

**Appeal Nos. 23-1512, -1513, -1514**

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**United States Court of Appeals**

*for the*

**Federal Circuit**

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ALIVECOR, INC.

*Appellant,*

v.

APPLE INC.

*Appellee.*

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On Appeal from the United States Patent and Trademark Office,  
Patent Trial and Appeal Board  
Nos. IPR2021-00970, IPR2021-00971, and IPR2021-00972

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**REPLY BRIEF OF APPELLANT ALIVECOR, INC.**

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## INTRODUCTION

Unable to dispute that its Petition expert has no qualifications in machine learning (“ML”), Apple treats its own proffered expert testimony as irrelevant and is reduced to arguing that AliveCor’s ML claims are obvious, regardless of their scope. Apple’s arguments are agnostic as to whether the claims apply ML to PPG (as expressly required) or ECG data, and whether a POSITA would have been motivated to combine the ML references that Apple included in its grounds. Apple thus would have this Court affirm obviousness of the ML claims by disregarding the lion’s share of evidence submitted in the proceedings below. The evidence, when viewed as a whole, is insufficient to support a finding of obviousness.

Apple’s arguments in connection with the “confirm” limitations fare no better. Apple asks this Court to affirm a decision that reads disclosures into Shmueli that simply are not there, and, indeed, are not in the Board’s analysis. The Board never explained why the claimed “confirm” maps to Shmueli’s search correlations. This is unsurprising, because they do not.

Finally, Apple is unable to justify its failure to produce known relevant evidence of secondary considerations, as required by the Board’s rules. Apple’s non-compliance with its disclosure obligations was highly prejudicial to AliveCor and led the Board to reach its obviousness determinations on an incomplete record.

At the very least, this Court should vacate the decisions and remand for further proceedings.

## ARGUMENT

### **I. APPLE IS UNABLE TO IDENTIFY SUBSTANTIAL EVIDENCE SUPPORTING THE BOARD’S MACHINE LEARNING RULINGS**

#### **A. Apple Offered No Reliable Expert Testimony Or Other Evidence On ML**

Apple concedes (Br. 21, 42) that its Petition expert, Dr. Chaitman, is unqualified to render ML opinions. His testimony thus holds no weight with respect to ML. *Kyocera Senco Indus. Tools Inc. v. Int’l Trade Comm’n*, 22 F.4th 1369, 1376-77 (Fed. Cir. 2022). Instead, Apple ignores its expert, arguing that the claims are invalid irrespective of expert testimony. But these fallback arguments rely on a misreading of cases that are in any event inapplicable and thus cannot salvage the Board’s ruling. This error alone warrants reversal of the Board’s ruling on the ML claims of the ’499 and ’731 patents.

#### **1. Dr. Chaitman’s Opinion Testimony Was Irrelevant And Unreliable**

Apple’s only rebuttal to Dr. Chaitman’s conceded lack of expertise is to note (Br. 43-44) “his extensive literature review” to prepare his expert declaration and his “attempts to understand arrhythmias using [ML] techniques” (*i.e.*, he used clinical tools for AFib detection that employed ML). This turns the standard for expert testimony on its head: Expert opinion must be based on “specialized knowledge,

training, or experience.” *Kyocera*, 22 F.4th at 1377. One does not “become an expert on a topic simply by testifying about it in court .... [A]n expert must have specific knowledge, not mere capacity to acquire knowledge.” *Doe v. AE Outfitters Retail Co.*, 2015 WL 9255325, \*5 (D. Md. Dec. 17, 2015) (quotation omitted). Likewise, “a person does not become an expert simply by reviewing an expert’s reports or research.” *Larson v. Kempker*, 414 F.3d 936, 941 (8th Cir. 2005). But that is essentially what Apple suggests Dr. Chaitman did here. His testimony cannot, therefore, be used to establish obviousness. *See, e.g., Sundance, Inc. v. DeMonte Fabricating Ltd.*, 550 F.3d 1356, 1362 (Fed. Cir. 2008) (“Admitting testimony from a person ... with no skill in the pertinent art[] serves only to cause mischief and confuse the factfinder.”). Otherwise, anyone could become an expert simply by reviewing certain documents in the midst of litigation.

Apple also leans (Br. 41) into the Board’s finding (Appx83) that “one of ordinary skill in the art with an understanding of cardiac monitoring technology” would “understand how these types of data work.” But this finding is unsupported and illogical: Using a technology does not render one an expert in how that technology works, just as driving a car does not make one an expert mechanic.

Apple cites *Carnegie Mellon Univ. v. Marvell Tech. Grp., Ltd.*, 807 F.3d 1283, 1303 (Fed. Cir. 2015) (*see* Br. 44), for the proposition that “[e]xperts routinely rely upon other experts’ or other facts or data ‘for expertise outside of their field.’” But



*Carnegie Mellon* simply recognizes that *an expert qualified in one field* may rely on other experts, facts, or data from another field to help them provide an opinion *relevant to their field of expertise*. Thus, in *Carnegie Mellon*, this Court held it was appropriate for CMU’s *damages* expert to rely on CMU’s *technical* experts for non-damages information when rendering damages opinions. 807 F.3d at 1303. In contrast, Dr. Chaitman is an expert in cardiology, not ML, and can only offer opinions within the scope of his expertise regardless of how many articles he read on ML when preparing his expert declaration. And even if *Carnegie Mellon* could be stretched to permit expertise to be gained through an expert’s work on a case, as Apple wrongly suggests, it would still not support the Board’s reliance on Dr. Chaitman because, as *Carnegie Mellon* also holds, any knowledge gained through Dr. Chaitman’s “extensive literature review” (Br. 43) would need to “be demonstrated by mastery displayed in [his] analysis” on ML. 807 F.3d at 1303. Dr. Chaitman displayed no such mastery. Even after his review, Dr. Chaitman lacked any understanding of basic ML terms used in the patents. *See AliveCor* Br. 16-17, 31-32. Thus, he still—as even Apple admits (Br. 43)—has no ML expertise. That, too, is fatal under *Carnegie Mellon*.

