

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. 11,823,217

Case No. IPR2025-01065

PATENT OWNER'S DISCRETIONARY DENIAL BRIEF

TABLE OF CONTENTS

I.	INTRODUCTION	1
II.	THE DIRECTOR SHOULD DENY INSTITUTION PURSUANT TO 35 U.S.C. § 325(d)	3
A.	All of Petitioner’s References Were Previously Considered.....	4
B.	Petitioner Has Not Shown Any Material Error	6
1.	Petitioner’s Proposed Nguyen-Black Combination is Nearly Identical to the Nguyen-Al Shawi Combination Applied During Prosecution ...	7
2.	The Examiner Committed no Error by Not Applying Petitioner’s Proposed Nguyen-Hirsh Combination	12
3.	No Meaningful Additional Evidence or Facts	13
III.	THE PARALLEL LITIGATION WILL MOST EFFICIENTLY RESOLVE THE PARTIES’ ENTIRE DISPUTE	14
IV.	THE <i>FINTIV</i> FACTORS FAVOR DISCRETIONARY DENIAL	15
V.	THE PETITION IS NOT SUPPORTED BY ADEQUATE EXPERT TESTIMONY.....	20
VI.	CONCLUSION.....	20

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).....	3, 6, 11
<i>Apple Inc. v. Fintiv, Inc.</i> , IPR2020-00019, Paper 11 (PTAB Mar. 20, 2020).....	<i>passim</i>
<i>Becton, Dickinson & Co. v. B. Braun Melsungen AG</i> , IPR2017-01586, Paper 8 (PTAB Dec. 15, 2017)	4, 13
<i>DeJule v. MillerKnoll, Inc.</i> , No. 1:23-CV-969, 2024 WL 5680071 (W.D. Mich. Feb. 2, 2024).....	16
<i>Ecto World, LLC v. RAI Strategic Holdings, Inc.</i> , IPR2024-01280, Paper 13 (PTAB May 19, 2025)	4, 6
<i>Extreme Networks, Inc. v. Enterasys Networks, Inc.</i> , 395 F. App'x 709 (Fed. Cir. 2010).....	20
<i>Gen. Plastic Indus. Co. v. Canon Kabushiki Kaisha</i> , IPR2016-01357, Paper 19 (PTAB Sept. 6, 2017).....	14
<i>Ingenico Inc. v. IOENGINE, LLC</i> , 136 F.4th 1354 (Fed. Cir. 2025)	19
<i>Kyocera Senco Indus. Tools Inc. v. ITC</i> , 22 F.4th 1369, 1376 (Fed. Cir. 2022)	20
<i>Motorola Sols., Inc. v. Stellar, LLC</i> , IPR2024-01205, Paper 19 (PTAB Mar. 28, 2025).....	18
<i>Samsung Bioepis Co, Ltd. v. Regeneron Pharmas., Inc.</i> , IPR2025-00176, Paper 12 (PTAB Jun. 2, 2025)	17

<i>Shenzen Tuozhu Tech. Co., Ltd. v. Stratasys, Inc.,</i> IPR2025-000354, Paper 11 (PTAB Jun. 12, 2025)	19
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<i>Weatherford U.S., L.P. V. Enventures Global Tech., Inc.,</i> IPR2020-01661, Paper 19 (PTAB Apr. 15, 2021)	12
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Statutes

35 U.S.C. § 314.....	1
35 U.S.C. § 316.....	17
35 U.S.C. § 325	<i>passim</i>

LISTING OF EXHIBITS

Exhibit No.	Description
2001	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)
2002	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)
2003	U.S. Patent Publication No. 2014/0162209 ("Nguyen '209 Publication")
2004	U.S. Patent Publication No. 2014/0212841 ("Nguyen '841 Publication")
2005	U.S. Patent Publication No. 2014/0212838 ("Nguyen '838 Publication")
2006	U.S. Patent No. 9,358,086 ("Hirsch '086 Patent")
2007	U.S. Patent Publication No. 2015/0335409 ("Hirsch '409 Publication")
2008	U.S. Patent Publication No. 2009/0274991 ("Black Publication")
2009	U.S. Patent Publication No. 2018/0153637 ("Al-Shawi")
2010	U.S. Pat Pub. No. 2017/0156832 ("Reyes")
2011	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)

