Final Office Action dated April 12, 2017, the Examiner rejected pending claims 1-4, 6-12, 17-18, and 20 are anticipated by Hirsch. EX1002, 387-90. However, the Examiner indicated that claims 15-16, which include the same details on the “bridge structure” that appear in the issued claims were allowable over Hirsch if rewritten in independent form. *Id.*, 390.

Thereafter, Applicant amended claims 15 and 16 to depend from new independent claim 21 and argued against the Hirsch rejections. EX1002, 454-60. In a Final Office Action dated October 20, 2017, the Examiner again rejected the claims based on Hirsch. EX1020, 30-33. The Examiner withdrew the previous allowance of claims 15-16 given that they were amended to from a broader independent claim. *Id.*, 33. The Examiner maintained these rejections based on Hirsch in a Non-Final Office Action dated October 4, 2018. *Id.*, 129-33.

As discussed above, in a Final Office Action dated July 11, 2019, the Examiner rejected claims 15-16 based on Black and Hirsch, alleging that Hirsch discloses a “bridge structure.” EX1020, 175-76; *supra*, § II.A.2.a. The Examiner maintained the same rejection based on Black and Hirsch in a Final Office Action dated January 10, 2020. *Id.*, 226-27. Then, in a Non-Final Office Action dated November 27, 2020, the Examiner withdrew all prior art references of claims 15-16

and instead rejected these claims for double patenting over the Parent '232 Patent and Hirsch. *Id.*, 324-330.

b) Hirsch was Applied During Prosecution of Counterpart Applications

Similar to Black, Hirsch and/or a substantially similar version of Hirsch was thoroughly considered by the Office during prosecution of related applications in the same family as the '970 Patent. For example, Hirsch was during prosecution of related '969 Patent. EX2016, 428-30. U.S. Patent Publication No. 2006/0063129 to Hirsch ("Hirsch '129"), which is a continuation-in-part³ of Hirsch, was applied in three other Office Actions. EX2017, 221-25; *Id.*, 287-89; *Id.*, 479. In relevant part, the claims of the '969 Patent were allowed after the Applicant explained that Hirsch does not disclose a "bridge structure" with "a wave shape comprising one or more crests and one or more troughs." EX2018, 120-24. As another example, Hirsch was

³ There are no material differences between Hirsch and Hirsch '129; FIGS. 1-20 are identical. *Compare* EX1012, FIGS. 1-20 *with* EX2005, FIGS. 1-20.

applied in *eight* Office Actions during prosecution of the related '686 Patent. EX2019, 383-86; EX2020, 7-10, 100-02, 138-40, 175-80, 215-20, 313-14, 379-384.

4. Baughan was Considered or is Cumulative (Grounds 1-3)

While Baughan is not cited on the face of the '970 Patent, Baughan was expressly identified by the same Examiner during prosecution of the related '969 Patent and it is cumulative of other references that were considered.

a) Baughan was Applied During Prosecution of the Counterpart '969 Patent

During prosecution of the related '969 Patent, the same Examiner, Hao D. Mai, applied Baughan to reject the claims during a telephone interview in March 2021. EX2017, 424 ("During 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"). Petitioner likewise relies on Baughan for allegedly disclosing the "bridge structure" in the challenged claims of the '970 Patent. *See* Petition, 44-49.

The Examiner was unquestionably aware of and considered Baughan during prosecution of the '970 Patent. The '969 and '970 Patents were examined in the same timeframe: the Examiner issued Office Actions between November 2015 and January 2023 during prosecution of the '969 Patent (EX2016, 188-92 and Ex. EX2018, 296-301) and Office Actions between December 2015 and November 2022 during prosecution of the '970 Patent (EX1002, 181-87 and EX2021, 248). The