Nor can Apple salvage the Board’s reliance on Dr. Chaitman by pointing (Br. 42, 44) to its finding (Appx83-84) that ML skills “are not prerequisites for qualifying a [POSITA] for this proceeding.” This ruling lacks substantial evidence, as the

dependent claims—which specifically require ML algorithms—necessitate expertise in ML. Indeed, the Board also found that “programming skills”—referring to ML—are “relevant to the implementation of certain of the challenged claims,” and that *Dr. Chaitman lacks those skills*. Appx83-84 (noting “neither of the parties’ experts possesses advanced skills in” ML). Apple admits (Br. 21, 42) as much. Thus, Dr. Chaitman is unqualified to render an opinion on any of the claims directed to ML, and the Board’s contrary ruling was legal error. *See, e.g., Sundance*, 550 F.3d at 1362.<sup>1</sup>

Indeed, even Apple’s ITC expert (Dr. Stultz) agreed that ML is “very complex” and are “black box entities” (Appx8287 (211:10-22)), which further demonstrates that Dr. Chaitman’s testimony cannot support a finding of obviousness. Apple attempts to avoid Dr. Stultz’s testimony (Br. 44-45) by arguing that it was “specific to deep learning” and “not other areas within machine learning.” Dr. Stultz’s testimony on this point, however, is unequivocal—when asked “why are healthcare professionals wary of using [machine] learning for healthcare applications,” he answered: “I think that machine learning—deep learning, very

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<sup>1</sup> At a minimum, the Board’s finding that ML programming skills are relevant to the ML claims is inconsistent with its finding that a POSITA need not possess any ML skills. *See* Appx83-84.

complex machine learning algorithms are black—black box entities.” Appx8287 (211:10-22).<sup>2</sup>

## 2. Apple’s “Other Evidence” Does Not Support Obviousness

Apple fares no better in arguing (Br. 46) that the Board considered “a litany of additional evidence” beyond Dr. Chaitman’s testimony. Apple relies (*id.*) heavily on testimony from its ITC expert, Dr. Stultz, that “the claims recite nothing inventive over what was known in the art because ‘a machine learning algorithm without specifics is nothing more than generic, functional language.’” (Citing Appx110.) But Dr. Stultz did not testify in the IPRs—he was Apple’s *ITC* expert. Moreover, Dr. Stultz gave his ITC testimony in the context of an *Alice* step-two analysis of a § 101 motion, *not* obviousness. Not only did his testimony fail to mention a single prior art reference from the Petition, the ITC **ruled against** Apple, finding that the claims added an inventive concept under *Alice* step two. *See In the Matter of Certain Wearable Electronic Devices with ECG Functionality & Components Thereof*, 2022

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<sup>2</sup> Apple wrongly asserts (Br. 45 n.6) that AliveCor’s expert, Dr. Efimov, was limited to industry-skepticism of deep-learning algorithms because he cited one paper that discusses those algorithms. Dr. Efimov explained the industry skepticism of ML, stating that this paper teaches a POSITA that the nature of ML generally presents an “impediment to their adoption in the clinical community and their use for patients.” Appx7787 (¶ 85); Appx8884 (¶ 103).

Apple also wrongly tries (Br. 21) to excuse Dr. Chaitman’s lack of expertise by arguing that AliveCor’s expert Dr. Efimov similarly lacked that expertise. Appx84. This is unfounded and irrelevant: Obviousness was Apple’s burden.

WL 2981155, \*78 (U.S.I.T.C. July 27, 2022) (“*ITC ID*”). In so doing, the ITC rejected Dr. Stultz’s position that the ML claims merely use generic, functional language. *Id.* Thus, Dr. Stultz’s testimony is not substantial evidence for the Board’s conclusion. *See* Appx110.

None of these facts regarding Dr. Stultz’s ITC testimony are disputed. *See* Br. 47-51. Apple instead argues (Br. 49) that his testimony is nevertheless relevant here because “the § 101 and § 103 inquiries may ‘overlap.’” (Quoting *Berkheimer v. HP Inc.*, 881 F.3d 1360, 1368 (Fed. Cir. 2018).) But this oversimplifies the analysis. Under *Alice* step two, courts consider whether the claim elements “transform the nature of the claim into a patent eligible application.” *Berkheimer*, 881 F.3d at 1367 (quoting *Alice Corp. Pty. Ltd. v. CLS Bank Int’l*, 573 U.S. 208, 217 (2014)). This second step is satisfied if the claim limitations do more than recite “well-understood, routine, and conventional activities previously known to the industry.” *See id.* (cleaned up). But even if *Alice* step two were not satisfied as Apple argued—*i.e.*, there was no inventive concept—that would not mean the claims are necessarily obvious,<sup>3</sup> and it certainly would not mean the claims are obvious over

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<sup>3</sup> This is because obviousness is a fact-intensive inquiry requiring consideration of, *inter alia*, specific prior art references, the motivation to combine those references, and secondary indicia of obviousness. *See KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007); *Graham v. John Deere Co.*, 383 U.S. 1 (1966). These facts cannot be derived from the § 101 inquiry. Thus, even if the Board was right that the ML claims are “generic,” that still would not lead to a conclusion the claims are obvious in view

specific prior art not considered. Indeed, Dr. Stultz did not consider the specific references at issue here or any of the obviousness factors required under *Graham*. Nor did Dr. Stultz consider whether a POSITA would have been motivated to combine the IPR references. Accordingly, Dr. Stultz’s § 101 ITC testimony is not relevant to the obviousness issues in these IPRs.