2012	Docket Navigator Statistics, Western District of Michigan
2013	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
2014	Defendant/Counter-Plaintiff Ascentcare Dental Products, Inc.'s Invalidity Contentions Claim Chart for the '217 Patent, <i>Solmetex, LLC v. Ascentcare Dental Products, Inc.</i> , Case No. 1:24-cv-00954-RJJ-MV, served July 18, 2025
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	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)
2017	Zyris, Inc. Virtual Patent Marking, https://www.zyris.com/patents/ (last accessed Aug. 25, 2025)
2018	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)

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

I. INTRODUCTION

There are four independent reasons why the Director should exercise her discretion and deny institution pursuant to 35 U.S.C. § 314(a). First, the Petition presents a classic case for discretionary denial under 35 U.S.C. § 325(d). **Every** reference Petitioner relies on was already considered during prosecution of the ‘217 Patent. In particular, Ground 1, which uses Nguyen (EX1005) as the primary reference, is nearly indistinguishable from a § 103 rejection based on Nguyen that Patent Owner overcame during prosecution.

The parties are engaged in litigation concerning the ‘217 Patent in *Solmetex, LLC v. Ascentcare Dental Products, Inc.*, Case No. 1:24-cv-00954, in the Western District of Michigan (“the Parallel Litigation”). There, Petitioner admitted that it is applying “the same prior art cited during prosecution in the exact same manner in the IPRs as the Examiner did during prosecution.” EX2001, 15. Petitioner also represented that it began conducting prior art searches in February 2025. EX2002, ¶14. Considering that Petitioner’s searching apparently did not locate **any** new reference for this IPR, it is clear that the Office previously located and applied the most pertinent art for the ‘217 Patent. On this record, Petitioner cannot show any

material error by the Office.

Second, the Parallel Litigation involves not just the '217 Patent but also six other utility patents, three design patents, and Petitioner's Lanham Act counterclaim.

As set forth below, Petitioner is seeking to initiate seven proceedings in the Office:

Patent No.	Case No.	Discretionary Denial Brief	Institution Deadline
11,589,969	IPR2025-01020	Aug. 18, 2025	Dec. 18, 2025
11,589,970	IPR2025-01057	Aug. 25, 2025	Dec. 23, 2025
11,744,686	IPR2025-01059	Aug. 25, 2025	Dec. 24, 2025
11,826,217	IPR2025-01065	Sept. 1, 2026	Jan. 1, 2026
12,011,329	IPR2025-01104	Sept. 1, 2026	Jan. 1, 2026
12,167,948	PGR2025-00058	Sept. 8, 2026	Jan. 8, 2026
12,290,418	IPR2025-01175	Sept. 8, 2026	Jan. 8, 2026

The Director should exercise her discretion to deny these petitions (including this one) because even if the Board instituted and issued seven final written decisions ("FWD") in Petitioner's favor, this would not resolve all of the parties' disputes, including the design patent claims and 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 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. While the court has not set a trial date yet, the parties have already exchanged infringement, non-infringement, and invalidity contentions and are engaged in discovery. By the time

the Board decides whether to institute in January 2026, the parties will have already completed claim construction and will be just weeks away from the fact discovery cutoff. The Parallel Litigation will therefore likely proceed to trial before the Board would issue a FWD concerning the '217 Patent in January 2027.

Fourth, 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 flawed because he is not a POSITA under Petitioner's definition.

II. THE DIRECTOR 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) “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 several factors to consider in exercising discretion under § 325(d), including “the extent to which the asserted art was evaluated during examination, including whether the prior art was the basis for rejection” and “whether Petitioner has pointed out

sufficiently how the Examiner erred in its evaluation of the asserted prior art.”
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).

These factors overwhelming favor discretionary denial under § 325(d). Each of the references in Ground 1-3 (Nguyen, Hirsch, and Black), or a substantively identical version thereof, was considered by the Office during prosecution of the ‘217 Patent. Petitioner did not meet its burden to show how the Office allegedly erred in allowing the claims over these references.

