

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

VITAL CONNECT, INC.,
Petitioner,

v.

BARDY DIAGNOSTICS, INC.,
Patent Owner.

IPR2023-00381
Patent 11,051,743 B2

Before ULRIKE W. JENKS, KIMBERLY McGRAW, and
KRISTIL R. SAWERT, *Administrative Patent Judges*.

SAWERT, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

Vital Connect, Inc. (“Petitioner”) filed a petition to institute *inter partes* review of claims 1–20 of U.S. Patent No. 11,051,743 B2 (Ex. 1001, “the ’743 patent”). Paper 1 (“Pet.”). Bardy Diagnostics, Inc. (“Patent Owner”) filed a Preliminary Response. Paper 6 (“Prelim. Resp.”). Patent Owner also filed a statutory disclaimer of claims 1–10. Ex. 2003.

The Board has discretion to determine whether to institute *inter partes* review. *See* 35 U.S.C. § 314 (2018); 37 C.F.R. § 42.4(a) (2022). Under 35 U.S.C. § 325(d), “[i]n determining whether to institute [*inter partes* review], the Director may take into account whether, and reject the petition or request because, the same or substantially the same prior art or arguments previously were presented to the Office.”

For the reasons stated below, we determine that the same or substantially the same prior art or arguments previously were presented to the Office and Petitioner has failed to show error in the consideration of that art or argument. *Advanced Bionics, LLC v. Med-El Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 at 8–9 (PTAB Feb. 13, 2020) (precedential) (“*Advanced Bionics*”). We, therefore, deny institution of *inter partes* review.

II. BACKGROUND

A. Related Matters

The parties identify the following district-court proceeding as a related matter involving the ’743 patent: *Bardy Diagnostics, Inc. v. Vital Connect, Inc.*, No. 1:22-cv-00351 (D. Del.). Pet. 2; Paper 5, 2 (Patent Owner’s Mandatory Notices). Patent Owner also identifies U.S. Patent

Application No. 17/946,933 and U.S. Patent No. 11,445,967 B2 as related to the '743 patent. Paper 5, 2.

B. Real Parties in Interest

Petitioner identifies its real party in interest as Vital Connect, Inc. Pet. 2. Patent Owner identifies Bardy Diagnostics, Inc., Hill-Rom Company, Inc., Hill-Rom Services, Inc., Hill-Rom, Inc., Hill-Rom Holdings, Inc., Welch Allyn, Inc., Baxter Healthcare Corporation, Baxter Healthcare, S.A., and Baxter International, Inc. as its real parties in interest. Paper 5, 2.

C. Overview of the '743 patent

The '743 patent, titled “Electrocardiographic Patch,” relates to an electrocardiography monitor that includes a flexible, extended-wear electrode patch and a removable, reusable monitor recorder. Ex. 1001, code (54), 3:46–49. Figure 2, reproduced below, is a diagram of an electrocardiography monitor according to the '743 patent.

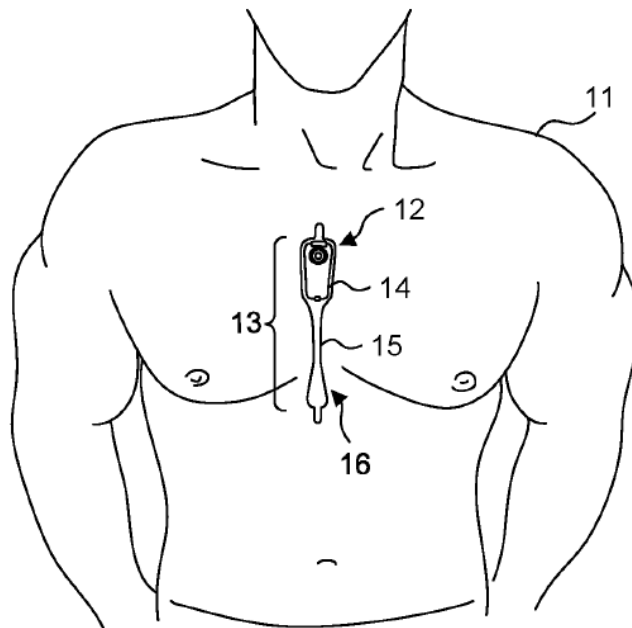


FIG. 2 is a diagram of an extended-wear electrocardiography and physiological sensor monitor according the '743 patent fitted to the sternal region of a patient. Ex. 1001, 5:7–10.

