

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APPLE, INC.,
Petitioner,

v.

ALIVECOR, INC.,
Patent Owner.

IPR2021-00970
Patent 9,572,499 B2

Before ROBERT A. POLLOCK, ERIC C. JESCHKE, and
DAVID COTTA, *Administrative Patent Judges*.

POLLOCK, *Administrative Patent Judge*.

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

I. INTRODUCTION

A. Background

Apple, Inc. (“Petitioner”) filed a Petition for an *inter partes* review of claims 1–20 of U.S. Patent No. 9,572,499 B2 (“the ’499 patent,” Ex. 1001). Paper 2 (“Pet.”). AliveCor, Inc. (“Patent Owner”) timely filed a Preliminary Response. Paper 6. (“Prelim. Resp.”). Petitioner further filed an authorized Reply to the Preliminary Response (Paper 7, “Prelim. Reply”); Patent Owner filed a responsive Sur-reply (Paper 8, “Prelim. Sur-reply”).

B. Summary of the Institution Decision

For the reasons provided below, Petitioner has satisfied the threshold requirement set forth in 35 U.S.C. § 314(a). Because Petitioner has demonstrated a reasonable likelihood that at least one claim of the ’499 patent is unpatentable, we institute an *inter partes* review of all challenged claims on each of the Grounds raised in the Petition. *See* 37 C.F.R. § 42.108(a) (2021) (“When instituting *inter partes* review, the Board will authorize the review to proceed on all of the challenged claims and on all grounds of unpatentability asserted for each claim.”).

C. Real Parties-in-Interest

Petitioner identifies itself, Apple Inc., as the real party-in-interest. Pet. 84. Patent Owner, identifies itself, AliveCor, Inc., as the real party-in-interest. Paper 4, 2.

D. Related Matters

According to Patent Owner:

U.S. Patent No. 9,572,499 has been asserted by Patent Owner against Petitioner in *AliveCor, Inc. v. Apple, Inc.*, Case No. 6:20-cv-01112-ADA, filed in the United States District

Court for the Western District of Texas, and in Investigation No. 337-TA-1266 before the International Trade Commission, *In the Matter of Certain Wearable Electronic Devices with ECG Functionality and Components Thereof*. Apple also filed IPR petitions against the other patents asserted in those actions: PR2021-00971 (USP 10,595,731) and IPR2021-00972 (USP 10,638,941).

Paper 4, 2; *see* Pet. 84. We refer to the above litigations as the “Texas Litigation” and the “ITC Investigation,” respectively. *See* Pet. 78, 80. We further note that US Patent No. 10,595,731 (“the ’731 patent”), at issue in IPR2021-00971, is related by a chain of continuation applications to Application No. 14/730,122, which issued as the ’499 patent challenged here. *See* US Patent No. 10,595,731 code (63); Ex. 1001, code (21); Prelim. Resp. 3–4. As such, the ’731 and ’499 patents share substantially the same specification.

The ’499 patent claims priority to, *inter alia*, a series of provisional applications filed between December 12, 2013, and June 19, 2014. Ex. 1001, code (60); *see* Pet. 2; Prelim. Resp. 3–4. Petitioner contends, and Patent Owner does not presently contest, that the claims of the ’499 patent are not entitled the benefit of the earliest of those applications such that the critical date is December 12, 2014, the filing date of application No. 14/569,513. Pet. 2–3; *see* Prelim. Resp. 4, 31–43. For the purpose of institution, we need not determine whether the challenged claims are entitled to the benefit of the earliest filed provisional application. Accordingly, and solely for purposes of this decision, we apply December 12, 2014, as the critical date.

E. Asserted Grounds of Unpatentability

Petitioner asserts the following grounds of unpatentability (Pet. 1):

Ground	Claims Challenged	35 U.S.C §	Reference(s)/Basis
1	1–6, 10–16, 20	§ 103	Shmueli, ¹ Osorio ²
2	7–9, 17–19	§ 103	Shmueli, Osorio, Hu ³

In support of its patentability challenge, Petitioner relies on, *inter alia*, the Declaration of Dr. Bernard R. Chaitman, M.D. Ex. 1003. Patent Owner similarly relies on the Declaration of Dr. Igor Efimov, Ph.D. Ex. 2001.

F. The '499 Patent and Relevant Background

The '499 patent relates to medical devices, systems, and methods for detecting cardiac conditions, including cardiac arrhythmias. Ex. 1001, 1:20–24, 2:8–16. In general:

In response to the continuous measurement and recordation of the heart rate of the user, parameters such as heart rate (HR), heart rate variability (R-R variability or HRV), and heart rate turbulence (HRT) may be determined. These parameters and further parameters may be analyzed to detect and/or predict one or more of atrial fibrillation, tachycardia, bradycardia, bigeminy, trigeminy, or other cardiac conditions.

Id. at 2:48–55; *see id.* at 18:44–54 (Table 2, listing atrial fibrillation, sinus and supraventricular tachycardias, bradycardia, bigeminy, and trigemini among the types of arrhythmias).

According to Dr. Chaitman, “HRV analysis is an important tool in cardiology to help diagnose various types of arrhythmia.” Ex. 1003 ¶ 35. “HRV is defined as the variation of RR intervals with respect to time and

¹ WO2012/140559, publ. Oct. 18, 2012. Ex. 1004.

² U.S. 2014/0275840, publ. Sept. 18, 2014. Ex. 1005

³ Hu et al., 44(9) “*A Patient-Adaptable ECG Beat Classifier Using a Mixture of Experts Approach*,” IEE Transactions On Biomed. Engineering 891–900 (1997). Ex. 1049.

reflects beat-to-beat heart rate (HR) variability,” and “can be accurately determined based on either ECG data or PPG data.” *Id.* ¶¶ 35–36. With respect to the former, this involves measuring RR intervals. *Id.* ¶ 29. “An R-R interval represents a time elapsed between successive R-waves of a QRS complex of the ECG that occur between successive heart beats.” *Id.* “If the RR intervals over a time period are close to each other in value, then ventricular rhythm is understood to be ‘regular.’ In contrast, if there are significant variations in the RR intervals over a time period, then the ventricular rhythm is understood to be ‘irregular.’” *Id.* ¶ 37 (citations omitted).

The Specification explains that during cardiac arrhythmia, “the electrical activity of the heart is irregular or is faster (tachycardia) or slower (bradycardia) than normal,” and in some forms, “can cause cardiac arrest and even sudden cardiac death.” *Id.* at 1:31–35. According to the Specification, although the most common cardiac arrhythmia, atrial fibrillation, may cause no symptoms, it is associated with palpitations, shortness of breath, fainting, chest pain, congestive heart failure, as well as atrial clot formation, which can lead to clot migration and stroke. *Id.* at 1:33–45.

The Specification discloses body-worn devices for detecting the occurrence of arrhythmias using a combination of PPG and ECG electrodes. *See, e.g., id.* at 24:58–25:16, Fig. 14. PPG, or photoplethysmography, uses an optical sensor to detect the fluctuation of blood flow, and can provide a measure of heart rate. *See id.* at 25:13–16. According to the Specification, fluctuations in heart rate not explained by changing activity levels may be interpreted as an advisory condition for recording an ECG, or

electrocardiogram, which is a typical method for diagnosing episodes of arrhythmia. *Id.* at 1:43–45, 1:51–56, 24:58–25:33.

Figure 14, reproduced below, shows one embodiment of a body-worn device. *Id.* at 6:11–13.

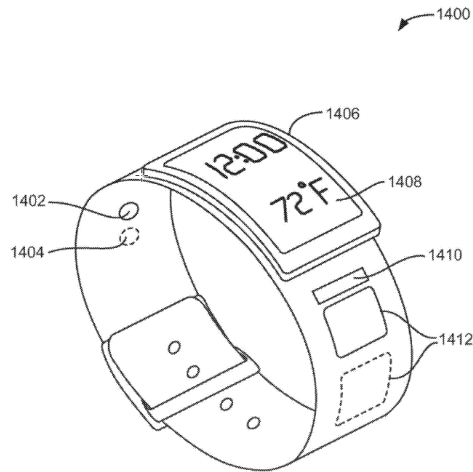


Figure 14, shows “smart watch 1400 which includes at least one heart rate monitor 1402 and at least one activity monitor 1404,” such as an accelerometer. *Id.* at 24:58–60, 25:5–22. Analysis of signals from these monitors can be used to “determine if heart rate and activity measurements represent an advisory condition for recording an ECG,” and trigger signals for recording an ECG if an advisory condition is detected. *Id.* at 24:63–25:4. The collected data may also be analyzed using machine learning algorithms to provide a heart health score. *See, e.g., id.* at 3:34–4:14, 8:28–31, 8:65–9:1, 12:34–54.

Figure 10, illustrated below shows another embodiment involving a body-worn device.” *Id.* at 5:61–63.