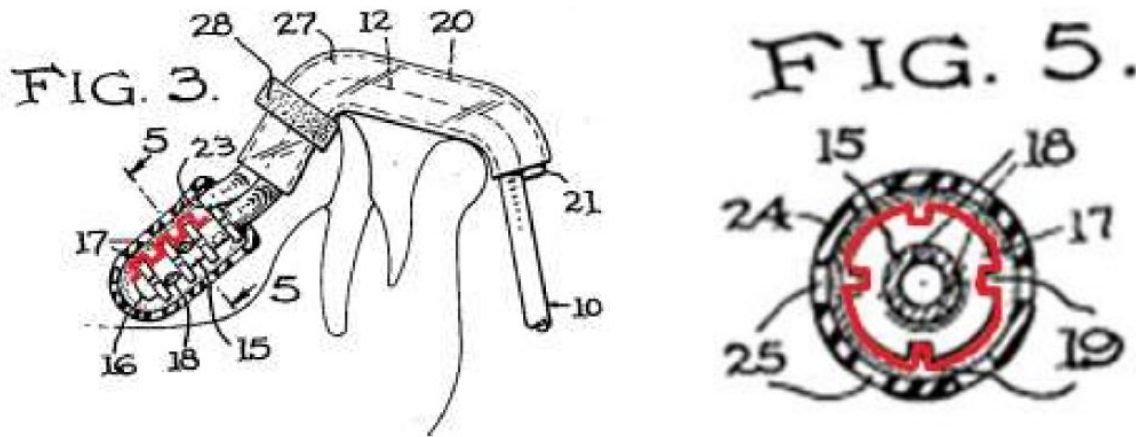
Office Actions from the related '969 Patent were cited in IDS's and considered by the Examiner during prosecution of the '970 Patent. EX1002, 254, 395, 400; EX1020, 37, 140, 183, 233, 380, 475; EX1021, 275. There is no reason to believe that the Examiner was not aware of Baughan during prosecution of the '970 Patent even though it was not expressly cited or applied in a rejection.

b) Baughan is Cumulative

To the extent Petitioner argues that the Examiner's consideration of Baughan during prosecution of the related '969 Patent does not satisfy the first part of the *Advanced Bionics* test, Baughan 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 relies on Baughan for allegedly teaching "a mechanical element that prevents collapse under suction." Petition, 44. Specifically, Petitioner contends that Baughan discloses "a saliva ejector that includes projecting discs 17 that prevent a

sleeve 24 from collapsing upon a suction tube 15 during applied suction. *Id.*, 31 (citing EX1007, 3:43-48). In Ground 1, Petitioner argues that Baughan's "spaced-apart discs result in a square wave shape having crests and troughs" and that "notches 18 in the disc also form a square wave shape." Petition, 48-49.



EX1007, FIGS. 5-6 (annotations by Petitioner)

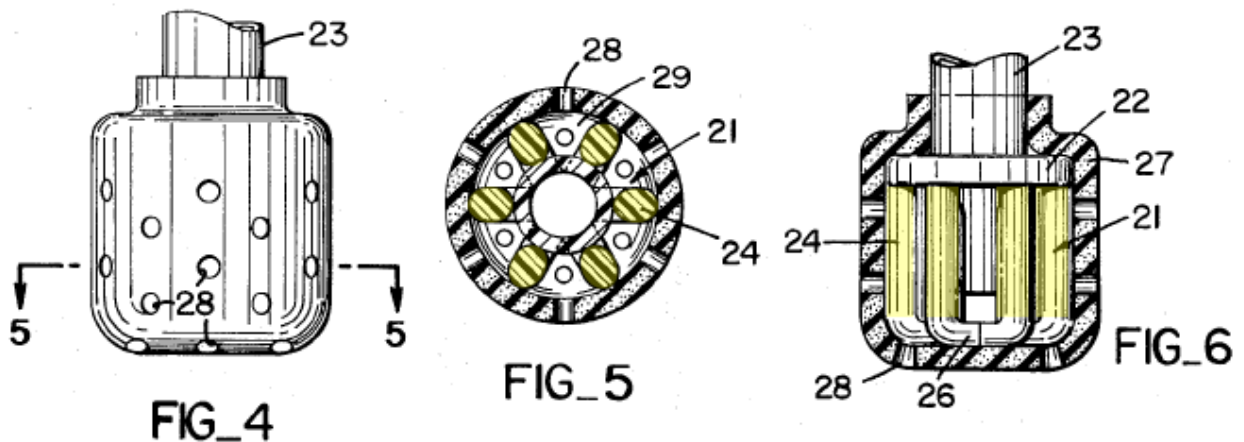
The portions of Baughan that Petitioner relies on are cumulative of at least three references that were considered during prosecution.

First, Baughan is cumulative of Krouzian (EX2004), which was used to reject the claims during prosecution. Baughan is cited on the face of Krouzian as prior art. EX2004, Cover. In a Final Office Action dated April 29, 2021, the Examiner rejected pending claims 3-12, 15-18, and 20-24 based on Krouzian and Schubert. EX1020, 367-71. The Examiner asserted that Krouzian discloses:

The second wall 21/22 comprising a bridge structure 21 that includes a plurality of protrusions 24 integral with and protruding from the interior surface of the second wall 21 and substantially extending a distance

between the first wall 27 and the second wall 21/22. The bridge structure 24 is not attached to the first/outer wall 27, wherein the protrusions 24 of the bridge structure protrude from the interior surface of the second wall in a wave shape comprising one or more crests (bars 24) and one or more troughs (between bars 24).