As shown in Figure 2, the electrocardiography monitor 12 sits in the sternal region 13 of patient 11. *Id.* at 5:47–55. The electrocardiography monitor includes a monitor recorder 14 and an electrode patch 15 that “is shaped to fit comfortably and conformal to the contours of the patient’s chest approximately centered on the sternal midline 16.” *Id.* at 5:57–61.

According to the ’743 patent, the placement of the electrocardiography monitor at the patient’s sternal midline “significantly improves the ability of the wearable monitor 12 to cutaneously sense cardiac electric signals . . . while simultaneously facilitating comfortable long-term wear for many weeks.” *Id.* at 6:1–8.

Figure 5, reproduced below, illustrates the monitor recorder portion of the electrocardiography monitor.

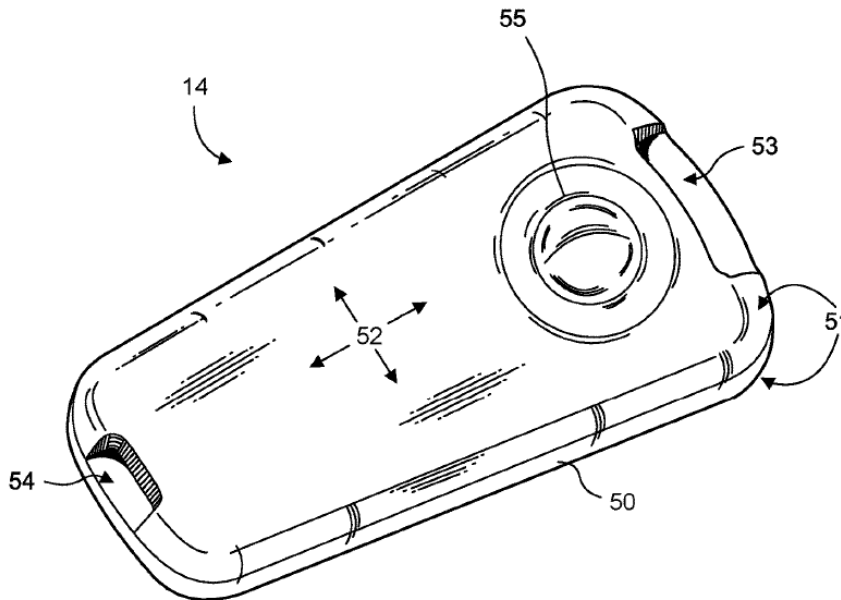


FIG. 5 is a perspective view of the monitor recorder according to the ’743 patent. Ex. 1001, 5:17–18.

Monitor recorder 14 senses and records the patient’s ECG data, e.g., directly into an onboard memory or wirelessly into a remote device. *Id.* at 6:19–23, 7:36–38. The monitor recorder includes a sealed housing 50 having a

compartment 36 and electrical pads 34 provided within a moisture-resistant seal 35. *Id.* at 9:63–64, 10:5–8.

In use, the monitor recorder is snapped into the non-conductive receptacle. *Id.* at 9:10–11. The flexible circuit comprises a pair of circuit traces—distal circuit trace 33 and proximal circuit trace (not shown)—that electronically couple ECG electrodes to the electrical pads. *Id.* at 9:58–62. The electrical pads, in turn, couple with electrical contacts on the monitor recorder. *Id.* at 9:64–10:4. The battery component powers the monitor recorder. *Id.* at 10:11–13.

D. The Challenged Claims

Petitioner challenges claims 1–20 of the '743 patent. Pet. 4. Patent Owner has statutorily disclaimed claims 1–10. Ex. 2003. Of the remaining claims, claim 11, reproduced below, is independent and illustrative of the subject matter recited in the challenged claims.

11. An electrocardiography monitor, comprising:
 - a backing comprising an elongated strip with a mid-section connecting two ends of the backing, wherein the midsection is narrower than the two ends of the backing;
 - an electrocardiographic electrode on each end of the backing to capture electrocardiographic signals;
 - a flexible circuit comprising a pair of circuit traces electrically coupled to the electrocardiographic electrodes;
 - a wireless transceiver to communicate at least a portion of the electrocardiographic signals;
 - a battery on one of the ends of the backing;
 - a processor powered by the battery; and

memory electrically interfaced with the processor and operable to store samples of the electrocardiographic signals.

Ex. 1001, 17:11–28.