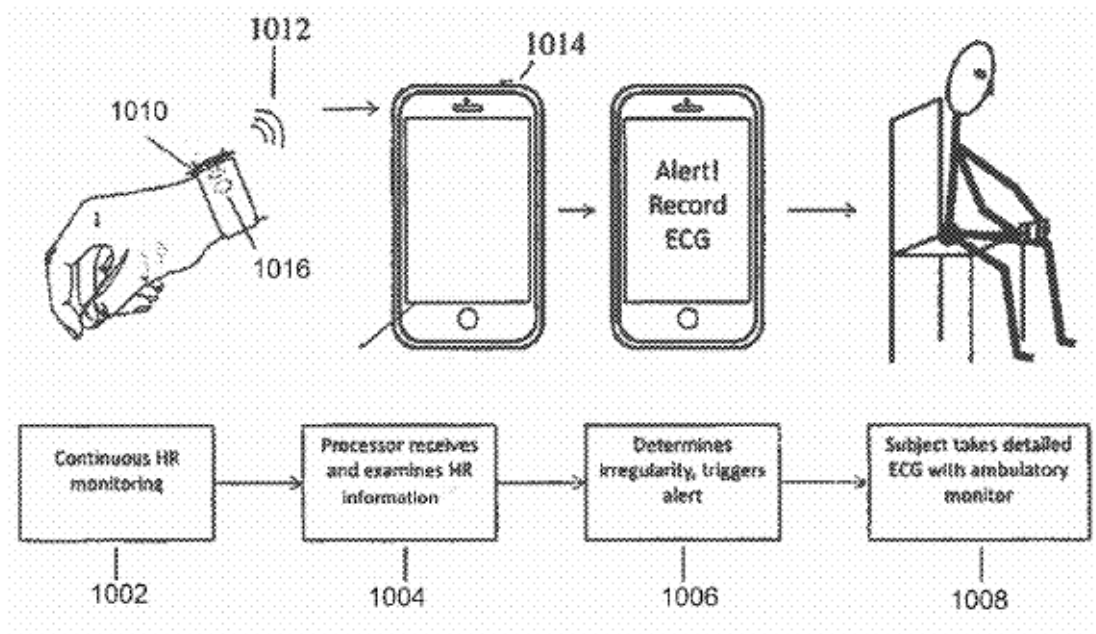


Figure 10 illustrates “a method for monitoring a subject to determine when to record an electrocardiogram (ECG).” *Id.* at 23:12–14. According to the Specification:

In FIG. 10, a subject is wearing a continuous heart rate monitor (configured as a watch 1010, including electrodes 1016), shown in step 1002. The heart rate monitor transmits (wirelessly 1012) heart rate information that is received by the smartphone 1018, as shown in step 1004. The smartphone includes a processor that may analyze the heart rate information 1004, and when an irregularity is determined, may indicate 1006 to the subject that an ECG should be recorded.

Id. at 23:14–23. In some embodiments, the ECG device is “present in a smart watch band or a smart phone.” *Id.* at 25:28–29. “The ECG, heart rate, and rhythm information can be displayed on the computer or smartphone, stored locally for later retrieval, and/or transmitted in real-time to a web server.” *Id.* at 25:40–44.

G. Challenged Claims

Petitioner challenges claims 1–20, of which claims 1 and 11 are independent. Claims 1 and 11 recite:

1. A method of determining a presence of an arrhythmia of a first user, said method comprising
 - sensing a heart rate of said first user with a heart rate sensor coupled to said first user;
 - transmitting said heart rate of said first user to a mobile computing device, wherein said mobile computing device is configured to sense an electrocardiogram;
 - determining, using said mobile computing device, a heart rate variability of said first user based on said heart rate of said first user;
 - sensing an activity level of said first user with a motion sensor;
 - comparing, using said mobile computing device, said heart rate variability of said first user to said activity level of said first user; and
 - alerting said first user to sense an electrocardiogram of said first user, using said mobile computing device, in response to an irregularity in said heart rate variability of said first user.

11. A system for determining the presence of an arrhythmia of a first user, comprising
 - a heart rate sensor coupled to said first user;
 - a mobile computing device comprising a processor, wherein said mobile computing device is coupled to said heart rate sensor, and wherein said mobile computing device is configured to sense an electrocardiogram of said first user; and
 - a motion sensor
 - non-transitory computer readable medium encoded with a computer program including instructions executable by said processor to cause said processor to receive a heart rate of said first user from said heart rate sensor, sense an activity level of

said first user from said motion sensor, determine a heart rate variability of said first user based on said heart rate of said first user, compare an activity level of said first user to said heart rate variability of said first user, and alert said first user to record an electrocardiogram using said mobile computing device.

The dependent claims recite, for example, that the mobile computing device comprises a smartphone (claims 5 and 15) or a smartwatch (claims 6 and 16); that the presence of an arrhythmia is determined using a machine learning algorithm (claims 7 and 17); and the use of biometric data such as temperature, blood pressure, or inertial data of the first user (claims 3–4, 13–14).

II. DISCRETIONARY DENIAL UNDER 35 U.S.C. § 314(A)

Under § 314(a), the Director possesses “broad discretion” in deciding whether to institute an *inter partes* review. *See* 35 U.S.C. § 314(a); *Saint Regis Mohawk Tribe v. Mylan Pharm. Inc.*, 896 F.3d 1322, 1327 (Fed. Cir. 2018); *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1367 (Fed. Cir. 2016) (“[T]he PTO is permitted, but never compelled, to institute an [*inter partes* review (IPR)] proceeding.”). The Board decides whether to institute an *inter partes* review on the Director’s behalf. 37 C.F.R. § 42.4(a).

Patent Owner argues that we should exercise our discretion to deny the Petition in view of the copending ITC Investigation. Prelim. Resp. 16–30; Prelim. Sur-reply 1–5. According to Patent Owner, instituting an *inter partes* review in this proceeding would result in a duplication of efforts that “would not be an efficient use of the Board’s resources and would not serve the primary purpose of AIA proceedings: to provide an effective and efficient *alternative* to litigation.” Prelim. Resp. 17. Petitioner argues that

we should decline to exercise our discretion under § 314(a) to deny institution. *See* Pet. 77–83; Prelim. Reply 1–5.

The Board has held that the advanced state of a parallel district court action is a factor that may weigh in favor of denying a petition under § 314(a). *See NHK Spring Co. v. Intri-Plex Techs., Inc.*, IPR2018-00752, Paper 8 at 20 (PTAB Sept. 12, 2018) (precedential) (“*NHK*”); Patent Trial and Appeal Board Consolidated Trial Practice Guide (Nov. 2019), 58 & n.2, (“Trial Practice Guide”).⁴ We consider the following factors to assess “whether efficiency, fairness, and the merits support the exercise of authority to deny institution in view of an earlier trial date in the parallel proceeding”:

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

Apple Inc. v. Fintiv, Inc., IPR2020-00019, Paper 11 at 5–6 (PTAB Mar. 20, 2020) (precedential) (“*Fintiv*”). In evaluating these factors, we “take[] a holistic view of whether efficiency and integrity of the system are best

⁴ Available at <https://www.uspto.gov/TrialPracticeGuideConsolidated>.

served by denying or instituting review.” *Id.* at 6. Upon consideration of these factors, we decline to exercise our discretion to deny the Petition.

A. Whether the Court Granted a Stay or Evidence Exists That One May Be Granted if a Proceeding is Instituted

Fintiv factor 1 recognizes that a stay of litigation pending resolution of the PTAB trial allays concerns about inefficiency and duplication of efforts, which strongly weighs against exercising the authority to deny institution. *Fintiv*, Paper 11 at 6.

Here, the ’499 patent is involved in two parallel proceedings. One of those proceedings, the Texas Litigation, has been stayed. Pet. 78; Ex. 1053. As to the other proceeding, Petitioner asserts that it “intends to move for a stay at the ITC upon institution.” Prelim. Reply 5. Accordingly, Petitioner asserts that *Fintiv* factor 1 is “at worst, neutral.” *Id.*

Patent Owner argues that “[a] stay of the ITC proceedings is extremely unlikely” given the Commission’s “statutory mandate to conclude its investigation at ‘the earliest practicable time.’” Prelim. Resp. 17. According to Patent Owner, the ITC has “refused requests, in essentially all instances, to stay Investigations pending instituted IPRs.” *Id.*

We decline to speculate about the likelihood of a stay. Accordingly, we find that this factor is neutral.

B. Proximity of the Court’s Trial Date to the Board’s Projected Statutory Deadline for a Final Written Decision

Fintiv factor 2 looks to the “proximity of the court’s trial date to the Board’s projected statutory deadline.” *Fintiv*, Paper 11 at 9. “If the court’s trial date is earlier than the projected statutory deadline, the Board generally

has weighed this fact in favor of exercising authority to deny institution under *NHK*.” *Id.*

The Administrative Law Judge (ALJ) in the ITC Investigation set October 26, 2022 as the target date for completion of the Investigation. Ex. 2006, 5. This date falls approximately seven weeks before our deadline for submitting a final written decision (“FWD”).

Petitioner argues that the Order Setting the Procedural Schedule for the ITC Investigation states that “dates . . . for the scheduled hearings . . . are subject to change because of restrictions and uncertainty due to the COVID-19 pandemic.” Prelim. Reply 1 (alterations in original). Petitioner contends that the possibility that the ITC schedule may slip makes it “more likely that the FWD precedes ITC resolution.” *Id.* In addition, Petitioner offers to truncate the typical 3-month period for the Petitioner Reply by “up to 7 weeks.” *Id.* According to Petitioner, “[w]ith this adjustment in schedule, the FWD date would be able to precede the ITC’s target date.” *Id.* at 1–2.

Patent Owner argues that “[i]n other cases where the conclusion of a parallel ITC investigation proceeding pre-dates the FWD by a similar length of time, the Board has found this factor weights against institution.” Prelim. Resp. 20 (citing *Regeneron Pharmaceuticals, Inc. v. Novartis Pharma AG, et al.*, IPR2020-01317, Paper 15 at 15 (PTAB Jan. 15, 2021), *Philip Morris Products, S.A. v. RAI Strategic Holdings, Inc.*, IPR2020-00919, Paper 9 at 9 (Nov. 16, 2020), and *Stanley Black & Decker, Inc., et al. v. Zircon Corporation*, IPR2020-01572, Paper 10 at 13 (PTAB Apr. 19, 2021)). As to Petitioner’s offer to shorten the period for the Petitioner Reply, Patent Owner argues that Petitioner’s offer should have been, but was not, made when it filed the Petition, and that shortening the schedule would prejudice

Patent Owner because it “shortens the deposition window.” Prelim. Sur-reply. 3.

We typically take courts’ trial schedules at “face value,” and decline Petitioner’s invitation to speculate that the target date for completion of the ITC Investigation will slip as a result of the COVID-19 pandemic. *Fintiv*, IPR2020-00019, Paper 15 at 13 (informative). Accordingly, for purposes of analyzing this factor, we assume that the ITC Investigation will conclude on October 26, 2022.

We also decline Petitioner’s invitation to assume an earlier issuance date for our FWD. Although we appreciate Petitioner’s willingness to expedite resolution of this case, Patent Owner raises valid concerns that compressing the reply period will also compress the window for taking depositions. Moreover, the statutory due date for our FWD is triggered by the date of our institution decision and is unaffected by the date on which Petitioner files its reply. *See* 35 U.S.C. § 316(a)(11).