A. All of Petitioner's References Were Previously Considered

1. Nguyen was Considered (Grounds 1-2)

The Petition relies on U.S. Pat. No. 8,911,232 (“Nguyen” or “Nguyen Patent”), which originally published as U.S. Pat. Pub. No. 2014/0162209 (“Nguyen ‘209 Publication”). EX1005, 1; EX2003. Both versions were cited in an IDS and were considered. EX1015, 92-93. This satisfies 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”). Other versions of Nguyen were also considered. *See* EX1002, 66 (citing U.S. Pat. No., 9,788,924, which is a continuation of Nguyen), 67 (citing

six related publications, including U.S. Pat. Pub. No. 2014/0212841 (discussed below)), 68 (citing Canadian, Chinese, European, and PCT counterparts).

The Examiner applied Nguyen in at least three rejections. *Becton*, Paper 8 at 17-18. First, the Examiner applied the Nguyen '209 Publication (which the Examiner referred to as "Incept") as a secondary reference in § 103 rejections in a Non-Final Office Action dated Dec. 3, 2021. EX1015, 53-56; *id.*, 249 (clarifying that "Incept" referred to the Nguyen '209 Publication). Second, in a Final Office Action dated May 12, 2022, the Examiner applied an identical published version of Nguyen, U.S. Pat. Pub. No. 2014/0212841 ("Nguyen '841 Publication," EX2004), which is a continuation of the Nguyen Patent (EX1005), as a primary reference in § 103 rejections of all pending claims, except for allowable claim 16. EX1015, 262-77. Third, in a Non-Final Office Action dated Feb. 17, 2023, pending claims 4-5, 14, 17, and 24-25 were rejected over Hirsch and the Nguyen '841 Publication. EX1016, 237-39.

2. Hirsch was Considered (Grounds 2-3)

The Petition relies on Hirsch (U.S. Pat. No. 9,532,858), which is not cited on the face of the '217 Patent. However, Hirsch is a continuation of U.S. Patent No. 9,358,086 ("Hirsch '086 Patent"), which was published as U.S. Patent Publication No. 2015/0335409 ("Hirsch '409 Publication"), both of which were cited in an IDS and considered by the Examiner. EX2006; EX2007; EX1015, 92-93; *Ecto World*,

IPR2014-01280, Paper 13 at 4. Indeed, Petitioner acknowledges that Hirsch (EX1006) and the Hirsch '409 Publication are the same when it admits that "Hirsch" was used in rejections during prosecution of the '217 Patent. Pet., 20-21.

Additionally, the Hirsch '409 Publication was applied in rejections in a Non-Final Office Action dated Feb. 17, 2023. EX1016, 230-39. The Examiner characterized the Hirsch '409 Publication as "the best prior art." *Id.*, 239. Following a response (*id.*, 255-66), the Examiner allowed the claims over Hirsch and again reiterated that the Hirsch '409 Publication was "the best prior art." *Id.*, 340.

3. Black was Considered (Grounds 1-2)

Black (U.S. Pat. No. 8,029,280) and the corresponding publication (U.S. Pub. No. 2009/0274991, "Black Publication," EX2008) were cited in an IDS and were considered by the Examiner. EX1015, 92-93. This satisfies the first part of the *Advanced Bionics* test. *Ecto World*, Paper 13 at 4.

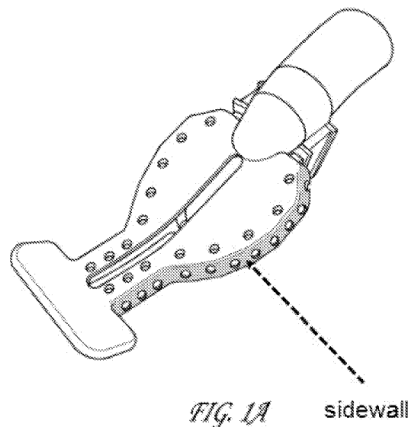
B. Petitioner Has Not Shown Any Material Error

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"). Petitioner identifies no material error in Grounds 1 and 3, which challenge the only two independent claims (claims 1 and 17) of the '217 Patent.