E. Evidence

Petitioner submits evidence including:

Evidence	Exhibit No.
Declaration of Dr. Joseph Akar	1002
WO 2010/104952 A2 (published Sept. 16, 2010) (“Mazar”)	1003
U.S. Patent Appl. Pub. No. 2011/0077497 A1 (published Mar. 31, 2011) (“Oster”)	1004
U.S. Patent No. 11,116,447 B2 (Sept. 14, 2021) (“Yang”)	1005

F. Asserted Grounds of Unpatentability

Petitioner asserts the following grounds of unpatentability for the non-disclaimed claims of the ’743 patent:

Claim(s) Challenged	35 U.S.C. §	Reference(s)
11–20	103 ¹	Mazar, Yang
11–20	103	Oster, Yang

Pet. 5. Patent Owner disputes Petitioner’s asserted grounds of unpatentability. *See generally* Prelim. Resp.

G. The Prior Art

We now provide brief summaries of the asserted references.

¹ The Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) (“AIA”), amended 35 U.S.C. § 103. Petitioner states that its Petition “treats September 25, 2013, as the priority date for the ’743 patent,” which is after the effective date of the applicable AIA amendment. Pet. 4. Patent Owner does not contest or comment on Petitioner’s asserted priority date. Thus, we refer to the AIA version of 35 U.S.C. § 103. Our decision would be the same were we to apply the pre-AIA version of the statute.

1. *Mazar (Ex. 1008)*

Mazar relates to a flexible health-monitoring device comprising an adherent patch and a display. Ex. 1003, code (57). The health-monitoring device attaches to a patient's skin and includes sensors that can monitor a patient's electrocardiograms (ECGs). *Id.* ¶¶ 6, 14. Figure 1B, reproduced below, shows a bottom view of a health-monitoring device according to Mazar.

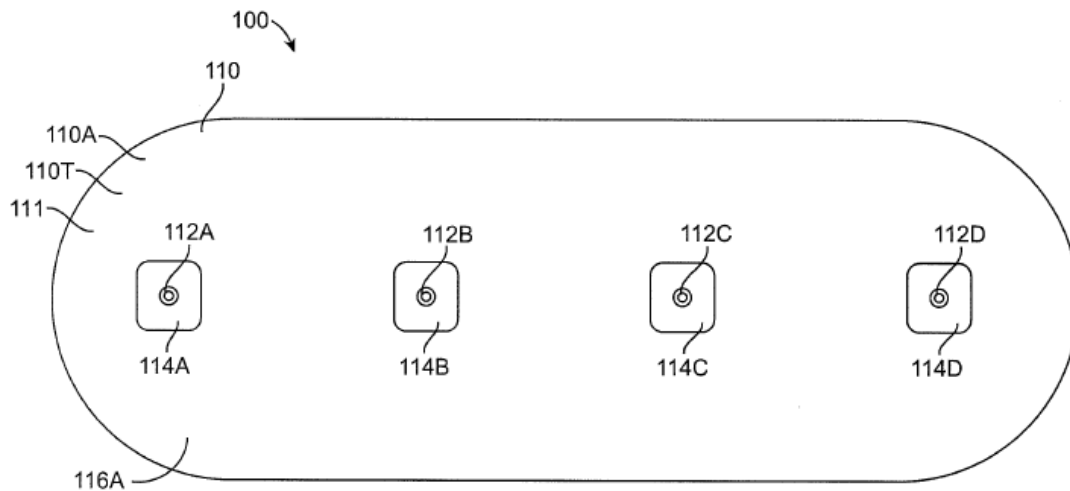


FIG. 1B is a bottom view of the adherent health-monitoring device according to Mazar. Ex. 1003 ¶ 60.

The bottom of health-monitoring device 100 has an adherent patch 110 comprising tape 110T and an adhesive 116A for fixing the device to the skin of a patient. *Id.* ¶ 98. Electrodes 112A, 112B, 112C, and 112D on the adherent patch measure, for example, the ECGs of the patient. *Id.*

Figure 1F1, reproduced below, shows a top view of a health-monitoring device according to Mazar.