*In re NuVasive, Inc.*, 842 F.3d 1376 (Fed. Cir. 2016), which Apple (Br. 50) fails to distinguish, is instructive on this point. There, this Court held that the Board erred in crediting expert testimony that “addresses neither the benefits that could have been obtained by combining the prior art references nor the [POSITA’S] motivation to combine at the time of the invention.” 842 F.3d at 1384. Dr. Stultz’s § 101 ITC testimony fits squarely into this mold, as it does not address any of the obviousness issues presented in the IPRs. At best, Dr. Stultz’s testimony amounts to an argument that the claims are obvious *per se*, which is legally erroneous. *See, e.g., In re Ochiai*, 71 F.3d 1565, 1570-72 (Fed. Cir. 1995) (holding that there are no

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of the cited prior art references. *See Parker v. Flook*, 437 U.S. 584, 593 (1978) (“The obligation to determine what type of discovery is sought to be patented [§ 101] must precede the determination of whether that discovery is, in fact, new [§ 102] or obvious [§ 103].”); *Synopsys, Inc. v. Mentor Graphics Corp.*, 839 F.3d 1138, 1151 (Fed. Cir. 2016) (“The search for a § 101 inventive concept is thus distinct from demonstrating § 102 novelty.”).

“*per se* rules of obviousness” because obviousness is always a “fact-intensive inquiry”).<sup>4</sup>

Apple also asserts (Br. 47) that the Board “considered and cited numerous additional articles and patents” supporting obviousness of the ML claims. But as Apple notes (*id.*), those “articles and patents” merely show that ML was a “popular technique to detect arrhythmia based on heart rate data.” Appx47. That evidence is not tied to the claims at all—instead, it merely relates to ML generally. *See* Appx47.<sup>5</sup> And while Apple maintains (Br. 48) that its obviousness case did not “rest” on Dr. Chaitman’s testimony, it does not dispute that *all* of the “additional” evidence on which it relies was entered into the record through Dr. Chaitman’s declaration—making *Dr. Chaitman* the *sole support* for the significance of the “additional evidence” that the Board cited. *See* Appx42-49 (citing Ex. 1003, Dr. Chaitman’s declaration, for support); *see also, e.g.*, Appx3203-3204 (citing Appx4642); Appx272-277 (showing Exhibits 1001-1055 submitted with Petition for ’499 patent). But because this evidence goes to the state of the art in a field with which

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<sup>4</sup> Relying on generic invalidity testimony, as Apple does here, is impermissible in an IPR—invalidity must be based on specific prior art references. *Qualcomm Inc. v. Apple Inc.*, 24 F.4th 1367, 1377 (Fed. Cir. 2022) (“[I]t is therefore impermissible for a petition to challenge a patent relying on solely AAPA without also relying on a prior art patent.”).

<sup>5</sup> This, again, improperly converts invalidity into a *per se* obviousness test. *See, e.g., Ochiai*, 71 F.3d at 1570-72.

Dr. Chaitman was unfamiliar prior to preparing his expert report here, his testimony cannot render it substantial evidence. *See Sundance*, 550 F.3d at 1362; *supra*, Part I.A.1.

For these reasons, Apple is also wrong to argue (Br. 51) that this Court could affirm the FWDs, even if it disregarded Dr. Chaitman’s unsupported testimony and Dr. Stultz’s irrelevant § 101 testimony, because the Board supposedly “considered extensive additional evidence highlighting the advantages and ease of using [ML] algorithms to detect arrhythmias based on heart data.” As discussed, that evidence is not sufficient to support the Board’s obviousness determination, and it was legal error for the Board to rely on “additional evidence,” instead of prior art references, in finding the claims obvious. *See Qualcomm*, 24 F.4th at 1377.<sup>6</sup>

**B. The Board’s Obviousness Determination Based On Shmueli Lacks Substantial Evidence**

Given the lack of evidence on the ML combinations, Apple shifts gears and argues that Shmueli *alone* renders the claims obvious. In doing so, Apple elevates (Br. 51-56) what had been a single-sentence from its petitions (*see* Appx1002; Appx346)—that Shmueli alone could render the ML claims obvious—into its

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<sup>6</sup> Nor does the single case on which Apple relies (Br. 51) support that result. In *Belden Inc. v. Berk-Tek LLC*, 805 F.3d 1064 (Fed. Cir. 2015), this Court evaluated whether a petitioner’s expert’s reply declaration was “necessary for [Petitioner] to establish a *prima facie* case.” *Id.* at 1078. Here, the non-expert evidence does not supply a *prima facie* case of obviousness.

centerpiece argument for affirming on obviousness. Apple’s shift not only stretches the outer boundaries of the IPR proceedings,<sup>7</sup> it fails on the merits for several reasons.

*First*, there is no analysis supporting the Board’s conclusion that Shmueli alone renders ML obvious. Shmueli does not mention ML, and the Board does not explain why Shmueli’s brief mention of “search correlations,” without more, renders ML obvious. Apple reads ML into Shmueli through the testimony of Dr. Chaitman who, as discussed above, has no ML qualifications, despite his testimony providing the only basis for the Board’s conclusion that Shmueli’s search correlations are ML.

*Second*, Apple argues (Br. 52) that the Board’s finding is supported by its reference to the “state of the art as [a] whole.” Appx111. But the Board did not explain *what* in the art supports finding that a POSITA would understand Shmueli’s search correlations to refer to ML. None of the portions of the FWD Apple cites (Br. 52) provides an answer. *See* Appx110; Appx48. And for good reason: The “state of the art” does not explain what search correlations are.

Apple is thus left to insist (Br. 53) that the Board’s finding is supported by the allegedly “agreed-upon definition” of ML: Algorithms “capable of learning and/or

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<sup>7</sup> *See Click-to-Call Techs. LP v. Ingenio, Inc.*, 45 F.4th 1363, 1369 (Fed. Cir. 2022) (“[I]t is the petition, not the institution decision, that defines the scope of the IPR.”) (quoting *Cal. Inst. of Tech. v. Broadcom Ltd.*, 25 F.4th 976, 990 (Fed. Cir. 2022)).



adapting their structure (e.g., parameters) based on a set of observed data.” Appx1002. To the contrary, AliveCor did not agree to that definition. Below, AliveCor explained that Apple’s ML definition is incomplete, because it is derived from a paper that provides additional detail:

Machine learning, a subdiscipline in the field of artificial intelligence (AI), focuses on algorithms capable of learning and/or adapting their structure (e.g., parameters) based on a set of observed data, *with adaptation done by optimizing over an objective or cost function.*

Appx670-671 (emphasis added). Apple does not argue—and the Board did not find—that Shmueli’s “search correlations” algorithm has “adaptation done by optimizing over an objective or cost function.” Shmueli cannot meet the full definition of ML. Moreover, there is no evidence what “search correlations” are or how, if at all, they are “capable of learning and/or adapting their structure.” Instead, once again Apple’s analysis hinges on Dr. Chaitman’s say-so. Accordingly, there is insubstantial evidence that Shmueli’s search correlations are ML under any definition.