Given that our FWD in this case is due seven weeks after the targeted completion of the ITC Investigation, this factor weighs marginally in favor of exercising our discretion to deny institution.

C. Investment in the Parallel Proceeding by the Court and the Parties

Fintiv factor 3 considers the “investment in the parallel proceeding by the court and parties,” including “the amount and type of work already completed in the parallel litigation by the court and the parties at the time of the institution decision.” *Fintiv*, Paper 11 at 9. For example, if, at the time of institution, the court in the parallel proceeding has issued “substantive orders related to the patent at issue in the petition” or “claim construction orders,” this favors denial. *Id.* at 9–10.

Petitioner argues that “[n]othing of substance has occurred in the Texas [Litigation] because it was stayed in favor of the ITC case before Apple’s deadline to answer.” Prelim. Reply 3. As to the ITC Investigation, Petitioner argues that many significant events remain, including e.g., “expert reports, summary determination motions, pre-trial briefs, hearing, etc.” *Id.* at 2. Petitioner also asserts that its diligence weighs against exercising our discretion to deny institution. According to Petitioner, it filed the Petition “less than three weeks after the ITC instituted the investigation . . . and before filing its response to the ITC Complaint” or an answer to the complaint in the Texas Litigation. *Id.* Petitioner argues that because it filed its Petition so early, any duplicative investment in the ITC Investigation cannot be attributed to Petitioner’s delay. *Id.*

Patent Owner argues that “significant resources have been, and will continue to be, invested before the Board makes its institution decision.” Prelim. Sur-reply 4. As an example, Patent Owner identifies the *Markman* Order recently issued in the ITC Investigation. *Id.* Patent Owner also points out that, according to the Procedural Schedule in the ITC Investigation (Ex. 2006),

by the December 15, 2021 institution decision deadline . . . , Apple will have filed notices of prior art, the parties’ positions on invalidity will be finalized, the parties will have filed witness lists for the evidentiary hearing, the parties will have completed all fact discovery in the case, and the parties will be less than a week away from the initial exchange of expert reports.

Prelim. Resp. 20–21.

Based on the ITC’s Order Setting Procedural Schedule, the parties have completed *Markman* proceedings, completed fact discovery and negotiated to reduce the number of asserted claims and invalidity theories.

Ex. 2006, 3–4. The parties have yet to exchange expert reports, file dispositive motions, or file pre-trial pleadings. *Id.* at 4–5. We find the investment in the ITC Investigation to date to be significant, but note that much remains to be done and that, of the work that has been done, much appears unrelated to the validity issues raised in the Petition. In this regard, we note that Patent Owner did not identify any claim terms in need of construction in its Preliminary Response and we did not find it necessary to construe any claim terms to issue this decision.⁵ *See* Section III.C, below; *see also generally* Prelim. Resp. On the current record, it thus does not appear likely that claim construction will play a significant role in addressing Petitioner’s unpatentability arguments. In sum, we find that the investment in the ITC Investigation weighs modestly in favor of discretionary denial.

Turning now to Petitioner’s diligence, we are not persuaded by Patent Owner’s argument that Petitioner failed to exercise diligence because it waited until six months after the Texas Litigation was filed. Prelim. Resp. 22. The Board has previously explained that, “[i]f the evidence shows that the petitioner filed expeditiously, such as promptly after becoming aware of the claims being asserted, this fact has weighed against” discretionary denial. *Fintiv* Paper 11 at 11–12 (noting that filing at or around the time of a patent owner’s response to invalidity contentions may reveal a lack of diligence). Here, Petitioner filed this challenge even *before* its deadline to

⁵ Patent Owner argues that “the *Markman* Order that issued in the ITC conflicts with [Petitioner’s] positions in this proceeding.” Prelim. Sur-reply 5. Although Patent Owner appears to refer to the definition of one of ordinary skill in the art, it identifies no claim term dependent on that definition.

file an answer in the Texas Litigation (which was stayed in view of the ITC Investigation before an answer was due) and *before* it filed a response to Patent Owner's ITC complaint. Accordingly, we find that Petitioner's diligence in filing weighs against exercise of our discretion to deny institution.

Overall, considering both investment and diligence, we determine this factor weighs against discretionary denial of the Petition.

D. Overlap between Issues Raised in the Petition and in the Parallel Proceeding

Fintiv Factor 4 considers whether “the petition includes the same or substantially the same claims, grounds, arguments, and evidence as presented in the parallel proceeding.” *Fintiv*, Paper 11 at 12. If the issues in the Petition overlap substantially with those raised in the parallel proceeding, “this fact has favored denial.” *Id.* “Conversely, if the petition includes materially different grounds, arguments, and/or evidence . . . this fact has tended to weigh against exercising discretion to deny institution.” *Id.* at 12–13.

Petitioner argues that it has not “advanced the IPR prior art in the ITC *at all*, making clear in its invalidity contentions that “[Petitioner] *is not relying on the art cited in its petitions* at this time . . . and only ‘intends to rely on such art in the future in the event that the PTAB denies institution.’” Prelim. Reply 3 (quoting Ex. 2004, 3). In addition, on the deadline set forth in the ITC's Order Setting Procedural Schedule for “reduc[ing] the number of asserted invalidity theories for each asserted patent (including narrowing the number of prior art references and combination(s) thereof” (Ex. 2006, 3 (ITC Order No. 6: Setting Procedural Schedule)), Petitioner notified Patent

Owner that it “intends to no longer pursue in this investigation the prior art asserted in [Petitioner’s] IPRs” (Ex. 1057). Further, Petitioner asserts that “to eliminate any doubt as to the absence of meaningful overlap between the proceedings,” Petitioner stipulates that it “will not seek resolution in the parallel proceedings of invalidity based on any ground that utilizes Shmueli, Osorio, Lee-2012, Kleiger-2005, or Chan.” Pet. 81 (citing Ex. 1051). Finally, Petitioner argues that *inter partes* review of the ’499 patent would include all of the claims of the ’499 patent and would thus include claims not addressed in the ITC Investigation because the ITC’s Order Setting Procedural Schedule requires Patent Owner to reduce the number of asserted claims. Prelim. Reply 4 (citing Ex. 2006).

Patent Owner argues that Petitioner’s stipulation carries little weight because it is not a *Sotera* stipulation, i.e., a stipulation precluding Petitioner from pursuing any ground that was raised or could reasonably have been raised in the IPR proceeding. Prelim. Resp. 23–27; *see Sotera Wireless, Inc. v. Masimo Corp.*, IPR2020-01019, Paper 12 at 18–19 (PTAB Dec. 1, 2020) (precedential as to § II.A) (“*Sotera*”) (finding the stipulation that petitioner would not pursue the specific ground asserted as well as any other ground “*that was raised or could have been reasonably raised in an IPR*” “weighs strongly in favor of not exercising discretion to deny institution”). According to Patent Owner, the “only effect” of Petitioner’s narrow stipulation is “to create the possibility of inconsistent judgments, where the ITC will rule on validity issues months before the PTAB.” Prelim. Resp. 24–25. Indeed, Patent Owner argues that the prior art cited in the Petition has “already entered the ITC case.” Prelim. Sur-reply 1–2 n.1. Finally, Patent Owner dismisses Petitioner’s argument that the ITC Investigation will address only

a subset of the claims challenged in this proceeding because Petitioner has not provided “any indication the narrowed set of claims would be substantially different than those challenged in the IPR petition.” *Id.* at 2.

We agree with Petitioner that the Petition includes materially different grounds, arguments, and/or evidence than the ITC Investigation. Although Patent Owner argues that the prior art cited in the Petition has “already entered the ITC case,” that argument was made before Petitioner narrowed the number of prior art references it intended to rely upon, as required by the ITC’s Order Setting Procedural Schedule. Ex. 2006; Ex. 1057. Currently there does not appear to be any overlap in arguments or evidence between the two proceedings. Moreover, we agree with Petitioner that its stipulation mitigates to some degree concerns of duplicative efforts and possibly conflicting decisions between the Board and the ITC. Indeed, Petitioner’s stipulation echoes the one cited in *Sand Revolution II, LLC v. Continental Intermodal Group-Trucking LLC*, which the Board determined weighed “marginally in favor of not exercising discretion to deny institution.” IPR2019-01393, Paper 24 at 16 (PTAB June 16, 2020) (informative). Finally, we agree with Petitioner that this proceeding will likely include claims that are not at issue in the ITC Investigation. We are not persuaded by Patent Owner’s argument that Petitioner has failed to explain why the narrowed set of claims would be substantially different than those challenged in the IPR petition because, based on the ITC’s Order Setting Procedural Schedule, Patent Owner had yet to narrow the number of asserted claims as of the deadline for Petitioner to brief this issue. *See* Ex. 3001 (email from the Board authorizing the parties to brief discretionary denial issues, setting a deadline of October 25, 2021 for Petitioner to file its

responsive brief); Ex. 2006 (setting a deadline of November 12, 2021 for Patent Owner to reduce the number of asserted claims).

Considering the absence of overlap in issues, claims, and evidence, further supported by Petitioner's stipulation, this factor weighs against discretionary denial.

E. Whether the Petitioner and the Defendant in the Parallel Proceeding Are the Same Party

Fintiv Factor 5 looks to “whether the petitioner and the defendant in the parallel proceeding are the same party.” *Fintiv*, Paper 11 at 14. “If a petitioner is unrelated to a defendant, the Board has weighed this fact against exercising discretion to deny institution under *NHK*.” *Id.* at 13.

Petitioner is the defendant in the Texas Litigation and the ITC Investigation. This fact weighs in favor of the Board exercising its discretion to deny institution under § 314(a). *Id.* at 15.

F. Other Circumstances That Impact the Board's Exercise of Discretion, Including the Merits

Fintiv factor 6 looks to whether “other circumstances” exist that might “impact the Board's exercise of discretion, including the merits.” *Fintiv*, Paper 11 at 14.

Petitioner argues that we should consider that the ITC “does not have the authority to invalidate patent claims in a manner that is binding upon the Board or district courts.” Pet. 83; Prelim. Reply 5. Petitioner also argues that the merits of its patentability challenges are strong and, thus, favor institution. Pet. 83; Prelim. Reply 5.