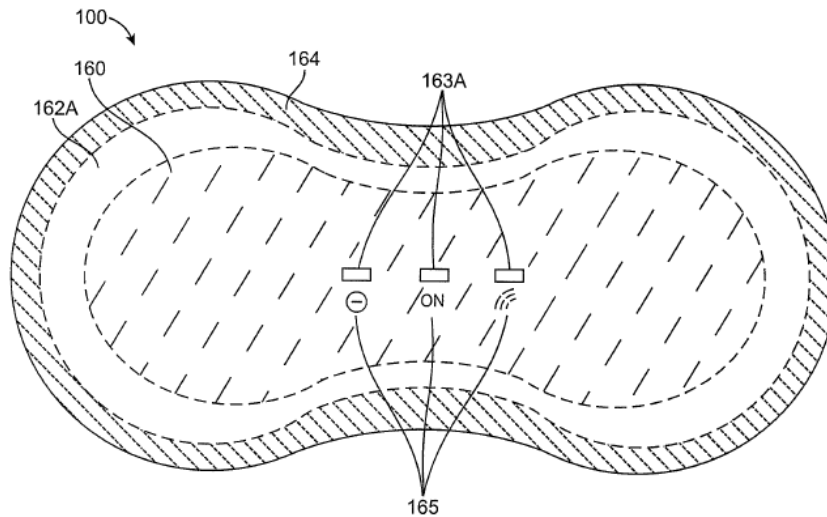


FIG. 1F1

FIG. 1F1 is a top view of the adherent health-monitoring device according to Mazar. Ex. 1003 ¶ 65.

The top of the health-monitoring device 100 contains an electronics housing 160 located under a cover 162A. *Id.* ¶ 114. The cover includes at least one visual indicator 163A, such as an LED light, and one or more symbols 165, such as marks or words. *Id.* ¶ 116.

The electronics housing contains electronic components necessarily for measuring and wirelessly transmitting physiological data from the patient. *Id.* ¶ 101. These components include sensors, batteries, circuitry, a processor, and memory. *Id.* ¶¶ 100–114.

2. Oster (Ex. 1004)

Oster relates to a biomedical sensor system having a sensor and a hub. Ex. 1004, code (57). In some embodiments, the biomedical sensor monitors the electrical activity of a subject's heart “in developing an electrocardiogram (ECG).” *Id.* ¶ 28. Figure 1, reproduced below, shows a top plan view of a biomedical sensor according to Oster.

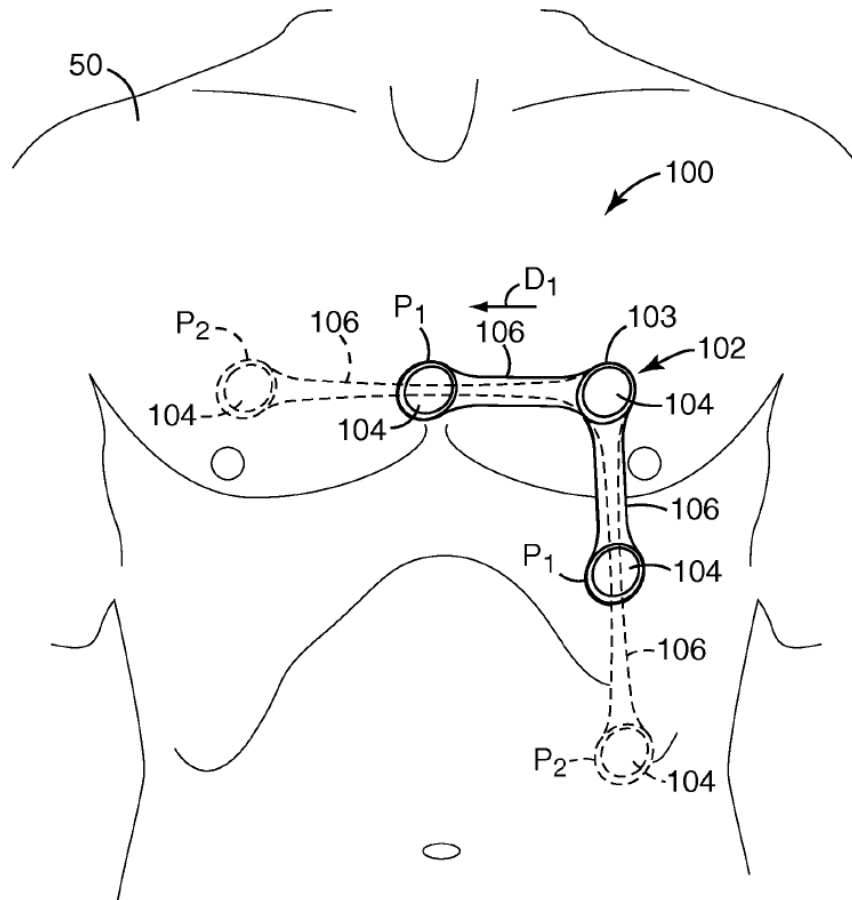


FIG. 1 is a top plan view of one embodiment of the biomedical sensor according to Oster. Ex. 1004 ¶ 7.