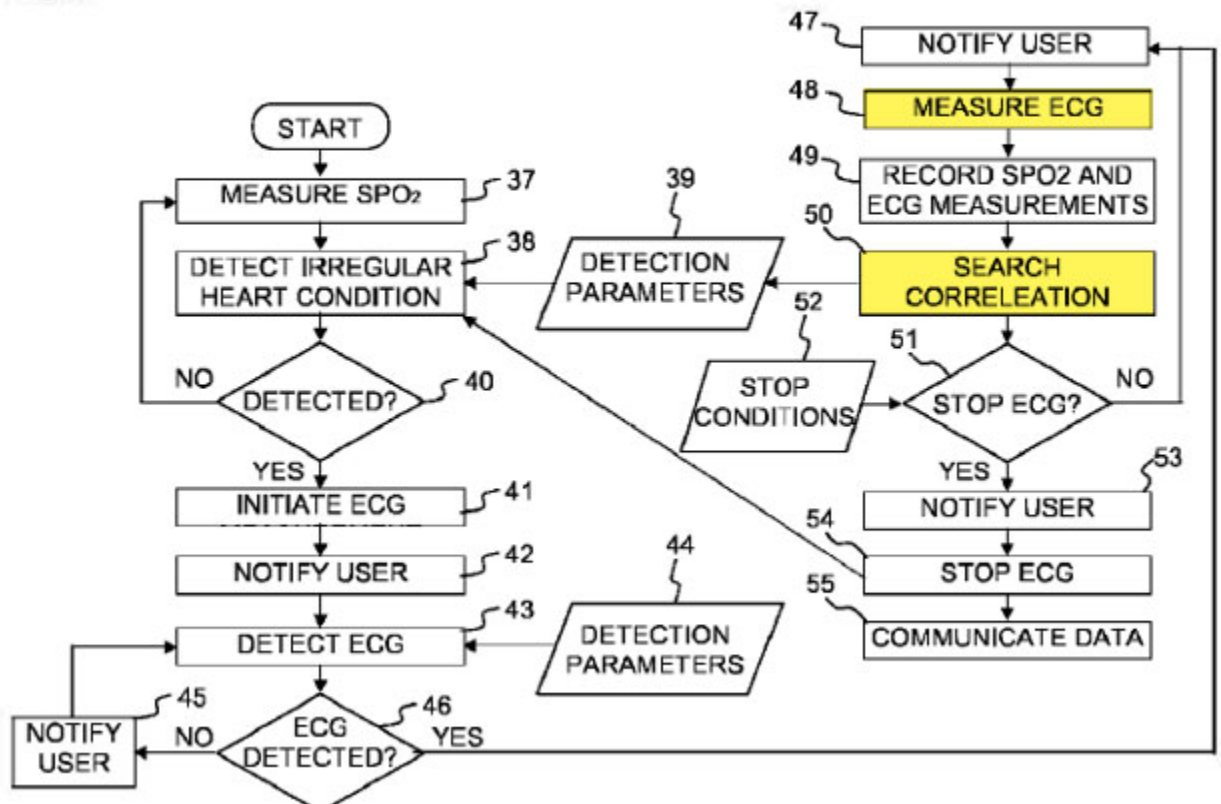
*Third*, Apple wrongly takes issue (Br. 55-56) with the claims’ clear requirement that, at a minimum, ML must be used with PPG data for arrhythmia detection. The ’731 patent’s ML claims expressly recite “input[ting] *the PPG data* into a [ML] algorithm trained to detect arrhythmias.” Appx238 (claim 3). And Apple concedes in its proposed combination that ML is applied to PPG data, not

ECG data, for the claimed arrhythmia detection. Appx1002 (in combination, arrhythmia detection using ML is “based on the PPG data”); *see* Appx986-987.

Similarly, the ’499 patent’s ML claims are also tied to PPG data. Those claims recite “determining a presence of said arrhythmia,” which is done by “comparing ... heart rate variability,” derived from PPG data, to an “activity level” and, *only if there is an irregularity in the heart rate variability (PPG data)*, causing an ECG to be performed. Appx206 (claims 1, 7). And once again, arrhythmia detection (and therefore ML) using PPG rather than ECG data was required by the obviousness combination Apple proposed for the ML claims. Appx348 (in combination, arrhythmia detection using ML is “based on the PPG data”); *see* Appx304-305. Thus, in the proposed combinations for both patents, PPG is taken first, ML is applied to that PPG measurement, and then an ECG is taken second.

In Shmueli, however, as shown in Figure 7, the search correlations (element 50) are unambiguously derived from the *ECG data*, as the search correlations box follows “measure ECG” (element 48) in the flowchart:

Fig. 7



Appx3817.<sup>8</sup> Thus, Apple’s Shmueli ML position—that the search correlations (and therefore the alleged ML) is applied to ECG data—conflicts with its proposed combination.

Apple’s *NuVasive* arguments (Br. 54) merely rehash arguments that AliveCor has addressed above; *NuVasive* supports AliveCor’s position. *See supra*, Part I.A.2.

<sup>8</sup> In Figure 7, “record” means “save.” PPG is measured in element 37.

### C. The Board's Obviousness Determination Based On Li 2012 Lacks Substantial Evidence

Apple fails to rehabilitate the Board's Li 2012 conclusions. *First*, Apple fails to confront the Board's critical factfinding that precludes invalidity based on Li 2012: While the claims of the '731 patent recite using ML with PPG data, Li 2012 teaches a PPG-only embodiment that ***does not use ML***. Appx108 n.22. As the Board stated, this PPG-only embodiment is a "rule-based, heuristic algorithm," not an ML embodiment. Appx108 n.22. Thus, Li 2012 teaches the ***opposite*** of what the claims require—specifically, that when using PPG only to detect an arrhythmia (the claims unquestionably cover using PPG data alone), ML should ***not*** be used. A POSITA therefore would never have found the ML claims obvious in light of that disclosure. Appx8879-8882.

