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Paper 10
Date: December 8, 2021

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.

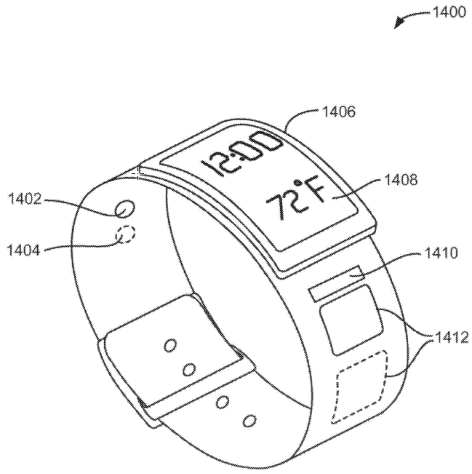

Figure 14, shows "smart watch 1400 which includes at least one heart rate monitor 1402 and at least one activity monitor 1404," such as an accelerometer. *Id.* at 24:58–60, 25:5–22. Analysis of signals from these monitors can be used to "determine if heart rate and activity measurements represent an 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.

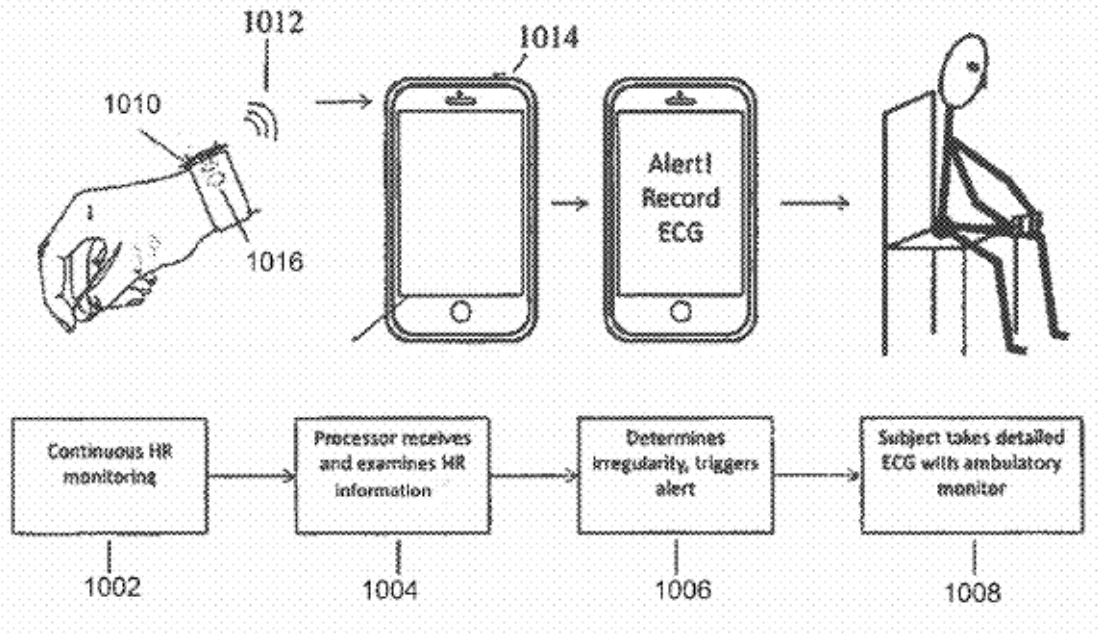

Figure 10 illustrates "a method for monitoring a subject to determine when to record an electrocardiogram (ECG)." *Id.* at 23:12–14. According to the Specification:

> 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;
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> 2. proximity of the court's trial date to the Board's projected statutory deadline for a final written decision;
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> 3. investment in the parallel proceeding by the court and the parties;
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> 4. overlap between issues raised in the petition and in the parallel proceeding;
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> 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.

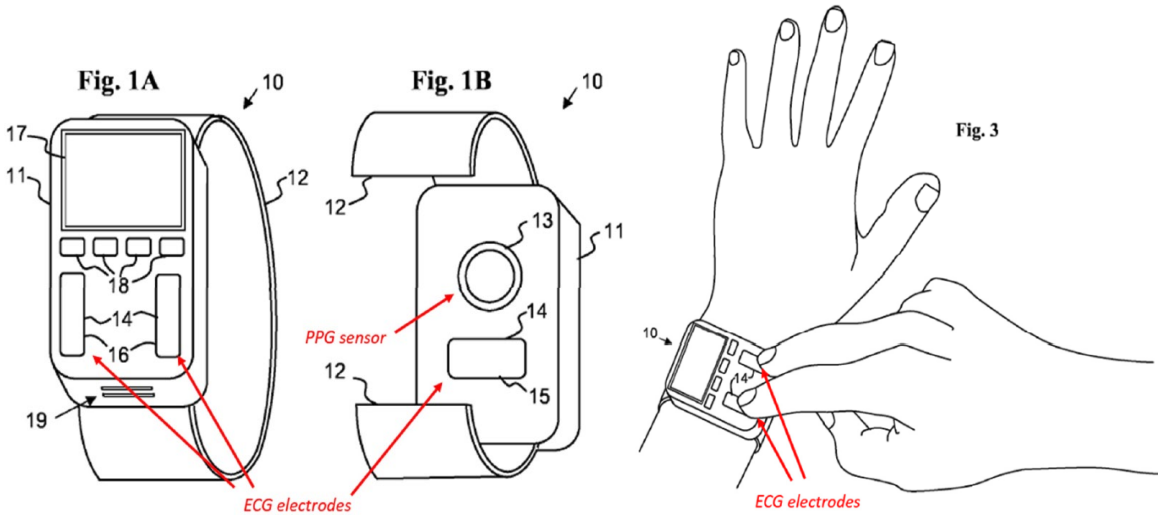
D. Ground 1: Obviousness over Shmueli and Osorio

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 (SpO_2) 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, SpO_2, 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.

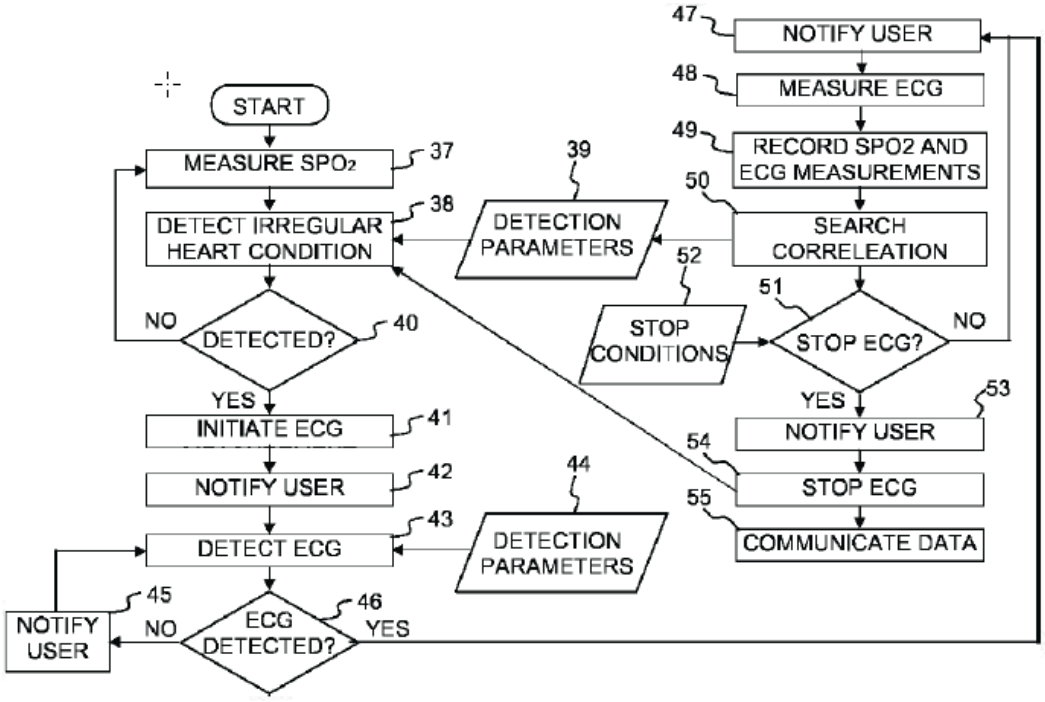
Shmueli explains that "[d]eriving heart beat rate from oximetry, as well as other artifacts of the heart activity and blood flow, is [] known in the art," as are various body-worn oximetry devices. *Id.* at 8. Shmueli further explains that the use of oximetry in combination with ECG measurements is also 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 SpO_2 measuring device." *Id.* However, Shmueli, notes "Goldreich does not teach interrelated measurements of ECG and SpO_2" 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.

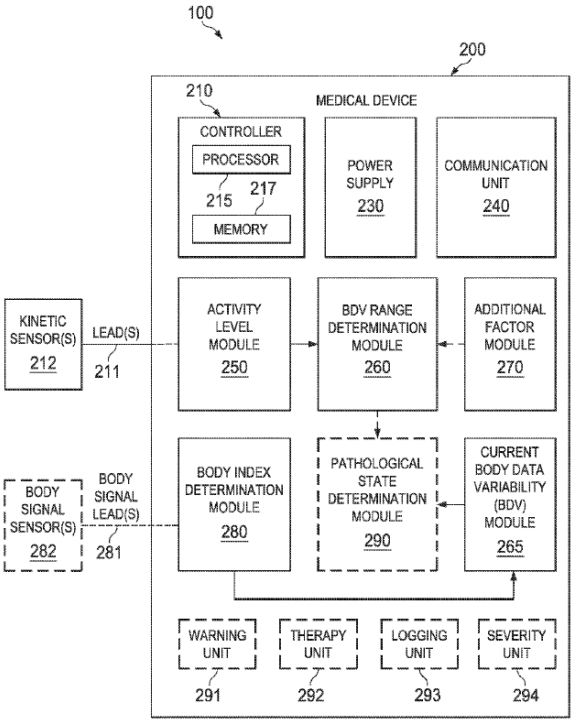


FIG. 1

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 O_2 saturation variability (O2SV) module 330 configured to determine O2SV from O_2 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.

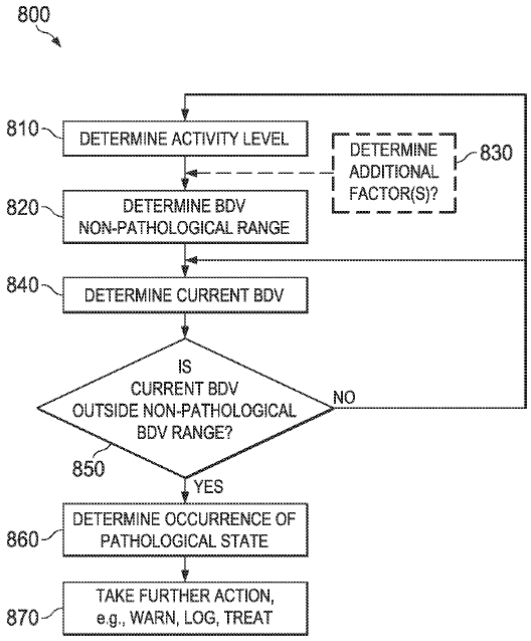


FIG. 8

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.