1. Petitioner's Proposed Nguyen-Black Combination is Nearly Identical to the Nguyen-Al Shawi Combination Applied During Prosecution

As discussed above, the Examiner applied Nguyen as a primary reference to reject the claims under § 103. EX1015, 262-77; *supra*, § II.A.1. The Examiner found that Nguyen discloses (1) "a main body portion" including anterior and posterior walls; (2) "a suction connector portion"; (3) a "cheek retractor"; and (4) "a side wall . . . that extends along the edge of both the anterior and posterior wall." *Id.*, 264-65 (rejection for claim 1); *see also id.*, 272 (same for claim 19). The Examiner annotated the "sidewall" Nguyen as shown below:



EX1015, 265 (annotating EX1005, FIG. 1A).

But the Examiner found that Nguyen did not disclose all limitations of the pending claims, including the "intervening wall" feature with "alternating crests and troughs":

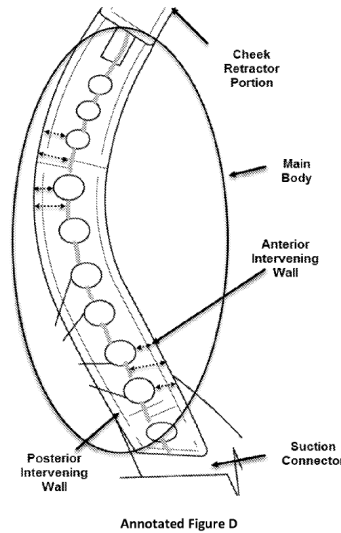
Nugyen is silent to the sidewall being made from an at least one anterior intervening wall extending along an edge of the anterior wall partially across the distance towards the posterior wall, and at least one posterior intervening wall extending along an edge of the posterior wall partially across the distance towards the anterior wall, the at least one anterior intervening wall and the at least one posterior intervening wall each having alternating crests and troughs.

EX1015, 265-66 (rejecting claim 1); *see also id.*, 272 (asserting the same for claim 19). For these limitations, the Examiner applied Al-Shawi (EX2009) and asserted that it discloses “suction conduits . . . formed by two half-walls (401, 402) having mating projections (422) . . . with interspaced flow channels form crest and trough shapes on the two mating half-walls (401, 402) that extend toward each other and abut each other to provide the flow channels within the device.” *Id.*, 266 (rejecting claim 1); *see also id.*, 272 (same for claim 19).

The Examiner then asserted that it would have been obvious to open Nguyen's sidewall and to create two abutting sidewalls with crests and troughs:

It would have been obvious to someone skilled in the art before the effective filing date to modify the single solid sidewall of Nguyen to be made from two abutting anterior and posterior sidewalls with complementary mating and abutting crests and troughs to form the flow channels as taught by Al-Shawi in order to use an alternative sidewall arrangement shown in the prior art which would yield predictable results of forming flow channels through a double walled suction device.

EX1015, 266 (claim 1); *id.*, 272 (same for claim 19). The Examiner illustrated how Nguyen's single sidewall would be modified to open it to create abutting anterior and posterior intervening walls with crests and troughs:



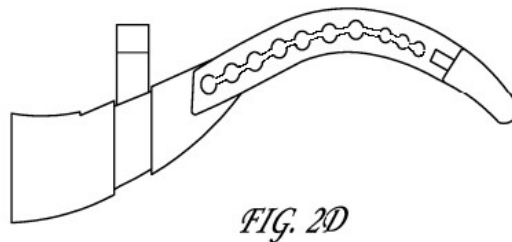
EX1015, 269 (annotating EX1005, FIG. 1D)

In response, Applicant argued, among other things, that “there is no motivation that would have led a person having ordinary skill in the art to combine the teachings of Al-Shawi with Nguyen to arrive at the claimed ‘dental mouthpiece.’” *Id.*, 195-96. The Examiner subsequently withdrew the § 103 rejections using Nguyen as the primary reference. EX1016, 239.

In Ground 1, Petitioner applies Nguyen as the primary reference in its § 103 combination, just like the Examiner. Pet., 28; *see also* EX2001, 15. Consistent with the Examiner’s findings, Petitioner admits Nguyen does not disclose Limitations 1(d) and 1(e), which are directed to an “anterior intervening wall” and a “posterior intervening wall.” *See* Pet., 32-45.