Id., 367 (citing EX2004, FIGS. 5-6, 4:3-14). This alleged bridge structure in Krouzian is shown below:

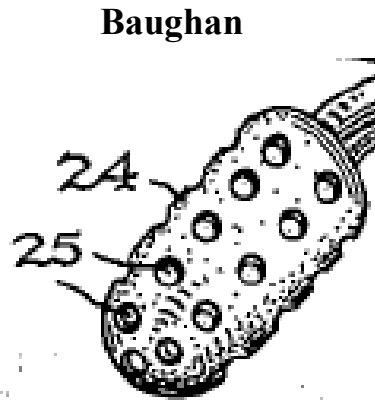


EX2004, FIGS. 4-6 (annotated)

In a response dated July 29, 2021, Applicant argued, *inter alia*, that Krouzian does not disclose the claimed “wave shape comprising one or more crests and one or more troughs.” EX1020, 439-40. The Examiner applied Krouzian again in a Non-Final Office Action dated December 8, 2021. *Id.*, 462-68. In response, the Applicant explained that Krouzian does not disclose the claimed “bridge structure” for several reasons, including because “the bars 24 of Krouzian are not configured in ‘a wave

shape comprising one or more crests and one or more troughs as claimed.” EX1021, 124-25. The claims were then allowed over Krouzian. *Id.*, 252-55.

Baughan is cumulative of Krouzian. Both references are directed to a dental saliva ejector. EX1007, 1:7-8; Ex. 2004, 5:45-47.



EX1007, FIG. 1 (excerpted)

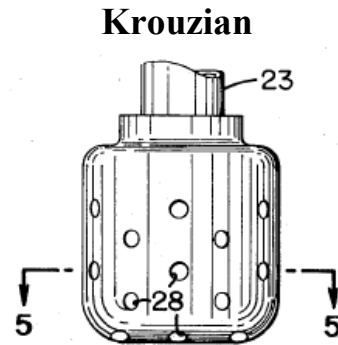
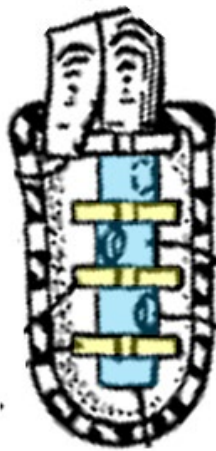


FIG_4

EX2004, FIG. 4

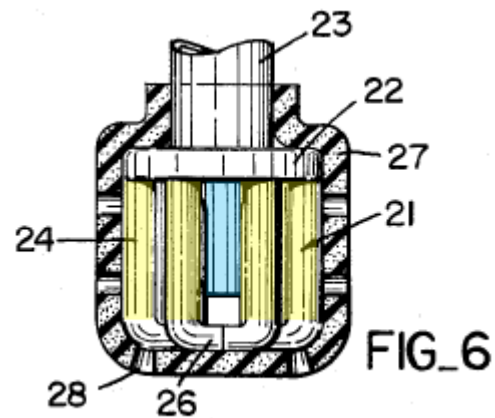
Both references show protrusions extending from and around the circumference of a central cylindrical tube, as shown below.

Baughan



EX1007, FIG. 3 (excerpted, rotated,
and annotated)

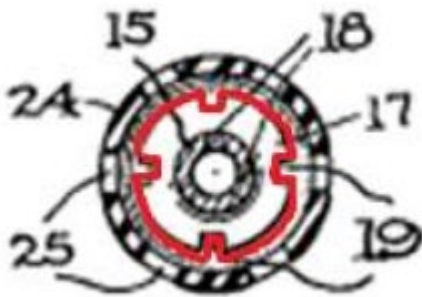
Krouzian



EX2004, FIG. 6 (annotated)

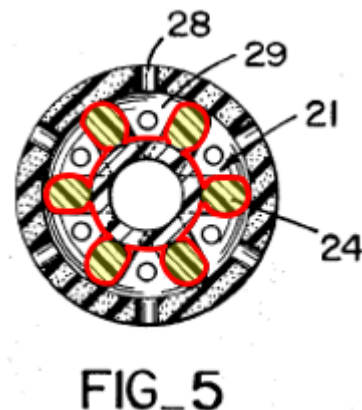
According to Petitioner's arguments, both references allegedly disclose a bridge structure with a wave shape comprising one or more crests and one or more troughs.

