

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

RESMED CORP.,
Petitioner,

v.

CLEVELAND MEDICAL DEVICES, INC.,
Patent Owner.

Case IPR2025-00158
U.S. Patent No. 11,690,512

PATENT OWNER'S SUR-REPLY

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I. INTRODUCTION

The Challenged Claims are patentable because Orbach does not disclose “a computer (or processor) that receives sleep data over cell towers from cell phone/PDA and executes software to analyze and display the sleep data for diagnosis” limitation. See Patent Owner Resp. (“POR”) at 1 (citing ’512 Patent, Claim 1 (claim limitations [1.d]-[1.g])). Because ResMed cannot demonstrate that the Challenged Claims are obvious under CleveMed’s plain language interpretation, it attempts to rewrite the claims to encompass the prior art. This Sur-Reply is limited to addressing Petitioner’s newly raised claim-construction theories and mischaracterizations that first appear in the Reply.

Furthermore, Petitioner misinterprets Federal Circuit law in order to argue that a motivation to combine exists simply because two references address similar problems, while ignoring the undisputed evidence that Ciulla already solves the very problems Petitioner identifies. Petitioner, however, ignores that the motivation to combine requirement is not met simply because concepts are well-known in the art. *Virtek Vision Int’l ULC v. Assembly Guidance Sys., Inc.*, 97 F.4th 882, 888 (Fed. Cir. 2024) (providing that prior art references that “were commonly known and would have been obvious to combine as indicated” does not show a motivation to combine).

As Dr. Borkholder and Dr. Goodrich explain, adding Orbach's techniques to Ciulla would have been redundant, technically risky and commercially irrational at the time of the '512 Patent filing. *See* Ex. 2015 at ¶¶45, 52-53; Ex. 2014 at ¶¶48, 51-52. Thus, the Board should reject Petitioner's attempts to rewrite Orbach and Ciulla and confirm the patentability of the challenged claims.

II. ORBACH DOES NOT DISCLOSE A “COMPUTER OR . . . SECOND PROCESSOR” THAT DISPLAYS AND ANALYZES, OUTPUTS, AND/OR FORMATS DATA

ResMed does not dispute that Orbach fails to teach “second software when executed by the computer or the second processor **configured to analyze, output and/or format the sleep data** at the one or more sites remote from the first location where the sleep data was collected; and . . . configured to **display** both, in part, the sleep data and/or analyzed sleep data” under CleveMed's plain language interpretation of the claims. *See* Reply at 2-11 (advancing new claim construction arguments to avoid giving the claim terms their plain and ordinary meaning); *id.* at 11-19 (arguing that the claims are unpatentable under ResMed's newly-proposed constructions); '512 Patent, Claim 1(f), 1(g) (emphasis added).

Conceding that Orbach does not reach the Challenged Claims under CleveMed's plain language interpretation, ResMed advances three meritless new claim construction arguments that rewrite the plain language of the claims to encompass the teachings of Orbach. For the reasons that follow, the Board should

adopt CleveMed's plain language interpretation of the claims and confirm that the Challenged Claims are patentable because to the extent that Orbach teaches the functionality performed by executing the claimed "second software," those functions are split between the remote server 140, which analyzes the data, and viewing station 150, which displays it for expert analysis. Orbach at 13-14.

A. Claim Construction

1. "a computer" refers to one computer at one or sites

As properly construed, the term "a computer" refers to one computer at one or more remote sites. Similarly, the term "a second processor" refers to "a second processor at one or more remote sites."

ResMed's argument that the functions performed by the "second software" may be split between two different computers executing different instantiations of the second software exactly tracks the argument rejected in *Salazar v. AT&T Mobility LLC*, 64 F.4th 1311, 1315 (Fed. Cir. 2023) ("According to Mr. Salazar, the court should have interpreted the claim terms to require one or more microprocessors, any one of which may be capable of performing each of the 'generating,' 'creating,' and 'retrieving' functions recited in the claims."). In rejecting this construction, the Court explained that although "the claim term 'a microprocessor' does not require there be only one microprocessor, the subsequent limitations referring back to 'said microprocessor' require that **at least one**

microprocessor be capable of performing each of the claimed functions.” *Id.* at 1317 (emphasis added). For the reasons that follow, the Board must adopt the same interpretation with respect to the Challenged Claims.