Apple argues (Br. 61) only that this finding is irrelevant because the Board also found that Li 2012 states it is preferable to keep the number of data inputs "as low as possible." Appx109. Based on this lone statement, the Board extrapolated that a skilled practitioner would have found it obvious to adapt Li 2012's ML embodiment to use only PPG data. But there is no need here to speculate what a POSITA would have found obvious, because Li 2012 expressly teaches that when using only PPG data, ML should not be used. Moreover, this ruling also ignores Li 2012's express teaching that removing any data source reduces the effectiveness of its algorithm. *See* Appx3878-3879. Li 2012 thus already teaches the four inputs

that comprise “keep[ing] the number of free parameters ... as low as possible.” Appx3876. The Board, by finding it nevertheless would have been obvious to eliminate all inputs except PPG, engaged in impermissible hindsight. *KSR*, 550 U.S. at 421.

Indeed, the novelty in the claims of AliveCor’s patents centers on applying ML to continuous PPG data for *detection*, while using ECG, sparingly, for *confirmation*. Detection (and by extension ML) is thus applied to PPG data and *not* ECG data (which is only used for confirmation). Applying ML to Li 2012’s combined dataset embodiment, which includes ECG data, is antithetical to these claims, because it would extend the claimed ML beyond detection to confirmation. Therefore, because Li 2012 dictates that *ML should not be used* when the dataset includes PPG but not ECG data, Li 2012’s ML teachings cannot invalidate the claims.

*Second*, the ML claims of the ’731 patent are directed to using ML “to detect the presence of the arrhythmia.” *See, e.g.*, Appx238 (claim 3). Yet the Board found only that it would have been obvious to “confirm” an arrhythmia using ML. Appx111. Apple does not dispute (*see* Br. 56-65) that the Board’s obviousness determination fails to match the claim language—it found the prior art discloses “confirming,” *not* “detecting.” This is dispositive. Apple attempts to justify the Board’s conclusion by arguing (Br. 57) that confirmation requires detection. This

fails because, in the context of the '731 claims, confirming a detected arrhythmia is done *following* an ECG measurement. *See, e.g.*, Appx238 (claim 1). However, the claimed ML algorithms are unambiguously applied to PPG data for detection *prior to* confirmation (*i.e.*, prior to an ECG measurement). *See, e.g.*, Appx238 (claim 3).

**D. The Board's Obviousness Determination Based On Hu 1997 Lacks Substantial Evidence**

Neither of Apple's two primary arguments (Br. 65-71) in defense of the Board's obviousness determination for the '499 patent based on Hu 1997 provides substantial evidence.

*First*, contrary to Apple's assertion (Br. 66-68) and the Board's finding (Appx51-52), applying Hu 1997's ML to ECG data cannot render the claims obvious. As discussed, *supra*, Part I.B-C, the '499 patent's claims require determining the presence of an arrhythmia using heart rate data, and then later, if an irregularity is detected in that data, alerting the user to perform an ECG. Moreover, Apple's proposed combination likewise *requires* that the heart rate data used for detection be PPG, not ECG, data. Appx348. Thus, under Apple's obviousness theory, *prima facie* obviousness cannot be established by applying ML to ECG data.

*Second*, contrary to Apple's argument (Br. 68-71), the Board's finding (Appx46-47) that the claims are rendered obvious by applying Hu 1997's ML to PPG data (whether it includes ECG data or not) has no support in any of the references in Apple's proposed invalidity ground. Indeed, Hu 1997 *does not teach*

*PPG data*; instead, it teaches only ECG data. Appx4801-4810. Accordingly, because none of Shmueli, Osorio, or Hu 1997 teaches applying ML to PPG, there can be no motivation to modify Hu 1997 to apply ML to PPG, contrary to its ECG-only disclosures. Unsurprisingly then, Apple’s motivation-to-combine arguments, which require applying ML to PPG data, are all necessarily derived from external sources, on the back of its expert’s declaration. *See* Appx710-711 (citing Dr. Chaitman (Ex. 1003) for all propositions). As explained above in Part I.A.1, Dr. Chaitman lacks the skill necessary to offer reliable expert testimony on ML. Since Dr. Chaitman’s testimony is the foundation on which Apple’s proffered motivations to combine rests, there is insubstantial evidence to support an obviousness finding. *See Kyocera*, 22 F.4th at 1376-77; *Sundance*, 550 F.3d at 1362.

## **II. APPLE IS UNABLE TO IDENTIFY SUBSTANTIAL EVIDENCE SUPPORTING THE BOARD’S “CONFIRMING” RULING**

### **A. There Is No Evidence That Shmueli Teaches Confirmation Of The Same Arrhythmia**

Apple’s confirmation arguments based on Shmueli’s “search correlations” are pure hindsight. Apple recognizes (Br. 32) that Shmueli does not explain its search correlations but nevertheless argues that a POSITA “would understand to use the collected ECG data for its traditional purpose: to confirm the presence of the suspected arrhythmia.” Apple relies (Br. 32-33) on the fact that Shmueli collects

ECG data,<sup>9</sup> teaches stop conditions for the ECG measurement,<sup>10</sup> discloses “*further analysis*” of ECG data,<sup>11</sup> and teaches “on-device processing.”<sup>12</sup> None of this, however, teaches “detecting” or “confirming” arrhythmia (or, indeed, any irregular heart condition) using ECG data. It is simply not in the reference, and Apple thus has to rely on Dr. Chaitman to improperly gap-fill. *See, e.g., Arendi S.A.R.L. v. Apple Inc.*, 832 F.3d 1355, 1362 (Fed. Cir. 2016) (“[R]eferences to ‘common sense’—whether to supply a motivation to combine or a missing limitation—cannot be used as a wholesale substitute for reasoned analysis and evidentiary support ....”).