Baughan



EX1007, FIG. 5 (annotated by
Petitioner)

Krouzian



EX2004, FIG. 5 (annotated)

Second, Baughan is also cumulative of Black, which as discussed above, was considered at length during prosecution. *Supra*, § II.A.2. The Examiner asserted that Black discloses a wave-shaped “bridge structure” at least twice during prosecution

of the '970 Patent and Patent Owner overcame these rejections. EX1002, 186 (asserting that Black discloses "a wave-shaped bridge structure 48c"), 246 (asserting same). Indeed, Petitioner admits that Baughan and Black are substantially similar. For example, after alleging that Baughan discloses "a plurality of spaced-apart projections . . . to prevent collapsing of the . . . walls under suction," Petitioner admits that "Black taught this same concept." Petition, 46. Petitioner even explains that the analogous projecting structures in both Black and Baughan by admitting that "the concept of using perpendicularly projecting structures to prevent collapse of parallel walls under suction was demonstrated by Black and by Baughan." *Id.* Thus, by Petitioner's own admissions, Baughan is cumulative of Black on this point.

Third, Baughan is cumulative of Riddle (EX2002), which was cited in an IDS and considered by the Examiner. EX1021, 274 (showing Examiner considered Riddle). During prosecution of the related '969 Patent, the Examiner applied Riddle in multiple rejections and asserted:

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.

EX2016, 247; *see also* EX2017, 127, 172-73. Similar to Riddle, Petitioner relies on Baughan for 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, 44-45. Petitioner’s argument is effectively the same as how the Examiner applied Riddle during prosecution of the ‘969 Patent, rendering Baughan and Petitioner’s obviousness theory cumulative.

5. Park is Cumulative (Grounds 1-3)

Park is the *only* reference Petitioner relies on that was not already considered by the Office during prosecution of the ‘970 Patent or a related application. But that is immaterial because Petitioner has admitted that Park is substantially similar to, and cumulative of, references that were considered and used in rejections during prosecution. *Becton*, Paper 8 at 17-18; *see also Intel*, Paper 13 at 15-16; *Helena Labs.*, Paper 10 at 12.

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, 29-33. For example, Petitioner’s expert testifies:

It must be noted that all four mouthpieces I considered for this report (the ‘970 Patent, Hirsch, Park, Black) have similar shapes and structure due to their function. EX1001, FIG. 1B; EX1005, FIG. 4C; EX1006, FIG. 3; EX1012, FIG. 19A.

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

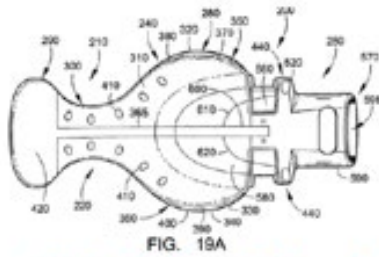


FIG. 19A of Hirsch

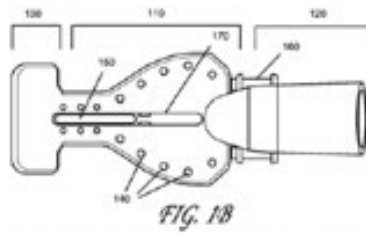


FIG. 1B of '969 Patent

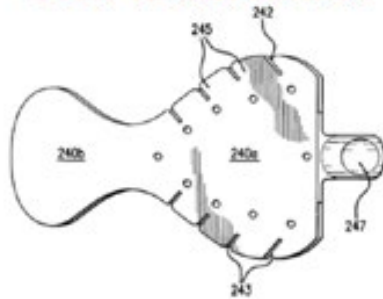


FIG. 4C of Black

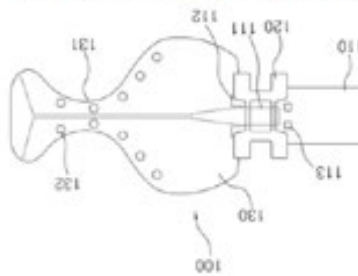


FIG. 3 of Park

Id. (annotations added); Petition, 20

Park is therefore substantially similar to and cumulative of Black and Hirsch.

After admitting that Park, Hirsch, and Black have substantially identical structures, Petitioner's expert then admits that Park fails to expressly teach anything about any internal structures within the mouthpiece 100:

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, ¶100. Because Park fails to disclose any internal features, Petitioner and its expert are forced to rely on Johnson and Baughan as allegedly teaching the bridge structure having a plurality of protrusions and that the plurality of protrusions protrude in a wave shape comprising one or more crests and one or more troughs.

Yet in the IPR for the related '969 Patent, Petitioner contends that Black *anticipates* independent claim 19 of that patent, which also requires a bridge structure with plurality of protrusions that protrude in a wave shape comprising one or more crests and one or more troughs. EX2022, 36-50. And like independent claim 1 of the '970 Patent that is challenged here, claim 19 of the '969 Patent also has similar claimed outer structures – the main body, first and second walls, a connecting wall, and a suction connector. Hence, in addition to Petitioner's admissions in this IPR confirming that Park is cumulative to Black, Petitioner's analysis of Black in the IPR of the '969 Patent further validates the cumulative nature of Park because, according to Petitioner, Black teaches *more* of the claimed structures than Park. Again, the Office already considered and applied Black in several rejections. *Supra*, § II.A.3. In short, Petitioner's own admissions and its own analysis confirm that Park is cumulative to Black.