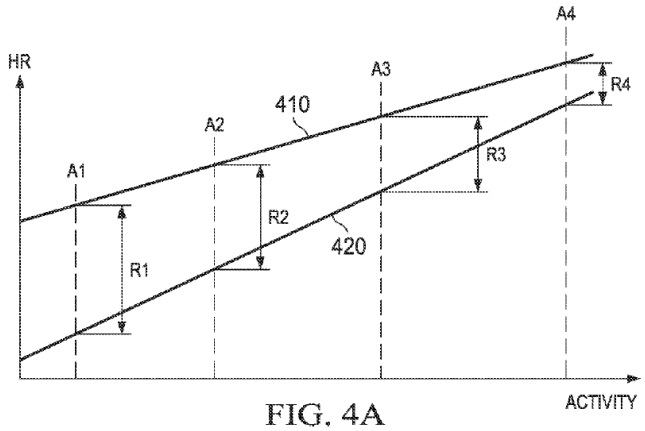


FIG. 4A

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 though 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, 52[12]). 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 SpO_2. The element of measuring SpO_2 (e.g. oxygen saturation in the blood). The SpO_2 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 SpO_2 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,"

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[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 finger-tip 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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Paper 10
Date: December 8, 2021

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APPLE, INC.,
Petitioner,

v.

ALIVECOR, INC.,
Patent Owner.

IPR2021-00971
Patent 10,595,731 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 1–15 of U.S. Patent No. 10,595,731 B2 ("the '731 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 '731 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. 88. 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. 10,595,731 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: IPR2021-00970 (USP 9,572,499) and IPR2021-00972 (USP 10,638,941).

Paper 4, 2; *see* Pet. 88. We refer to the above litigations as the "Texas Litigation" and the "ITC Investigation," respectively. *See* Pet. 81–82. We further note that the '731 patent at issue here is related by a chain of continuation applications to Application No. 14/730,122, which issued as U.S. Patent No. 9,572,499 ("the '499 patent), challenged in IPR2021-00970. *See* Ex. 1001, code (63); Prelim. Resp. 4. As such, the '731 and '499 patents share substantially the same specification.

The '731 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* Prelim. Resp. 4; Pet. 2 & nn. 1–3. Petitioner contends, and Patent Owner does not presently contest, that the claims of the '731 patent are not entitled the benefit of the earliest of those applications such that the critical date is March 14, 2014, the filing date of provisional application No. 61/953,616. Pet. 2–3; Prelim. Resp. 4. 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 March 14, 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, 7, 12, 13, 16, 17, 23–26, 30	§ 103	Shmueli[1]
2	1, 2, 4, 7, 12–14, 16–18, 20, 23–26, 30	§ 103	Shmueli, Osorio[2]
3	3, 5, 6, 19, 21, 22	§ 103	Shmueli, Osorio, Li[3]
4	8–11, 27–29	§ 103	Shmueli, Osorio, Kleiger[4]
5	15	§ 103	Shmueli, Osorio, Chan[5]

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 '731 Patent and Relevant Background

The '731 patent relates to medical devices, systems, and methods for detecting cardiac conditions, including cardiac arrhythmias. Ex. 1001, 1:29–33, 2:17–25. 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

[1] WO2012/140559, publ. Oct. 18, 2012. Ex. 1004.
[2] U.S. 2014/0275840, publ. Sept. 18, 2014. Ex. 1005.
[3] Li Q, Clifford GD, "*Signal quality and data fusion for false alarm reduction in the intensive care unit*," 45(6) J Electrocardiol. 596-603 (2012). ("Li" or "Li-2005") Ex. 1006.
[4] Kleiger RE, Stein PK, "*Bigger JT Jr. Heart rate variability: measurement and clinical utility*." 10(1) Ann Noninvasive Electrocardiol. 88-101 (2005). ("Kleiger" or "Kleiger-2005") Ex. 1033.
[5] U.S. Pat. No. 7,894,888, publ. Feb. 22, 2011. Ex. 1048.

> 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 2:57–64; *see id.* at 18:52–63 (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 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." Ex. 1001, 1:40–44. 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 1:44–51.

The Specification discloses body-worn devices for detecting the occurrence of arrhythmia's using a combination of PPG and ECG electrodes. *See*, *e.g.*, claim 1. PPG, or photoplethysmography, uses an optical sensor to detect the fluctuation of blood flow, and can provide a measure of heart rate. *Id.* at 25:21–24. 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 1:52–54, 1:60–65, 25:1–35. The collected data may also be analyzed using machine learning algorithms to, for example, determine appropriate trigger thresholds, detect and predict health conditions, or provide a heart health score. *See, e.g.*, *id.* at 3:43–4:16, 8:38–41, 9:8–11, 12:44–64.

Figure 14, reproduced below, shows one embodiment of a body-worn device. *Id.* at 6:21–23.

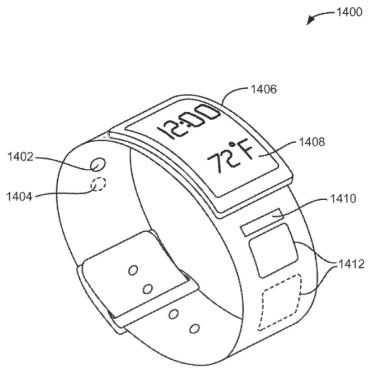


Figure 14, shows "smart watch 1400 which includes at least one heart rate monitor 1402 and at least one activity monitor 1404," such as an accelerometer. *Id.* at 24:66–25:1, 25:13–30. Analysis of signals from these monitors can be used to "determine if heart rate and activity measurements

represent an advisory condition for recording an ECG," and trigger signals for recording an ECG if an advisory condition is detected. *Id.* at 25:1–12.

Figure 10, illustrated below, shows another embodiment involving a body-worn device. *Id.* at 6:3–5.

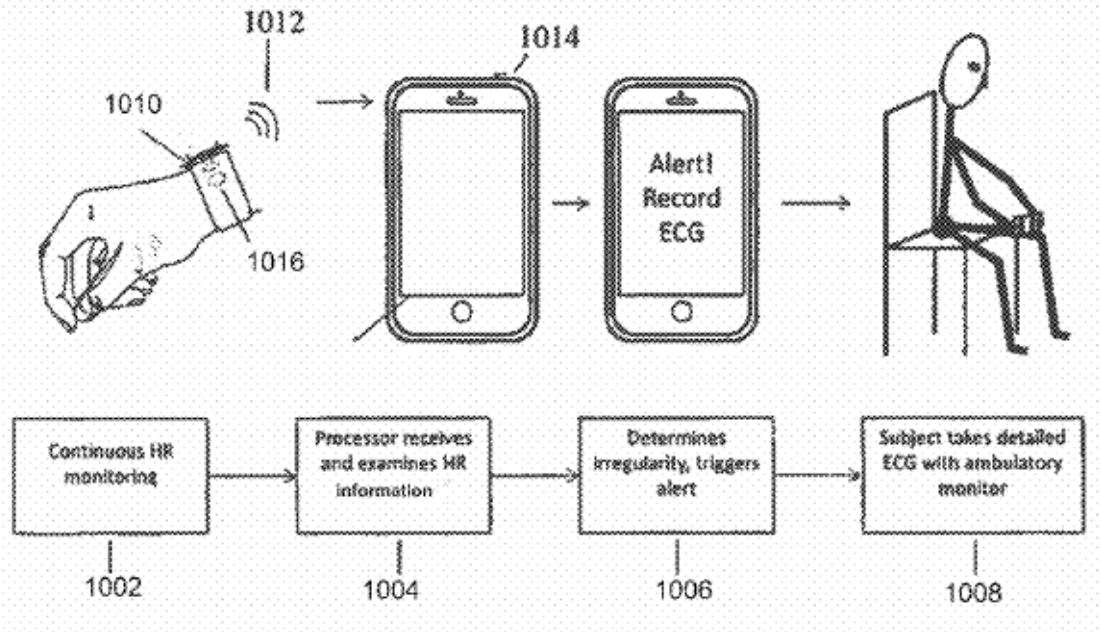


Figure 10 illustrates "a method for monitoring a subject to determine when to record an electrocardiogram (ECG)." *Id.* at 23:20–22. According to the Specification:

> 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 23:22–30. In some embodiments, the ECG device is "present in a smart watch band or a smart phone." *Id.* at 25:36–37. "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 25:48–50.

G. Challenged Claims

Petitioner challenges claims 1–30, of which claims 1, 17, and 25 are independent. Of these, claim 1 recites:

> 1. A smart watch to detect the presence of an arrhythmia of a user, comprising:
>
> a processing device;
>
> a photoplethysmography ("PPG") sensor operatively coupled to the processing device;
>
> an ECG sensor, comprising two or more ECG electrodes, the ECG sensor operatively coupled to the processing device;
>
> a display operatively coupled to the processing device; and
>
> a memory, operatively coupled to the processing device, the memory having instructions stored thereon that, when executed by the processing device, cause the processing device to:
>
> receive PPG data from the PPG sensor;
>
> detect, based on the PPG data, the presence of an arrhythmia;
>
> receive ECG data from the ECG sensor; and
>
> confirm the presence of the arrhythmia based on the ECG data.

Independent claims 17 and 25 recite similar limitations but are drawn to "[a] method to detect the presence of an arrhythmia of a user on a smart watch," and "non-transitory computer-readable storage medium including instructions," respectively.

Among the dependent claims, claims 2, 14, and 18 relate to the use of motion sensor (inertial) data; claims 4 and 20 relate to "determin[ing] heartrate variability ("HRV") data from the PPG data, and detect[ing], based

on the HRV data, the presence of the arrhythmia;" claims 3, 5, 6, 19, 21, and 22 recite "a machine learning algorithm trained to detect arrhythmias;" and claim 15 recites a device "configured to display an ECG rhythm strip for the ECG data."

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) (2018); *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) (2021).

Patent Owner argues that we should exercise our discretion to deny the Petition in view of the copending ITC Investigation. Prelim. Resp. 15–30; 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. 16. Petitioner argues that we should decline to exercise our discretion under § 314(a) to deny institution. *See* Pet. 81–87; 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").[6] 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 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

[6] Available at https://www.uspto.gov/TrialPracticeGuideConsolidated.

efforts, which strongly weighs against exercising the authority to deny institution. *Fintiv*, Paper 11 at 6.

Here, the '731 patent is involved in two parallel proceedings. One of those proceedings, the Texas Litigation, has been stayed. Pet. 82; 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. 16. 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. 19 (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 (PTAB 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 16, 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.

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.[7] *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. 21. 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 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

[7] 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.

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. 85 (citing Ex. 1051). Finally, Petitioner argues that *inter partes* review of the '731 patent would include all of the claims of the '731 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. Indeed, Patent Owner argues that the prior art cited in the Petition has "already entered the ITC case." Prelim. Sur-reply 1 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. 87; Prelim. Reply 5. Petitioner also argues that the merits of its "patentability challenges are strong, which favors institution." Pet. 87; 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. 27. Patent Owner also contends that

Petitioner "raised claim construction disputes at the ITC that it did not include in its Petition," including identifying "confirm[ing] the presence of the arrhythmia based on the ECG data" and "receiv[ing] ECG data from the ECG sensor." *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 proceedings 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, as support for its position. Prelim. Resp. 27. 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. 2, 27 (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 infra* § III.H. As to the possibility of inconsistent POSA definitions, again, it does not appear that the definition of the POSA 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 infra* § III.G (discussing this issue). To the extent Dr. Chaitman does not qualify as one of ordinary skill under the definition adopted by the ITC, which requires "at least five years of relevant work experience designing wearable devices and/or sensors for measuring physiological signals or parameters of mammal,[8] we note that we do not require a perfect match between an expert's experience and the relevant field. *See* Trial Practice Guide at 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. 1003 ¶¶ 4–8, curriculum vitae. To the extent that Dr. Chaitman lacks experience designing wearable devices, we are able to

[8] Patent Owner cites to Exhibit 2010 as providing the ITC's claim construction and definition of the POSA. *See* Prelim. Reply i, 4–5. No Exhibit 2010 has 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.