Instead, as with ML above (*see supra*, Part I.B), there is no express disclosure in Shmueli, meaning Apple’s “a POSITA would understand” argument is wholly unsupported. As AliveCor has explained (AliveCor Br. 52-56), “search correlations” refers to the process of aligning the PPG and ECG data in time.

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<sup>9</sup> The fact that ECG data is collected does not mean it is used for confirmation. *See* Appx3829.

<sup>10</sup> Shmueli does not expressly disclose that the stop conditions for the ECG measurement are derived from analysis of the ECG data. *See* Appx3830.

<sup>11</sup> Shmueli does not disclose what the “further” off-device analysis is or what, if any, analysis precedes it. *See* Appx3831. One possibility is that no analysis of ECG data is performed on device. Moreover, Apple wrongly assumes, contrary to Shmueli’s disclosure, that “further” analysis refers to ECG data. Shmueli is clear that “the data” analyzed remotely includes “the recorded concurrent SpO<sub>2</sub> measurement,” *i.e.*, the PPG data. Appx3831.

<sup>12</sup> Shmueli teaches only that there *is* an on-device processor, not that “all analysis shown in Figure 7 ‘preferably occurs locally,’” as Apple wrongly asserts. *See* Appx3824.



Appx3830. But neither Apple nor the Board adequately explains *why* the circumstantial evidence on which it relies constitutes confirmation. Instead, Apple’s expert merely asserts—and the Board baselessly found—they are. *See* Appx3462-3464. This conclusory expert testimony does not constitute substantial evidence. *See, e.g., Acoustic Tech., Inc. v. Itron Networked Sol’ns, Inc.*, 949 F.3d 1366, 1375 (Fed. Cir. 2020); *TQ Delta, LLC v. Cisco Sys., Inc.*, 942 F.3d 1352, 1362 (Fed. Cir. 2019).

### **B. Shmueli’s “Search Correlation” Is Vague And Undefined**

Apple also fails to refute AliveCor’s showing that any disclosure in Shmueli of on-device analysis is too vague and non-specific to support an obviousness finding.<sup>13</sup> Apple, in describing AliveCor’s position (*see* Br. 35), accurately captures the full scope of Shmueli’s disclosures with respect to ECG data: “collecting ECG data, applying time stamps, and storing it” and not “analyz[ing] the collected ECG data in any way.”<sup>14</sup> Indeed, Shmueli’s figures undisputedly depict only the following steps with respect to ECG data: “measure ECG” (*i.e.*, collect ECG data),

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<sup>13</sup> Apple’s argument also contains a logical inconsistency. Shmueli’s “search correlations” cannot be both “confirmation” of a detected arrhythmia and also ML trained to detect arrhythmia. Put differently, the search correlations cannot simultaneously be both confirmation and detection; however, that is exactly what Apple’s obviousness theories—and the Board’s conclusions—require.

<sup>14</sup> Further, the claims require that these steps happen on device. Appx238 (“A smart watch to detect the presence of an arrhythmia of a user ....”).

“record SpO<sub>2</sub> and ECG measurements” (*i.e.*, store ECG data), “search correlation” (*i.e.*, apply time stamps), and “communicate data” (*i.e.*, send the data elsewhere for analysis) steps. See Appx3817; *see also supra*, at p. 14 (Figure 7 reprinted). And other than vague mention of “further” analysis (Appx3831) and reference to an on-device processor (Appx3824), Shmueli does not disclose what, if any, analysis happens on device. The only thing that Shmueli discloses that *does* happen on device is “search correlation” step 50. After that, the ECG is stopped, and data is communicated off-device for remote analysis (step 55). Appx3829-3831.

Apple nowhere suggests that Shmueli explains what the “search correlation” *is* or expressly teaches that it is a confirmation. At most, Shmueli obliquely describes a “procedure for identifying correlations between SpO<sub>2</sub> measurement and ECG measurement of a particular subject to detect user-specific irregular heart conditions” (Appx3828) and using that correlation “in said step of detecting an irregular heart condition from said [PPG] measurement” (Appx3829). The *only* mention of any specific correlation is correlating the PPG and ECG signals by time-stamping them. Appx3830.<sup>15</sup>

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<sup>15</sup> Apple asserts (Br. 36) that this is not relevant because it is part of the “recording and storage” step 49 and not the “search correlation” step 50. But that time stamping is the *only* specific disclosure of any kind regarding a correlation between the PPG and ECG signals.

From these vague disclosures, however, Apple *assumes* (Br. 35-36) that Shmueli teaches confirmation,<sup>16</sup> falling back on Dr. Chaitman’s “knowledge, creativity, and common sense” to fill the gaps in the prior art. But as Apple’s own authority makes clear, a POSITA’s “creativity” “cannot be used ‘as a wholesale substitute for reasoned analysis and evidentiary support.’” *Fleming v. Cirrus Design Corp.*, 28 F.4th 1214, 1223 (Fed. Cir. 2022) (quoting *Arendi*, 832 F.3d at 1362). This is especially true “when dealing with a limitation missing from the prior art references specified,” as is the case here with “confirming.” *Arendi*, 832 F.3d at 1362. “Creativity,” therefore, cannot fill gaps in wholly-lacking disclosures.

Apple also misplaces reliance on *Koninklijke Philips N.V. v. Google LLC*, 948 F.3d 1330 (Fed. Cir. 2020). Contrary to Apple’s assertion (Br. 39), this Court did not hold there that expert testimony can “supply [a] missing limitation” in the prior art. Instead, as this Court explained, it is *error* to have creativity “supply a limitation that was admittedly *missing* from the prior art.” *Koninklijke Philips*, 948 F.3d at

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<sup>16</sup> Apple wrongly argues (Br. 37) that Shmueli’s disclosure that search correlations “enhance” arrhythmia-detection algorithms requires that “the system first knows whether the ECG data indicates arrhythmia.” Apple cites no evidence to support this argument, which, in any event, Apple waived by not raising it below. *See Fresenius USA, Inc. v. Baxter Int’l, Inc.*, 582 F.3d 1288, 1295 (Fed. Cir. 2009). And Apple’s fallback (Br. 37) to Shmueli’s “core insight” also fails. Apple is correct (*id.*) that Shmueli uses “PPG data as a screen to trigger *collection* of ECG data.” (Emphasis added.) It does not use PPG data as a screen to trigger *analysis* of ECG data, or *confirmation* as the claims of the AliveCor patents require.