In Figure 1, the biomedical sensor 100 is shown in both an “unstretched state” (solid line) and a “stretched state” (dashed lines) related to the subject 50. *Id.* ¶ 30. The biomedical sensor includes a hub 102, two satellite electrodes 104, and two connectors 106 “positioned to couple each satellite electrode 104 to the hub 102.” *Id.* ¶ 31. The satellite electrodes sense different signals and communicate those signals to the hub via the connectors. *Id.* The hub “can wirelessly communicate with downstream computing, processing, displaying and/or archiving equipment.” *Id.* ¶ 32. In some embodiments, the hub 102 can also include a controller that provides

“computing, data processing and/or control functions for the hub 102.” *Id.*
¶ 37. For example, the controller may include one or more signal processor
and transmitter components. *Id.* The connector 106 can include an adhesive
backing that allows the biomedical sensor to be extended from the
unstretched to the stretched state. *Id.* ¶ 86.

3. *Yang (Ex. 1005)*

Yang relates to a wearable sensor device for measuring a patient’s
physiological data, such as ECG and respiratory rates. Ex. 1005, code (57),
4:11–15. Figure 3, reproduced below, shows an exploded view of a
wearable sensor device according to Yang.

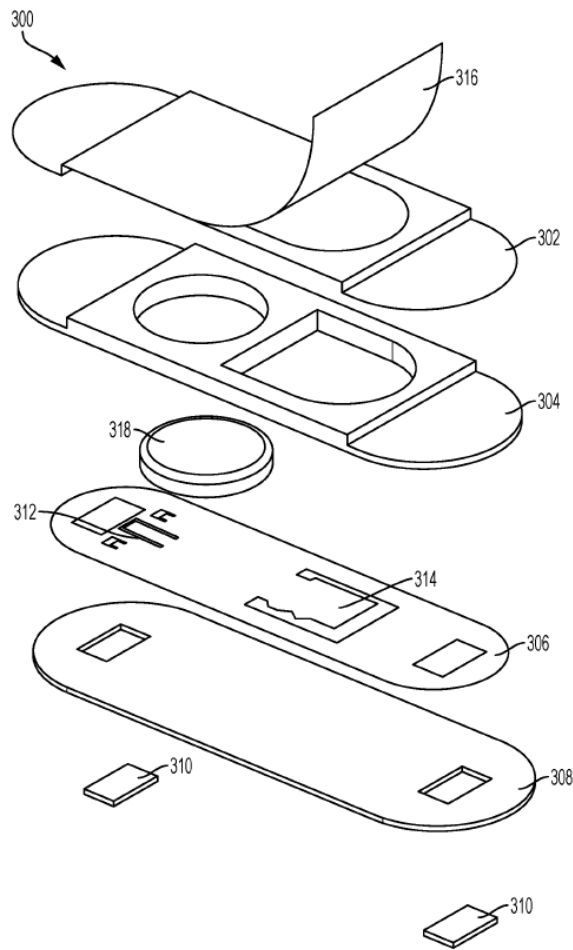


FIG. 3 is an exploded view of a wearable sensor device according
to Yang. Ex. 1005, 2:9–10.

The sensor device 300 includes a top cover layer 302, a top foam layer 304, a flexible printed circuit board (PCB) 306, a bottom foam layer 308, and at least two electrodes 310. *Id.* at 3:63–4:2. The flexible PCB includes an electrical component unit 312 that may be coupled to a battery 318. *Id.* at 4:4–8, 28–32. In some embodiments, the bottom foam layer “is a double adhesive layer so that it adheres to the flexible PCB 306 and to a user at the same time.” *Id.* at 4:9–11.

III. DISCRETION UNDER 35 U.S.C. § 325(d)

Patent Owner argues that we should exercise our discretion under § 325(d) and deny institution. Prelim. Resp. 9–24. Specifically, Patent Owner argues that the same or substantially the same prior art that Petitioner relies on for its grounds of unpatentability—namely, Mazar, Yang, and Oster—were presented previously to the Office. *Id.* at 10. Patent Owner argues that “even though Petitioner had the burden of establishing that the Office materially erred when examining the ’743 Patent, the Petition is completely silent on the § 325(d) issue.” *Id.* Petitioner argues that “[n]one of the references on which [its] grounds are based was applied by the Examiner during prosecution of the ’743 patent,” Pet. 5, but otherwise provides no substantive argument or analysis on the issue of discretionary denial under § 325(d).