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.[9] *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 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

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

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. 7–8. 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.* at 8; *see also* Ex. 1003 ¶ 10 (Dr. Chaitman's

similar testimony based on his "knowledge and experience in the field and [his] review of the '731 patent and file history").

Patent Owner, however, argues that the '731 patent 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. 8–9 (quoting Ex. 1001, 2:17–19, 2:39–41). 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.* at 9 (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.* at 9 (citing Ex. 2001 ¶ 52) (emphasis added); *see also id.* at 9–10 (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 9–11. 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 9; 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, 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 states:

> 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 ¶¶ 52–53 (emphasis added).[10] Indeed, considering that the '731 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.

[10] Further supporting the concept of a multidisciplinary team, we note that authors of the asserted Kleiger reference consist of a Ph.D. and two M.D.s. Ex. 1003, 1.

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))).

At this stage of the 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.

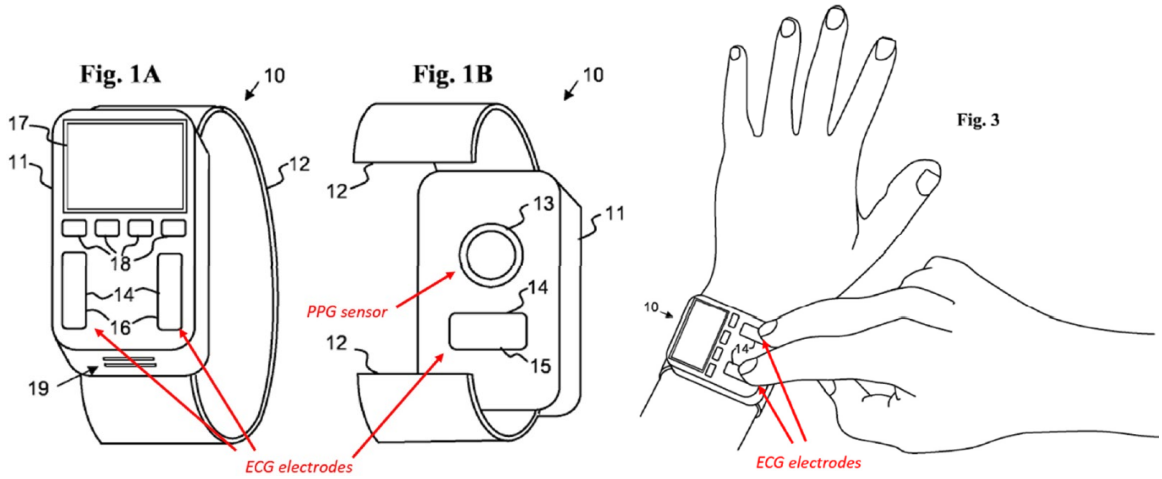
D. Ground 1: Obviousness over Shmueli

As Ground 1, Petitioner challenges claims 1, 7, 12, 13, 16, 17, 23–26, and 30 as obvious over Shmueli. Pet. 8–39. Patent Owner opposes. Prelim. Resp. 30–33. We begin with an overview of Shmueli.

1) Overview of Shmueli (Exhibit 1004)

Shmueli addresses "solutions . . . for monitoring infrequent events of

irregular ECG." Ex. 1004, 2.[11] Shmueli's solutions include body-worn cardiac monitoring devices "equipped with two types of sensing devices: an oximetry (SpO_2) measuring unit and an ECG measuring unit." *Id.* at 9.[12] 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. 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 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:

[11] We refer to native pagination wherever possible.
[12] Shmueli uses the terms oxygen saturation in the blood, blood oxygen saturation, pulse oximeter, oximetry, SpO_2, as synonymous with photoplethysmography, except where otherwise specified. *Id.*

> 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 SpO_2 measuring device." *Id.* However, Shmueli, notes "Goldreich does not teach interrelated measurements of ECG and SpO_2" 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 claims:

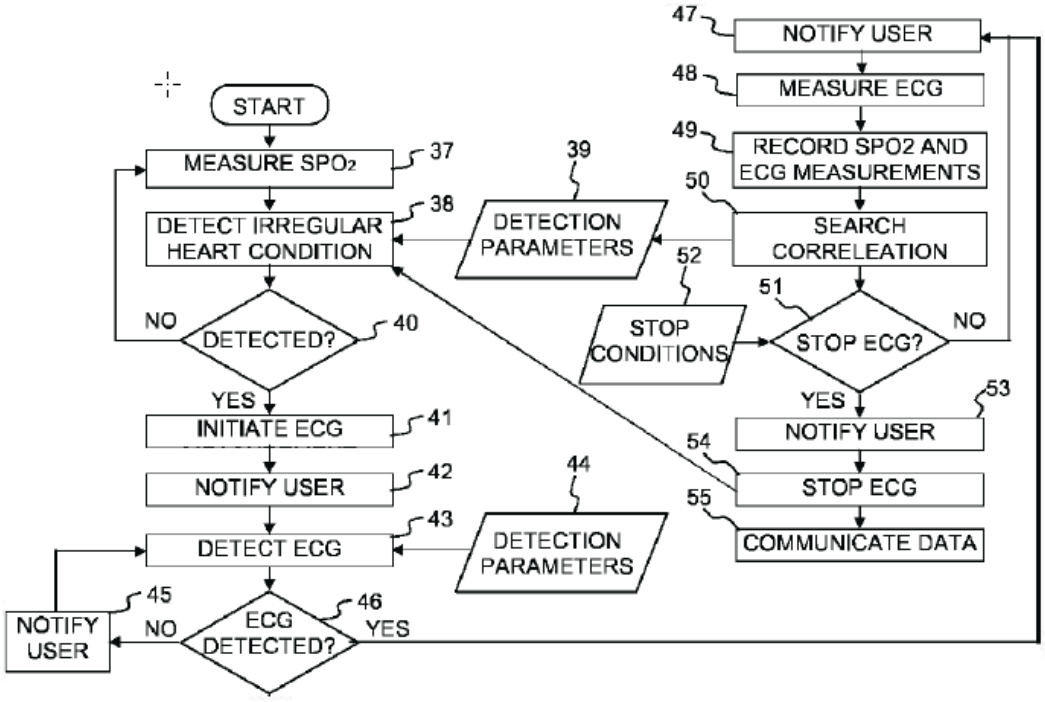
> 1. A method for triggering measurement of electrocardiogram (ECG) signal of a subject, the method comprising the steps of:
>
> continuously measuring SpO2 at least one of a wrist and a finger of said subject;

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.

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 7; *see also id.* at 12–13 (further describing the steps of the software program illustrated in Figure 7).

2) Analysis of Ground 1

Petitioner contends that Shmueli discloses or renders obvious each element of claims 1, 7, 12, 13, 16, 17, 23–26, and 30, and sets forth an element-by-element comparison of the asserted art to the challenged claims. Pet. 13–39. Patent Owner contends, first, that Ground 1 fails because Petitioner has not shown that Shmueli discloses "a device that detects

arrhythmia," as required by the independent claims. Prelim. Resp. 31; *see e.g.*, Ex. 1001, claim 1 (requiring that a "processing device . . . detect, based on the PPG data, the presence of an arrhythmia").

Patent Owner argues that Shmueli does not use the term "arrhythmia," but instead refers to an "irregular heart condition," which "is not a standard term in medicine." Prelim. Resp. 31 (citing Ex. 1004; Pet. 10; Ex. 2001 ¶ 68). 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.* at 31–32. In this respect Dr. Efimov testifies 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 ¶ 68.

At this stage of the proceeding, however, 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 ¶ 48 (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. 10–12 (citing, *e.g.*, Ex. 1003 ¶ 48).

Patent Owner also argues that Ground 1 fails because "Shmueli does not disclose confirming the presence of an arrhythmia based on the ECG data." Prelim. Resp. 32; *see, e.g.*, Ex. 1001, claim 1 (requiring that a "processing device . . . confirm the presence of the arrhythmia based on the ECG data"). Patent Owner first contends that Shmueli does not disclose arrhythmia detection at all and, thus, also "does not disclose a device capable of confirming an arrhythmia detection through analysis of ECG data." Because, as discussed above, Petitioner has sufficiently established that Shmueli discloses detecting arrhythmia, Patent Owner's argument is unavailing.

Further in support of its contention that Shmueli does not disclose "confirming the presence of an arrhythmia based on the ECG data," Patent Owner focuses on Shmueli's statement that a "remote server preferably further analyzes" collected ECG data." Prelim. Resp. 32–33 (referencing Ex. 1004, 14). Patent Owner argues that "[b]ecause the only analysis of the ECG data disclosed in Shmueli occurs at a remote server, Shmueli does not disclose the idea of confirming the presence of the arrhythmia on a wearable device as required by the independent claims of the '731 Patent. *Id.* at 33 (citing Ex. 2001 ¶ 73). We do not find Patent Owner's argument availing on the current record.

As an initial matter, the processing device of claim 1 "receiv[es] ECG data from an ECG sensor or the smart watch; and confirm[s] the presence of the arrhythmia based on the ECG data." As claim 1, and the similarly worded independent claims 17 and 25, are drafted using "comprising" language, we do not read them to exclude "further analy[sis]" of EEG data on a remote server. *See* Ex. 1004, 14; *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1319 (Fed. Cir. 2009) ("The claim uses the term 'comprising,' which is well understood in patent law to mean 'including but not limited to.'"). But to the extent the claims are read to require all such steps to be performed on the smart watch that would seem an obvious variant to conducting some part of the analysis on a remote server.

Further, Shmueli states that "the wrist-mounted heart monitoring device *preferably* transmits to the remote server the collected data, such as the recorded ECG measurement" whereupon the "remote server preferably *further* analyzes" collected ECG data." *See* Ex. 1004, 14 (emphasis added). Shmueli's disclosure that ECG data may be transmitted to a remote server for *further* analysis presupposes that the data is also analyzed prior to transmission. In addition, the software program illustrated in Shmueli's Figure 7 includes "element 48 to perform the ECG measurement and to element 49 to record the SpO2 and the ECG measurements and store them in the memory unit 28." *Id.* at 12. The program may then

> proceed[] to element 50 to search for correlations between the SpO2 signal and the ECG signal to produce new detection parameters, or modify existing detection parameters, so as to enhance the detection algorithms of the irregular heart conditions. Searching for correlation (element 50) can be executed in real-time (together with elements 37, 47 and 49) or later after the ECG measurement is concluded.

Id. at 13. Shmueli further teaches that "[t]he SpO2 measurement, the ECG measurement and their recordation and storage (elements 37, 47 and 49 respectively) are continued and performed in parallel until a stopping condition is met." *Id.* Conditions for stopping the ECG measurement include a determination that "[t]he irregular heart condition has stopped," at which point "the software program preferably notifies the user that the ECG measurement has stopped." *Id.*

According to Petitioner and its expert, one of ordinary skill in the art would have understood that determining whether "[t]he irregular heart condition has stopped," and notifying the user requires, as a predicate, that the software program confirm the presence of arrhythmia using the ECG data. Pet. 28 (emphasis omitted); Ex. 1003 ¶¶ 109–113. On the present record, we agree with Petitioner that one of ordinary skill reading the above portions of Shmueli

> would have found it obvious that the software at element 38 causes the processing device to detect, based on the PPG data, the presence of arrhythmia. [Ex. 1003 ¶ 112]. Thus, a POSITA would have understood that the software at element 50, element 39, and element 38 causes the processing device to confirm the presence of the arrhythmia based on the ECG data, by searching for correlations between the PPG and ECG data, modifying detection parameters, and confirming the presence of arrhythmia. [*Id.*]

Pet. 27. Shmueli further teaches that, in a subsequent step, "[a]fter concluding the ECG measurement (element 54) the software program preferably proceeds to element 55 to communicate with a remote server," which would appear to show that the step of confirming the presence of arrhythmia occurs prior to communication with any remote server. *See* Ex. 1004, 14.