ResMed’s reliance on *Baldwin Graphics Systems, Inc. v. Siebert, Inc.*, 512 F.3d 1338 (Fed. Cir. 2008), which was discussed extensively in *Salazar*, is misplaced. Reply at 4. In *Baldwin Graphics*, the term “a pre-soaked fabric roll” was construed to mean “one or more” pre-soaked fabric rolls, and the Court held that a subsequent reference to “said fabric roll” carries the same “singular or plural meaning.” 512 F.3d at 1342-43. Yet as the Federal Circuit explained in *Salazar*, this rule does not apply when subsequent recitations of the element “further defines the element with subsequently recited functionality”:

[T]he question is not whether there can be more than one request in a claim-covered system: there can. Rather, the question is whether “a” can serve to negate what is required by the language following “a”: a “request” (a singular term) that “correspond[s]” to “two or more selected investments.” It cannot. For a dog owner to have “a dog that rolls over and fetches sticks,” it does not suffice that he have two dogs, each able to perform just one of the tasks.

Salazar, 64 F.4th at 1317 (quoting *In re: Varma*, 816 F.3d 1352, 1362-63 (Fed. Cir. 2016)). Here, as in *Salazar*, the claim does not merely require the presence of

multiple computing devices, but requires that *the same executable instance of the “second software”* perform all recited functions on “the computer” or “second processor.”

Applying this principle to ResMed's proposed construction, although the first recitation of “a computer” in the limitation [1.d] may be read as “one or more computers,” the subsequent references to “the computer” in limitations [1.f] and [1.g] require that at least one computer “be capable of performing each of the claimed functions.” ’512 Patent, Claim 1; *Salazar*, 64 F.4th at 1317. Similarly, while the first recitation of “a second processor” may be read as “one or more second processors,” the subsequent references to “the second processor” require at least one second processor “capable of performing each of the claimed functions.” *Id.* Accordingly, ResMed's new argument that the Challenged Claims are broad enough to encompass Orbach's “remote server” and “viewing station” each performing some aspects of the second software's functionality must be rejected. Reply at 2-6.

The surrounding claim language confirms CleveMed's construction. In limitation [1.d], for example, the “second software” is stored on a non-transitory computer readable medium that is executable “at one or more sites remote to the first location.” ’512 Patent, Claim 1(d). Where the term “a computer” is read to mean “one or more computers,” the claims refer to a single computer or processor

executing the second software on the computer readable media at each of the “one or more sites remote to the first location.” *Id.*

Accordingly, like the claims in *Varma* and *Salazar*, the Challenged Claims the first recitation of “a computer” or “a processor” may refer to one or more of those devices, but because subsequent references to those elements recite functionality that must be performed by the same single computer or processor.

2. The Claims Do Not Encompass a Combination of a Computer and a Processor Executing the Second Software

The Board should also reject Petitioner's claim that the word “or” in the term “a computer or a second processor” broadens the meaning of the claims to “a computer, a processor, **or a combination thereof**” because *Brown v. 3M* does not stand for the rule that ResMed cites it for. Reply at 7 (emphasis added). Accordingly, and for the reasons that follow, the same “computer or second processor” that receives the sleep data from the cell phone or PDA must also display and analyze, format, and/or output the sleep data.

In *Brown*, the relevant claim recited “a[t] least one database file stored in the memory containing records with year-date data with years being represented by **at least one of** two-digit, three-digit, or four-digit year-date representation.” 265 F.3d 1349, 1352 (Fed. Cir. 2001). Given the “**at least one**” phrase in the claim, the Court agreed that the proper construction required an apparatus “capable of converting ‘only two-digit, only three-digit, only four-digit, **or any combination of** two-,

three-, and four-digit date-data.” *Id.* (“We agree with this construction of the claim, for it is the plain reading of the claim text. These are not technical terms of art, and do not require elaborate interpretation.”).