Patent Owner argues that “the disputes between the petitioner and the patent owner are far ranging, including complex antitrust claims” and thus

“instituting this IPR would do little to efficiently resolve the disputes between the parties.” Prelim. Resp. 28. Patent Owner also contends that Petitioner “raised claim construction disputes at the ITC that it did not include in its Petition,” including the identification of “heart rate sensor,’ ‘alerting said first user to sense an electrocardiogram,’ and ‘alert’ as requiring construction.” *Id.* at 28–29. According to Patent Owner, this creates a “very high likelihood of confusion and inconsistent rulings.” *Id.* at 29. Finally, Patent Owner argues that the ALJ in the ITC Investigation “rejected Apple’s arguments regarding the proper level of ordinary skill,” applying a definition that “excludes [Petitioner’s] expert.” Prelim. Sur-reply 5. Patent Owner asserts that this creates the potential for inconsistent decisions if we credit Petitioner’s expert’s arguments “when he may not constitute a person of ordinary skill” under the ITC’s definition. *Id.*

As an initial matter, we are not persuaded by Petitioner’s argument that our *Fintiv* analysis should account for the fact that the ITC lacks the authority to invalidate patents (Pet. 83; Prelim. Reply 5) because *Fintiv* contemplates application of the enumerated factors to ITC Investigation notwithstanding that the ITC cannot invalidate patents. *Fintiv*, Paper 11 at 8–9 (“We recognize that ITC final invalidity determinations do not have preclusive effect, but, as a practical matter, it is difficult to maintain a district court proceeding on patent claims determined to be invalid at the ITC. Accordingly, the parties should also indicate whether the patentability disputes before the ITC will resolve all or substantially all of the patentability disputes between the parties, regardless of the stay.”).

With respect to the merits, Petitioner has met its institution burden as addressed below, but we are not prepared on this preliminary record to

characterize the merits of Petitioner’s challenge as especially “strong.” At the same time, we do not see glaring weaknesses in Petitioner’s case based on the arguments made to date. The merits are neutral for purposes of the *Fintiv* analysis.

As to Patent Owner’s argument that the disputes between Petitioner and Patent Owner are “far ranging, including complex antitrust claims,” we are not persuaded that the existence of antitrust claims should be given weight in our *Fintiv* analysis. Patent Owner cites *Regeneron Pharmaceuticals, Inc. v. Novartis Pharma AG, et al.*, IPR2020-01317, Paper 15 (PTAB Jan. 15, 2021) as support for its position. Prelim. Resp. 28. In that case, the Board found that the existence of antitrust claims weighed in favor of exercising discretion to deny institution where “Petitioner . . . chose to pursue complex antitrust claims that implicate many of the same issues before us.” *Regeneron*, Paper 15 at 23–24. In contrast, here, the antitrust claim appears to be asserted by Patent Owner. Prelim. Resp. 1, 28 (describing the anticompetitive activity as being that Petitioner “shut [Patent Owner] out of the relevant markets”). More importantly, Patent Owner does not direct us to persuasive evidence supporting that the antitrust claim implicates any of the issues before us. Absent a persuasive connection to the issues before us, Patent Owner’s assertion that Petitioner has engaged in anti-competitive activity does not weigh in favor of discretionary denial.

Finally, we turn to Patent Owner’s arguments regarding inconsistent claim construction positions and POSA definitions. We recognize the potential that if we construe the claims, we could determine that a construction other than that adopted by the ITC is appropriate. However, at this point in the proceeding, it does not appear that claim construction is

likely to be dispositive of any of the issues before us. Indeed, at this stage in the proceeding, we determined that it was not necessary to construe any claim terms. *See* Section III.C, below. As to the possibility of inconsistent POSA definitions, again, it does not appear that the definition of one of ordinary skill in the art is likely to be dispositive as to any issues before us at least because Petitioner’s declarant, Dr. Chaitman, appears to qualify as one of ordinary skill in the art under Patent Owner’s proposed POSA definition. *See id.* (discussing this issue). To the extent Dr. Chaitman does not qualify as one of ordinary skill under this definition, which requires “at least five years of relevant work experience designing wearable devices and/or sensors for measuring physiological signals or parameters of mammal,”⁶ we note that we do not require a perfect match between an expert’s experience and the relevant field. *See* Trial Practice Guide 34 (citing *SEB S.A. v. Montgomery Ward & Co.*, 594 F.3d 1360, 1373 (Fed. Cir. 2010)). A person need not be a person of ordinary skill in the art to testify as an expert under Federal Rule of Evidence 702, but rather must be “qualified in the pertinent art.” *Sundance, Inc. v. DeMonte Fabricating Ltd.*, 550 F.3d 1356, 1363–64 (Fed. Cir. 2008). Here, Dr. Chaitman is qualified in the pertinent art. *See* Ex.

⁶ Patent Owner cites to Exhibit 2010 as providing the ITC’s claim construction and definition of the POSA. *See* Prelim. Reply i, 4–5. Exhibit 2010 has not been entered in this proceeding. Exhibit 2010 in copending IPR2021-00972, however, appears to be patent prosecution material from U.S. Patent Application No. 15/154,849. The current record does not appear to include the claim construction from the ITC Investigation. In addition, certain of the exhibits of record appear not to correspond to the Exhibit List provided with Patent Owner’s Sur-reply. These exhibit issues do not impact our consideration of the issues necessary to issue this institution decision. Nonetheless, we flag the issue in the event Patent Owner wishes to rely upon these exhibits at trial.

1003 ¶¶ 4–8, curriculum vitae. To the extent that Dr. Chaitman lacks experience designing wearable devices, we are able to consider the value of his opinions and give them appropriate weight. *See Perreira v. Sec’y of the Dept. of HHS*, 33 F.3d 1375, 1377 n.6 (Fed. Cir. 1994). In sum, the possibility of inconsistent claim constructions and POSA definitions is neutral to marginally weighing in favor of discretionary denial for purposes of the *Fintiv* analysis.

Considering the merits, the authority of the ITC with respect to patents, the existence of antitrust claims, and the potential for inconsistencies between tribunals, we consider *Fintiv* factor 6 to weigh marginally in favor of discretionary denial.

G. Holistic Assessment of *Fintiv* Factors

We consider the above factors and take “a holistic view of whether efficiency and integrity of the system are best served by denying or instituting review.” *Fintiv*, Paper 11 at 6. In our view, the facts weighing against exercising discretion to deny institution collectively outweigh those favoring denial and concerns about potential inefficiency or integrity of the system. For these reasons, we decline to exercise our discretion to deny institution under § 314(a).

III. ANALYSIS OF THE MERITS

A. Legal Standards

“In an IPR, the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable.” *Harmonic*, 815 F.3d at 1363 (citing 35 U.S.C. § 312(a)(3) (requiring *inter partes* review petitions to identify “with particularity . . . the evidence that supports the

grounds for the challenge to each claim”)). This burden of persuasion never shifts to Patent Owner. *See Dynamic Drinkware, LLC v. Nat’l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015) (discussing the burden of proof in *inter partes* review).

In *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), the Supreme Court reaffirmed the framework for determining obviousness set forth in *Graham v. John Deere Co.*, 383 U.S. 1 (1966). The *KSR* Court summarized the four factual inquiries set forth in *Graham* (383 U.S. at 17–18) that are applied in determining whether a claim is unpatentable as obvious under 35 U.S.C. § 103 as follows: (1) determining the scope and content of the prior art; (2) ascertaining the differences between the prior art and the claims at issue; (3) resolving the level of ordinary skill in the art; and (4) considering objective evidence indicating obviousness or non-obviousness, if present.⁷ *KSR*, 550 U.S. at 406.

“[W]hen a patent ‘simply arranges old elements with each performing the same function it had been known to perform’ and yields no more than one would expect from such an arrangement, the combination is obvious.” *Id.* at 417 (quoting *Sakraida v. Ag Pro, Inc.*, 425 U.S. 273, 282 (1976)). But in analyzing the obviousness of a combination of prior art elements, it can also be important to identify a reason that would have prompted one of skill in the art “to combine . . . known elements in the fashion claimed by the patent at issue.” *Id.* at 418. A precise teaching directed to the specific subject matter of a challenged claim is not necessary to establish obviousness. *Id.* Rather, “any need or problem known in the field of endeavor at the time of

⁷ At this stage of the proceeding, Patent Owner does not rely on evidence of objective indicia of non-obviousness.

invention and addressed by the patent can provide a reason for combining the elements in the manner claimed.” *Id.* at 420. Accordingly, a party that petitions the Board for a determination of unpatentability based on obviousness must show that “a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so.” *In re Magnum Oil Tools Int’l, Ltd.*, 829 F.3d 1364, 1381 (Fed. Cir. 2016) (quotations and citations omitted). Under the proper inquiry, “obviousness cannot be avoided simply by a showing of some degree of unpredictability in the art so long as there was a reasonable probability of success.” *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1364 (Fed. Cir. 2007).

B. Level of Ordinary Skill in the Art

In determining the level of skill in the art, we consider the type of problems encountered in the art, the prior art solutions to those problems, the rapidity with which innovations are made, the sophistication of the technology, and the educational level of active workers in the field. *See Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc.*, 807 F.2d 955, 962 (Fed. Cir. 1986); *see also Orthopedic Equip. Co. v. United States*, 702 F.2d 1005, 1011 (Fed. Cir. 1983).

Petitioner asserts that a person of ordinary skill in the art would have been someone with

at least a combination of Bachelor’s Degree (or a similar Master’s Degree, or higher degree) in an academic area emphasizing health science, or a related field, and two or more years of work experience with cardiac monitoring technologies (e.g., as a cardiologist).

Pet. 8. Petitioner further contends that “[a]dditional education or industry experience may compensate for a deficit in one of the other aspects of the requirements stated above.” *Id.*; *see also* Ex. 1003 ¶ 10 (Dr. Chaitman’s similar testimony based on his “knowledge and experience in the field and [his] review of the ’499 patent and file history”).