In light of the above, we find that the record also sufficiently supports Petitioner's contention that Shmueli renders obvious at least those claims challenged under Ground 1, claims 1, 7, 12, 13, 16, 17, 23–26, and 30.

E. Ground 2: Obviousness over Shmueli and Osorio

As Ground 2, Petitioner challenges claims 1, 2, 4, 7, 12–14, 16–18, 20, 23–26, and 30 as obvious over Shmueli in combination with Osorio. Pet. 39–67. Claims 2, 4, 14, 18, and 20—not common to those challenged under Ground 1—relate to a motion sensor (claims 2 and 4), "motion sensor data" (claims 18 and 20) or "inertial data of the user" (claim 14). Petitioner provides an element-by-element comparison of the asserted art to the challenged claims. *Id.* at 43–67. Patent Owner opposes. Prelim. Resp. 33–42. Having discussed Shmueli above, we begin with an overview of Osorio.

1) Overview of Osorio (Exhibit 1005)[13]

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

[13] 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. 3–6; Prelim. Resp. 33–42), we need not cite to the Provisional Application.

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 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.

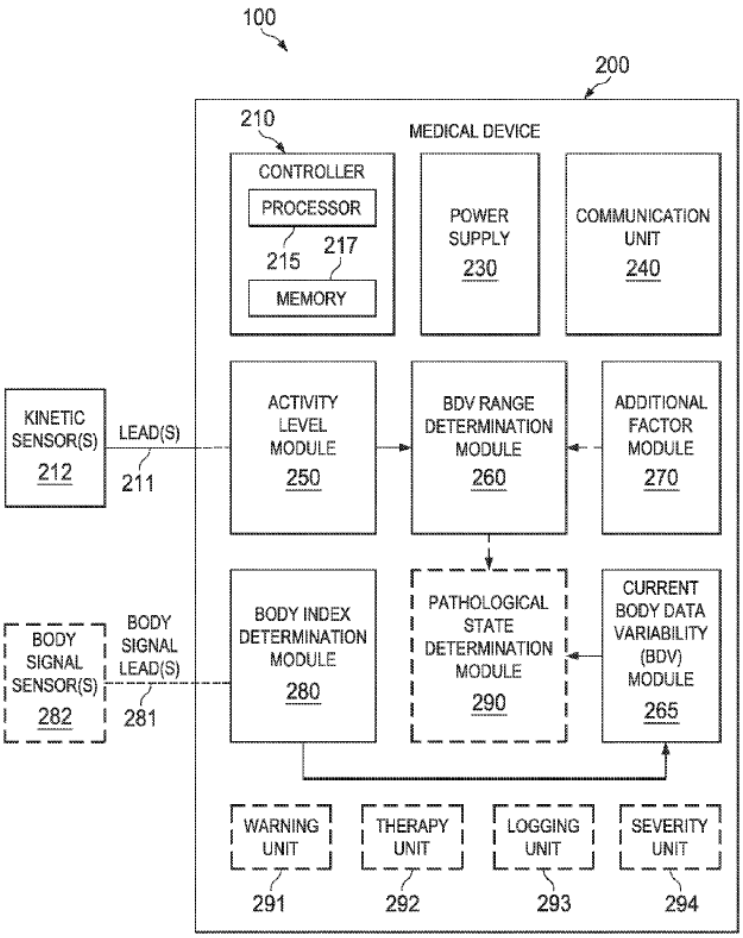


FIG. 1

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 O_2 saturation variability (O2SV) module 330 configured to determine O2SV from O_2 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.

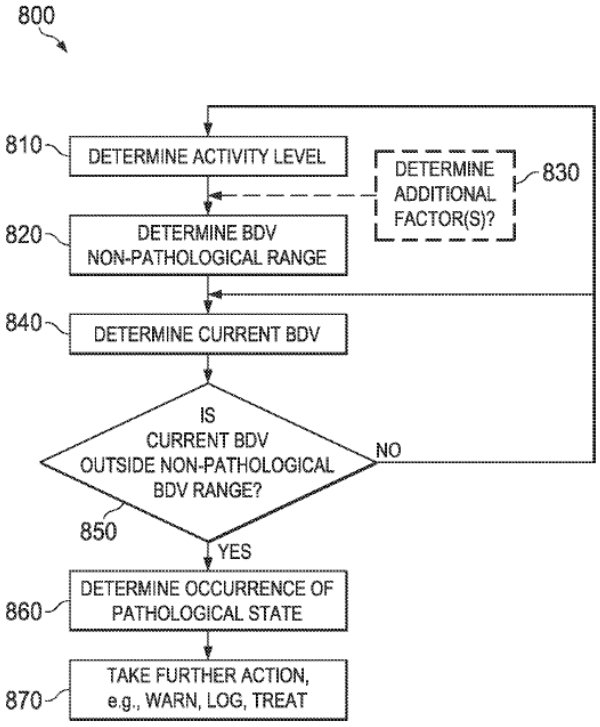


FIG. 8

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.

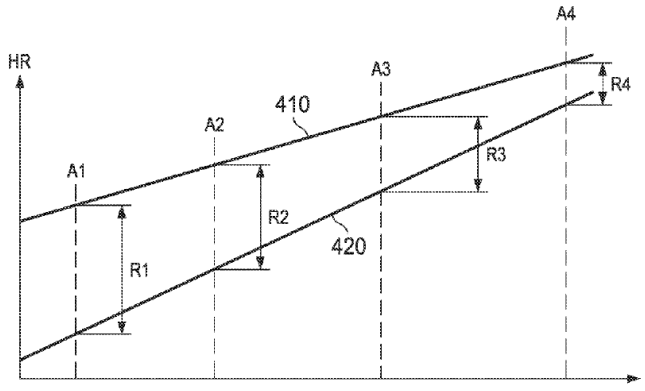


FIG. 4A

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 though 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[14] 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 illustration, Osorio shows that HRV values falling below 0.5 bpm and above

[14] "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/.

4 bpm are always 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*.

2) Analysis of Ground 2

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." Pet. 43. 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 43–44 (citing Ex. 1003 ¶ 152).

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 ¶ 151). 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 43–44 (citing Ex. 1005 ¶ 29; Ex. 1003 ¶¶ 151–152). 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 48–50 (citing Ex. 1003 ¶¶ 159, 162; Ex. 1039,

52[15]). 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 ¶ 162. 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. 45–48.

Patent Owner contends that Ground 2 fails because "neither Shmueli nor Osorio contains any specific disclosure of arrhythmia detection" and, thus, do not teach "detecting an arrhythmia using PPG data, or confirming the presence of the arrhythmia based on the ECG data, as required in each of the independent claims. Prelim. Resp. 42 (citing Ex. 2001 ¶¶ 84–85). We do not find this argument availing. As discussed in Section III.D.2, above, Petitioner has shown sufficiently that, although Shmueli broadly refers to the detection of an "irregular heart condition" as opposed to the less expansive, art-standard term "arrhythmia," one of ordinary skill in the art would have understood that Shmueli discloses both detecting arrhythmia based on PPG data and confirming the diagnosis with an ECG measurement. Osorio further discloses monitoring heart rate for episodes of tachycardia and bradycardia, and, more generally, monitoring a patient for "the emergence of one or more cardiac arrhythmias." Ex. 1005 ¶¶ 46, 71; *see* Ex. 1003 ¶ 54.

Patent Owner further contends that Ground 2 is predicated on improper hindsight insofar as Petitioner has not shown that one of ordinary skill in the art would have been motivated to modify Shmueli to incorporate

[15] 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.

Osorio's teachings regarding activity level monitoring. Prelim. Resp. 33–41. In this respect, Patent Owner first argues that "[n]either reference specifically discloses detection of arrhythmias, and a POSITA would therefore not look to Shmueli and Osorio, in combination, to solve the problem of detecting potential tachyarrhythmias using the combination of sensors disclosed in the '731 Patent." *Id.* at 34 (citing Ex. 2001 at 77). As noted above, however, Petitioner has shown sufficiently that one of ordinary skill in the art would have understood that Shmueli to disclose detecting arrhythmia based on PPG data and confirming the diagnosis with an ECG measurement. In addition, Osorio expressly discloses monitoring a patient for cardiac arrhythmias, including tachycardia and brachycardia. *See, e.g.,* Ex. 1005 ¶¶ 45–46, 71.

Patent Owner further argues 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. 34–35 (citing Ex. 2001 ¶ 79). Patent Owner also argues that Osorio teaches away from the invention claimed in the '731 patent because it teaches that some sensors "may be fully or partially implanted" in a patient, and implantation is inconsistent with a wrist-worn medical device. *Id.* at 35 (citing Ex. 1005 ¶ 33; Ex. 2001 ¶ 80) (emphasis omitted). 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 "as 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 37, 39 (citing Ex. 2001 ¶¶ 82–83). We do not find Patent Owner's argument availing on the present record.

As set forth in Section III.E.1, 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. 34 (citing Ex. 1005 ¶¶ 37, 45, 46, 56, 58, 66–68, 73, 83, 90, 96).

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").

As discussed above, Shmueli broadly refers to "irregular ECG" rather than the more specific "arrhythmia." Nevertheless, Petitioner has shown sufficiently that one of ordinary skill in the art would have understood Shmueli to disclose detecting arrhythmia based on PPG data and confirming the diagnosis with an ECG measurement. *See* Pet. 43–44 (citing Ex. 1003 ¶¶ 151–152). Petitioner also reasonably argues that Osorio discloses certain benefits of incorporating a patient's activity level to detect an irregular heart condition. *See Id.* at 43 (citing Ex. 1005 ¶¶ 29, 36; Ex. 1003 ¶¶ 151–152).

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 the challenged claims.

F. Grounds 3–5: Obviousness over Shmueli and Osorio further in view of Li, Kleiger, or Chan

As Ground 3, Petitioner challenges claims 3, 5, 6, 19, 21, and 22 as obvious over Shmueli, Osorio, and Li. As Ground 4, Petitioner challenges claims 8–11 and 27–29 as obvious over Shmueli, Osorio and Kleiger; and as Ground 5, Petitioner challenges claim 15 as obvious over Shmueli and Chan, with or without Osorio. Pet. 1, 67–81. Petitioner provides an element-by-element comparison of the asserted art to the challenged claims. *Id.* Patent Owner opposes. Prelim. Resp. 33–42. Having discussed Shmueli and Osorio, above, we begin with an overview of Li, Kleiger, and Chan.

1) Overview of Li (Exhibit 1006)

According to Li, a lack of integration between different sensors results in frequent false alarms in intensive care units. Ex. 1006, Abstract. To reduce these false alarms, Li discloses a machine learning approach combining up to 114 features extracted from the electrocardiogram, photoplethysmograph, and optionally the arterial blood pressure waveform data. *Id.* The resulting algorithm could reduce false alarms with without substantial suppression of true alarms. *Id.* at Abstract, 7, Table 6. For example, "[f]or the ventricular tachycardia alarms, the best FA suppression performance was 30.5% with a TA suppression rate below 1%." *Id.* at Abstract.

