

Filed on behalf of: ResMed Corp.

Filed: April 8, 2026

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

RESMED CORP.,

Petitioner,

v.

CLEVELAND MEDICAL DEVICES, INC.,

Patent Owner.

Case No. IPR2025-00246
U.S. Patent No. 11,857,333

**PETITIONER'S SUR-REPLY TO PATENT OWNER'S REPLY TO
OPPOSITION TO CONTINGENT MOTION TO AMEND AND REQUEST
FOR PRELIMINARY GUIDANCE**

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I. INTRODUCTION

The Contingent Motion to Amend the claims of the '333 Patent ("Motion") should be denied. The Substitute Claims (claims 30-41) lack written description support for a subject's cell phone that adjusts PAP therapy in at least two (of four total) applications in the priority chain, in contravention of 37 C.F.R. § 42.121. Moreover, the Substitute Claims are unpatentable over Toge in view of Kumar. PO does not dispute that Toge and Kumar render obvious all limitations of the Substitute Claims except "remote internet site" and a subject's cell phone. PO merely disputes (incorrectly) that a POSITA would not implement these well-known features in the combination. The Opposition to the Motion ("Opposition") definitively established that these limitations are obvious, and PO's arguments to the contrary are meritless.

II. THE SUBSTITUTE CLAIMS LACK WRITTEN DESCRIPTION SUPPORT AS REQUIRED BY 37 C.F.R. § 42.121

PO has failed to satisfy the written description requirements of 37 C.F.R. § 42.121. First, PO, has not demonstrated how each application in the priority chain "reasonably conveys to those skilled in the art that the inventor had possession of the [later-claimed] subject matter as of the filing date." *Arthrex, Inc. v. Smith & Nephew, Inc.*, 35 F.4th 1328, 1343 (Fed. Cir. 2022) (internal citations omitted); *see also* Prelim. Guid., 6. Fatally, PO has presented no evidence of any disclosures in two applications in the '333 Patent priority chain (U.S. Patent App. Nos. 13/074,901 and 11/879,934) that purportedly support the Substitute Claims. Thus, PO's showing

under 37 C.F.R. § 42.121 is deficient on its face and fails as a matter of law.

Second, even as to the two applications for which PO performed an analysis—U.S. Patent App. Nos. 15/641,715 (EX1002) and 11/266,899 (EX2033)—PO fails to demonstrate support for the limitation “wherein the therapy administered by the PAP or CPAP device is configured to be adjusted by the first software on the subject’s cell phone” (“a subject’s cell phone that adjusts PAP therapy”).

A. The '899 application does not provide written description support for a subject's cell phone that adjusts PAP therapy

PO identifies additional disclosures in the '899 application that purportedly provide written description support for a subject's cell phone that adjusts PAP therapy. Rep., 2-3 (citing EX2033, 33:14-21, 33:22-23, 34:14-21, 38:24-39:3). They do not. None, taken alone or in combination, suggest a subject's cell phone that adjusts PAP therapy. The passage at 33:14-21 states a cell phone/processor can be tethered to sensors and analyze sensor data (no PAP therapy adjustment), 33:22-23 states “the processor” can be “part of a remote communications station” (no cell phone nor PAP therapy adjustment), 34:14-21 states the remote communication station/cell phone transmits data to a “remote site” (no PAP therapy adjustment), and 38:24-39:3 states “a clinician or the subject [] adjust[ing] the [treatment] device” based on an output from a “diagnostic device” (no tie to a cell phone). *Id.*

PO claims that “[w]hat is relevant is that the patient uses the output such as the level of severity to adjust their therapy and that this value is found on the patient's

cell phone.” Rep., 5. But a “value” displayed on a patient’s cell phone does not suggest that the patient adjusts the PAP therapy *using* a cell phone. *Id.* In fact, there is no disclosure in the ’899 application of how a patient would adjust their PAP therapy. See EX2051, 10:11-18 (“Q: So it’s your opinion that no disclosure in the specification describes an – expressly describes a cell phone of any kind that adjusts therapy? A: Yes, and I think on top of that, ... the proposed amended claims include software that’s downloadable onto the cell phone as well.”).

B. The ’715 application does not provide written description support for a subject’s cell phone that adjusts PAP therapy

PO also identifies additional disclosures in the ’715 application that purportedly provide written description support for a subject’s cell phone that adjusts the PAP therapy. Rep., 2-3 (citing EX1002, 5:5-8, 11:30-12:1, 29:22-29, 30:9-31:12, 34:20-23). Likewise, they do not because again no disclosure ties the subject’s cell phone to adjusting PAP therapy. The passage at 29:22-29 discloses a cell phone/receiver that transmits PAP data to a remote site “for analysis” (no PAP therapy adjustment) and 30:9-31:12 discloses a cell phone/processor that can be tethered to sensors or be part of a remote communication station (no PAP therapy adjustment). And as discussed (Opp., 2-4), the passage at 5:5-8 (transmission of PAP data from a diagnostic device to an intermediary device/cell phone), 34:20-23 (diagnostic device output used for clinician or subject PAP adjustment), and 11:30-12:1 (remote programming of the PAP), do not disclose or even suggest that it is a

subject's cell phone that adjusts PAP therapy.