A. *Legal Standard*

Section 325(d) provides that the Director² may “reject the petition” if “the same or substantially the same prior art or arguments previously were presented to the Office.” The Board analyzes this issue under a two-part framework:

² The Board institutes trial on behalf of the Director. 37 C.F.R. § 42.4(a).

(1) whether the same or substantially the same art previously was presented to the Office or whether the same or substantially the same arguments previously were presented to the Office; and (2) if either condition of [the] first part of the framework is satisfied, whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of challenged claims.

Advanced Bionics, 8.

In analyzing whether the same or substantially the same art or arguments were previously presented to the Office, we consider factors including: (i) the similarities and material differences between the asserted art and the prior art previously presented to the Office; (ii) the cumulative nature of the asserted art and the prior art previously evaluated by the Office; and (iii) the extent of the overlap between the arguments made before the Office and the manner in which the petitioner relies on the prior art or the patent owner distinguishes the prior art. *Id.* at 8–10; *see also Becton, Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8, 17–18 (Dec. 15, 2017) (precedential as to § III.C.5, first paragraph) (“*Becton, Dickenson*”).

In analyzing whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of challenged claims, we consider factors including: (iv) the extent to which the asserted art was evaluated by the Office, including whether the prior art was the basis for rejection during examination; (v) whether the petitioner has pointed out sufficiently how the Office erred in its evaluation of the asserted prior art; and (vi) the extent to which additional evidence and facts presented in the petition warrant reconsideration of prior art or arguments. *Advanced Bionics*, 8–10; *Becton, Dickinson*, 17–18.

B. Analysis

1. Part 1: Whether the same or substantially the same art or arguments were presented previously to the Office

The first part of the *Advanced Bionics* framework requires us to determine whether the Petition advances the same or substantially the same art or arguments that were previously presented to the Office. *Advanced Bionics*, 8. For the reasons explained below, we determine that the same or substantially the same art was previously presented, and thus, the first part of the framework is satisfied.

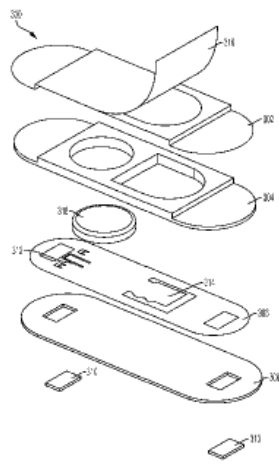
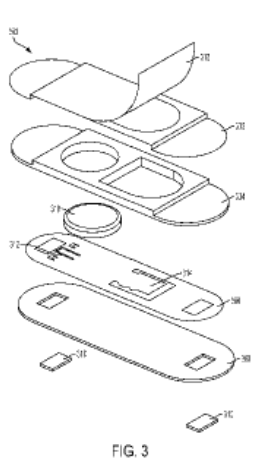
Petitioner relies on three references in its asserted grounds of unpatentability: Mazar, Yang, and Oster. Pet. 5. Petitioner argues that “[n]o ground presented here was considered by the Examiner or otherwise previously considered by the Patent Office.” Pet. 6. Patent Owner, however, argues that Oster, Yang, and Mazar “are the same, or [substantially] the same for all material purposes, as art previously considered by the Office.” Prelim. Resp. 12.

There can be no dispute that Oster was before the Office. Oster was listed in an information disclosure statement (IDS) and appears on the face of the ’743 patent. Ex. 1007, 87 (entry 114); Ex. 1001, code (56). The examiner also certified that he considered all references listed in the IDS “except where lined through,” and Oster is not lined through. Ex. 1007, 87. Accordingly, Oster is “[p]reviously presented art.” *See Advanced Bionics*, 7–8 (indicating that “previously presented art” includes “art made of record by the Examiner”).

On the other hand, Yang and Mazar were not before the Office during examination of the application leading to the ’753 patent and therefore are not the “same art” previously presented to the Office. *Advanced Bionics*,

13–14; *see also* Prelim. Resp. 12 (stating that “*Yang* itself was not before the Office during examination of the ’743 Patent”); *id.* at 14 (stating that “Mazar was not presented to the Office during examination”). But, Patent Owner argues, art substantially similar to these references were before the Office during examination.

