

Filed on behalf of: ResMed Corp.

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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 OPPOSITION TO PATENT OWNER'S
CONTINGENT MOTION TO AMEND AND REQUEST FOR
PRELIMINARY GUIDANCE**

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I. INTRODUCTION

The Substitute Claims of the '333 patent (directed to a networked PAP device) not only lack written description support but also remain unpatentable over the prior art combinations that the Petition established rendered the original claims obvious. PO primarily argues that a Toge-Kumar PAP system does not render obvious a proposed claim amendment adding a patient cell phone configured to adjust the PAP therapy. But Kumar already incorporates a patient cell phone in its telemedicine network system (as PO acknowledges), and in combination with Toge's disclosure, renders obvious a patient's cell phone's ability to adjust the PAP therapy. PO's other arguments that the Substitute Claims are patentable are unsupported, ignore disclosures in Toge and Kumar, and overlook the law.

II. LEVEL OF ORDINARY SKILL IN THE ART

Petitioner and PO agree on the definition of a person of ordinary skill in the art ("POSITA") in this proceeding. *See* Pet., 3-4; Mot. Amd., 12.

III. THE SUBSTITUTE CLAIMS DO NOT MEET THE PROCEDURAL REQUIREMENTS OF 37 C.F.R. § 42.121.**A. The Proposed Amendments Do Not Have Written Description Support in the Prior Specifications**

To satisfy the written description requirement under 35 U.S.C. § 112, ¶ 1 (pre-AIA), the specification disclosure "must clearly allow [a POSITA] to recognize that the inventor invented what is claimed." *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc) (internal quotation marks and brackets

omitted). In other words, the written description must demonstrate that “the inventor possessed the invention.” *LizardTech, Inc. v. Earth Resource Mapping, Inc.*, 424 F.3d 1336, 1345 (Fed. Cir. 2005). “[P]ointing to an amalgam of disclosures from which an artisan *could have* created the claimed invention does not satisfy this requirement.” *Flash-Control, LLC v. Intel Corp.*, 2021 WL 2944592, *3 (Fed. Cir. 2021) (internal quotation marks omitted) (emphasis added). Similarly, “a description which renders obvious a claimed invention is not sufficient to satisfy the written description requirement of that invention.” *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1567 (Fed. Cir. 1997).

1. The added limitation of “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” lacks written description support in the ’715 application

PO alleges that U.S. Patent App. No. 15/641,715 (the “’715 Application,” Ex. 1002), which matured into the ’333 patent, supports the amendment that “the therapy administered by the PAP or CPAP device is configured to be adjusted by the first software on the subject’s cell phone.” Mot. Amd., 4, 24. But none of PO’s citations to the ’715 application disclose or suggest a patient’s (“subject’s”) cell phone is able to be configured to adjust PAP/CPAP therapy. Chatterjee Opp. ¶¶4-8; see Mot. Amd., 7 (citing “Ex. 1002 at 5:2-12, 11:17-12:1, 34:20-24, 72:25-73:18”).

PO first identifies a passage which only discloses that a diagnostic device (e.g., sensors) can transmit signals to “an intermediary device or to the treatment

device itself” (e.g., PAP), where the intermediary device could be “a cell phone, a modem, a wireless router, a router, a PDA, a computer, [or] a processor.” EX1002, 5:2-12. The “intermediary device,” however, is not mentioned again in the specification; that is, it is not disclosed in the context of any of the dozens of embodiments described in the ’715 application. There is no disclosure of the “intermediary device” transmitting any signals to a treatment device and certainly not as a device that adjusts the PAP/CPAP therapy. Indeed, there is no disclosure in the specification at all of a “cell phone” that adjusts PAP/CPAP therapy. *See* Chatterjee Opp. ¶¶6-8.