Unlike the claim at issue in *Brown*, the Challenged Claims use the disjunctive “or” **without** the “at least one of” phrase recited in *Brown*. ’512 Patent, Claim 1(d) (reciting “at least second software stored on a non-transitory computer readable medium and executable by a **computer or a second processor** at one or more sites remote to the first location.”) (emphasis added). Accordingly, there is no basis to rewrite the claims to reach a **combination** of a computer and processor that collectively execute the claimed “second software.” Consistent with the conclusion above that the claims encompass multiple single computers or processors that individually executes software at different remote locations, the claims encompass a single computer (or second processor) that executes the second software at each of one or more remote sites. Nothing in Claim 1 authorizes collective execution of the “second software” across heterogeneous devices, particularly where the claim language recites a single executable medium and execution by *the* computer or *the* second processor.

That CleveMed’s interpretation of the claims excludes one or more embodiments disclosed in the specification (Reply at 7-8) is no impediment to giving the claims their plain and ordinary meaning. *TIP Sys., LLC v. Phillips &*

Brooks/Gladwin, Inc., 529 F.3d 1364, 1373 (Fed. Cir. 2008) (“[T]he mere fact that there is an alternative embodiment disclosed in the [patent] that is not encompassed by [the] district court’s claim construction does not outweigh the language of the claim, especially when the court’s construction is supported by the intrinsic evidence.”). Indeed, ResMed concedes that the specification discloses an embodiment in which “a computer can receive, analyze, and display sleep data as PO identifies,” so the Board should construe the claims as directed to that disclosed embodiment because it is the only construction that is consistent with “the intrinsic evidence.” Reply at 8; *TIP Sys.*, 529 F.3d at 1373.

There is also nothing “imprecise” about CleveMed’s argument. Reply at 7 n.2. As discussed in the following section, if the cell phone or PDA **transmits** sleep data “over cell towers to the computer or the second processor for analysis,” then the “computer or the second processor” **receives** that data from the cell phone or PDA, even if it passes through one or more intervening routers or relays because intervening devices are not the **destinations** of the transmission. See Section II.3, *infra* (the Challenged Claims do not require a “direct” connection between the “computer or second processor” and the cell towers). In any event, the Challenged Claims are patentable even under ResMed’s interpretation because (1) Orbach’s remote server is not merely an intervening router or relay. See Sections II.B.2-3, *infra*.

The Board should, therefore, reject ResMed's reading of *Brown* and decline to broaden the claims beyond their plain meanings merely to encompass unclaimed embodiments, including those where the cell phone or PDA transmits sleep data to a first destination device before that a device at the first destination sends data to a second destination device that executes software analyzing and displaying sleep data.

3. CleveMed's Construction Does Not Demand a "Direct" Connection Between Cell Towers and the Computer

ResMed's final claim construction argument rests on a disagreement that does not exist. Reply at 9 ("The Board should reject PO's implicit construction that a system only transmits sleep data '**over cell towers to the computer**' (Element 1.e) if the computer and cell towers have a direct connection.") (emphasis added). CleveMed agrees that the **transmission** of the sleep data must be "over cell towers" and that the "computer or second processor" need not have a direct connection to a cellular tower. However, for the reasons discussed in Section II.B.3, below, this construction does not help ResMed's case.

B. Orbach Does Not Disclose the Second Software Limitations as Properly Construed

1. Orbach's Remote Server and Viewing Station Together are Not a Computer

The Board should reject ResMed's argument that "Orbach's remote server 140 and viewing station 150 together constitute '**a computer or a second processor**'

at one or more sites” because it depends entirely on its overbroad construction. Reply at 13-14; POR at 5-9. The claims are not amenable to construction that splits the functionalities of the second software over two different devices. See Section II.A, *supra*; POR at 5-9.