Park is also cumulative of Hirsch, which was extensively considered during prosecution. *Supra*, § II.A.3. In addition to the admissions noted above from Petitioner's expert about the similarity between Park and Hirsch, in Ground 2, Petitioner proposes combining Park and Hirsch and argues that "both mouthpieces perform the same function and have very similar designs (Hirsch simply lacks

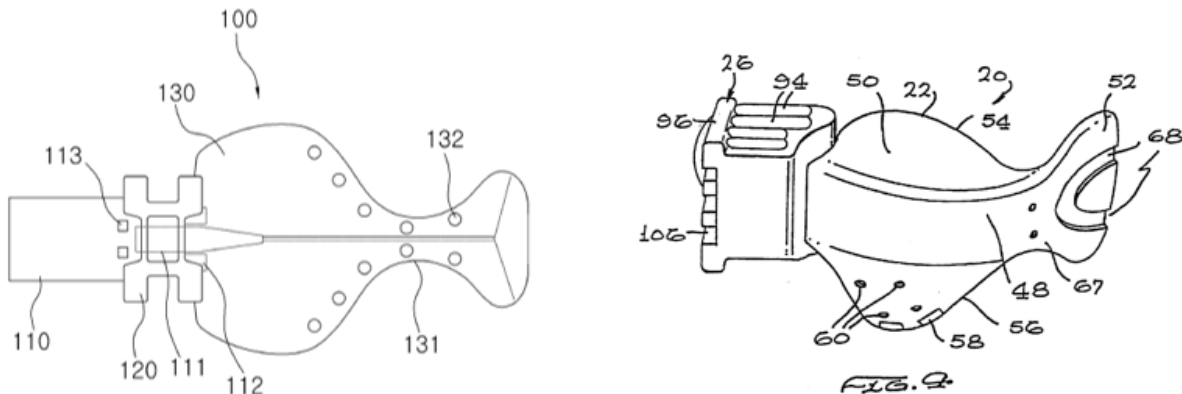
sidewalls).” Petition, 61; *see also id.*, 20 (arguing that the ‘970 Patent, Park, and Hirsch have “the same basic structure”).

Attempting to find something different about Park, Petitioner can only identify Hirsch’s alleged lack of “sidewalls” as the **only** difference between Park and Hirsch. This alleged distinction is a red herring. **None** of the challenged claims recite a “sidewall.” Instead, they recite a “connecting wall.” EX1001, 6:37-40 (claim 1), 8:35-38 (claim 18). Petitioner acknowledges that the ‘970 Patent is not “limited to claims having ‘sidewalls’” and characterizes the difference between “sidewall” and “connecting wall” as a “dramatic shift in claim scope.” Petition, 16, 26 n.2. This is consistent with the 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 further acknowledges that the claim term “connecting wall” is **broader** than “sidewall” in arguing that “almost all prior art dental isolation mouthpieces disclose a connecting wall that satisfies Patent Owner’s new interpretation of the ‘970 Patent’s claim language.” Petition, 16.

Petitioner has not proposed any specific claim construction for “connecting wall,” let alone a construction that would suggest its breadth compared to “sidewall” (which is not recited in the claims) has any relevance to patentability of the ‘970 Patent. Petition, 27-28. In other words, whether or not Park discloses “sidewalls” is not material to the patentability of the claims because the claims do not recite a