Patent Owner, however, argues that the ’499 encompasses ““devices, systems, and methods for managing health and disease such as cardiac diseases, including arrhythmia and atrial fibrillation”” and the use of “[a] portable computing device”” that is specifically configured to ““measure one or more physiological signals of a user.”” Prelim. Resp. 10 (citing Ex. 1001, 2:8–10, 30–32). According to Patent Owner, one of ordinary skill in the art “would need to understand the specific aspects of the design, configuration, and operation of these devices, which are specialized engineering skills that a cardiologist may or may not possess in his or her background.” *Id.* (citing Ex. 2001 ¶¶ 50–51). Accordingly, Patent Owner asserts that one of ordinary skill in the art would necessarily have “a degree in biomedical or electrical engineering (or an equivalent), *and/or extensive experience working with tools for detecting cardiac conditions.*” *Id.* (citing Ex. 2001 ¶ 52) (emphasis added); *see also id.* at 11–12 (further citing Ex. 2004, 6 (Petitioner’s proposed definition in the ITC Investigation)).

The parties’ dispute appears to center on whether Dr. Chaitman, a cardiologist, qualifies as one of ordinary skill in the art. *See id.* at 10–12. As an initial matter, however, Dr. Chaitman’s Declaration and attached curriculum vitae seemingly evidence the “extensive experience working with tools for detecting cardiac conditions,” as required under Patent Owner’s proposed definition. *See id.* at 10; Ex. 1003 ¶¶ 4–8. Dr. Chaitman’s

curriculum vitae indicates, for example, that he is the Director of Cardiovascular Research and Medical Director of the Core ECG/MI Classification Laboratory at the Saint Louis University School of Medicine; has been Board Certified by, for example, National Board of Echocardiography and the Board of Cardiovascular Computed Tomography; and been engaged in numerous NIH-funded clinical trials, including those related to the Core Rest and Exercise Laboratory. Ex. 1003, attached curriculum vitae.

Consistent with his curriculum vitae, Dr. Chaitman testifies that his “areas of expertise in Cardiovascular Medicine include rest and exercise ECG analysis, diagnostic noninvasive testing, large scale multinational clinical trials testing different treatment strategies.” *Id.* ¶ 7. Dr. Chaitman further asserts:

I have served as a consultant to the Food and Drug Administration on ECG related issues, and the use of the rest and exercise ECG as a diagnostic instrument. I also served as a committee member for the American Heart Association, American College of Cardiology, and the European Society of Cardiology in matters related to ECG analysis and the use of ECG analysis as a diagnostic and prognostic tool.

Id. ¶ 8.

As such, Dr. Chaitman would appear to qualify as one of ordinary skill in the art under Patent Owner’s proposed definition. Given Patent Owner’s focus on “specialized engineering skills necessary for the design, configuration, and operation of portable computing devices,” however, we consider the weight of his, or any other expert’s opinions, in light of the strengths and weaknesses of their background.

We further note that the research and development of medical devices is often the work of a multidisciplinary team, and courts and tribunals have

frequently identified the hypothetical person of ordinary skill as a composite or team of individuals with complementary backgrounds and skills. *See, e.g., AstraZeneca Pharm. LP v. Anchen Pharm., Inc.*, 2012 WL 1065458, at *19, *22 (D.N.J. Mar. 29, 2012), *aff'd*, 498 F. App'x 999 (Fed. Cir. 2013) (collecting cases); *Apotex Inc. v. Novartis AG*, IPR2017-00854, Paper 109 at 10–11 (PTAB July 11, 2018) (collecting cases). In the present case, such a team might include specialists in electrical engineering, mechanical engineering, biomedical engineering, computer science, and cardiology. In this respect, Patent Owner's expert does not discount the benefit of a background in cardiology. In particular, Dr. Efimov testifies that although a cardiologist may or may not possess the specialized engineering skills to understand the design, configuration, and operation of the subject technology, "a degree in biomedical or electrical engineering (or an equivalent), and/or extensive experience working with arrhythmia detection tools *would also be necessary*" Ex. 2001 ¶¶ 51–52 (emphasis added). Indeed, considering that the '499 patent "relates to methods and systems for managing health and disease such as cardiac diseases including arrhythmia and atrial fibrillation," we find it reasonable that one of ordinary skill in the art would encompass a multidisciplinary team including a cardiologist.

In view of the above, we provisionally define one of ordinary skill in the art as a multidisciplinary team comprising persons with advanced degrees in electrical engineering, mechanical engineering, biomedical engineering, computer science, and/or cardiology. The parties are welcome to further address the level of ordinary skill in the art at trial.

C. Claim Construction

We interpret a claim “using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. 282(b).” 37 C.F.R. § 42.100(b). Under this standard, we construe the claim “in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent.” *Id.* Furthermore, at this stage in the proceeding, we need only construe the claims to the extent necessary to determine whether to institute *inter partes* review. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co. Ltd.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (“[W]e need only construe terms ‘that are in controversy, and only to the extent necessary to resolve the controversy.’” (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999))).

Patent Owner notes that claim terms “heart rate sensor” and those relating to “alert” are at issue in the related ITC Investigation but neither party proposes any construction here. *See Prelim. Resp. 29* (citing Ex. 2009). At this stage of the instant proceeding no term requires construction. *See Vivid Techs.*, 200 F.3d at 803 (“[O]nly those terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy.”). The parties are, of course, welcome to address the meaning of any relevant claim term at trial.

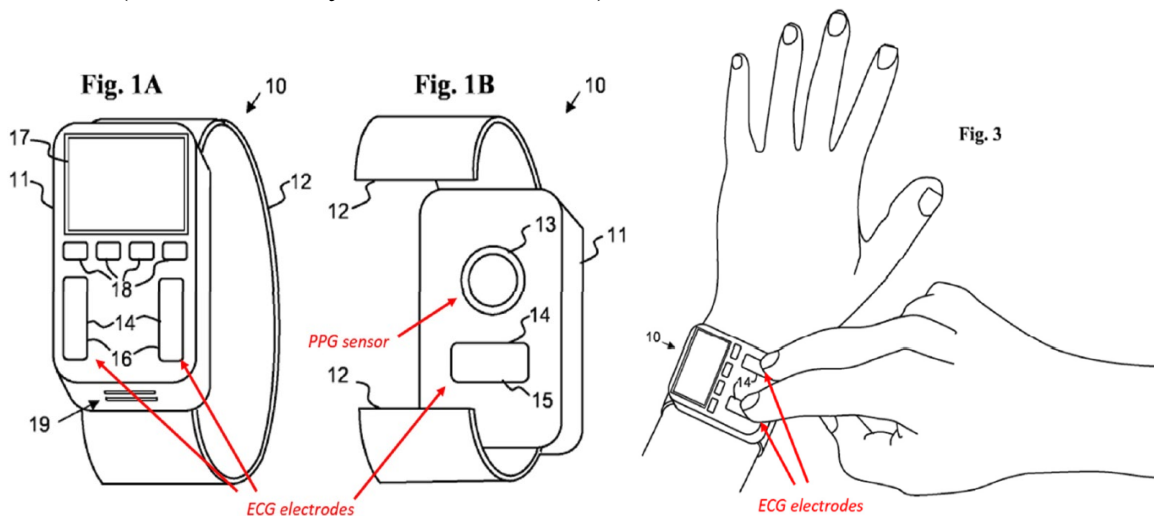
D. Ground 1: Obviousness over Shmueli and Osorio

As Ground 1, Petitioner challenges claims 1–6, 10–16, and 20 as obvious over Shmueli in combination with Osorio. Pet. 8–68, Petitioner provides an element-by-element comparison of the asserted art to the

challenged claims. *Id.* at 17–68. Patent Owner opposes. Prelim. Resp. 31–42. We begin with an overview of the asserted references.

1) Overview of Shmueli (Exhibit 1004)

Shmueli addresses “solutions . . . for monitoring infrequent events of irregular ECG.” Ex. 1004, 2.⁸ Shmueli’s solutions include body-worn cardiac monitoring devices “equipped with two types of sensing devices: an oximetry (SpO₂) measuring unit and an ECG measuring unit.” *Id.* at 9.⁹ Exemplifying one embodiment, Shmueli’s Figures 1A, 1B, and 3 are shown below (annotations by Petitioner in red):



Figures 1A, 1B, and 3 show three views of a wrist-mount heart monitoring device having three ECG electrodes 14 and a PPG sensor 13. *Id.* at 6, 9. In particular, Figure 1A shows two of the ECG electrodes, 14/16, on the face of the device. *Id.* at 9. Figure 1B shows a third ECG electrode, 14/15, along with PPG sensor 13, of the back of the device. *Id.* Figure 3 shows the device

⁸ We refer to native pagination wherever possible.

⁹ Shmueli uses the terms oxygen saturation in the blood, blood oxygen saturation, pulse oximeter, oximetry, SpO₂, as synonymous with photoplethysmography, except where otherwise specified. *Id.*

as worn on a patient's wrist, with PPG sensor 13 and ECG electrode 14/15 in contact with the patient's left wrist and ECG electrodes 14/16 in contact with two fingers of the patient's right hand. *Id.* In connection with these devices, Shmueli discloses

a method for triggering measurement of electrocardiogram (ECG) signal of a subject, the method including the steps of: continuously measuring SpO₂ at least one of a wrist and a finger of the subject, detecting an irregular heart condition from the SpO₂ measurement, notifying the subject to perform an ECG measurement, and initiating ECG measurement at least partially at the wrist.

Id. at 2; *see* Abstract.