2. Orbach Does Not Disclose Transmitting Sleep Data from a Cell Phone or PDA Over Cell Towers to the Same Device that Analyzes and Displays the Sleep Data

The Board should reject ResMed's argument that the Challenged Claims are met by first transmitting sleep data to Orbach's remote server and then sending sleep data to Orbach's viewing station for analysis and display for several reasons. See Reply at 17.

First, this argument fails because it depends on ResMed's overly broad construction. See Section II.A.2. The Challenged Claims recite a “cell phone or PDA, configured to wirelessly receive and re-transmit the sleep data . . . over cell towers to the computer or the second processor for analysis.” '512 Patent, Claim 1 (e). Accordingly, the same “computer or second processor” that is the target of the cell phone's or PDA's transmission must also analyze and display the data. In Orbach, the cell phone transmits data to the “remote server,” and although the remote server **analyzes** data, it is uncontested that the remote server does not **display** the data. Orbach at 13 (“Optionally, a communication link 128 is used to connect the mobile monitor 120 to a remote server 140 where in-depth analysis of data obtained

by the sensor unit 110 may be done and, optionally, data can be transmitted to an expert or another user.”).

Second, the Challenged Claims are also patentable under ResMed's proposed construction because viewing station 150 does not execute second software that **analyzes** sleep data. Rather than viewing station 150 executing **second software** that analyzes sleep data, Orbach teaches sending data to the viewing station so that a “human expert may provide interpretation of the data and transmit recommendations to the user.” Orbach at 13-14. Accordingly, although viewing station 150 executes software that outputs, formats, and displays, Orbach does not disclose executing software that analyzes sleep data.

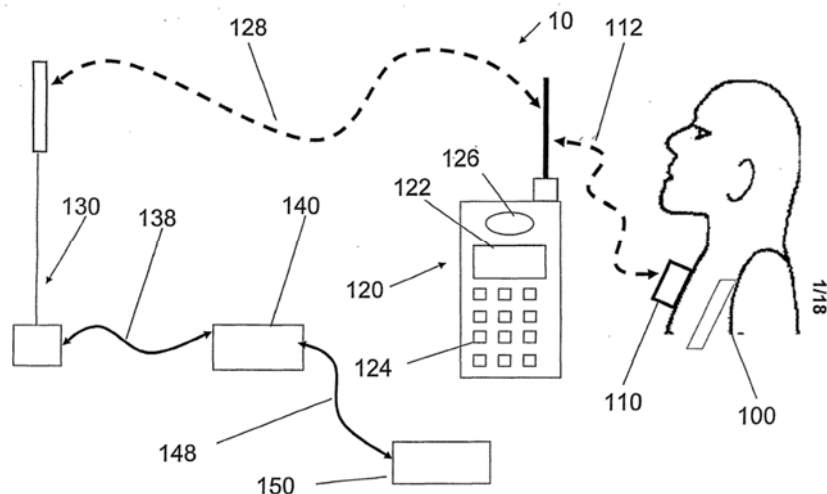
3. CleveMed's Arguments Distinguishing Orbach do Not Depend on “Direct” Communication Between the Computer or Second Processor and the Cell Towers

As discussed above, CleveMed agrees that the Challenged Claims do not require a “direct” connection between the “computer or second processor.” See Section II.A.3.

CleveMed's argument distinguishing Orbach does not depend on the existence of a “direct” connection between the claimed “computer” that executes the “second software” and the claimed “cell towers.” POR at 6-7; see Reply at 12-13 (providing that a “remote server 140 (and not a cell tower) sends sleep data to viewing station 150”). Instead, CleveMed argued that Orbach does not disclose

transmitting sleep data over cell towers **to** the same device that displays and analyzes, outputs, and/or formats the sleep data. *Id.* In Orbach's system, sleep data is sent "**to** a remote server 140 where in-depth analysis of data obtained by the sensor unit 110 may be done and, **optionally**, data can be transmitted to an expert or another user [150]" for display. Orbach at 13-14 ("**Optionally**, an additional data link 148 such as Local Area Network (LAN) or Internet networking or RF cellular link connects the remote server 140 to a viewing station 150 where a human expert may provide interpretation of the data and transmit recommendations to the user.") (emphasis added).