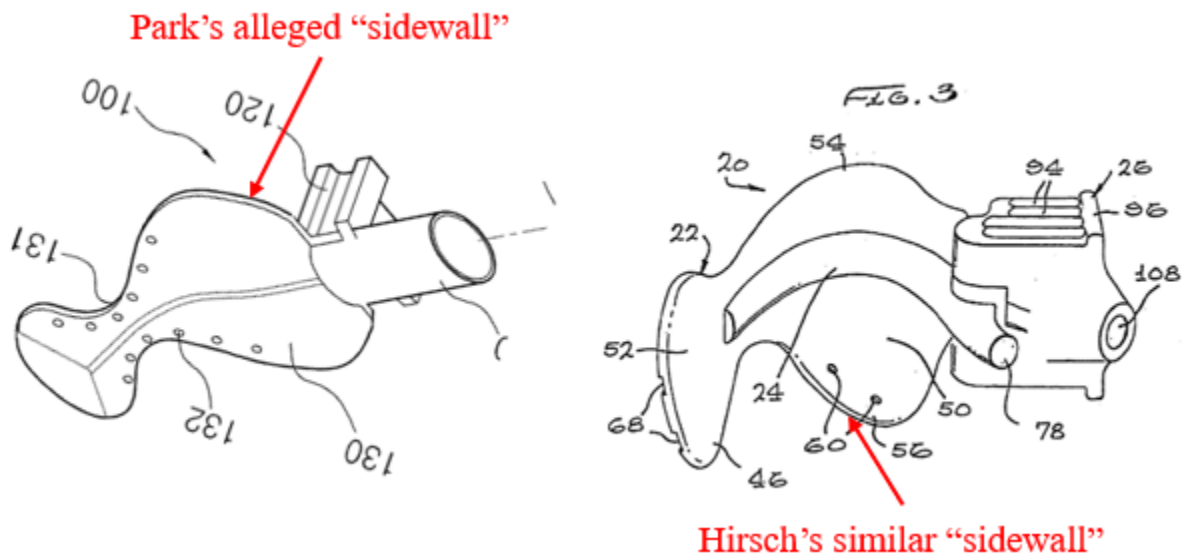
“sidewall.” As such, Petitioner’s attempt to rely on this purported distinction between Park and Hirsch does not render Park non-cumulative of Hirsch. *See Helena Labs*. Paper 10 at 12 (finding reference was cumulative because any differences did “not affect . . . [the] analysis of the independent claims”).

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



EX1006, FIG. 3; EX1012, FIG. 9

A similar “sidewall” in Hirsch is more clearly shown in perspective views of the respective mouthpieces:



EX1006, FIG. 2 (rotated and annotated); EX1012, FIG. 3 (annotated)

Indeed, the Examiner even found that Hirsch discloses a “sidewall” on several occasions. EX1002, 388 (Non-Final Office Action dated Apr. 12, 2017); EX1020, 30 (Final Office Action dated Oct. 20, 2017), 129 (Non-Final Office Action dated Oct. 4, 2018). In summary, in addition to Petitioner’s own admissions that support a finding that Park is cumulative of Hirsch, the file history itself supports finding as well.

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.⁴

1. Petitioner's Arguments Regarding the Term "Connecting Wall" are a Red Herring

In an attempt to suggest the Examiner erred in allowing the claims, Petitioner advances a narrative that "through an aggressive continuation application practice aimed at Petitioner's product, Patent Owner sought exceedingly broad patent protection." Petition, 15. Specifically, Petitioner makes much of the fact that the challenged claims recite a "connecting wall" rather than a "sidewall," with the former being broader than the latter, and characterizes this change as a "dramatic shift in claim scope." Petition, 16-18, 26 n.2. Petitioner claims that the applicant argued "the importance of enclosing sidewalls in a co-pending application before the same Examiner" and that "the Examiner does not appear to have appreciated the impact of Patent Owner's broadening effort." *Id.*, 17. Petitioner also argues "almost

⁴ Patent Owner reserves the right to seek a reply brief should Petitioner identify an alleged material error for the first time in any opposition. Director Memo at 2.

all prior art dental isolation mouthpieces disclose a connecting wall that satisfies Patent Owner's new interpretation." *Id.*, 16.

This is yet another of Petitioner's red herrings. None of the grounds in the Petition are based on a broad claim construction for the term "connecting wall" that would have allegedly changed the outcome of prosecution. Instead, Petitioner appears to be interpreting "connecting wall" narrowly to mean "enclosed sidewall." Petition, 35. This is not a situation where Petitioner presents an alleged anticipatory reference that the Examiner could have applied with the understanding that "connecting wall" is broader than "sidewall." Indeed, Petitioner is forced to rely on combinations of multiple references because like the references considered during prosecution, Petitioner's arguments regarding the terms "connecting wall" and "sidewall" are untethered to the substance of the grounds in the Petition and cannot demonstrate any alleged error by the Office.

More importantly, even if the difference between "sidewall" and "connecting wall" were somehow relevant to the reasons for allowance (which it was not), Petitioner's suggestion that the Examiner did not appreciate "the impact of Patent Owner's broadening effort" is readily belied by the record. Petition, 17. The Examiner was acutely aware of this change yet still allowed the claims. In a Non-Final Office Action dated December 8, 2021, the Examiner specifically mentioned the "connecting wall" term in an "essential elements" rejection. EX1020, 460-62.

Contrary to Petitioner's contention the Examiner did not "appreciate" the difference between the "sidewall" and the "connecting wall," the Examiner was aware of the transition from "sidewall" to "connecting wall" and yet still allowed the claims.