2) Overview of Kleiger (Exhibit 1033)

Kleiger is a review article regarding the measurement and clinical utility of heart rate variability (HRV). Ex. 1033, Title. Kleiger discloses various methods for quantifying HRV including time domain, spectral or frequency domain, geometric, and nonlinear methods. *Id.* at 88. According to Kleiger:

> The greatest variation of heart rate occurs with circadian changes, particularly the difference between night and day heart rate, mediated by complex and poorly understood neurohormonal rhythms. Exercise and emotion also have profound effects on heart rate. Fluctuations in heart rate reflect autonomic modulation and have prognostic significance in pathological states.

Id. (internal citation numbers omitted).

> Long-term, usually 24-hour recordings, can be used to assess autonomic nervous responses during normal daily activities in health, disease, and in response to therapeutic interventions, e.g., exercise or drugs. RR interval variability is useful for assessing risk of cardiovascular death or arrhythmic events,

> especially when combined with other tests, e.g., left ventricular ejection fraction or ventricular arrhythmias.

Id. at Abstract.

3) Overview of Chan (Exhibit 1048)

Chan discloses:

> A wristwatch worn by a user for measuring a three-lead ECG three electrodes placed separately on the front, either side, and back or strap thereof. The wristwatch further includes an electrode panel having the electrode on the front or either side of the watch, sensing elements, pressure, infrared or impedance detectors, and circuits. The electrode panel is capable of sensing the contact or press of fingers to trigger the ECG measuring. While the electrode in the back-side of the watch contacts the hand wearing the watch, the electrode and electrode panel on the front or either side of the watch are pressed by fingers from the other hand, and the electrode in the strap contacts the abdomen or left leg simultaneously. Thus, a three-lead ECG can be measured. ECG data can be transmitted to a personal or hospital computer by wireless networks or flash memory.

Ex. 1048, Abstract.

Chan's figures 1A and 1B, reproduced below, show an embodiment of the disclosed three-lead ECG wristwatch.

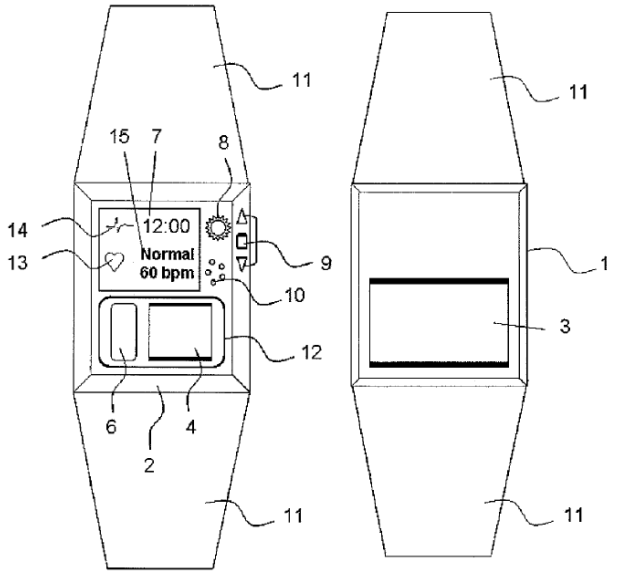


FIG.1A FIG.1B

Figures 1A and 1B, respectively, show the front and rear of a three-lead ECG wristwatch. *Id.* at 2:21–22. Figure 1A shows ECG electrode 4, sensing element 6 (which can detect pressure, impedance or infrared for recognizing the contact or press made by fingers to initiate an ECG measurement"), and display 7, which may be an LCD. *Id.* at 2:44–56. Display 7 can display text (e.g., time, hear rate, and, condition (normal vs arrhythmia) as well as "graph/animation, for an event reminding 13 and ECG waveforms 14." *Id*. at 2:56–59; *see also id.* at 4:56–59 (stating, with reference to Figure 7, that "display 57 can show users 59 time, heart rate, waveforms and any other information 61, such as activity level and temperature, if needed).

Chan Figure 2 is reproduced below.

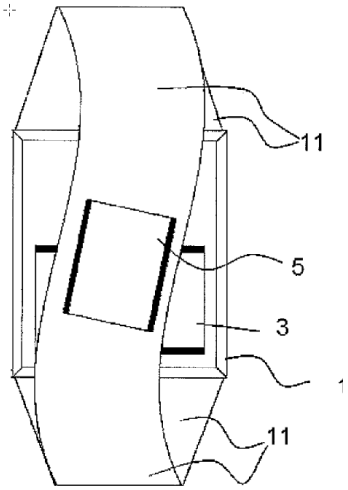


Figure 2 shows an embodiment of the three-lead ECG watch having a third lead 5 on the strap 11. *Id.* at 2:24–25, 3:1–4.

Chan Figure 3B is reproduced below.

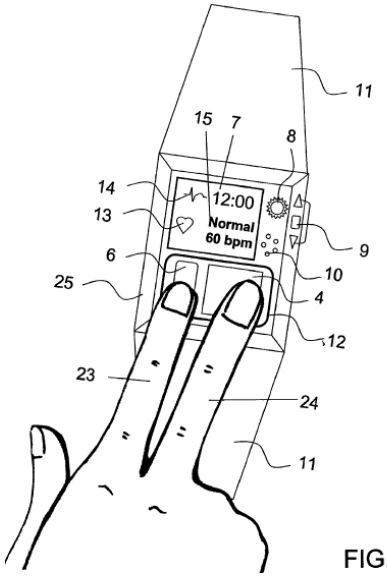


FIG.3B

Figure 3B "demonstrate[s] how to place the wristwatch to make electrodes be contacted by both hands." *Id.* at 2:26–28, 3:5–22.

4) Analysis of Grounds 3–5

Patent Owner raises no additional arguments with respect to Grounds 3–5 and merely argues that Petitioner does not rely on Li, Kleiger, and Chan to correct the alleged deficiencies of Shmueli and Osorio discussed with respect to Grounds 1 and 2. Prelim. Resp. 42. As discussed above, however, we do not find Petitioner's arguments with respect to Grounds 1 and 2 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 claim 1 of the '731 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 '731 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 1–30 of the '731 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 '731 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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Paper 10
Entered: December 8, 2021

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APPLE, INC.,
Petitioner,

v.

ALIVECOR, INC.,
Patent Owner.

IPR2021-00972
Patent 10,638,941 B2

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

COTTA, *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 1–23 of U.S. Patent No. 10,638,941 B2 ("the '941 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, we determine 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 '941 patent is unpatentable, we institute an *inter partes* review of all challenged claims on each of the Grounds raised in the Petition. *See SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1359–60 (2018); 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. 10,638,941 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: IPR2021-00970 (USP 9,572,499) and IPR2021-00971 (USP 10,595,731).

Paper 4, 2; *see also,* Pet. 84. We refer to the above litigations as the "Texas Litigation" and the "ITC Investigation," respectively.

The '941 patent claims priority to, *inter alia*, a provisional application filed on May 13, 2015. Ex. 1001, code (60); *see* Prelim. Resp. 4; Pet. 1. The prior art relied upon in the Petition precedes the filing date of this provisional application. Accordingly, and solely for purposes of this Decision, we apply May 13, 2015, as the effective filing date.

E. Asserted Grounds of Unpatentability

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

Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
1, 5, 7–9, 11, 12, 16, 18–20, 22, 23	103[1]	Shmueli,[2] Osorio[3]

[1] The Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) ("AIA"), amended 35 U.S.C. §§ 102 and 103. Based on the filing date of the '941 patent, we apply the AIA versions of §§ 102 and 103.
[2] Shmueli et al., WO 2012/140559 A1, published Oct. 18, 2012, (Ex. 1004, "Shmueli").
[3] Osorio, U.S. Patent Publication No. 2014/0275840 A1, published Sept. 18, 2014, (Ex. 1005, "Osorio").

Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
2–4, 6, 13–15, 17	103	Shmueli, Osorio, Lee-2013[4]
10, 21	103	Shmueli, Osorio, Chan[5]

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 '941 patent

The '941 patent discloses that "[i]rregular heartbeats and arrhythmias are associated with significant morbidity and mortality in patients." Ex. 1001, 1:17–18. According to the '941 patent, "[n]on-invasive cardiac monitoring is useful in diagnosing cardiac arrhythmia." *Id.* at 1:21–22. In furtherance of this use, the '941 patent discloses "systems, devices, and methods for cardiac monitoring," including, for example "portable computing devices such as smartphones, smartwatches, laptops, and tablet computers." *Id.* at 1:26–30.

The '941 patent explains that "certain parameter values may be conveniently sensed continuously such as, for example, heart rate and activity level, and analyzed to predict or determine the presence of an arrhythmia." *Id.* at 1:58–61. For example, the '941 describes analyzing heart rate and activity level and identifying discordance between these two parameters to determine the presence or the future onset of an arrhythmia.

[4] Jinseok Lee et al., *Atrial Fibrillation Detection using a Smart Phone*, 15:1 INT'L. J. OF BIOELECTROMAGNETISM 26–29 (2013) (Ex. 1011, "Lee-2013").
[5] Chan et al., U.S. Patent No. 7,894,888 B2, issued Feb. 22, 2011 (Ex. 1048, "Chan").

Id. at 1:61–66. If the presence or the future onset of an arrhythmia is identified, an electrocardiogram (ECG) may be initiated. *Id.* at 2:1–3.

Figure 7 of the '941 patent is reproduced below.

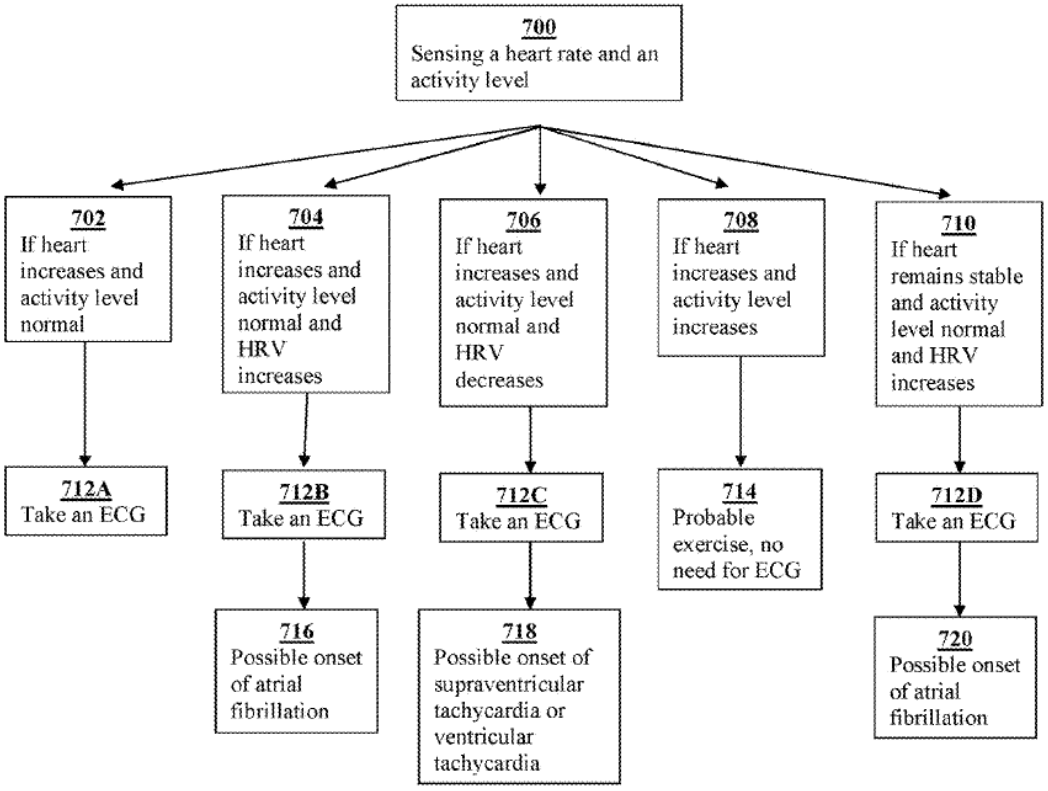

FIG. 7

Figure 7 schematically depicts "an algorithm for discordance monitoring." *Id.* at 3:53–54. The '941 patent explains that a heart rate and an activity level are sensed in step 700. *Id.* at 14:49–51. The '941 patent describes sensing an activity level with a gyroscope or an accelerometer and sensing heart rate using "light based or other commonly used heart rate sensors." *Id.* at 14:51–54. Figure 7 depicts various possible outcomes from the sensing of heart rate and activity level. *Id.* at Fig. 7, elements 702, 704, 706, 708, 710. For example, in step 702, the sensors detect "an increased heart rate . . . together with a normal or resting activity level." *Id.* at 14:59–60. This result

is identified as a "discordance [that] may indicate the present of an arrhythmia." *Id.* at 14:59–66. "As such, an ECG is caused to be sensed in step 712A." *Id.* at 14:60–67. Steps 704, 706, 708, and 710 depict other potential outcomes from the sensing of heart rate and activity level as well as the actions taken for each potential outcome. *Id.* at 15:22–58.