Even under ResMed's framing, Orbach's viewing station 150 is not "the eventual destination for the data" (Reply at 10) transmitted from its "mobile monitor 120":



Orbach, Fig. 1. Instead, the “eventual destination for the data” transmitted from Orbach’s mobile monitor 120 is the remote server 140, and that is the case **even though** it passes through other intermediary devices, including cellular base station 130. *Id.* at 13; *cf.* Reply at 9-10. Optional downstream forwarding cannot convert a non-destination device into the claimed “computer or second processor” without rewriting the claim language. To drive this point home, any further transmission to viewing station 150 is entirely optional, meaning that it could not possibly be the “destination” for the transmission from cell phone/mobile monitor 120. Orbach at 13-14.

Accordingly, while CleveMed agrees that “communicating ‘**over cell towers to the computer or the second processor**’ includes from cell towers to the remote computer or second processor destination, with or without the user of an intervening router, relaying device, etc.,” it disagrees with ResMed’s ultimate conclusion. Reply at 10-11. Orbach’s remote server 140 is the **destination** for data transmitted from mobile module 120, not a mere “intervening router [or] relaying device” on the way to viewing station 150.

4. Orbach’s Viewing Station is not a Monitor, and its Remote Server Does Not “Display” Sleep Data

Finally, the Board should reject ResMed’s Reply position that Orbach’s remote server 140 “displays” sleep data on viewing station 150 is a “computer” that receives analyzed sleep data from the remote server and executes its own software

to display the data to an expert for interpretation. *Compare* Orbach at 13-14 with Reply at 19-22.

Contrary to ResMed's new attorney argument, viewing station 150 is not merely a monitor. As ResMed argued in the Petition, the "viewing station" is a device with a "***second processor***" that "provide[s] additional processing" of received "sensor[] data." Pet. at 48. As ResMed argued in the Petition, Orbach's remote server 140 analyzes, formats, outputs sleep data and, ***optionally***, transmits the data to viewing station 150, which displays the data to an expert. *Id.* at 52; Orbach at 13-14. Indeed, the viewing station 150 could not merely be a "monitor" and also act as "a remote call center [or] an interactive expert system," as disclosed in Orbach. POR at 7 (citing Orbach at 8:13-15). Accordingly, Orbach's viewing station is a "computer," not merely a monitor that displays signals driven by the remote server. Pet. at 48 ("The remote server with a viewing station (***either being the computer***)....") (emphasis added).

Accordingly, while ResMed is correct that "[n]o compelling reason exists to read out the '512 Patent's descriptions of software executing on a first device that uses external monitor hardware to display and analyze data from Claim 1," the Challenged Claims remain patentable because Orbach does not disclose such an arrangement. Reply at 21.

III. A POSITA WOULD NOT HAVE BEEN MOTIVATED TO TRANSFER SLEEP DATA FROM A WEARABLE DEVICE TO A CELL PHONE OR PDA AND FROM THE CELL PHONE/PDA TO CELL TOWERS

A. Ciulla Already Solves the Alleged Problem

It would not have been obvious to modify Ciulla's wearable sleep data acquisition system with Orbach's cell phone because Ciulla's system already achieves the alleged benefits of Orbach's system *without* adding an extra, unnecessary device. POR at 10-14.