As to *Yang*, Patent Owner argues that *Yang*’s parent patent—U.S. Patent No. 9,277,864 (“*Yang Parent*”)—was listed on an IDS and considered by the Examiner. Prelim. Resp. 12 (citing Ex. 1005, code (63); Ex. 1007, 39 (entry 13); Ex. 1019 (*Yang Parent*)). Patent Owner argues that *Yang* is cumulative of *Yang Parent* because “[p]ractically by definition, parent and child patents are substantially the same because the patents have nearly identical specifications and the exact same figures.” *Id.* (citing, *e.g.*, MPEP § 201.7; Ex. 1005; Ex. 1019). Patent Owner presents a table, reproduced below, purporting to show that the material Petitioner cites to in *Yang* is also present in the *Yang Parent*:

<i>Yang</i>	<i>Yang Parent Considered by Examiner</i>
Ex. 1005 at 2:24–50	Ex. 1019 at 2:16–43
Ex. 1005 at 3:2–4, 63–4:2	Ex. 1019 at 2:62–64, 3:57–63
Ex. 1005 at 4:2–4	Ex. 1019 at 3:63–65
Ex. 1005 at 4:39–42	Ex. 1019 at 4:32–35
Ex. 1005 at 2:48–55	Ex. 1019 at 2:41–48
Ex. 1005 at 4:28–38	Ex. 1019 at 4:21–31
Ex. 1005 at 5:41–53	Ex. 1019 at 5:33–45
Ex. 1005 at 4:67–5:4	Ex. 1019 at 4:59–4:63
Ex. 1005 at 5:23–31	Ex. 1019 at 5:15–23
 <p>FIG. 3</p>	 <p>FIG. 3</p>

Id. at 13. Thus, Patent Owner argues, Yang “is substantially the same as, and cumulative with, the *Yang Parent*, which was previously reviewed and considered by the Office during examination.” *Id.* at 14.

Having considered the record, we agree with Patent Owner that Yang is cumulative of Yang Parent and, therefore, “substantially the same art” that was previously presented to the Office. *Advanced Bionics*, 8. First, Yang Parent was presented to the Office during the prosecution of the application that matured into the ’743 patent. The Yang Parent is listed on an IDS and not lined through, indicating that the Examiner considered this reference. Ex. 1007, 39 (entry 13)). The face of the ’743 patent also identifies Yang Parent as a cited reference. Ex. 1001, code (56).

Second, in asserting unpatentability of the challenged claims, Petitioner relies on portions of Yang that are also present in Yang Parent. For example, all the citations to Yang that Petitioner relies on to teach the limitations of independent claim 11 are also present in Yang Parent, as illustrated in Patent Owner's table, above. Prelim. Resp. 13; *see also* Pet. 30 (citing Ex. 1005, 2:24–50), 34 (citing Ex. 1005, 3:2–4, 3:63–4:2, Fig. 3), 36 (citing Ex. 1005, 3:63–4:2, Fig. 3); 37 (citing Ex. 1005, 4:2–4, 39–42), 38 (citing Ex. 1005, 2:48–55); 41 (citing Ex. 1005, 3:63–4:2, 4:28–38, Fig. 3), 42 (citing Ex. 1005, Fig. 3, 3:63–4:2, 4:28–38), 43 (citing Ex. 1005, 4:67–5:4, 5:41–53), 44 (citing Ex. 1005, 5:23–31). Importantly, Petitioner relies extensively on Yang's Figure 3, which also appears identically in the Yang Parent. *Compare* Ex. 1005, Fig. 3, *with* Ex. 1019, Fig. 3.

Finally, as to Mazar, Patent Owner argues that several other U.S. Patents and Patent Applications listing Mazar as an inventor were presented to the Office during examination and considered by the Examiner. Prelim. Resp. 14 & n.1. Patent Owner points to U.S. Patent No. 8,116,841 (“the ’841 patent”), and argues that the ’841 patent has “the same or substantially the same disclosures as *Mazar*.” *Id.* (citing Ex. 2004). Patent Owner also presents several tables comparing the material Petitioner cites to in Mazar to the disclosure of the disclosure of the ’841 patent. *See id.* at 16–18 (citing Ex. 1003; Ex. 2004).