In attempt to address this deficiency in Nguyen, Petitioner argues that “it would have been obvious to open the sidewalls of Nguyen in view of Black, thereby

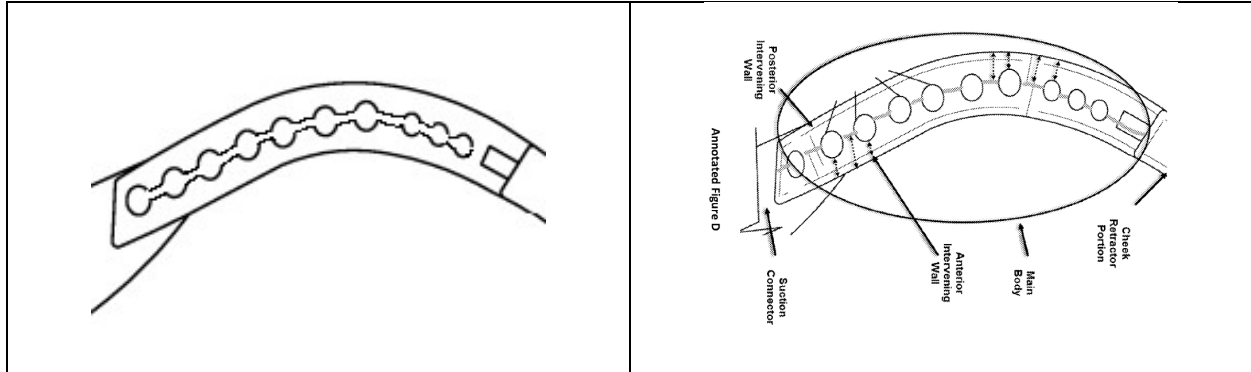
creating two intervening walls that each partially extend across the distance between the anterior and posterior walls.” Pet., 33. Petitioner shows its proposed modification to Nguyen using the modified version of Nguyen FIG. 2D reproduced below:



Pet., 43 (modifying EX1005, FIG. 2D)

Ground 1 is nearly indistinguishable from the obviousness combination the Examiner applied in the May 2022 Final Office Action. Both rely on Nguyen as the primary reference. Just like the Examiner's reliance on Al-Shawi, Petitioner relies on Black to argue that Nguyen's sidewall should be “cut” down the middle so as to be opened to create the two intervening walls. Pet., 42-44. As shown below, Petitioner's proposed Nguyen-Black combination is nearly identical to the Examiner's combination of Nguyen and Al-Shawi in that both “open” Nguyen's singular sidewall with a “cut” between Nguyen's circular apertures.

Petitioner's Proposed Modification to Nguyen	The Examiner's Proposed Modification to Nguyen
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Pet., 43 (modifying EX1005, FIG. 2D); EX1015, 269 (modifying EX1005, FIG. 2D). Based on this striking similarity and Petitioner's admission it is applying the art in exactly the same way as the Examiner (EX2001, 15), the Director should find that Petitioner has identified no error by the Examiner but is instead attempting to relitigate the same rejection that Patent Owner already overcame.

Petitioner has not met its burden to show the Examiner erred in finding the claims non-obvious over Nguyen, Black and Hirsch and "that no reasonable examiner could have found" the claims allowable over these references. *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 Petitioner argues that the Office erred by not combining Black (instead of Al-Shawi) with Nguyen, that argument fails. The Board routinely finds § 325(d) applicable when the petition relies on a combination of previously considered references, even if the specific combination was not applied during prosecution. *See, e.g., Weatherford*

U.S., L.P. V. Enventures Global Tech., Inc., IPR2020-01661, Paper 19 at 28-30 (PTAB Apr. 15, 2021) (rejecting argument that the examiner erred by not combining two references that were considered separately and denying institution).

Moreover, Black is not just a random reference buried in an IDS. The Search Report and Written Opinion (“ISR/WO”) for the ‘217 Patent’s PCT counterpart was cited in an IDS. EX1002, 272 (IDS), 279-286 (ISR/WO). The ISR/WO identified: (1) U.S. Pat Pub. No. 2017/0156832 (“Reyes”); (2) U.S. Pat. Pub. No. 2014/0212838 (“the Nguyen ‘838 Publication,” EX2005), which is another continuation of Nguyen; (3) the Hirsch ‘409 Publication (EX2007); and (4) the Black Publication (EX2008); and (5) another Hirsch publication. EX1002, 280. The ISR/WO rejected the PCT claims based on Reyes and Nugyen. EX1002, 283-86.