Next, PO cites to where the ’715 application discloses a method to transmit data obtained from the sensors to a “data acquisition system and a PAP or CPAP,” which then retransmits/transmits a signal based on that data to “a remote monitoring station and the PAP or CPAP.” EX1002, 11:17-28. A “set of final values for the flow of pressurized gas delivered by the PAP or CPAP” is determined and transmitted to the remote monitoring station, which, after “evaluat[ion] and approv[al]” are used to “remotely program[] the PAP or CPAP to deliver a flow of pressurized gas.” *Id.*, 11:28-12:1. The device or component that “remotely programs” the PAP/CPAP is not disclosed or described. And the “data acquisition system” is not a cell phone; instead, it is described as “a single box, such as a patient interface box, containing a sensor interface module, a pre-processor module, and a transmitter module” ... or

“several boxes” “containing one or more modules.” *See id.*, 21:30-22:3. A POSITA would not have understood the disclosed “data acquisition system” to be a cell phone based on those disclosures. Chatterjee Opp. ¶7. Importantly, the “data acquisition system” is not disclosed as adjusting the PAP/CPAP, as its sole function is to receive and transmit sensor signals to a remote location. *See, e.g.*, EX1002, 21:21-24 (“data acquisition system [is] capable of both (a) receiving signals from the [subject’s] sensors ... and (b) retransmitting the signals or transmitting another signal based at least in part on at least one of the collected signals”).

PO also cites to a portion of specification that says a “diagnostic device” (e.g., sensors) can “provide an output” which is used for adjustment of the treatment device either “automatically” or “by a clinician or the subject.” EX1002, 34:20-24. But this does not disclose or suggest that it is a patient’s cell phone that adjusts the treatment device. The passage simply discloses what was already in the prior art- a PAP/CPAP device that titrates air pressure delivered to a patient based on sensor (“diagnostic device”) data. *See, e.g.*, EX1044; EX1050; EX1059.

Finally, PO cites to FIG. 10 as support for the amendment, which the ’715 application describes as a “remote data acquisition device and system” that transmits a signal received from the sensors over communication systems like the internet or cellular networks “to a server [] for analysis” and storage in a database, where the data can be reviewed by “clinicians, technicians, researchers, doctors and the like.”

See EX1002, 72:25-73:11. The '715 application goes on to state that “[s]ignal 84 is a command signal for adjusting a parameter of the treatment device.” *Id.*, 73:11-12. But the specification does not disclose what device or component sends or receives “signal 84,” nor is it illuminated by Fig. 10 itself, which associates “signal 84” (depicted as 684 in the actual Fig. 10) with an arrow pointing from the internet (e.g., remote location) to a home. There is no illustration or identification of a cellular phone in Fig. 10. *See* EX1002, Fig. 10. Moreover, the '715 application does not disclose or suggest that a patient cell phone receives “signal 84” to adjust the PAP/CPAP.

“The written description requirement is not met when, as here, the specification provides *at best* disparate disclosures that an artisan *might* have been able to combine in order to make the claimed invention.” *Flash-Control*, 2021 WL 2944592, at *5 (emphasis added). In this case, the specification nowhere discloses a cell phone that adjusts a PAP/CPAP, and the “disparate disclosures” do not suggest it. *Id.* Given the deficiencies of the disclosures, a POSITA would not have believed at the time that the patentee was in possession of a cell phone that could adjust the therapy administered by a PAP/CPAP. Chatterjee Opp. ¶¶6-8.

2. The added limitation of “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” lacks written description support in the '899 application

The parent application of the '333 patent, U.S Patent App. No. 11/266,899

(the “’899 Application,” EX2033), similarly fails to disclose or suggest a patient cell phone configured to adjust PAP/CPAP therapy. Chatterjee Opp. ¶¶4, 9-11. PO cites to the specification where it describes a “remote communication system” as being a “wireless router” “PDA, computer, or cell phone” that can receive data from the PAP and send it “to a remote site for analysis,” “preferably for further input by the subject’s physician or another clinician.” EX2033, 34:9-21. But there is no disclosure of a “remote communication system” sending signals or data to adjust the PAP/CPAP therapy. The specification certainly does not disclose or suggest a patient cell phone that sends signals to the PAP or adjusts PAP therapy.¹ See Chatterjee Opp. ¶¶9-11. In fact, PO’s cited passage does not mention a treatment device at all; there is no disclosure of the transmission of any signals or data to a PAP/CPAP, let alone any that would adjust the PAP/CPAP therapy. There is no disclosure that would form a basis for the “remote communication system” to do so. Chatterjee Opp. ¶10. The limitation is not described with any detail, let alone “sufficient” detail to allow a POSITA to recognize a cell phone adjusting the PAP therapy as patentee’s invention.