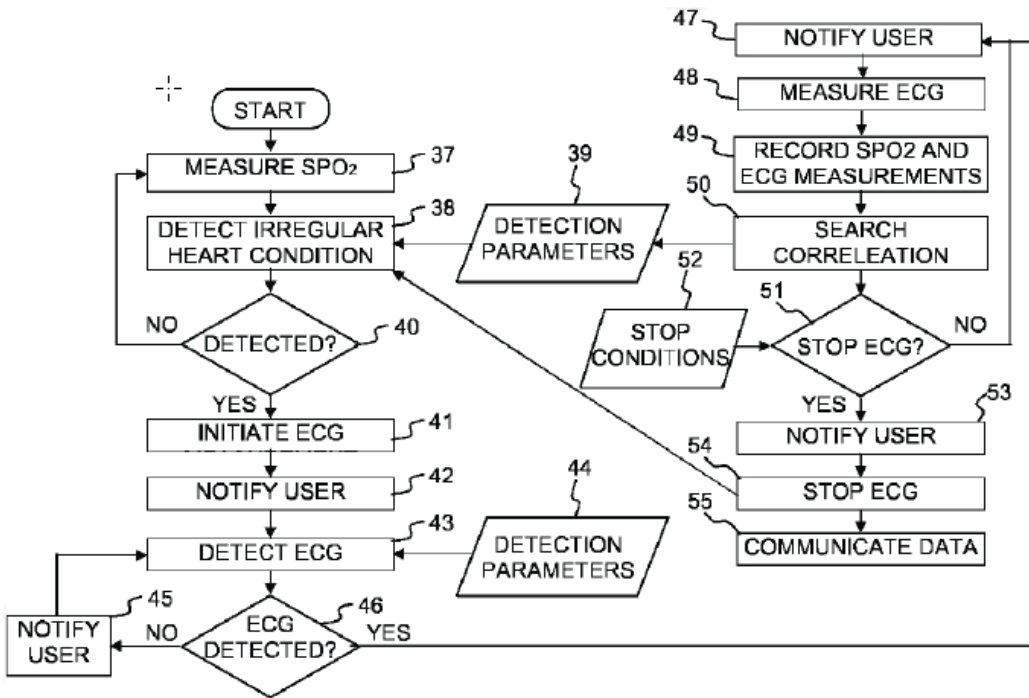
Shmueli explains that “[d]eriving heart beat rate from oximetry, as well as other artifacts of the heart activity and blood flow, is [] known in the art,” as are various body-worn oximetry devices. *Id.* at 8. Shmueli further explains that the use of oximetry in combination with ECG measurements is also known in the art. *Id.* Shmueli further states, for example, that “US patent No. 7,598,878 (Goldreich) describes a wrist mounted device equipped with an ECG measuring device and a SpO₂ measuring device.” *Id.* However, Shmueli, notes “Goldreich does not teach interrelated measurements of ECG and SpO₂” and, thus, does not “enable a patient to perform ECG measurement as soon as an irregular heart activity develops and without requiring the ECG to be constantly wired to the patient.” *Id.* According to Shmueli:

The present invention resolves this problem by providing a combined oximetry and electrocardiogram measuring system and a method in which the oximetry measurement is performed continuously and/or repeatedly, and the ECG measurement is triggered upon detection of an intermittent irregular heart-related events without requiring the fixed wiring of the ECG device to the patient.

Id. Consistent with this disclosure, Shmueli's claim 1 recites:

1. A method for triggering measurement of electrocardiogram (ECG) signal of a subject, the method comprising the steps of:
 - continuously measuring SpO₂ at least one of a wrist and a finger of said subject;
 - detecting an irregular heart condition from said SpO₂ measurement;
 - notifying said subject to perform an ECG measurement;
 - and
 - initiating ECG measurement at least partially at said wrist.

Id. at 16. Shmueli Figure 7 is reproduced below:



“Fig. 7 is a simplified flow chart of a software program preferably executed by the processor of the wrist-mounted heart monitoring device.” *Id.* at 8; *see also id.* at 12–13 (further describing the steps of the software program illustrated in Figure 7).

2) Overview of Osorio (Exhibit 1005)¹⁰

Osorio “relates to medical device systems and methods capable of detecting a pathological body state of a patient, which may include epileptic seizures, and responding to the same.” Ex. 1005 ¶ 2. Although broadly referencing “a pathological body state,” Osorio repeatedly exemplifies such conditions in terms of detecting epileptic events. *See, e.g., id.* ¶ 37 (referencing values “be indicative of a certain pathological state (e.g., epileptic seizure)”) ¶ 46 (In one embodiment, the pathological state is an epileptic event, e.g., an epileptic seizure.”), ¶ 56 (“HRV range may be taken as an indication of an occurrence of a pathological state, e.g., an epileptic seizure”), ¶ 57 (“The dynamic relationship between non-pathological HRVs and activity levels may be exploited to detect pathological states such as epileptic seizures”). Consistent with the broad disclosure and narrow exemplification in the body of its specification, Osorio’s claim 1 is directed to “[a] method for detecting a pathological body state of a patient,” whereas claim 7 limits the pathological state to an epileptic event. *Compare id.* at claim 14, *with* claim 17 (similarly limiting a pathological state to an epileptic event).

According to Osorio, the disclosed methods, systems, and related devices, detect a pathological state of a patient by determining when a body data variability value, or “BDV,” is outside of a “value range,” and where the threshold levels of that range vary in response to the patient’s physical

¹⁰ Osorio is a United States Patent Application Publication of Application No. 14/208,952, filed March 13, 2014, and claiming the benefit of priority of Provisional Application No. 61/794,540, filed March 15, 2013 (Ex. 1010). Insofar as Patent Owner has not asserted that Osorio fails to qualify as prior art (*see* Pet. 3–5; Prelim. Resp. 14–15, 31–43), we need not cite to the Provisional Application.

activity (measured by, e.g., an accelerometer) or mental/emotional state. *See, e.g., id.* at Abstract, ¶¶ 3–8, 28, 33, 35. In this respect, Osorio states that “false negative and false positive detections of pathological events may be reduced by dynamically determining pathological or non-pathological ranges for particular body indices based on activity type and level or other variables (e.g., environmental conditions).” *Id.* ¶ 36.

Osorio’s Figure 1 is reproduced below.

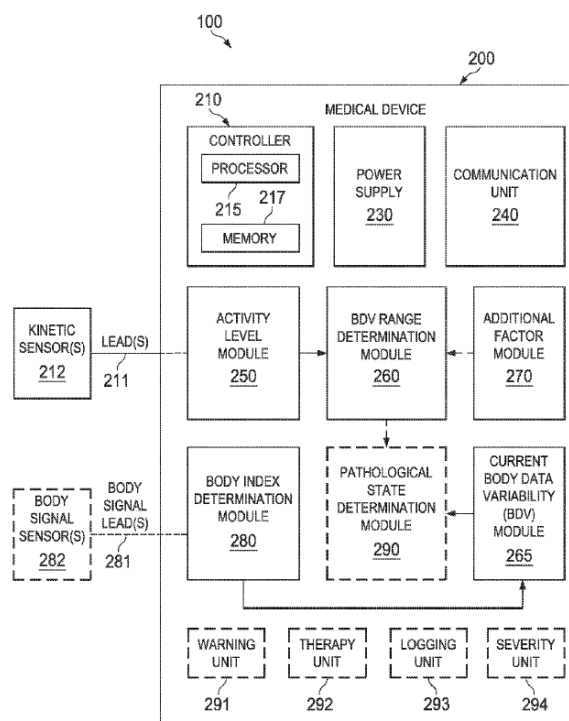


FIG. 1

Figure 1 shows a schematic representation of medical device system 100, including kinetic sensor(s) 212 and body signal sensor(s) 282 connected to medical device 200 by leads 211 and 281, respectively. *Id.* ¶ 33.

“[A]ctivity sensor(s) 212 may each be configured to collect at least one signal from a patient relating to an activity level of the patient,” and include, for example, an accelerometer, an inclinometer, a gyroscope, or an ergometer. *Id.* Figure 1 also shows a current body data variability (BDV)

module 265, which may “may comprise an O₂ saturation variability (O2SV) module 330 configured to determine O2SV from O₂ saturation data,” and “an HRV module 310 configured to determine HRV from heart rate data.” *Id.* ¶¶ 13, 53, Fig. 2C. Osorio discloses that “medical device system 100 may be fully or partially implanted, or alternatively may be fully external.” *Id.* ¶ 33.

Figure 8, reproduced below, shows one embodiment of Osorio’s monitoring method.

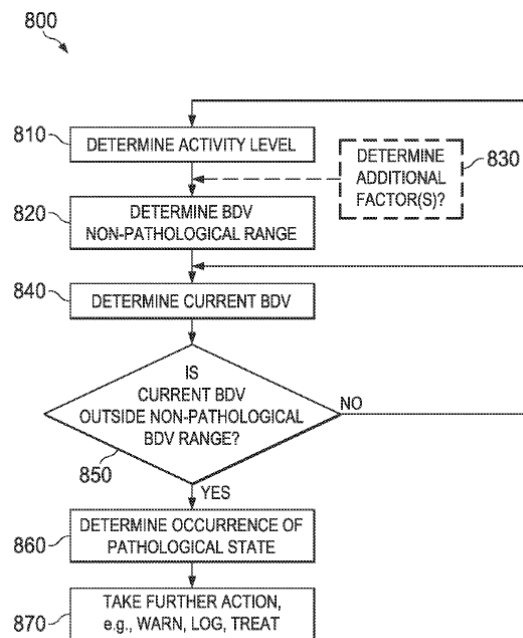


FIG. 8

Figure 8 shows an activity level is determined at 810, and a non-pathological BDV range is determined at 820 based on the activity level. *Id.* ¶ 77. A current BDV is determined at 840 and compared to the non-pathological BDV range at 850. *Id.* ¶ 78. If the current BDV is outside the non-pathological range, then a pathological state is determined at 860 and a further action, such as warning, treating, or logging the occurrence and/or severity of the pathological state, is taken at 870. *Id.*

According to Osorio, many body indices may be the subject of BDV monitoring including

heart rhythm variability, a heart rate variability (HRV), a respiratory rate variability (RRV), a blood pressure variability (BPV), a respiratory rhythm variability, respiratory sinus arrhythmia, end tidal CO₂ concentration variability, power variability at a certain neurological index frequency band (e.g., beta), an EKG morphology variability, a heart rate pattern variability, an electrodermal variability (e.g., a skin resistivity variability or a skin conductivity variability), a pupillary diameter variability, a blood oxygen saturation variability, a kinetic activity variability, a cognitive activity variability, arterial pH variability, venous pH variability, arterial-venous pH difference variability, a lactic acid concentration variability, a cortisol level variability, or a catecholamine level variability.