Notably, the U.S. Examiner used most of these references in rejections during prosecution of the ‘217 Patent. *See, e.g.*, EX1015, 47-55 (similar to PCT ISR/WO, rejecting claims under § 102 based on Reyes and other claims under § 103 based on Nguyen); *supra*, II.A.1-II.A.2. It is therefore clear that the U.S. Examiner was aware of and considered the PCT ISR/WO during prosecution and used it as a template at least for the first Office Action and therefore must have considered the teachings in each reference, including Black.

2. The Examiner Committed no Error by Not Applying Petitioner’s Proposed Nguyen-Hirsh Combination

For Ground 3, Petitioner suggests there was error because “[t]he Examiner never proposed modifying Nguyen in view of Hirsch.” Pet., 21. Yet this argument ignores that the Examiner: (1) applied Nguyen as a primary reference in § 103 rejections (EX1015, 262-77); applied Nguyen as a secondary reference in multiple § 103 rejections (*id.*, 53-55; EX1016, 237-39); (3) applied Hirsch in § 102 rejections (EX1016, 230-36); and (4) applied Hirsch as a primary reference in §103 rejections (*id.*, 237-39).

Considering the Examiner applied (i) Hirsch in a § 102 rejection and as the primary reference in a § 103 rejection and (ii) Nguyen as a primary reference in a § 103 rejection, the Examiner was clearly aware of the teachings (and shortcomings) in both Nguyen and Hirsch relative to the pending claims. Indeed, the Examiner's last § 103 rejections were based on the *combination of Hirsch and Nguyen* and directed at two claims (then-pending claims 24-25) that now depend from independent claim 17 of the '217 Patent, which is being challenged in Ground 3. EX1016, 237-39. The Examiner committed no error in its examination of the claims of the '217 Patent and correctly determined the claims were allowable over Nguyen, Hirsch, and any combination of Nguyen and Hirsch.

3. No Meaningful Additional Evidence or Facts

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 mere inclusion of an expert declaration, standing alone, cannot avoid § 325(d). Moreover, as explained below, Dr. Black's declaration is facially flawed. *Infra*, § V.

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

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

By contrast, the Parallel Litigation will resolve not just the parties' dispute regarding the '217 Patent but ***all*** of the parties' disputes for all seven patents in a single proceeding. It will also resolve the parties' other disputes. 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 '217 Patent would merely result in the creation of an ***additional*** proceeding.

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 proceedings that would only potentially resolve some of the parties' disputes. Patent Owner submits that the Office should decline Petitioner's request to initiate such piecemeal and duplicitous litigation. It would also be less burdensome for the parties to litigate all of their disputes in one proceeding. For these additional reasons, the Director should exercise her discretion to deny institution.

IV. THE *FINTIV* FACTORS FAVOR DISCRETIONARY DENIAL

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 FWD;
- (3) investment in the parallel proceeding by the court and the parties;
- (4) overlap between issues 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). "[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 factor weighs against institution.

Factor 1: Petitioner has moved to stay the Parallel Litigation. EX2008; EX2010. While that motion remains pending, the court will unlikely grant a stay because when recently faced with a similar request, the presiding judge denied it because “the PTAB has not yet granted” “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). That reasoning holds true in this case.

A pre or post-institution stay is also unlikely because (1) there are more claims in the Parallel Litigation that cannot be resolved by the Board (*supra*, § III); (2) the parties are direct competitors (EX2010, 11-13; *DeJule*, 2024 WL 5680071, at *2); and (3) by the time the Board issues an institution decision, the parties will have already completed claim construction and will be just weeks away from the fact discovery cutoff (*Infra*, § IV.C).

Factor 2: “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. In the Parallel Litigation, the court has scheduled a *Markman* hearing for Dec. 15, 2025 and set a Dec. 3, 2025 deadline for substantial completion of document production and a Jan. 21, 2026 fact discovery cutoff. EX2011, 2-3.