ResMed's primary argument in Reply misreads the Federal Circuit's opinion in *Intel Corp. v. PACT XPP Schweiz AG*, 61 F.4th 1373 (Fed. Cir. 2023). In *Intel*, the Federal Circuit held that "[t]here is a motivation to combine when a known technique 'has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way.'" *Id.* at 1380-81. However, unlike the "global, segmented secondary cache" that undisputedly improved "cache coherency" in *Intel*, ResMed does not identify any improvement associated with Orbach's cell phone, let alone one that would "improve" Ciulla's system. *Id.*

Thus, ResMed falls back to arguing that a POSITA would have had a motivation combine Ciulla and Orbach simply because they "address similar sleep data communications problems, but use different means to communicate." Reply at 23-25. That is not true. Like Orbach, Ciulla communicates wirelessly over RF and

WANs to send patient data to a researcher and/or medical practitioner. Ciulla, [0213]. However, Ciulla performs this task without introducing an entirely new device, like Orbach's cell phone. *Id.*

As noted in the POR, the Federal Circuit dealt with this same issue *In re Schweickert*, 676 F. App'x 988 (Fed. Cir. 2017). POR at 13-14. When faced with a proposed modification to a device that “worked without trouble” and which would “add[] additional complexity and computations,” the Board was required to explain “why a skilled artisan **would still** have a reason to combine” the references to reach the claimed invention. 676 F. App'x at 995 (emphasis added). And like in *Schweickert* ResMed makes unsubstantiated claims that it would be more “cost-effective” to add a cell phone to Ciulla's system than to use the communications apparatus that Ciulla's system is already equipped with. *Id.* at 995-96. Indeed, ResMed has not performed even the most basic analysis to determine whether its proposed combination would be more cost-effective than merely using Ciulla's system as designed. Reply at 26-27.

ResMed struggles to identify any other reason to combine Ciulla with Orbach that could overcome the increased complexity that would come with adding a cell phone to a system that already had a display and the capability to communication over Wide Area Networks (WANs) using RF signals. Although ResMed suggests that adding a cell phone to Ciulla's system would have offered “convenience and

familiarity,” (Reply at 26), that *post-hoc* rationalization is entirely conclusory. Ciulla’s system *already* includes all of the features that Orbach’s cell phone would allegedly provide **without** the need to add an entirely new device to the system.

Ciulla describes a “data recorder” in the disclosed system, which is “wirelessly connected to the main back module, so that data could be reported in real time and displayed in real time at a location spatially removed from the main back module.” Ciulla, [0125]). In other words, Ciulla’s system could already transmit the patient’s analyzed data to a remote location for display. Ciulla further states that “data could be reported in real time and displayed in real time” on an LCD or another device (*id.*, [0103], [0125]). This, again, indicates Ciulla’s ability to provide live data viewing, either on the patient’s device or elsewhere.

Ciulla also envisions comprehensive telemedicine functionality: “The system is . . . designed to permit total monitoring, control and analyses to be performed in a different location from where the patient is sleeping by being capable of transmitting data it obtains at any distance.” Ciulla, [0230]. This Ciulla passage shows that Ciulla’s inventors had already contemplated data transmission of the sensor outputs without needing a cell phone intermediary. Ciulla even mentions that in the preferred embodiment, the microprocessor will “directly transmit these [analyzed] reports by IT to the therapist’s computer” (*id.*, [0214]) and that the system’s display screen can be used to display reports or “directly transmit these [analyzed] reports

. . . to the therapist's computer and/or . . . the [healthcare provider]." *Id.*, [0213]-[0214]. Thus, Ciulla already contemplated remote data communication to a clinician's computer and did so in real time.

Given these disclosures, a POSITA reading Ciulla would understand that Ciulla achieved real-time data transfer from the patient's wearable device to an external display or even a remote computer. As Dr. Borkholder's unchallenged testimony establishes, Ciulla's system is "designed to permit total monitoring, control and analyses to be performed in a different location . . . by being capable of transmitting data it obtains at any distance." Ciulla, [0230]; *see also* Ex. 2015, Borkholder Decl. at ¶47 (citing Ciulla, [0230]), ¶¶ 48-53. Therefore, a POSITA would have found Orbach's cellular transmission technique to add unnecessary cost and complexity over and above Ciulla's system, which already could handle real-time remote data reporting via an internal RF transmitter or similar built-in communication module. Ex. 2015, Borkholder Decl. at ¶¶46, 52.