1338 (citing *Arendi*, 832 F.3d at 1361-62) (emphasis added). That is precisely what Apple does here, using Dr. Chaitman’s “creativity” to shoehorn “confirmation” into Shmueli.

Nor can Apple salvage the Board’s conclusory “indirect confirmation” finding by pointing (Br. 38) to two supposedly “explicit disclosures.” Once again, Shmueli merely teaches that there *are* detection parameters, updated as a result of search correlations. Appx3829-3830; Appx3843. Shmueli does not explain what they are or how they are updated as a result of the search correlation step. Instead, whatever these detection parameters are, Apple’s expert Dr. Chaitman admitted that their purpose is to improve the PPG sensor’s ability to detect irregular heart conditions—confirmation is not required for the detection parameters to achieve this purpose. Appx7996-7997 (87:19-88:2). Most importantly, Shmueli does not teach or suggest whether an arrhythmia must be detected or confirmed in the ECG data to update them, as required by the claims. Appx3829-3830; Appx3843. The Board did not find otherwise. *See, e.g.*, Appx94.

### **III. APPLE IS UNABLE TO JUSTIFY ITS FAILURE TO PRODUCE SECONDARY CONSIDERATIONS EVIDENCE**

37 C.F.R. § 42.51(b)(1)(iii) required Apple to produce all “relevant information that [was] inconsistent with” the positions that it advanced before the Board. This obligation was “self-executing and self-enforcing.” *BlackBerry Corp. v. Wi-Lan USA Inc.*, IPR2013-00126, 2013 WL 8695861 (Paper 15) (PTAB Aug.

19, 2013), at 2. It flowed from and was reinforced by Apple’s duty of candor to the Board, *L’Oreal USA, Inc. v. Liqwd, Inc.*, PGR2017-00012, 2017 WL 4340409, \*6 (Paper 37) (PTAB Sept. 27, 2017), which already required Apple to “disclose to the [Board] all information known to [Apple] to be material to patentability,” 37 C.F.R. § 1.56. Section 42.51(b)(1)(iii) is a specific application of that general duty.

Despite these clear obligations, Apple chose not to produce secondary considerations evidence in the IPRs—evidence that the ITC has found to contradict Apple’s claims of obviousness. Apple cannot point to any authority—either from the PTAB or elsewhere—blessing its suggested approach: withholding critical documents from the Board while simultaneously barring AliveCor from bringing them to the Board’s attention. The Court should vacate the decisions if it does not reverse them outright.

#### **A. Apple Violated Its Routine Discovery Obligations**

Apple does not dispute that the ITC has found internal Apple documents bearing on secondary considerations to “weigh[] against a finding of obviousness.” *ITC ID*, 2022 WL 2981155, at \*66. Nor does it contest that it failed to produce those documents below. And it concedes—indeed it produces an email exchange showing—that it wielded the ITC protective order to block AliveCor from bringing the critical documents to the Board’s attention. Appx8814-8819. These omissions and concessions are dispositive on the routine-discovery issue.

Instead, Apple argues (Br. 75) that the secondary considerations evidence was not “inconsistent” with its obviousness positions, because it never specifically mentioned secondary considerations in its filings. That cramped interpretation of section 42.51(b)(1)(iii) is simply wrong. Apple has argued from start to finish that AliveCor’s patents are obvious. And it is that claim of obviousness that the internal Apple documents contradict. To conclude otherwise would flout the blackletter law that secondary considerations of non-obviousness “*must* be considered in every case.” *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1328 (Fed. Cir. 2016) (emphasis added). Consistent with the clear import of section 42.51, the Board itself has held that “petitions may be denied if they do not address known evidence of secondary considerations.” *Stryker Corp. v. KFx Med. LLC*, No. IPR2019-00817, 2019 WL 4419363, \*10 (Paper 10) (P.T.A.B. Sept. 16, 2019); see *Robert Bosch Tool Corp. v. SD3, LLC*, IPR2016-01751, 2017 WL 1096609, \*10 (Paper 15) (Mar. 22, 2017) (“We have cautioned petitioners in prior proceedings that known evidence of secondary considerations should be addressed in the petition.”). The Court should thus reject Apple’s argument that it can on the one hand assert that the patents *are obvious*, but then on the other hand say evidence found *by another tribunal to overcome the prima facie case of obviousness* does not contradict its assertion of obviousness. That logical knot would sap section 42.51(b)(1)(iii) of any force.

Apple's authority (Br. 76-77) does not suggest otherwise. *First*, in Apple's lone case, *Garmin Int'l Inc. v. Cuozzo Speed Technologies, LLC*, IPR2012-0001, 2013 WL 11311697 (Paper 9) (PTAB Mar. 5, 2013), the patent owner sought to serve sprawling discovery requests, including nine interrogatories and ten requests for production going generally to secondary considerations of non-obviousness. *See id.* at \*1. The patent owner sought to classify these "very broad discovery requests as narrowly tailored routine discovery" inconsistent with the petitioner's position. *Id.* at \*2. The Board correctly found that the patent owner failed to pinpoint any specific document known to be inconsistent with the petitioner's position and was simply "cast[ing] a wide net directed to broad classes of information which may not include anything inconsistent with positions taken by Garmin." *Id.* The Board thus rightly concluded that section 42.51(b)(1)(iii) does not authorize broad discovery requests "directed to any subject area in general within which the requesting party *hopes to discover such inconsistent information.*" *Id.* (emphasis added).

*Garmin* thus is about rooting out fishing expeditions masquerading as routine-discovery requests. But the generic-discovery requests in *Garmin* are a far cry away from the internal Apple documents at issue here. AliveCor identified 51 bates-stamped documents relevant to secondary considerations of non-obviousness that Apple should have produced. Appx8815-8817. This is not a *Garmin*-style fishing expedition.