If an IPR is instituted, the Board would issue its FWD by January 1, 2027. 35 U.S.C. § 316(a)(11). While a trial date is not scheduled yet, with fact discovery set to close in Jan. 2026, trial will likely occur before the Board's FWD deadline in January 2027. Patent Owner expects that the court will set deadlines for expert disclosures/discovery and dispositive motions in Feb. 2026. Given that the current fact discovery period is 9 months (between Apr. 2025 and Jan. 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. EX2012. That said, this figure is based on a small sample size of only four cases, and two of the four cases reached a jury trial within 2 years. *Id.* Given the current schedule, it is likely that trial will similarly occur within approximately two years of the complaint (filed in Sept. 2024), i.e., before the FWD deadline. The Board has denied petitions 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).

Factor 3: 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. Here, the parties have invested substantial time and resources in the Parallel Litigation and will continue to do so before institution. The parties are currently engaged in fact discovery, including serving and

responding to dozens of interrogatories and hundreds of requests for production. EX2018, 1-2. The parties have exchanged initial infringement, non-infringement, and invalidity contentions. EX2013; EX2014; EX2015. By the time the Board issues an institution decision, even more work will have been done: the parties will have completed claim construction, substantially completed document production, and will be weeks from the fact discovery cutoff. EX2011, 2-3.

Factor 4: The “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*, Paper 11 at 12. Petitioner’s invalidity contentions rely on the same references and combinations as the Petition. EX2013, 12-17, 21-23, 68-74; EX2014. In an apparent effort to avoid discretionary denial, Petitioner recently filed a *Sotera* stipulation, but this is not dispositive. EX2016.

Petitioner’s invalidity contentions are far more expansive than the Petition and assert (1) alleged prior art products called “Isolite Mouthpiece,” “Mr. Thirsty,” and the “DryShield Autoclavable Mouthpiece (DM1)” and (2) a host of § 112 arguments. EX2013, 12-19, 23-25, 74-80, 92-98; EX2014. This weighs against institution. *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"); *see also* *Shenzen Tuozhu Tech. Co., Ltd. v. Stratasy, Inc.*, IPR2025-000354, Paper 11 at 2-3 (PTAB Jun. 12, 2025).

Petitioner's contentions state that the mouthpiece in Nguyen corresponds to the DryShield Autoclavable Mouthpiece and the mouthpiece disclosed in Black is sold as the "Mr. Thirsty" product. EX1003, ¶¶2, 8, 17. The mouthpiece in Hirsch is sold as the "Isolite" product. EX1003, ¶¶9-16; EX2017 (listing Hirsch on Zirc patent marking website). Petitioner's stipulation is limited to "ground[s] that could be raised ... on the basis of prior art patents or printed publications." EX2016, 4. As a result, the stipulation does not foreclose Petitioner from relitigating the same issues in the Petition with respect to Nguyen, Hirsch, and Black by substituting them for DryShield, Mr. Thirsty, and Isolite. Indeed, 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). Thus, Petitioner's stipulation does nothing to minimize the overlap between the Petition and the Parallel Litigation.

Factor 5: This factor weighs against institution because Petitioner and Patent Owners are the parties in the Parallel Litigation. EX1009; *Fintiv*, Paper 11 at 13-14.

V. THE PETITION IS NOT SUPPORTED BY ADEQUATE 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. EX1003. But Dr. Black is *not* a POSITA under the proposed definition in the Petition and in the Parallel Litigation, which is: “at least a B.S. degree in mechanical engineering or a related field with at least two years’ experience designing medical devices.” Pet., 21; EX2013, 42; 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, ¶40. Petitioner does not contend that mechanical engineering and dentistry are related fields. Pet., 21. An expert issue must possess the minimum level of skill in the art. *Kyocera Senco Indus. Tools Inc. v. ITC*, 22 F.4th 1369, 1376 (Fed. Cir. 2022); *Extreme Networks, Inc. v. Enterasys Networks, Inc.*, 395 F. App’x 709, 715 (Fed. Cir. 2010). Given this flaw in Petitioner’s evidence, the Director should deny institution.

VI. CONCLUSION

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

Patent No. 11,823,217
IPR2025-01065

Patent Owner's Discretionary Denial Brief

Respectfully submitted,

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CERTIFICATE OF SERVICE

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