G. Challenged Claims

The '941 patent includes twenty-three claims. All of those are challenged here. Pet. 1. Claims 1 and 12 are the only independent claims. Claim 1 is illustrative of the claims challenged in this Petition and reads as follows:

> 1. A method of cardiac monitoring, comprising:
> sensing an activity level of a user with a first sensor on a smartwatch worn by the user;
> when the activity level is resting, sensing a heart rate parameter of the user with a second sensor on the smartwatch;
> determining, by a processing device, that a discordance is present between the activity level value and the heart rate parameter;
> based on the presence of the discordance, indicating to the user, using the smartwatch, a possibility of an arrhythmia being present; and
> receiving electric signals of the user from an electrocardiogram sensor ("ECG") on the smartwatch to confirm a presence of the arrhythmia, wherein the ECG sensor comprises a first electrode and a second electrode.

Ex. 1001, 17:2–18.

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. 15–30; 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. 16. 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, *available at* https://www.uspto.gov/TrialPracticeGuideConsolidated ("Trial Practice Guide"). 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 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 '941 patent is involved in two parallel proceedings. One of those proceedings, the Texas Litigation, has been stayed. Pet. 77. 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. 16.

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. *See* 19 U.S.C. § 1337(b)(1). 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. 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. 19 (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 (PTAB 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. Resp. 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 date for issuance of 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, we determine that 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 [Investigation] 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. *Id.* 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 16, 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.

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 that we did not find it necessary to construe any claim terms to issue this decision.[6] *See supra* Section II.D; *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.

[6] Patent Owner argues that "the *Markman* Order that issued in the ITC conflicts with [Petitioner's] positions in this proceeding." Prelim. Sur-reply 5. As support, Patent Owner cites determination in the ITC Investigation that the term "discordance" should be "given its plain an ordinary meaning." *Id.* On this preliminary record, we do not see any conflict between Petitioner's proposed construction and the plain and ordinary meaning of the term discordance. *See,* Pet. 8–10.

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. 21. 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 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 that 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-2013 or Chan." Pet. 81 (citing Ex. 1051). Finally, Petitioner argues that *inter partes* review of the '941 patent would include all of the claims of the '941 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. 22–26; *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. Indeed, Patent Owner argues that the prior art cited in the Petition has "already entered the ITC case." Prelim. Sur-reply 1 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, we determine that 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 6, 14. "If a petitioner is unrelated to a defendant in an earlier court proceeding, the Board has weighed this fact against exercising discretion to deny institution under *NHK*." *Id*. at 13–14.

Petitioner is the defendant in the Texas Litigation and the respondent in 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 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, which favors institution." *Id.*

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. 27. Patent Owner also contends that Petitioner "raised claim construction disputes at the ITC that it did not include in its Petition and proposed a different construction for the 'discordance' term than what it asserted in the Petition." *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" and applied 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.

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 proceedings 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.")(internal footnotes omitted).

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. 27. 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. 27 (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 inconsistent definitions of the person of ordinary skill in the art ("POSA"). 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 determine that it is not necessary to construe any claim terms. *See infra* § III.C. As to the possibility of inconsistent POSA definitions, again, it does not appear that the definition of the POSA 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 infra* § III.B (discussing this issue). To the extent Dr. Chaitman does not qualify as one of ordinary skill under the definition adopted by the ITC, which requires "at least five years of relevant work experience designing wearable devices and/or sensors for measuring physiological signals or parameters of mammal" (Prelim. Sur-reply 5),[7] we

[7] Patent Owner cites to Exhibit 2010 as providing the ITC's claim construction and definition of the POSA. Prelim. Sur-reply 5. Exhibit 2010, however, appears to be patent prosecution material from U.S. Patent

note that we do not require a perfect match between an expert's experience and the relevant field. *See* Trial Practice Guide at 34 (citing *SEB S.A. v. Montgomery Ward & Co.*, 594 F.3d 1360, 1373 (Fed. Cir. 2010)). A person may not need to 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. 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

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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.

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.[8] *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 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).

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

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 ("POSA") 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).

Ex. 1003 ¶ 10 (Dr. Chaitman testimony defining the POSA based on his "knowledge and experience in the field and [his] review of the '941 patent and file history"). 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.*

Patent Owner argues that the '941 patent encompasses "'systems, devices, and methods for cardiac monitoring' and the use of 'portable computing devices' that are specifically configured to 'predict or identify the occurrence of arrhythmias.'" Prelim. Resp. 9 (citing Ex. 1001, 1:26–33). 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 requires specialized engineering skills that a cardiologist may or may not possess in his or her background." *Id.* (quoting

Ex. 2001 ¶¶ 51–52). Patent Owner thus 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 ¶ 53), *see also, id.* at 9–10 (further citing Ex. 2004, 6 (Petitioner's proposed POSA 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 9–11. 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 9; 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, 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, [and] large scale multinational clinical trials testing different treatment strategies." Ex. 1003 ¶ 7. He further testifies: "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 note that 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.,* No. 10-CV-1835 JAP TJB, 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 ¶¶ 52–53 (emphasis added).[9] Indeed, considering that the claims of the '941 patent relate to, e.g., "method[s] of cardiac monitoring" to "confirm a presence of the arrhythmia," we find it reasonable that one of ordinary skill in the art would encompass a multidisciplinary team including a cardiologist. Ex. 1001, 17:1–18.

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.

[9] Further supporting the concept of a multidisciplinary team, we note that Lee-2013, a prior art reference relied upon in one of Petitioner's three grounds and entitled "Atrial Fibrillation Detection using a Smart Phone," is authored by a group comprised of three people from the Department of Biomedical Engineering at Worcester Polytechnic Institute, and two people from the Department of Medicine at the University of Massachusetts, Worcester. Ex. 1011, 1.

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))).

Petitioner offers a construction for the claim term "discordance." Pet. 8–10. Patent Owner does not identify any claim terms as requiring construction and, in the ITC Investigation, proposed "[n]o construction required" for the term "discordance." Ex. 2009, 4. At this stage of the proceeding, we determine that no term requires construction in order for us to determine whether to institute review. *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

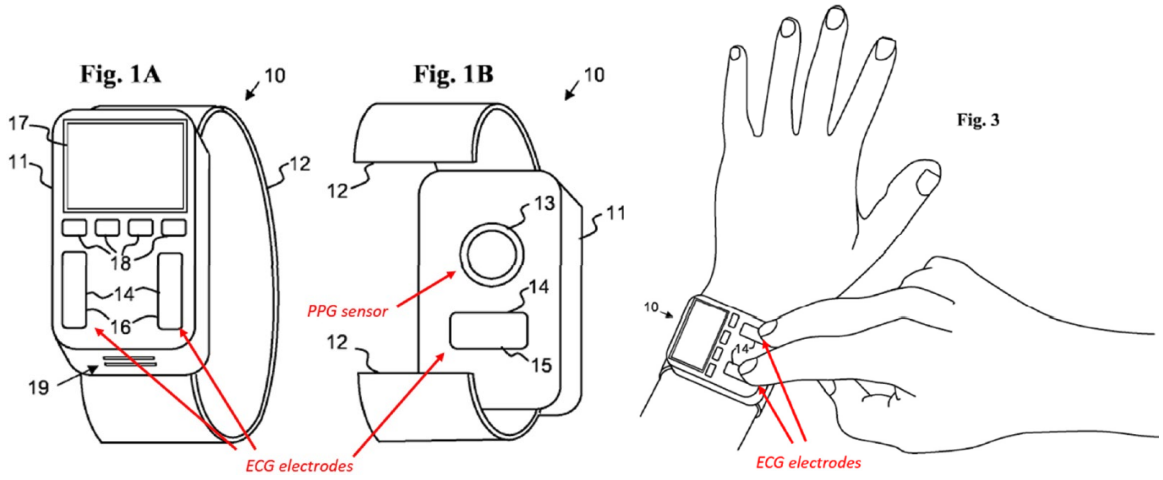
As Ground 1, Petitioner asserts that claims 1, 5, 7–9, 11, 12, 16, 18–20, 22, and 23 are unpatentable as obvious over the combination of Shmueli and Osorio. Pet. 11–65; *see id.* at 31–53 (claim 1), 54–60 (claims depending from claim 1), 60–63 (claim 12), and 63–65 (claims depending from claim 12). We begin with an overview of Shmueli and Osorio.

1) Overview of Shmueli (Exhibit 1004)

Shmueli is a publication of an international application under the Patent Cooper Treaty that published on October 18, 2012. Ex. 1004, code (43). Shmueli addresses "solutions . . . for monitoring infrequent events of irregular ECG." Ex. 1004, 2.[10] Shmueli's solutions include body-worn cardiac monitoring devices "equipped with two types of sensing devices:

[10] We refer to native pagination wherever possible.

an[] oximetry (SpO_2) measuring unit and an ECG measuring unit." *Id.* at 9.[11] 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 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 SpO_2 at least one of a wrist and a

[11] Shmueli uses the terms oxygen saturation in the blood, blood oxygen saturation, pulse oximeter, oximetry, SpO_2, as synonymous with photoplethysmography, except where otherwise specified. *Id.*

> finger of the subject, detecting an irregular heart condition from the SpO_2 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 (citations omitted). Shmueli further explains that the use of oximetry in combination with ECG measurements is also known in the art. *Id.* (citations omitted). Shmueli states, for example, that "US patent No. 7,598,878 (Goldreich) describes a wrist mounted device equipped with an ECG measuring device and a SpO_2 measuring device." *Id.* However, Shmueli notes "Goldreich does not teach interrelated measurements of ECG and SpO_2" 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.