*Second*, Apple misplaces reliance (Br. 77) on the Board’s Trial Practice Guide. The situation Apple cites from the Guide is just meant to “exemplify” what could be inconsistent statements. *PTAB Consolidated Trial Practice Guide*, Nov. 2019 (“TPG”) at (1)(F)(1)(a) at 23. Nothing in the TPG suggests that the list is exhaustive. Moreover, as already explained, the Board itself cautions petitioners to address “known evidence of secondary considerations” independently in their petitions. *Stryker*, 2019 WL 4419363, at \*10. The Board thus expects petitioners, like Apple, to put evidence of secondary considerations forward without waiting for the patent owner to raise it.

*Finally*, Apple wrongly suggests (Br. 77) that AliveCor’s interpretation of section 42.51(b)(1)(iii) would render the TPG’s examples meaningless by requiring petitioner to address secondary considerations in all circumstances. That misconstrues AliveCor’s position. Here, AliveCor advanced secondary considerations at the ITC, where additional evidence was made available under a protective order, which Apple argued prevented AliveCor from seeking production of the same evidence here (*see* Appx8814-8815). Apple knew this evidence existed—indeed, the ITC found it relevant to the non-obviousness of the claims. Thus, Apple should have produced that “known evidence of secondary considerations” pursuant to section 42.51(b)(1)(iii). *Stryker*, 2019 WL 4419363, at \*10; *Robert Bosch Tool*, 2017 WL 1096609, at \*10.



This is a common-sense result. And it ensures that the Board will not be led astray by petitioners seeking to have a more favorable record than exists in other proceedings. As *amicus* points out, agencies and tribunals should make decisions based on the complete record. *Amicus Brief of Medical Device Manufacturers Association*, Dkt. 25 at 4-5. Thus, if the Court does not reverse outright, it should vacate the decisions and remand to allow the Board to consider the full record relevant to secondary considerations.

**B. There Was No Waiver**

Unable to defend its failure to produce secondary considerations evidence under section 42.51(b)(1)(iii), Apple wrongly cries waiver (Br. 72-74) in hopes of avoiding the rule all together. As explained, section 42.51(b)(1)(iii) is a self-executing, ongoing obligation. In fact, “routine discovery does not require any action on the part of” the opposing party. *Nichia Corp. v. Emcore Corp.*, IPR2012-00005, 2013 WL 8149384, \*1 (Paper 19) (PTAB March 26, 2013). Thus, AliveCor’s actions are irrelevant; AliveCor simply cannot waive *Apple’s obligation*. Apple had the obligation to come forward with inconsistent evidence as it becomes known.

Indeed, AliveCor did attempt to gain Apple’s agreement to produce the evidence. Appx8815-8818. Apple, however, short circuited that effort by raising the ITC protective order, arguing that even mentioning the documents to the Board

would violate the protective order. Appx8814-8815. Apple cannot credibly accuse AliveCor of waiver when it was *Apple's own actions* that prevented AliveCor from bringing the documents to the Board's attention.

Apple's suggestion (Br. 73) that AliveCor did not raise this issue with Apple also fails. AliveCor did exactly that. Appx8814-8819. It pointed to the 51 ITC documents as being "relevant, non-public documents regarding secondary considerations of non-obviousness" that should be part of the record in the IPRs. Appx1815. In any event, the case that Apple cites (Br. 73) says only that AliveCor "may communicate" its routine-discovery concerns to Apple, not that it *must* do so. *BlackBerry*, IPR2013-00126, 2013 WL 8695861, (Paper 15) at 2 (emphasis added). And that makes sense because, again, Apple's duties under section 42.51(b)(1)(iii) are self-executing.

As for why AliveCor no longer needs to defer to Apple's protective-order threats (*see* Br. 73), the circumstances have changed since the parties' discussions in January 2022. *See* Appx8815-8819. The protective-order considerations that Apple then raised are no longer relevant because the existence of the secondary considerations evidence was disclosed in the ITC's public order. *See ITC ID*, 2022 WL 2981155, at \*65-66.

Apple also wrongly argues (Br. 74) that AliveCor waived its argument about routine discovery in the PTAB by not moving to modify the ITC protective order. It

cites no authority for this cross-forum waiver theory. In any event, moving in the ITC for modification would have been futile, as Apple well knows. Barely over a year ago, Apple successfully blocked a patent owner's attempt to do exactly what it now claims AliveCor should have done—move to modify an ITC protective order to produce evidence of secondary considerations before the PTAB. *See In re Certified Light-Based Physiological Measurements Devices*, 337-TA-1276, 2022 WL 17090432, \*1-2 (Paper 60) (ITC Nov. 17, 2022). In denying the patent owner's motion on Apple's request, the ITC explained that it would not “depart from Commission practice” of refusing to modify protective orders to allow for disclosure of confidential information before the Board. *Id.* at \*2. This practice stems from the ITC's policy that authorizing “the disclosure of a party's confidential business information in another forum without that party's consent may have a chilling effect on the willingness of parties to produce such information in future investigations.” *Id.* at \*3. There is no reason to think that the ITC would have veered from this customary practice for AliveCor. *See In re Micron Tech., Inc.*, 875 F.3d 1091, 1098 (Fed. Cir. 2017) (“A litigant need not engage in futile gestures merely to avoid a claim of waiver.”) (cleaned up) (quoting *Chassen v. Fidelity Nat'l Fin., Inc.*, 836 F.3d 291, 293 (3d Cir. 2016)).

### **CONCLUSION**

This Court should reverse, or alternatively vacate, the PTAB's FWDs.

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Respectfully submitted,

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**CERTIFICATE OF COMPLIANCE**

Counsel for Appellant AliveCor, Inc. certifies that the brief contained herein has a proportionally spaced 14-point typeface, and contains 6,977 words, based on the “Word Count” feature of Word for Microsoft 365 MSO, including footnotes, excluding the parts of the brief exempted by Fed. R. App. 32(a)(7) and Fed. Cir. R. 32(b).

Dated: September 25, 2023

*/s/ Sean S. Pak*

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