PO contends its conclusions are “corroborated by the *inventors' statements* on the disclosed inventions made during prosecution.” Rep., 3 (emphasis added). Untrue. PO points to bare applicant argument (EX1002, 308) made in an amendment. Foundational Federal Circuit law is clear this sort of argument is not evidence. *See In re Cole*, 326 F.2d 769, 773 (CCPA 1964) (“Statements by counsel in the brief cannot take the place of evidence”); *In re Schulze*, 346 F.2d 600, 602 (CCPA 1965) (same); MPEP § 2145 (“[A]rguments presented by applicant cannot take the place of factually supported objective evidence”). Even if applicant argument in the prosecution history was valid evidence (and it is not), it suggests that it is the physician that adjusts the therapy while the patient simply views the data. *See, e.g.*, EX1002, 308 (“[S]haring [therapy efficacy] information with the patient on their cellular phone *while at the same time sharing that information with the patient's clinician so the therapy can be adjusted*”).

C. *Hologic* is inapposite

PO cites *Hologic* as supporting its conclusion that the foregoing disclosures “[t]aken together” would allow a POSITA to “immediately discern that the patient *can* adjust their PAP/CPAP therapy using their cell phone.” Rep., 2-3 (citing *Hologic, Inc. v. Smith & Nephew, Inc.*, 884 F.3d 1357 (Fed. Cir. 2018)). But in *Hologic*, there was clear disclosure of the claimed invention in the figures and

specification—nothing needed to be “discerned” from disparate specification disclosures. *See id.* at 1362. Moreover, “pointing to an amalgam of disclosures from which an artisan could have created the claimed invention does not satisfy [the written description] requirement.” *Flash-Control, LLC v. Intel Corp.*, 2021 WL 2944592, *3 (Fed. Cir. 2021) (internal quotation marks omitted). *Hologic's* “[t]aken together” language is inapplicable.

PO accuses Petitioner of “viewing in isolation passages for express recitation of a cell phone adjusting PAP therapy.” Rep., 4. Incorrect. Petitioner's arguments in its Opposition (and here) repeatedly underscore that the language PO identified did not explicitly (disclose) or imply (suggest) a subject's cell phone that adjusts PAP therapy. *See Opp.*, 2-8; *see also, e.g.*, EX2051, 12:13-24 (“[T]he diagnostic device is not disclosed as a cell phone, and a POSITA would not have recognized the diagnostic device disclosures as describing one); 9:22-10:8 (“[N]one of [the disclosures] would lead a POSITA to understand that . . . the data acquisition system is [] disclosed as a cell phone, nor is one implied.”). A subject's cell phone that adjusts PAP therapy “was ‘not discussed even in passing in the disclosure’” which “r[uns] afoul of the written description requirement.” *Indivior Inc. v. Dr. Reddy's Labs., S.A.*, 930 F.3d 1325, 1348 (Fed. Cir. 2019) (quoting *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1327 (Fed. Cir. 2000)).

Overall, PO cannot show that a POSITA would have understood the inventors

“had possession” of a subject’s cell phone that adjusts PAP therapy based on the disclosures of the ’715 and ’899 applications. *See Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc).

III. THE SUBSTITUTE CLAIMS ARE UNPATENTABLE AS OBVIOUS OVER TOGE AND KUMAR

A. Toge in view of Kumar renders obvious a patient cell phone that adjusts PAP therapy (Substitute Claim 30.f)

PO contends Petitioner’s obviousness analysis is an “attempt to rely on the conclusory testimony of [] experts” to “gap-fill” the limitation based on the experts’ “general knowledge.” Rep., 5. False. Nowhere does the Opposition rely on “general knowledge,” and PO points to no such statements. For at least this reason, the Enforcement and Non-Waiver of 37 C.F.R. § 42.104(b)(4) and Permissible Uses of General Knowledge in Inter Partes Reviews” (the “Memo”) is inapplicable.¹

The Opposition explains that Toge discloses the transmission of PAP data to a physician’s cell phone that adjusts PAP therapy and Kumar discloses a patient cell phone with downloadable software that communicates with the PAP device. Opp.,

¹ *Aqua Prods., Inc. v. Matal*, 872 F.3d 1290 (Fed. Cir. 2017) is also irrelevant. PO’s convoluted interpretation that the Opposition *in response* to PO’s voluntarily amended claims “effectively operates as a renewed petition” “subject to the Memo” is inconsistent with the motion to amend procedures set forth in 37 C.F.R. § 42.121.