In addition to disclosing its own wireless transmitter, Ciulla also actively engages the patient in their therapy, providing feedback and interaction, which fulfills the "patient engagement" rationale. Petitioner suggested that adding a cell phone would allow for greater patient involvement or awareness of their data. Reply at 23. However, Ciulla's device already included a built-in user interface to involve the patient. Ciulla discloses that the patient can "navigate through the operation of

their device” using the interface (Ciulla, [0102]-[0103]) and that the LCD “displays alerts of poorer [sleep]” and other information to the patient (*id.*, [0192]). The Ciulla system provides the ability to give auditory or electrical stimuli to the patient to correct breathing events. Ciulla also can provide messages to encourage compliance. *Id.*, [0103], [0139], [0144], [0214].

Contrary to Petitioner's contentions, Ciulla's invention was interactive throughout the night to improve sleeping behavior. Any additional remote engagement via a cell phone would be at best marginal. This is because the patient already has the device's feedback and can see live data on the device's onboard screen. Ciulla, [0103]. If anything, introducing a cellphone as an intermediary would likely interfere with the user experience. Petitioner has not shown why a POSITA would consider a cell phone for patient engagement when Ciulla's own device served that role directly. Dr. Goodrich supports this observation by providing that Petitioner's combination rationale “create[s] a problem within Ciulla's system that does not exist.” Ex. 2014, Goodrich Decl. at ¶48. Specifically, the alleged lack of continuous tracking or patient engagement “to justify why its proposed combination would have solved the issues in Ciulla's system.” *Id.* Ciulla already solved those concerns.

In light of Ciulla's capabilities, Petitioner's proffered motivations to combine lack substantiation. A POSITA would understand that adding Orbach's cell phone

communications technique would merely add costly redundancies and complexities to Ciulla's existing system. Ex. 2015, Borkholder Decl. at ¶52 (continuing the device developer/network specialist would recognize the increased regulatory burden of adding a cell phone application into the medical device system [especially since] the FDA did not publish their first draft guidance on mobile medication application (e.g. software on smartphones) until 2011).

Dr. Goodrich's unchallenged testimony confirms this lack of motivation. "Petitioner (and its experts) create a problem within Ciulla's system that does not exist—continuous, real-time data tracking and reporting, and patient engagement—to justify [the] proposed combination." Ex. 2014, Goodrich Decl. at ¶48. In truth, Ciulla's system "already includes these capabilities," so a POSITA "would have found Orbach redundant and unnecessary." *Id.* at ¶¶48-51; Ex. 2015, Borkholder Decl. at ¶¶43-45. This means the only reason to combine would be if one were already set on the idea of the patented invention and looking to patch together pieces of prior art to match it. That is hindsight, not a legitimate motivation. As the Supreme Court in *KSR* noted, "a patent composed of several elements is not proved obvious merely by demonstrating that each of its element was, independently, known in the prior art." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007).

B. There Was No Reasonable Expectation of Success in Combining Orbach's Architecture with Ciulla

Even if a POSITA in 2006 had some reason to try to incorporate Orbach's cell phone relay into Ciulla's system, a POSITA would have faced significant technical and practical hurdles along the way. Petitioner's Reply glosses over these challenges, implying that using a cell phone as a telemetry link would have been straightforward. The evidence indicates otherwise. The fields of medical device design and cellular network engineering were quite distinct in 2006 and bridging them was non-trivial. *Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F3d 1359, 1367-68 (Fed. Cir. 2016).