¹ The relationship between the disclosed “remote communication system” and “remote communication station” is unclear though they appear to be different elements of the system. Regardless, neither is disclosed as adjusting PAP/CPAP therapy.

Regents, 119 F.3d at 1567; Chatterjee Opp. ¶10.

PO further cites a passage that discusses a “diagnostic device” “used to provide an output” that can be employed to adjust a “treatment device” “automatically ... or by a clinician or the subject.” EX2033, 38:24-26. The cited passage also describes an embodiment in which the “CPAP can be adjusted during the treatment based on the sleep diagnosis results,” preferably through the receipt of “some type of signal.” *Id.* 39:12-28. Here, the “diagnostic device” is undefined and is nowhere disclosed as a cell phone, let alone a patient’s cell phone. In one embodiment, “diagnostic device 441” is described as “a radio 436 and antenna 434; a microprocessor 438 for processing the data or signals to determine a level of severity of the subject's sleeping disorder or symptoms” that “transmits a signal” to the “CPAP device 428, which controls the flow of air or gas to the subject.” 41:11-17. But a POSITA would not have understood the “diagnostic device” to be a cell phone based on the disclosures in the '899 application. Chatterjee Opp. ¶10; *see also* EX2003, Fig. 8.

“[E]ven if a skilled artisan ‘would have understood how to implement’ the claimed functionality in software if the specification had described a [cell phone] containing the functionality, that does not mean that the written description itself demonstrates to a relevant artisan that the inventors possessed the invention of that functionality in a [cell phone].” *Impact Engine, Inc., v. Google LLC*, 2024 WL

3287126, *9-10 (Fed. Cir. 2024). A POSITA would not have believed at the time that the patentee was in possession of a cell phone that could adjust the therapy administered by a PAP/CPAP based on the '899 disclosures and, consequently, the '899 application does not provide adequate written support for the added limitation. Chatterjee Opp. ¶¶9-11.

Accordingly, because neither the '719 nor the '899 specifications adequately support the written description of a patient cell phone configured to adjust the PAP/CPAP therapy, the Substitute Claims do not meet the procedural requirements of 37 C.F.R. § 42.121.

B. The Substitute Claims Are Not Responsive to the Grounds of Unpatentability

The Substitute Claims also do not meet the requirements of 37 C.F.R. § 42.121(a)(2)(i) because they are not responsive to the grounds of unpatentability. As discussed in detail below, the prior art of record employed in the proposed combinations still render the Substitute Claims obvious. *See* discussion *infra*.

IV. THE SUBSTITUTE CLAIMS ARE NOT PATENTABLE OVER THE INSTITUTED GROUNDS

A. Toge in view of Kumar render obvious the limitations of Substitute Claim 30.d

1. Substitute Claim 30.d (amended claim 15.d)

“transmitting, in either order, both

1) the collected data and/or the quantified level of severity data to a subject's cellular phone with downloadable first software via a radio frequency wireless link; and

2) the collected data and/or the quantified level of severity data to a remote internet site hosted on at least one server from either

a) the PAP or CPAP device via a cellular system, or

b) the subject's cellular phone to the remote internet site via the cellular system or Internet for further analysis with a second processor on the at least one server and review of the collected data, the quantified level of severity and/or this analysis by a clinician, technician or physician at a remote computer”²

PO does not dispute that the Petition established that the Toge-Kumar system renders obvious the above limitations, even as amended (*see* highlighted additions). In particular, the Petition established that Toge in view of Kumar disclose transmitting the quantified level of severity data to a subject's cellular phone with downloadable first software (via a radio frequency wireless link) and a remote internet site (previously “remote station”) hosted on at least one server from the PAP/CPAP (via a cellular system) for further analysis with a second processor on the at least one server and review of the quantified level of severity by a clinician, technician or physician at a remote computer. *See* Pet., 18-39 (discussing claim 15.d-e), 39-41 (discussing claim 16 (patient-side cell phone)).