Having considered the record, we again agree with Patent Owner that Mazar is cumulative of the ’841 patent and, therefore, “substantially the same art” that was previously presented to the Office. *Advanced Bionics*, 8. The ’841 patent was considered by the Examiner because it was listed on an IDS (and not lined through), and the face of the ’743 patent identifies the

'841 patent as a cited reference. Ex. 1007, 73 (entry 85)); Ex. 1001, code (56). And, the portions of Mazar that Petitioner relies on in asserting unpatentability of the challenged claims portions are identically presented in the '841 patent. For example, in alleging the unpatentability of independent claim 11, Petitioner relies on Mazar's Figures 1B, 1D, 1E, and 1F1. *See* Pet. 30, 33, 36, 40. These figures, however, appear identically or substantially identically in the '841 patent. *See* Prelim. Resp. 15 (comparing figures of Mazar (Ex. 1003) to the '841 patent (Ex. 2004)). The only differences relate to visual indicators and symbols in Figure 1F1, which are not recited in the challenged claims. *Compare* Ex. 1003, Fig. 1F1 (identifying 163A, 165), *with* Ex. 2004, Fig. 1F1. In any event, Petitioner does not challenge Patent Owner's position that Mazar and the '841 patent are cumulative.

For these reasons, we determine that all the references that Petitioner advances in the Petition (i.e., Mazar, Yang, and Oster) are the same or substantially the same art that were previously presented to the Office. Accordingly, we determine that the first part of the *Advanced Bionics* framework is satisfied.

2. *Part 2: Whether the Petitioner Demonstrates Material Error*

Next, we consider "whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of challenged claims." *Advanced Bionics*, 8. Patent Owner argues that "a petitioner must demonstrate that the Office made a material error regarding examination to avoid discretionary denial." Prelim. Resp. 19 (citing *Advanced Bionics*, 8). Patent Owner also argues that "[w]here a petitioner fails to address the material-error requirement or otherwise is silent on the Section 325(d)

inquiry, the petitioner fails to meet its burden, and the Board should deny institution.” *Id.* at 20. Here, Patent Owner argues, “Petitioner is completely silent on the issue, as it outright ignores the Section 325(d) issue.” *Id.* at 21. Patent Owner argues that Petitioner was aware of the Office’s prior consideration of “substantially similar art to *Mazar*,” because Patent Owner raised the issue with Petitioner in correspondence “over half a year before Petitioner filed its Petition.” *Id.* at 23 (citing Ex. 1018, 2).

Having considered the record, we agree with Patent Owner that Petitioner has failed to demonstrate that the Office erred in its evaluation of the cited art as required by *Advanced Bionics*. As Patent Owner points out, Petitioner is silent on material error, even though its relied-upon references (or their substantially identical disclosures), were before the Office during examination of the application leading to the ’743 patent. It is unclear to us why Petitioner did not allege an error and/or substantively address § 325(d) in its Petition (or even request additional briefing), especially given that Petitioner was on notice of Patent Owner’s position that *Mazar* “is effectively identical to other *Mazar* art that was before by the U.S. Patent Office during the patent’s prosecution.” Ex. 1018, 1.

Petitioner argues only that the Petition presents grounds of unpatentability not previously considered and/or applied by the Examiner. Pet. 5–6. But these statements, without any further analysis, cannot persuade us of material error. *Advanced Bionics* cautions that “[i]f 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.” Paper 6, 9. *Advanced Bionics* also explains the rationale for this rule: “At bottom, this framework reflects a commitment to defer to

previous Office evaluations of the evidence of record unless material error is shown.” *Id.* Here, we defer to the Office’s previous consideration of the prior art of record because Petitioner’s statements (i.e., that the Petition presents grounds of unpatentability not previously considered and/or applied by the Examiner) do not “demonstrate[] that the Office erred in a manner material to the patentability of challenged claims.” *Advanced Bionics*, 8–9.

Moreover, while there are no “magic words” necessary to address material error, Petitioner’s alleged grounds of unpatentability cannot establish material error *per se* under our binding precedent. *See id.* (“If a condition in the first part of the framework is satisfied and the petitioner fails to make a showing of material error, the Director generally will exercise discretion not to institute inter partes review.”). Otherwise, the reasonable likelihood standard of § 314(a) and the second part of the *Advanced Bionics* framework (“material error”) would collapse into one.

C. Summary

For the reasons discussed above, we determine that both parts of the two-part framework of *Advanced Bionics* are satisfied. Thus, we exercise our discretion pursuant to 35 U.S.C. § 325(d) to deny institution of trial.

IV. CONCLUSION

Taking account of the information presented in the Petition and the Preliminary Response, and the evidence of record, we exercise our discretion under 35 U.S.C. § 325(d) and deny institution. Accordingly, the Petition is *denied*, and no trial is instituted.

V. ORDER

In consideration of the foregoing, it is hereby:

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

IPR2023-00381
Patent 11,051,743 B2

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