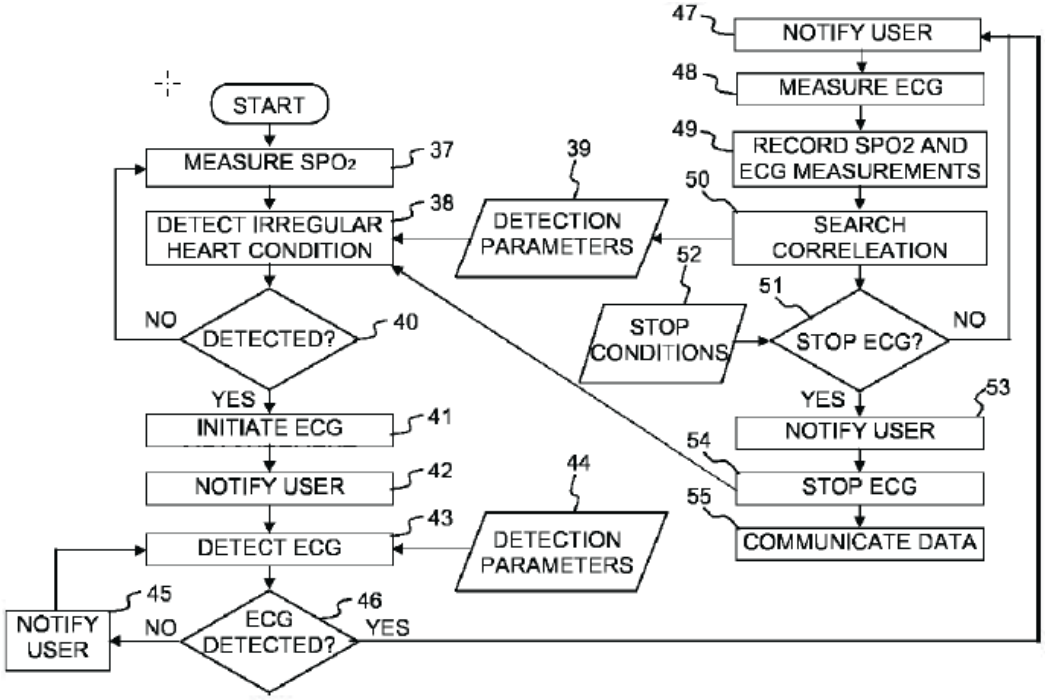
Id. Consistent with this disclosure, Shmueli claims:

> 1. A method for triggering measurement of electrocardiogram (ECG) signal of a subject, the method comprising the steps of:
>
> continuously measuring SpO_2 at least one of a wrist and a finger of said subject;
>
> detecting an irregular heart condition from said SpO_2 measurement;

notifying said subject to perform an ECG measurement; and

initiating ECG measurement at least partially at said wrist.

Shmueli's 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 7; *see also id.* at 12–13 (further describing the steps of the software program illustrated in Figure 7).

2) Overview of Osorio (Exhibit 1005)

Osorio is a U.S. Patent Application Publication that published September 18, 2014. Ex. 1005, code (43). 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. 1015 ¶ 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"), ¶ 66 ("The dynamic relationship between non-pathological HRVs and activity levels may be exploited to detect pathological states such as epileptic seizures"). Consistent with the body of its specification, for example, 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. *Cf. also* Osorio claims 14 and 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 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.

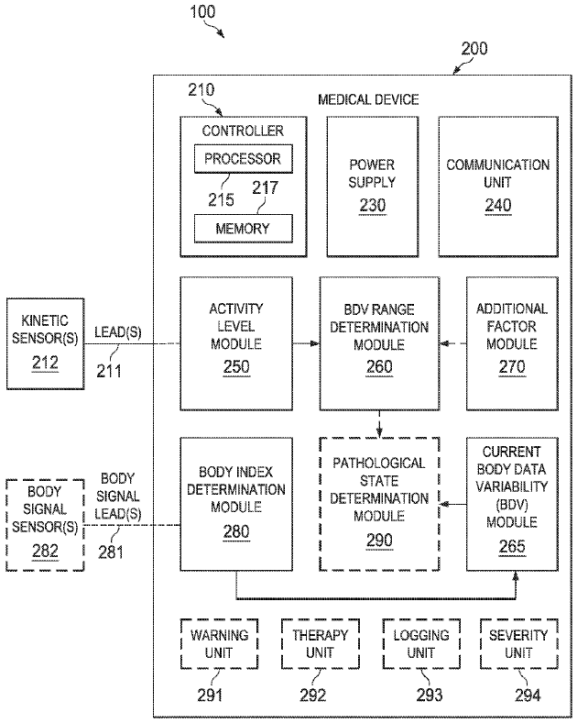


FIG. 1

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.* "The medical device system 100 may be fully or partially implanted, or alternatively may be fully external." *Id.*

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

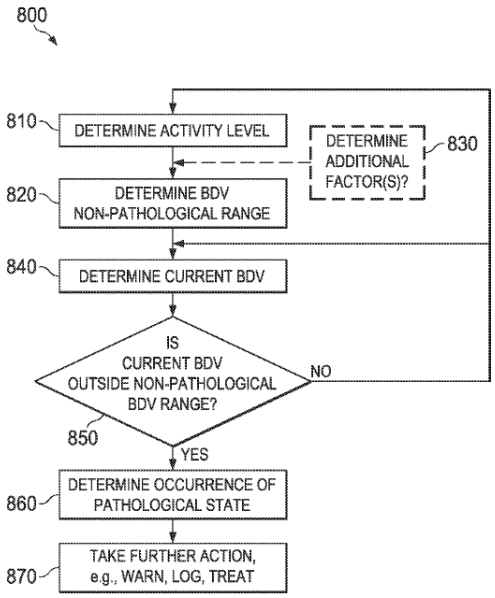


FIG. 8

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 CO_2 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.

Osorio's Figure 4A, reproduced below, relates the BDV of heart rate variability to the risk of having an epileptic seizure. *See id.* ¶ 58.

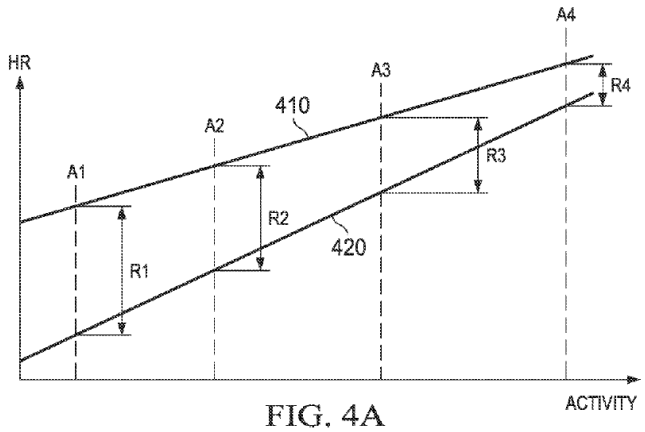


FIG. 4A

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 though 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[12] 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.

3) Analysis of Ground 1

Petitioner contends that the combination of Shmueli and Osorio discloses or renders obvious each element of claims 1, 5, 7–9, 11, 12, 16, 18–20, 22, and 23, and sets forth an element-by-element comparison of the asserted art to the challenged claims. Pet. 11–64. 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." Pet. 20 (citations omitted). Petitioner contends that it was "well-known that activity level is related to HR and HRV." *Id.* (citing evidence). Petitioner then points to Osorio as evidence of the "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). Petitioner contends that in view

[12] "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/.

of these benefits, a POSA "would have been motivated to incorporate Osorio's activity sensor and activity level analysis techniques into Shmueli's heart monitoring device." *Id.* (citing Ex. 1005 ¶ 29; Ex. 1003 ¶ 69).

Petitioner contends that the POSA would have incorporated two specific teachings from Osorio in a modified version of Shmueli's device: "(i) using activity level monitoring to improve the accuracy of detecting a pathological event (e.g., arrhythmia), and (ii) determining HRV from HR and using HRV to detect the pathological event (e.g., arrhythmia)." *Id.*

Petitioner shows, based on this preliminary record, where each of the limitations of the challenged claims is taught or suggested by the combination of Shmueli and Osorio. Pet. 11–64. Petitioner's assertions above are backed by the cited prior art and by the testimony of its declarant, Dr. Chaitman. *Id.*; *see also* Ex. 1003 ¶¶ 68–150. On this preliminary record, we determine that Petitioner's arguments and evidence are sufficient for purposes of institution. We focus our discussion on Patent Owner's arguments that Petitioner has not sufficiently supported a motivation to combine Shmueli and Osorio and that Shmueli and Osorio do not disclose "key elements" of the independent claims. Prelim. Resp. 30–42.

Each of the challenged claims require "confirm[ing]" the "presence of . . . arrhythmia." Ex. 1001, 17:16–17 (independent claim 1), 18:17–18 (independent claim 12). Patent Owner contends that Ground 1 fails because "Shmueli does not once mention 'arrhythmia' instead referring to an 'irregular heart condition,' which, as [Petitioner] admits, is not a standard term in medicine." Prelim. Resp. 31 (citing Ex. 1004; Pet. 14; Ex. 2001 ¶ 69). 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.* at 31–32. In this respect Patent Owner's declarant, Dr. Efimov, testifies 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 ¶ 69.

At this stage of the proceeding, however, 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 ¶ 54 (citing Ex. 1004, Abstract, Fig. 8; 8:23–28). And although Shmueli "offers an expansive definition of the '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.* 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. 13–14 (citing, *e.g.*, Ex. 1003 ¶ 54).

Patent Owner contends that Ground 1 fails because "[n]either reference [referring to Shmueli and Osorio] specifically discloses detection of arrhythmias" and, thus a POSA would not "look to Shmueli and Osorio, in combination, to solve the problem of detecting potential tachyarrhythmias using the combination of sensors disclosed in the '941 patent." Prelim. Resp. 32 (citing Ex. 2001 ¶ 7). We do not find this argument availing. As

discussed above, Petitioner has shown sufficiently that, although Shmueli broadly refers to the detection of an "irregular heart condition" as opposed to the less expansive, art-standard term "arrhythmia," one of ordinary skill in the art would have understood that Shmueli discloses both detecting arrhythmia based on PPG data and confirming the diagnosis with an ECG measurement. Osorio further discloses monitoring heart rate for episodes of tachycardia and bradycardia, and, more generally, monitoring a patient for "the emergence of one or more cardiac arrhythmias." Ex. 1005 ¶¶ 46, 71.

Patent Owner further contends that Ground 1 is predicated on improper hindsight insofar as Petitioner has not shown that one of ordinary skill in the art would have been motivated to modify Shmueli to incorporate Osorio's teachings regarding activity level monitoring. Prelim. Resp. 31–39. Patent Owner argues 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." *Id.* at 32–33 (citing Ex. 2001 ¶ 73). Patent Owner also argues that Osorio teaches away from the invention claimed in the '941 patent because it teaches that some sensors "may be fully or partially *implanted*" in a patient, and implantation is inconsistent with a wearable device. *Id.* at 33 (citing Ex. 1005 ¶ 33; Ex. 2001 ¶ 74) (emphasis omitted). Patent Owner further 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 as "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 35, 37 (citing Ex. 2001 ¶¶ 76–77). We do not find Patent Owner's argument availing on the present record.

As set forth in section III.E.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 refer[ence] 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 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). Absent additional and persuasive evidence, we decline to read an alternative 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").

As discussed above, Shmueli broadly refers to "irregular heart condition" rather than the more specific "arrhythmia." Nevertheless, Petitioner has shown sufficiently that one of ordinary skill in the art would have understood Shmueli to disclose detecting arrhythmia based on PPG

data and confirming the diagnosis with an ECG measurement. In addition Petitioner persuasively argues that Osorio discloses certain benefits of incorporating a patient's activity level to detect an irregular heart condition. *See* Pet. 20 (citing Ex. 1005 ¶¶ 29, 36; Ex. 1003 ¶¶ 69–85).