10-14, 21-25; Chatterjee Opp. ¶¶17-19, 39-46, Kirkness Opp. ¶¶14-20. As a known option, a POSITA would have found it obvious to implement the patient cell phone described in Kumar with the PAP-adjusting functionality of the physician cell phone disclosed in Toge using the described downloadable software. *See id.*; *see also* EX2051, 41:13-17 (“[T]he mobile device that can adjust the PAP ... was clearly disclosed and known at the relevant time period, for example, because Toge talks about it”). The Opposition goes on to identify several reasons a POSITA would configure Kumar’s patient cell phone to adjust PAP therapy. *See* Opp., 11-14, 23-25; Chatterjee Opp. ¶¶44-46; Kirkness Opp. ¶¶17-20. Thus, the obviousness analysis was based on the explicit disclosures in Toge and Kumar, not any “general knowledge” of experts. *See also* EX2051, 42:1-42:20, 48:17-21 (“[T]his is express disclosure in Toge where Toge is talking about [] a patient could have access to a device that can control the values that are set for the patient’s PAP device”), 47:5-12 (“Kumar is expressly disclosing the use of a downloadable software, a plug-in, that allows the patient’s cell phone to communicate with the PAP device, and it would have been natural, very natural, and there would be significant motivation for one of ordinary skill in that combined system to implement [] [Toge’s PAP adjustment] functionality at the patient-side cell phone.”).

PO further argues that Drs. Chatterjee and Kirkness “provide no evidence showing that it was known, let alone common, for a patient’s cell phone to adjust

PAP therapy.” Rep., 7. But the inquiry is whether “the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.” *Arendi S.A.R.L. v. Apple, Inc.*, 832 F.3d 1355, 1361 (quoting 35 U.S.C. § 103(a) (2012)); *see also KSR Intern. Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The analysis is done from the viewpoint of a POSITA. *Id.* Petitioner has described the explicit disclosures in Toge and Kumar of devices in the combined system having the required technical functionality (cell phone to adjust PAP therapy; cell phone with downloadable software) and corroborated with expert testimony that the “subject matter as a whole” (i.e., patient cell phone to adjust PAP therapy) “would have been obvious at the time of invention” to a POSITA. *Id.* No more is required.

PO complains about the outlined motivations to implement a patient cell phone that adjusts PAP therapy (Rep., 7-8) and their corroboration by Drs. Chatterjee and Kirkness. *See* Opp., 11-14, 23-25; Chatterjee Opp. ¶¶44-46; Kirkness Opp. ¶¶17-20. But PO cites to no testimony from the point of view of a POSITA that refutes the well-reasoned motivations. Rather, PO cites to unsupported argument in the ’715 application prosecution history that using a cell phone to adjust PAP therapy was unknown (Rep., 7), but this is contradicted by Toge’s disclosure. Indeed, PO undercuts its own argument by acknowledging known cell phones at the time were

“capable of downloading software necessary for the claimed functionality.” Rep., 7.

B. A POSITA would have been motivated to implement Kumar's patient-side cell phone that receives and displays PAP data in Toge's PAP system (Substitute Claim 30.e)

Substitute Claim 30.e, as properly interpreted, does not require a “subject's cellular phone ... further provided to receive and display the quantified level of severity data” given the disjunctive either/or language listed for the three elements recited in the claim (“*either* ... the PAP or CPAP device, the second processor...at the at least one server, *or* the subject's cellular phone...”). Mot., 7 (emphasis added); Opp., 18-20. Regardless, the Opposition demonstrates that Toge in view of Kumar discloses this element. *See* Opp., 20-21.

PO argues that a POSITA would not have been motivated to implement a patient cell phone in Toge's system, despite the numerous benefits discussed (*see* Opp., 23-25), because “only two percent of patient subscribers had” “cellular phone[s] capable of running downloadable applications.” Rep., 9. But this only confirms that this option was known. Regardless, PO identifies no support that it would have dissuaded inventors from implementing cell phones in a PAP/telemedicine system. Indeed, Toge and Kumar (2002) are evidence of the opposite—before the time of invention (2005), inventors included cell phones in PAP/telemedicine systems to perform a variety of functions (e.g., communicate information, display data, and manage device use and treatment). Indeed, numerous