2. Petitioner's Characterizations of the Parent '232 Patent's Prosecution History are Wrong and Irrelevant

In a further effort to identify an alleged error, Petitioner offers a discussion of prosecution of the Parent '232 Patent and certain rejections based on Black. Petition, 22-24. Specifically, Petitioner notes that during prosecution of the Parent '232 Patent, the Examiner found in a first Office Action that Black discloses a wave-shaped bridge structure, and that the applicant did not address this in its response. *Id.*, 23 (citing EX1015, 51-52). Petitioner also acknowledges that the Examiner subsequently found the wave-shaped bridge structure was not taught by Black, but calls it "[i]mportant[]" that "the Examiner found that Black taught a 'bridge structure protruding from an interior surface of the posterior wall, the protruding bridge structure comprising a plurality of spaced contact points that keep the anterior wall separated from the posterior wall during suction.'" *Id.*, 24 (citing EX1015, 109-11).

Petitioner appears to be suggesting that the Examiner was originally correct in finding that Black discloses a wave-shaped "bridge structure" and later made a mistake when finding that it does not. This is yet another red herring. Whether Black discloses a "bridge structure" is irrelevant to the Petition for the '970 Patent because it does not rely on Black for the "bridge structure" limitation. Petition, 41-49 (relying

on Baughan and Johnson).⁵ Petitioner's discussion of the Parent '232 Patent's prosecution is irrelevant and demonstrates no error by the Examiner in allowing the claims of the '970 Patent.

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. *Infra*, § VI.

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

As noted above, this IPR is one of seven IPR/PGR challenges directed to the seven utility patents that are asserted by Patent Owner in the Parallel Litigation, along with three design patents and the parties' Lanham Act claims. If each of the

⁵ Petitioner relies on Black for a similar "bridge structure" limitation in IPR2025-01020 for the '969 Patent. It may be that this argument was simply copied and pasted without regard to its inapplicability to the grounds in this Petition.

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 '970 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 (Sept. 6, 2017) (precedential) (emphasis added). In this case, instituting an IPR of the '970 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 (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 IP*"). "[I]n evaluating the factors, the Board takes a holistic view of whether efficiency and integrity of the system are

bested served by denying or instituting review.” *Fintiv*, Paper 11 at 6. Each of these factors weighs in favor of denying institution.

1. 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.⁶ 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

⁶ Patent Owner intends to seek authorization to supplement the record when the court rules on the motion.

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 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.

2. 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 24, 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 the end of 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 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.

3. 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, non-infringement, and invalidity contentions. *Id.*, EX2011; EX2012.

By the time the Board would decide whether to institute an IPR in late 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 almost two years to challenge the ‘970 Patent after being accused of infringement. EX2006. Indeed, the supposed “infringement contentions” Petitioner included as Exhibit 1011 were provided by Patent Owner long ago (they are not infringement contentions from the Parallel Litigation). After receiving the cease-and-desist letter, Petitioner attempted to design-around the ‘970 Patent with a new version of its infringing product, rather than challenging its validity. *See* EX2008, 3-4 (admitting Petitioner redesigned its product to attempt to avoid infringement).

To the extent Petitioner argues that it was justified in waiting to challenge the ‘970 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 '970 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 '970 Patent. *Supra*, § II.A. Accordingly, this factor weighs against institution.

4. 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.

Petitioner is relying on the same references and combinations in the Petition in its invalidity contentions in the Parallel Litigation. *See, e.g.*, EX2011, 12-17, 21-23, 68-74; EX2012. In an apparent effort to avoid discretionary denial, Petitioner filed a *Sotera* stipulation⁷ in the Parallel Litigation less than a week before this brief. EX2023. However, despite Petitioner's likely suggestions to the contrary, the *Sotera* stipulation is not dispositive and does not foreclose discretionary denial. *See*

⁷ Petitioner initially declined to offer a *Sotera* stipulation (EX2014, 1) and only did so after reviewing Patent's Owner discretionary denial brief for IPR2025-01020 for the related '969 Patent.

Guidance on USPTO's rescission of "Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings with Parallel District Court Litigation," (Mar. 24, 2025) (a *Sotera* stipulation is not "dispositive by itself").

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, EX2011, 12-19, 62-66, 92-98 (Invalidity Contentions Cover Pleading); EX2012 ('970 Patent Claim Chart). These facts weigh 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. Stratasys, 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).

As Petitioner's expert explains, the mouthpiece described in Black was commercially "sold under the name Mr. Thirsty." EX1003, ¶1; *see also id.*, ¶18 ("The patent for my intraoral isolation device is currently licensed to Zirc Dental Products, who manufactures, markets, and sells the device as 'Mr. Thirsty'"). Dr.