Id. ¶ 43; *see also id.* ¶ 42 (similar) ¶ 45–46 (monitoring heart rate for episodes of tachycardia and bradycardia). “In one embodiment, the severity [of a pathological state] may be measured by a magnitude and/or duration of a pathological state such as a seizure, a type of autonomic change associated with the pathological state (e.g., changes in heart rate, breathing rate, brain electrical activity, the emergence of one or more cardiac arrhythmias, etc.).”

Id. ¶ 71.

With respect to HRV, in particular, Osorio teaches: “By monitoring the patient’s activity level, HR, and HRV, it is possible to determine when the patient’s HRV falls outside the non-pathological ranges as the patient’s activity levels change over time.” *Id.* ¶ 66. Osorio’s Figure 4A, reproduced below, relates the BDV of heart rate variability as a function of activity level to the risk of having an epileptic seizure. *See id.* ¶ 58.

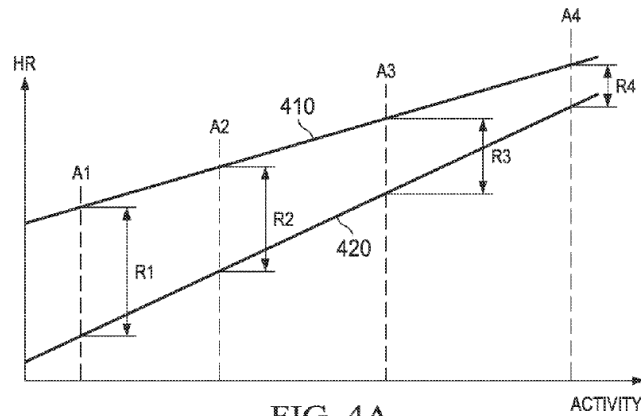


FIG. 4A

Figure 4A plots a patient's heart rate (HR) on the X-axis and a patient's activity level on the Y-axis. *Id.* A1 through A4 represent increasing activity from a sleep state (A1) through vigorous activity (A4). *Id.* Boundary lines 410 and 420, respectively, represent the upper and lower limits of non-pathological heart rate, and include representative ranges R1 through R4.

According to Osorio,

the upper and lower bounds of the non-ictal^[11] HR region increase as activity level increases (e.g., from a sleep state to a resting, awake state) and reach their highest values for strenuous exertion. In addition, the width of the non-pathological HR ranges narrows as activity levels and heart rates increase, which is consistent with the known reduction in HRV at high levels of exertion. When the patient is in a non-pathological state (e.g., when an epileptic patient is not having a seizure), for a particular activity level the patient's HRV should fall within a non-pathological HRV range associated with that activity level.

Id. Osorio further presents Figure 11 as “depict[ing] pathological and non-pathological BDV (e.g., HRV) value ranges.” *Id.* ¶¶ 11, 91. In this example, Osorio HRV values that fall below 0.5 bpm and above 4 bpm are always

¹¹ “Ictal” refers to the active, middle stage of a seizure and corresponds with intense electrical brain activity. *See* <https://epilepsyfoundation.org.au/understanding-epilepsy/seizures/seizure-phases/>.

pathological when activity level is low (e.g., resting or walking), whereas intermediate HRV values (0.5–4 bpm) may be pathological when considered in light of the patient’s activity level. *Id.*

3) Analysis of Ground 1

Petitioner contends that claims 1–6, 10–16, and 20 are obvious over Shmueli in combination with Osorio and provides an element-by-element comparison of the asserted art to the challenged claims. Pet. 17–68.

According to Petitioner, “Shmueli’s wrist-mounted heart monitoring device detects an irregular heart condition (arrhythmia) based on PPG and ECG measurements” but “does not expressly account for a user’s activity level.” *Id.* at 17. As a marker for activity level, Petitioner points to Osorio as teaching to “determin[e] HRV from HR and using HRV to detect the pathological event.” *Id.* at 17–18 (citing Ex. 1003 ¶ 66).

Relying on the testimony of Dr. Chaitman, Petitioner argues that “it was well-known that activity level is related to HR and HRV and a POSITA would have found it obvious to improve Shmueli’s method by considering activity level.” *Id.* (citing, e.g., Ex. 1003 ¶ 65). Petitioner further points to Osorio as evidencing benefits of using activity level to detect an irregular heart condition (e.g., improved accuracy, reliability, and reduced false detection). *Id.* (citing Ex. 1005 ¶¶ 29, 36). Accordingly, Petitioner contends, one of ordinary skill in the art “would have been motivated to incorporate Osorio’s activity sensor and activity level analysis techniques into Shmueli’s heart monitoring device . . . to improve the accuracy of detecting a pathological event (e.g., arrhythmia.)” *Id.* at 17–18 (citing Ex. 1005 ¶ 29; Ex. 1003 ¶ 66). Petitioner similarly asserts that one of ordinary skill in the art “would have been motivated to incorporate Osorio’s HRV analysis

because it is less affected by noise” and, thus, “improve[] the pathological event detection capabilities compared to Shmueli’s unmodified heart monitoring device.” *Id.* at 22–23, 24 (citing Ex. 1003 ¶¶ 73, 76; Ex. 1039, 52¹²). Supporting Petitioner’s position, Dr. Chaitman testifies that one of ordinary skill in the art would have understood that modifying Shmueli’s device to use Osorio’s HRV analysis would have improved the detection of certain arrhythmias, particularly atrial fibrillation. *See* Ex. 1003 ¶ 76. Petitioner further argues that one of ordinary skill in the art could have combined the teachings of Shmueli and Osorio with a reasonable expectation of success. Pet. 21–22, 25, 50, 70.

Independent claims 1 and 11 includes the steps of determining heart rate variability based on heart rate and comparing heart rate variability to a user’s activity level. According to Patent Owner, Petitioner has not established that these elements are disclosed in the asserted references. Prelim. Resp. 40–42. Patent Owner’s assertion is not availing on the present record.

With respect to determining heart rate variability based on heart rate, Patent Owner argues that “Shmueli does not disclose the concept of heart rate variability at all” and, thus, “provides no disclosure as to how a POSITA could determine a heart rate variability based on heart rate data.” Prelim. Resp. 41–42. Petitioner points to elements 37 and 38 of Shmueli’s Figure 7, which refer to steps of measuring SPO2 and detecting an irregular heart condition, respectively. *See* Pet. 36. Shmueli states:

¹² Asl and Mohebbi, “*Support vector machine-Based arrhythmia classification using reduced features of heart rate variability signal*,” 44(1) *Artif Intell Med.* 51–64 (2008), Ex. 1039.

As shown in Fig. 7, the software program starts in element 37 by measuring SpO₂. The element of measuring SpO₂ (e.g. oxygen saturation in the blood). The SpO₂ measurement is preferably executed continuously as long as the heart monitoring device is operative.”

* * *

The software program proceeds to element 38 to derive from the SpO₂ measurement physiological parameters such as pulse rate, pulse amplitude, pulse shape, rate of blood flow, etc. Then, the software program scans the derived physiological parameters to detect various irregularities of the heart condition.

Ex. 1004, 12 (emphasis added). According to Petitioner, “it was well-known that HRV can be accurately derived from heart rate sensed using PPG or ECG data,” and one of ordinary skill in the art “would have found it obvious that Shmueli’s method derives HRV based on this heart rate information because HRV is a common physiological parameter derived from heart rate measurements to detect irregular heart conditions.” Pet. 37 (citing Ex. 1003 ¶ 105; Ex. 1012,¹³ Abstract, 95-96; Ex. 1013,¹⁴ Abstract; Ex. 1014,¹⁵ Abstract; Ex. 1015,¹⁶ Abstract).

Petitioner further points to Osorio’s express teaching that HRV module 310 may be “configured to determine HRV from heart rate data,”

¹³ Tsipouras et al., “*Automatic arrhythmia detection based on time and time–frequency analysis of heart rate variability*,” 74 *Computer Methods and Programs in Biomedicine* 95–108 (2004).

¹⁴ Lu et al., “*Can photoplethysmography variability serve as an alternative approach to obtain heart rate variability information?*” *J. Clin. Monit. Comput.* (2007).

¹⁵ Selvaraj et al., “*Assessment of heart rate variability derived from fingertip photoplethysmography as compared to electrocardiography*,” 32(6) *J. Med. Eng. & Technol.* 479–484 (2008).

¹⁶ Lu et al., “*A comparison of photoplethysmography and ECG recording to analyse heart rate variability in healthy subjects*,” 33(8) *J. Med. Eng. Technol.* 634–41 (2009).

thereby indicating that Osorio also” discloses determining HRV from the sensed heart rate from the heart rate sensor.” Pet. 38 (citing, *e.g.*, Ex. 1003 ¶ 106; Ex. 1005 ¶ 53; Ex. 1010 ¶ 35) (emphasis omitted). As such, Petitioner has established sufficiently established that one of ordinary skill in the art reading Shmueli and Osorio, would have understood that heart rate variability can be determined from heart rate.

With respect to the second element, Patent Owner contends that Osorio fails to teach the step of comparing heart rate variability to a user’s activity level because, rather than *directly* compare HRV to activity level, it “describes a multi-step process” involving the calculation of a non-pathological range to which an actual value is compared. Prelim. Resp. 40–41. Patent Owner’s argument is not availing on the present record.

Claim 1, for example, requires the step of “comparing, using said mobile computing device, said heart rate variability of said first user to said activity level of said first user.” On its face, we do not read this (or similar language in independent claim 11)¹⁷ as excluding a multi-step process as implicitly advanced by Patent Owner. Nor has Patent Owner argued that such a construction is supported in the Specification or relevant prosecution history. *But see* Pet. 43–44 (discussing the comparing step within the meaning of the ’499 patent). The parties are, nevertheless, welcome to brief the construction of this term at trial.