other telemedicine/health systems similarly utilized cell phones. *See* EX1049 (Quy), 7:15-29; cl. 51 (“web-enabled cellular phone” “running an application” for consumer use in a health monitoring system); EX1045 (Orbach), [0011]-[0065], [0077]-[0079], [0292] (“mobile monitor” (cellular phone) that could collect, transmit, and display a person’s “physiological reading[s] ... to help identify and possibly correct sleep disorders”). These other systems belie PO’s baseless statement that a POSITA would not have utilized cell phones in telemedicine systems at the time due to consumer cell phone ownership. A POSITA’s understanding of the rapid uptake of cell phones, and trend in networked devices in general would have been ample motivation to add a cellular phone to systems to monitor and treat conditions like sleep disordered breathing. *See* Opp., 11-14, 20-25; Chatterjee ¶¶25-31, 88-89; Chatterjee Opp. ¶¶17-19, 25-28; Kirkness ¶¶93, 99-103; Kirkness Opp. ¶¶18-20.

C. A POSITA would have been motivated to implement Kumar’s remote internet site in Toge’s PAP system (Substitute Claim 30.d)

The Opposition establishes why a POSITA would have implemented Kumar’s remote internet site (web-based engine) in Toge’s PAP system. *See* Opp., 15-17; Chatterjee Opp. ¶¶27-32; Kirkness Opp. ¶¶12-13. PO complains Petitioner does not describe “*why* a POSITA would have implemented a web server” or “*how* such [an] implementation would arrive at the claimed ‘remote internet site...’” Rep., 10 (emphasis in original). But the Opposition describes exactly that. *See* III.A *supra*.

PO also continues to allege that a POSITA would not have implemented

Toge's physician-side computer with Kumar's web server, arguing it could not be done ("web servers and clients on the same machine is 'not suitable'" for the application) and would not be done because "it cannot 'take advantage of the distributed computing environment,'" and has "security and performance" issues. Rep., 10-11. All untrue. Toge's physician-side computer implemented with Kumar's web server would be part of a distributed computer system. It is not a personal computer (EX1044, [0017] ("computer installed at a medical institution")) or even a single computer. See EX2055, 4 ("the client process and server process can be ... distributed in two or more computers"); EX1008, [0069] ("multiple ... provider-side devices, and engines/central servers" in a "clinic, hospital" setting). And, by definition, it is not limited to single-tier architecture because it is in a distributed computing environment. See EX2055, 4 ("single-tier client/server application" "will not take advantage of the distributed computing environment").

PO also continues to advance the unsubstantiated theory that Kumar's remote internet site would have "interfered with Toge's purpose of pushing crucial data without a request" "in emergencies." Rep., 11-12. As a threshold, the combination does not modify how *the PAP device* sends data to other devices in emergencies. Opp., 14-17 (modifying just the physician-side computer). This ends the argument. And regardless, Toge's purpose is not limited to transmitting PAP data in emergency situations. See Opp., 16-17; Chatterjee Opp ¶¶30-32, Prelim. Guid., 12-13; EX2051,

28:10-14; 28:15-29:11, 30:11-21; 29:12-24, 32:8-33:12 (long polling); 31:22-32:4.

But even assuming the combination must effectively send data in real-time, PO's arguments fail. Dr. Goodrich warns of "performance issues" with continuous query and long-polling yet does not dispute that they transmit data in almost real-time. Rep., 11-12; Goodrich Rep. ¶¶37-38. Notably, PO and Dr. Goodrich ignore the fact that motivation to combine does not require a combination to be the most preferred or most desirable prior art combination, just that it be an option known to a POSITA. *See Novartis Pharms. Corp. v. West-Ward Pharms. Int'l Ltd.*, 923 F.3d 1051, 1059 (Fed. Cir. 2019); *In re Fulton*, 391 F.3d 1195, 1200 (Fed. Cir. 2004).

Finally, PO argues real-time streaming "does not rectify the issue because ... it requires the physician to log into the website and request real-time data." Rep., 12. This is simply incorrect. As discussed above, there were a number of ways data could have been streamed in real-time, automatically, without physician involvement. *See supra*; *see also* EX2051, 33:13-23 ("[I]f you allow the user to exit the browser, you could continue to maintain the connection open" for continuous or periodic request). Accordingly, a POSITA would have been motivated to implement Kumar's remote internet site with Toge's PAP system.

IV. CONCLUSION

All the amended claims should be found unsupported and unpatentable and PO's Motion to Amend should be denied.

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CERTIFICATE OF SERVICE

I hereby certify that on April 8, 2026, a true and correct copy of the foregoing **PETITIONER'S SUR-REPLY TO PATENT OWNER'S REPLY TO OPPOSITION TO CONTINGENT MOTION TO AMEND** is being served by electronic mail on Patent Owner's counsel of record listed below, pursuant to its Mandatory Notices:

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