Patent Owner argues that the "Shmueli-Osorio combination fails to teach the limitation requiring a determination that a discordance is present between the activity level value and the heart rate parameter." Prelim. Resp. 40. According to Patent Owner:

> Osorio teaches calculation of non-pathological "body data variability" (BDV) ranges in a "BDV range determination module" that is based, at least in part, on the calculated activity level. *Id.* at [0036]-[0041], [0077], Fig. 1, 8; Ex. 2001 at 79. Then, after the nonpathological BDV range is determined, an actual BDV value of the patient is determined in the current BDV module. *Id.* at [0043], [0077], Fig. 1, 8; Ex. 2001 at 79. The calculated actual BDV value is then compared against the previously calculated BDV range to determine a pathological state. *Id.* at [0044]-[0050]; Ex. 2001 at 79. Thus, Osorio fails to teach a medical device that compares activity level and HRV.

Id.

On this preliminary record, Petitioner sufficiently shows that Osorio discloses the disputed limitation. For example, Petitioner points to Osorio's Figure 4A, reproduced below as annotated by Petitioner.

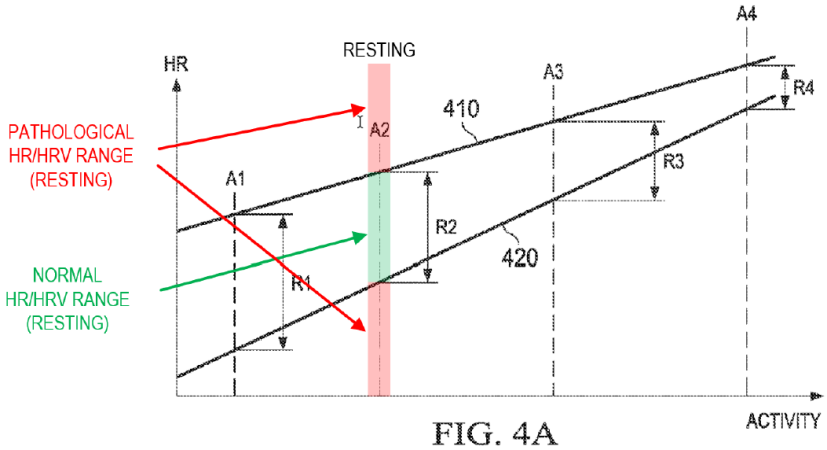


FIG. 4A

Pet. 44. "FIG. 4A shows a dynamic relationship between non-pathological patient activity levels (e.g., as determined from a tri-axial accelerometer) and an exemplary body data and BDV (e.g., heart rate and HRV)." Ex. 1005 ¶ 57. In Figure 4A, a "patient's activity level is shown on the x-axis, HR is on the y-axis, and HRV is represented by bars R1–R4," which span the gap between "upper non-pathological HR boundary line 410 and lower non-pathological HR boundary line 420." *Id.* ¶¶ 57, 58. Petitioner has annotated Figure 4A to highlight the normal HR/HRV range for resting activity level A2 in green and to highlight the pathological HR/HRV range for resting activity level A2 in red. Pet. 44.

Petitioner explains, and we agree, that in Figure 4A, "the resting awake activity level A2 corresponds to the 'activity level value' and either of the measured HR/HRV corresponds to the 'heart rate parameter.'" *Id.* (emphasis removed). Petitioner further explains, and we further agree, that "a determination that the measured HR/HRV value [is] greater than upper non-pathological HR boundary line 410 or less than lower non-pathological boundary line 420 corresponds to '*determining . . . that a discordance is present.*" *Id.* at 46 (emphasis removed).

It appears Patent Owner may be arguing that Osorio does not disclose "determining . . . that a discordance is present between the activity level value and the heart rate parameter" because it discloses only sequential measuring of the claimed "activity level value" and "heart rate parameter." Prelim. Resp. 40 (Arguing that "[t]he calculated BDV value is then compared against the previously calculated BDV range to determine a pathological state" and [t]hus, Osorio fails to teach a medical device that compares activity level and HRV."). To the extent this is Patent Owner's argument, we do find it persuasive.

As an initial matter, we note that claim 1 does not appear to require that the "heart rate parameter" and "activity level value" be sensed in any particular order. Claim 1 requires "determining, by a processing device, that a discordance is present between the activity level value and the heart rate parameter." Ex. 1001, 17:7–10. On its face, we do not read this (or similar language in independent claim 12)[13] as excluding a process in which the activity level value and the heart rate parameter are sensed in any particular sequence. Nor has Patent Owner argued that such a construction is supported in the Specification or relevant prosecution history. *Cf.* Pet. 46–47 (arguing that the discordance determination step does not require simultaneous sensing of the "heart rate parameter" and "activity level value"). At this point in the proceeding, we do not find it necessary to expressly construe this claim because, as discussed below, we agree with Petitioner that the prior art renders this step obvious even under the construction implicitly advanced by Patent Owner. The parties are, nevertheless, welcome to brief the construction of this term at trial.

[13] Patent Owner does not address claims 1 and 12 individually.

The preliminary record supports that it would have been obvious to simultaneously measure a "heart rate parameter" and an "activity level value." As Dr. Chaitman explains, "Osorio teaches that 'one must take into account the type and/or level of activity being performed by a subject **at the time** the pathological/nonpathological determination is made[]' in order to make determinations with 'a clinically worthwhile degree of accuracy and reliability . . . .'" Ex. 1003 ¶ 113 (citing Ex. 1005 ¶ 29). From this disclosure, Dr. Chaitman concludes that a POSA "would have found obvious that Osorio contemplates simultaneously measuring these parameters to allow its monitoring device to 'know whether or not a given increase in heart rate is associated with a change in activity.'" *Id.* On this preliminary record, we agree with Dr. Chaitman that Osorio supports that it would have been obvious to measure a "heart rate parameter" and an "activity level value" simultaneously.

Finally, Patent Owner argues that the combination of Shmueli does not disclose the step of "receiving electric signals of the user from an electrocardiogram sensor ('ECG') on the smartwatch to confirm a presence of the arrhythmia" (Ex. 1001, 17:14–16 (claim 1); *see also, id.* at 17:17–18 (claim 12, reciting similar language)) because the analysis of the ECG signal occurs on a remote server rather than on the claimed device itself (Prelim. Resp. 41). As support, Patent Owner characterizes Shmueli as teaching "that it is '[t]he remote server' that then 'further analyzes the data.'" *Id.* (referencing Ex. 1004, 15). Patent Owner argues that "[b]ecause the only analysis of the ECG data disclosed in Shmueli occurs at a remote server, Shmueli does not disclose the idea of confirming the presence of the arrhythmia on a wearable device as required by the independent claims of

the '941 patent." *Id.* (citing Ex. 2001 ¶ 83–84). We do not find Patent Owner's argument availing on the current record.

As an initial matter, claim 1 recites "[a] method of cardiac monitoring, comprising . . . receiving electric signals of the user from an electrocardiogram sensor ('ECG') on the smartwatch to confirm the presence of the arrhythmia." Ex. 1001, 17:1–19. Claim 12 similarly recites "[a] smart watch, comprising . . . a computer program including instructions executable by the processor to cause the processor to . . . receive electric signals of the user from the ECG sensor to confirm the presence of an arrhythmia." *Id.* at 17:53–18:18. As claims 1 and 12 are drafted using "comprising" language, we do not read them to exclude "further analy[sis]" of EEG data on a remote server. *See* Ex. 1004, 15; *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1319 (Fed. Cir. 2009) ("The claim uses the term 'comprising,' which is well understood in patent law to mean 'including but not limited to.'").

Further, Shmueli states that "the wrist-mounted heart monitoring device preferably transmits to the remote server the collected data, such as the recorded ECG measurement" whereupon the "remote server preferably *further* analyzes" collected ECG data." *See* Ex. 1004, 14 (emphasis added). Shmueli's disclosure that any ECG data transmitted to a remote server is *further* analyzed presupposes that the data is first analyzed prior to transmission. In this respect, we note that the software program illustrated in Shmueli's Figure 7 includes "element 48 to perform the ECG measurement and to element 49 to record the SpO_2 and the ECG measurements and preferably store them in the memory unit 28." Ex. 1004, 12. The program may then

> proceed[] to element 50 to search for correlations between the SpO_2 signal and the ECG signal to produce new detection parameters, or modify existing detection parameters, so as to enhance the detection algorithms of the irregular heart conditions. Searching for correlation (element 50) can be executed in real-time (together with elements 37, 47 and 49) or later after the ECG measurement is concluded.

Id. at 13. Shmueli further teaches that "[t]he SpO_2 measurement, the ECG measurement and their recordation and storage (elements 37, 47 and 49 respectively) are continued and performed in parallel until a stopping condition is met." *Id.* Conditions for stopping the ECG measurement include a determination that "[t]he irregular heart condition has stopped," at which point "the software program preferably notifies the user that the ECG measurement has stopped." *Id.*

According to Petitioner, "Shmueli criticizes other heart monitoring devices for 'not consider[ing] a requirement to 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.'" Pet. 53 (quoting Ex. 1004, 8:21–29). Petitioner thus contends that a POSA would have recognized "Shmueli's focus on enabling ECG measurements 'as soon as' an irregular heart condition is detected." *Id.* (citing Ex. 1004, 13:16–21; Ex. 1003 ¶ 121). Accordingly, Petitioner argues, a POSA "would have found it obvious that the Shmueli-Osorio device uses ECG data measured by the ECG measurement unit 31 ("electrical signals of the user") to "confirm" an irregular heart condition, such as an intermittently-occurring arrhythmia ("presence of the arrhythmia"). *Id.* (emphasis removed). On the present record, we agree.

In light of the above, we find that the record also sufficiently supports Petitioner's contention that Shmueli renders obvious at least one claim of the '941 patent.

E. Ground 2: Obviousness over Shmueli, Osorio, and Lee-2013

As Ground 2, Petitioner challenges claims 2–4, 6, 13–15, and 17 as obvious over the combination of Shmueli, Osorio, and Lee-2013. Pet. 65–72, Petitioner provides an element-by-element comparison of the asserted art to the challenged claims. *Id.* Petitioner provides documentary and testimonial evidence to back its assertions. *Id.*; *see* Ex. 1003 ¶¶ 151–170. Patent Owner does not contest this ground separately with particularity beyond asserting that Lee-2013 does not "correct the deficiencies addressed above with the Shmueli-Osorio combination." Prelim. Resp. 42. Also, if trial is instituted it must be instituted on all challenged claims and grounds. *See SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348, 1354 (2018).

F. Grounds 3: Obviousness over Shmueli, Osorio, and Chan

As Ground 3, Petitioner challenges claims 10 and 21 as obvious over Shmueli, Osorio and Chan. Petitioner provides an element-by-element comparison of the asserted art to the challenged claims. *Id.* Petitioner provides documentary and testimonial evidence to back its assertions. *Id.*; *see* Ex. 1003 ¶¶ 171–177. Patent Owner does not contest this ground separately with particularity beyond asserting that Lee-2013 does not "correct the deficiencies addressed above with the Shmueli-Osorio combination." Prelim. Resp. 42. Also, as noted above, if trial is instituted it must be instituted on all challenged claims and grounds. *See SAS Inst.*, 138 S. Ct. at 1354.

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 '941 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.

V. ORDER

ORDERED, pursuant to 35 U.S.C. § 314(a), an *inter partes* review of claims 1–23 of the '941 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 '941 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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