Dr. Borkholder, who has extensive experience in biomedical engineering and wireless systems, testifies that in 2006 a typical POSITA (with a biomedical or mechanical engineering background) "would not have independently combined the biomedical engineering aspects of a medical device with the network engineering aspects of wireless data transmission to a backend server." Ex. 2015, Borkholder Decl. at ¶37. At that time, developing a medical device that required wireless communication to a backend network was a substantial effort that usually required collaboration between different specialists such as the device engineer and a communications/network engineer. In fact, the FDA regulatory environment for mobile health technology was undeveloped in 2006. *Id.* ¶52. FDA's first guidance on mobile medical apps did not appear until years later. *Id.* Thus, any attempt to

turn Ciulla's device into a cell phone integrated system would have ventured into uncertain territory regarding safety, efficacy, and regulatory approval. This uncertainty would diminish any expectation of success for a POSITA. Further, a POSITA could not confidently predict that adding a cell phone link would work reliably and meet medical device standards.

Furthermore, Petitioner's own expert, Dr. Kirkness, acknowledged some of these difficulties. Dr. Kirkness argued that a POSITA might prefer Orbach's approach because otherwise "you have to build in and manufacture the communication device" into Ciulla's system. Ex. 2016, Kirkness Tr. at 101:13-15; Pet. at 10 (citing Ex. 1003, Kirkness Decl. at ¶¶104-105). But Dr. Kirkness overlooks that Ciulla already communicated wirelessly.

Dr. Borkholder responds that a device engineer in 2006 would recognize that Ciulla's approach avoids the complications of relying on an external consumer device. Ex. 2015, Borkholder Decl. at ¶¶52-53. All told, the path of combining Orbach with Ciulla was fraught with uncertainty, and there was no example in the record of a successful medical device in 2006 that used a patient's personal cell phone to live-stream physiological data for remote analysis. *Id.* at ¶¶ 50-53 (Dr. Borkholder further providing that: "At that time, only two percent of American cell phone subscribers even owned a smartphone that could receive and output data via applications downloaded on a device.") (citing Ex. 2019 at 2). Petitioner cites none.

The lack of such examples speaks to the unproven nature of that approach at the time, which undercuts any notion Petitioner attempts to put forward that success would have been expected.

In sum, even if one potentially had the motivation to combine Ciulla and Orbach, a POSITA would have had significant doubts about the success of that venture. The need for cross-disciplinary knowledge, the regulatory unknowns, and potential interference with Ciulla's primary function all would give trepidation. As Dr. Borkholder opines, the alleged benefits of adding Orbach into Ciulla's system "would not have prompted a [POSITA] to have made the combination proposed because Ciulla's system already provides these capabilities, so there is no problem that needed solving." Ex. 2015, Borkholder Decl. at ¶45.

This conclusion aligns with the bedrock principle that a claim is obvious only where a POSITA would have had a reasonable expectation of achieving the claimed invention's functionality. *See Intelligent Bio-Systems*, 821 F.3d at 1367-68 (rejecting obviousness theory where the evidence did not establish a POSITA would have had a reasonable expectation of success). Here, the expectation of any success is lacking. Petitioner's hindsight narrative obscures these real-world considerations that the Board must consider. The absence of a reasonable expectation of success is yet another reason the Ciulla in view of Orbach combination fails to render Claim 1 obvious.

IV. CONCLUSION

For the reasons discussed herein and, in the POR, the Board should conclude that the record supports upholding the patentability of the Challenged Claims.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE WITH 37 C.F.R. § 42.24

The undersigned hereby certifies that the portions of the foregoing **PATENT OWNER'S SUR-REPLY** has 5,214 words in compliance with the 5,600 word limit set forth in 37 C.F.R. § 42.24. This word count was prepared using the Microsoft Word word-processing system used to prepare this paper.

Dated: January 20, 2026

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CERTIFICATE OF SERVICE

The undersigned certifies, in accordance with 37 C.F.R. § 42.6(e), and pursuant to agreement by the parties that filing with the Board through the P-TACTS constitutes electronic service if Patent Owner provides the foregoing document (excluding exhibits), service was made on the Petitioner as detailed below.

<i>Date of service</i>	January 20, 2026
<i>Manner of service</i>	Electronic Filing and Electronic Mail (PH-ResMed-CleveMed@paulhastings.com)
<i>Documents served</i>	PATENT OWNER'S SUR-REPLY
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