Black also refers to “the Isolite device displayed and sold by the Company Isolite Systems (now Zyris)” throughout his declaration. EX1003, ¶11; *see also id.*, ¶¶10-17. According to Zyris, the Isolite product is covered by the patent corresponding to Hirsch. EX2024 (listing U.S. Patent No. 6,974,321 on patent marking website). These are the *same* products that Petitioner relies on in its invalidity contentions in the Parallel Litigation.

The Federal Circuit recently held that “IPR estoppel does not preclude a petitioner from relying on the same patents and printed publications as evidence in asserting a ground that could not be raised during the IPR, such as that the claimed invention was known or used by others, on sale, or in public use.” *Ingenico Inc. v. IOENGINE, LLC*, 136 F.4th 1354, 1366 (Fed. Cir. 2025). Accordingly, Petitioner may assert not only the product versions of Hirsch and Black in the Parallel Litigation as an invalidity ground but also the Hirsch and Black references themselves in the Parallel Litigation because Petitioner’s stipulation is expressly limited to “ground[s] that could be raised . . . on the basis of prior art patents or printed publications.” EX2023, 4. In other words, Petitioner’s stipulation does not prevent Petitioner from relitigating the same issues with respect to Black and Hirsch in the Parallel Litigation.

5. 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 ‘970 Patent was still pending and marketed its mouthpieces as a replacement for Patent Owner’s DryShield® mouthpiece. After the ‘970 Patent issued in 2023, Patent Owner notified Petitioner that its VacuLux mouthpieces infringe at least claim 1 of the ‘970 Patent. EX2006 (cease and desist letter dated May 17, 2023). Patent Owner provided an exemplary infringement claim chart⁸ showing how Petitioner’s product infringes each and every limitation of at least claim 1 of the ‘970 Patent. *Id.*

In response, Petitioner did not identify any alleged prior art or challenge the validity of ‘970 Patent (or any of the related patents). Instead, Petitioner chose to redesign the accused product and argued non-infringement. EX2008, 3-4

⁸ Exhibit 1011, which Petitioner refers to “Infringement Contentions,” is a copy of the claim chart provided in May 2023.

(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, confirming that the Patent Office already located and applied the most pertinent art during the lengthy prosecution history of the ‘970 Patent. *Supra*, § II.A.5. Petitioner’s failure to raise any 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 ‘970 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 ‘970 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 ‘970 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 '970 Patent would not be challenged more reasonable than in *iRhythm*. See also *Samsung Electronics Co., Ltd. et al. v. GenghisComm Holdings, LLC*, IPR2025-00788, Paper 11 at 2 (PTAB Aug. 22, 2025) (exercising discretion to deny petition challenging patent that issued in 2022).

Putting aside the parties' history, discretionary denial is appropriated based on settled expectations for another reason: as Petitioner acknowledges, the Office examined the application that led to the '970 Patent for *almost nine years*. Petition, 16, 23. After spending considerable time and resources for nearly nine years prosecuting the '970 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. THE PETITION IS NOT SUPPORTED BY PROPER EXPERT TESTIMONY

"The extent of the petition's reliance on expert testimony" is a relevant consideration for discretionary denial. Director Memo at 2. Here, Petitioner proffers testimony from Dr. Brian Black, who is the named inventor of the Black reference Petitioner relies on as part of Ground 2. See EX1003. But remarkably, Dr. Black is *not* a POSITA under Petitioner's proposed definition, 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, 26. Petitioner has been consistent with its definition of the POSITA because Petitioner advances the same definition in the Parallel Litigation in its Invalidity Contentions (EX2011, 42) and Non-Infringement Contentions (EX2015, 7).

Dr. Black does not have an engineering degree⁹ and admits, consistent with Petitioner's definition, that “some knowledge of mechanical engineering is probably required.” EX1004, p. 3; EX1003, ¶50. Petitioner does not contend that mechanical engineering and dentistry are related fields. *See* Petition, 26-27. Consequently, Dr. Black's testimony does not support the Petition 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). Given this facial flaw in the Petition and the near certainty that Dr. Black's declaration will be excluded.

⁹ Dr. Black opines on and uses a different definition for a POSITA in his declaration that does not require a mechanical engineering degree. EX1003, ¶45.

VII. CONCLUSION

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

Respectfully submitted,

Dated: August 25, 2025

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing **Patent Owner's Discretionary Denial Brief** was served on August 25, 2025, by email:

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CERTIFICATION OF WORD COUNT

Pursuant to 37 C.F.R. § 42.24(d), the undersigned hereby certifies that the foregoing Patent Owner's Preliminary Response is produced using a 14-point Times New Roman font and contains approximately 9,478 words, which is less than the 14,000 total words permitted by the U.S. Patent Trial and Appeal Board rules. Director Memo at p. 2. Counsel relies on the word count of the computer program used to prepare the response on August 25, 2025.

Dated: August 25, 2025

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