As explained in Section III.D.2, above, Osorio teaches HRV as one of the body indices or body data variability values (BDVs) within the scope of its disclosure. Ex. 1005 ¶¶ 43, 91; *see also id.* ¶ 66 (“By monitoring the patient’s activity level, HR, and HRV, it is possible to determine when the

¹⁷ Patent Owner does not address claims 1 and 11 individually.

patient’s HRV falls outside the non-pathological ranges as the patient’s activity levels change over time.”). Osorio’s Figure 8 illustrates that an activity level is determined at 810, and a non-pathological BDV range (*e.g.*, HRV) is determined at 820 based on the activity level. *Id.* ¶ 77. A current BDV is determined at 840 and compared to the non-pathological BDV range at 850. *Id.* ¶ 78. If the current BDV is outside the non-pathological range, then a pathological state is determined at 860 and a further action, such as warning, treating, or logging the occurrence and/or severity of the pathological state is taken at 870. *Id.*; *see also id.* ¶ 91, Fig 11 (comparing HRV values to HRV limit values adjusted for activity level).

Patent Owner further contends that Petitioner has not established that one of ordinary skill in the art “would have selected Osorio, a reference directed to the detection of a neurological condition like epileptic seizures, to combine with Shmueli, a reference directed to the detection of vague and undisclosed cardiac conditions, in order to utilize activity level monitoring to accurately detect cardiac arrhythmias.” Prelim. Resp. 33 (citing Ex. 2001 ¶ 71).

As set forth in Section III.D.2, above, Osorio provides general methods for monitoring a wide variety body indices—including heart rhythm variability and heart rate variability—in order to detect a pathological state in a patient. Osorio expressly recites monitoring the patient for the “emergence of one or more cardiac arrhythmias” including tachycardia and bradycardia. Ex. 1005 ¶¶ 45–46, 71. Despite Patent Owner’s assertion that Osorio “repeatedly makes clear reference to seizures,” we do not read Osorio as limited to the exemplified embodiments.

See Prelim. Resp. 32 (citing Ex. 1005 ¶¶ 37, 45, 46, 56, 58, 66–68, 73, 83, 90, 96).

With respect to Shmueli, Patent Owner contends that the reference “does not once mention “arrhythmia,” instead referring to an ‘irregular heart condition’ which, as [Petitioner] admits, is not a standard term in medicine.” *Id.* at 32 (citing Ex. 1004; Pet. 11; Ex. 2001 ¶ 67). Patent Owner contends that one of ordinary skill in the art would not automatically assume that Shmueli’s “irregular heart condition” refers to cardiac arrhythmia as opposed some other heart condition. *Id.* Patent Owner relies on Dr. Efimov’s testimony that Shmueli makes no attempt to define “irregular heart condition” with any specificity, and “one can only speculate” as to its meaning because “numerous conditions can be considered heart irregularities: normal autonomic nervous system control, autonomic dysfunction, heart failure, ischemia, myocardial infarction, heart block, etc.” Ex. 2001 ¶ 67.

As discussed above, Shmueli broadly refers to “irregular ECG” rather than the more specific “arrhythmia.” As an initial matter, we note that whereas the preamble of independent claim 1 refers to “arrhythmia,” the body of the claim recites “an irregularity in said heart rate variability.” Further, depending from claim 1, claim 8 refers to determining the presence of arrhythmia based, in part, on “heart rate variability data.” As such, the ’499 patent itself indicates a tight linkage between arrhythmia and an irregular heart condition. Moreover, at this stage of the proceeding, we credit Dr. Chaitman’s testimony that, “Shmueli discloses both detecting the ‘irregular heart condition’ based on PPG data and confirming the diagnosis with an ECG measurement.” Ex. 1003 ¶ 49 (citing Ex. 1004, Abstract, Fig.

8; 8:23–28). And although Shmueli “offers an expansive definition of ‘irregular heart condition,’” one of ordinary skill in the art would have understood this term as referring to arrhythmia, “which is one of the most obvious (if not the most obvious) types of ‘irregular heart condition[s]’ that can be determined using PPG and ECG data.” *Id.* (citing, Ex. 1016, 6081; Ex. 1020, Abstract, 44:29–32; Ex. 1011, Abstract; Ex. 1023, 2; Ex. 1047, 320–321; Ex. 1001, 1:40–42; Ex. 1004, 8:11–13, 15:3–5) (alteration in original). Considering the present record, Petitioner has established sufficiently that one of ordinary skill in the art would have understood Shmueli’s use of “irregular heart condition” as referring to—or at a minimum, encompassing—arrhythmia, and, thus, disclosing the detection of arrhythmia. *See* Pet. 10–13 (citing, *e.g.*, Ex. 1003 ¶ 49).

Patent Owner also argues that Osorio teaches away from the invention claimed in the ’499 patent because it discloses that some sensors “may be fully or partially implanted” in a patient, and implantation is inconsistent with Petitioner’s assertion that Shmueli discloses “a convenient yet comfortable device to measure ECG only upon detection of an irregular heart condition using PPG data.” Prelim. Resp. 33–34 (citing Ex. 1005 ¶ 33; Ex. 2001 ¶ 72; Pet. 19). Patent Owner argues that, although relationship between activity level and heart rate was generally known, one of ordinary skill in the art would have considered that relationship “limited primarily to normal physiology during normal sinus rhythm,” and “would not automatically know that activity should be considered and applied to recognize life threatening tachyarrhythmias, when nothing of the sort was disclosed or even referenced in Shmueli.” *Id.* at 36–38 (citing Ex. 2001 ¶

¶ 74–75). We do not find Patent Owner’s argument availing on the present record.

With respect to its implantation argument, the passage in Osorio relied on by Patent Owner states that “[t]he medical device system 100 may be fully or partially implanted, *or alternatively may be fully external.*” Ex. 1005 ¶ 33 (emphasis added). In considering obviousness, “a reference . . . is prior art for all that it teaches.” *Beckman Instruments, Inc. v. LKB Produkter AB*, 892 F.2d 1547, 1551 (Fed. Cir. 1989). Although fully or partially implanted embodiments may be relevant to the detection or amelioration of epileptic seizures, we do not read Osorio as so limited. And absent additional and persuasive evidence, we decline to read an optional embodiment as a teaching away. *See In re Fulton*, 391 F.3d 1195, 1201 (Fed. Cir. 2004) (“The prior art’s mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed”).

Petitioner persuasively argues that Osorio discloses certain benefits of incorporating a patient’s activity level to detect an irregular heart condition. *See* Pet. 17 (citing Ex. 1005 ¶¶ 29, 36; Ex. 1010 ¶¶ 38, 41–50; Ex. 1003 ¶ 65). Dr. Chaitman similarly testifies that one of ordinary skill in the art reading Osorio “would have understood that accurate detection of a pathological condition (e.g., arrhythmia) benefits from monitoring body data (e.g., HR) and activity level in tandem,” and notes that “Osorio explicitly describes the benefits (e.g., improved accuracy, reliability, and reduced false detection) of using activity level to detect an irregular heart condition.” Ex. 1003 ¶¶ 57, 65 (citing Ex. 1005 ¶¶ 29, 36). On the present record, Petitioner has shown sufficiently that one of ordinary skill “would have been

motivated to incorporate Osorio’s activity sensor and activity level analysis techniques into Shmueli’s heart monitoring device.” Pet. 17; Ex. 1003 ¶ 65.

Accordingly, and for the reasons discussed herein, Petitioner has reasonably established that one of ordinary skill in the art would have been motivated to combine, with a reasonable expectation of success, the teachings of Shmueli and Osorio as arranged in claims 1–6, 10–16, and 20.

E. Ground 2: Obviousness over Shmueli, Osorio, and Hu

As Ground 2, Petitioner challenges claims 7–9 and 17–19 as obvious over Shmueli, Osorio, and Hu. Pet. 68–77. Petitioner provides an element-by-element comparison of the asserted art to the challenged claims. *Id.* Patent Owner opposes. Prelim. Resp. 42–43.

1) Overview of Hu (Exhibit 1049)

Hu discloses “a “mixture-of-experts” (MOE) approach to develop customized electrocardiogram (ECG) beat classifier in an effort to further improve the performance of ECG processing and to offer individualized health care.” Ex. 1049, Abstract. Hu’s “approach is based on three popular artificial neural network (ANN)-related algorithms, namely, the selforganizing maps (SOM), learning vector quantization (LVQ) algorithms, along with the mixture-of-experts (MOE) method.” *Id.* at 892. According to Dr. Chaitman, Hu applied this “a machine learning method to detect arrhythmia by training the algorithm using both user-specific historical data (local expert) and historical data from other users (global expert).” Ex. 1003 ¶ 60. Hu reports that, “[t]ested with MIT/BIH arrhythmia database, we observe significant performance enhancement using this approach.” Ex. 1049, Abstract.

2) Analysis of Ground 2

Patent Owner raises no additional arguments with respect to Ground 2 and merely argues that Petitioner does not rely on Hu to correct the alleged deficiencies of Shmueli–Osorio combination of Ground 1. Prelim. Resp. 42–43. As discussed above, however, we do not find Petitioner’s arguments with respect to Ground 1 deficient for the purposes of institution.

Accordingly, on this record, Petitioner has shown sufficiently that one of ordinary skill in the art would have considered at least one claim of the ’499 patent obvious for the reasons set forth in the Petition.

IV. CONCLUSION

After considering the evidence and arguments presented in the current record, we determine that Petitioner has demonstrated a reasonable likelihood of success in proving that the challenged claims of the ’499 patent are unpatentable. We therefore institute trial on all challenged claims under the ground raised in the Petition. *See PGS Geophysical AS v. Iancu*, 891 F.3d 1354, 1360 (Fed. Cir. 2018) (Indicating that a decision whether to institute an *inter partes* review “require[s] a simple yes-or-no institution choice respecting a petition, embracing all challenges included in the petition.”); 37 C.F.R. § 42.108(a). At this stage of the proceeding, we have not made a final determination with respect to the patentability of any of the challenged claims.

Any argument not raised in a timely Patent Owner Response to the Petition, or as permitted in another manner during trial, shall be deemed waived even if asserted in the Preliminary Response. In addition, nothing in this Decision authorizes Petitioner to supplement information advanced in the Petition in a manner not permitted by the Board’s Rules.

V. ORDER

ORDERED, pursuant to 35 U.S.C. § 314(a), an *inter partes* review of claims 1–20 of the '499 patent is instituted with respect to the grounds set forth in the Petition; and

FURTHER ORDERED, pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4(b), that the *inter partes* review of the '499 patent shall commence on the entry date of this Order, and notice is hereby given of the institution of a trial.

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