² Given the alternative language recited in limitation [30.d], Petitioner once again color codes the step to identify the language it addresses.

(a) Toge in view of Kumar disclose “a subject’s cellular phone with downloadable first software” that receives a “quantified level of severity data”

To the extent the Petition does not explicitly outline the disclosure of “a subject’s cellular phone with downloadable first software” that receives “a quantified level of severity data” from “the PAP or CPAP device via a cellular system,” Toge in view of Kumar disclose it. *See* Pet., 18-41. In particular, Kumar discloses a plug-in (“first software”) sent (“downloaded”) to computing device 110 (“cellular phone”) that communicates with patient-side devices (e.g., Toge’s PAP) through a wireless protocol, where, in particular, the patient cell phone receives data from the PAP. EX1008, [0072], [0074]-[0075]; *see also* Pet., 39. Indeed, PO appears to agree that Kumar discloses a patient cell phone. *See* Mot. Amd., 14-15 (stating “Kumar discloses a patient-side computing device” and citing EX1008, “[0072]” which describes a “computing device 110, such as a ... wireless telephone”). A POSITA would have further understood that the plug-in would be executable on the processor of the computing device (“subject’s cellular phone”) and configured to be used by the computing device, so that it would be functional. Chatterjee Opp. ¶14. Kumar further discloses that computing device 110 (“cellular phone”) communicates with patient-side devices (e.g., Toge’s PAP) using a wireless protocol (wide area network (WAN)), through which the patient cell phone receives data from the patient-side device. EX1008, [0067]-[0068], [0075]; Chatterjee Opp. ¶¶13, 15.

And Toge discloses a “quantified level of severity data” transmitted from “the PAP or CPAP device via a cellular system.” *See* Pet., 19-20 (“[T]he treatment data, including tidal volume (‘the quantified level of severity data’)³,” is transmitted “from PAP device 2 (‘the PAP or CPAP device’) ... connected to network 1.”). A POSITA would have understood network 1 to be a mobile network connected via “a cellular system.” *See id.*; *see also* Chatterjee Opp. ¶15.

A POSITA would have found it obvious to configure Kumar’s patient-side cellular phone to receive a quantified level of severity data from the PAP/CPAP just as Toge’s physician-side cell phone receives such information. Chatterjee Opp. ¶¶12-19. The physician (Toge) and patient (Kumar) cell phones are both the same/similar devices that are structurally and functionally similar and have (or are capable of having) the same functionalities. Chatterjee Opp. ¶¶17-18.

A POSITA would have been motivated to incorporate Kumar’s patient-side cell phone into Toge’s PAP system to receive and analyze PAP/CPAP data (e.g., quantified level of severity data) for a number of reasons. For one, doing so would have allowed the patient to view the treatment data (e.g., “quantified level of severity data”) on the patient’s personal cell phone and store such information for later viewing even when away from the PAP device. Kirkness Opp. ¶7; Chatterjee Opp.

³ PO does not dispute here that tidal volume is a “quantified level of severity data.”

¶18. A POSITA would have understood that the plug-in (first software) would have been downloaded on to the computing device (cell phone) in order to communicate with the PAP device and display the data from the PAP device to the patient. *Id.*; *see also* EX1049 (Quy), 8:8-31 (“remote server located on the Internet, downloads an interactive user interface for that patient and an application for the measurement of the physiological data,” “control[ling] the manner, content, and display of information presented to the patient”). Toge already expressly describes that the doctor or other medical professionals are able to access treatment related data via a mobile phone. EX1044, [0019]. It would have been beneficial for the patient to also review such information indicating how the patient responded to the treatment, as it would have encouraged the patient to comply with the prescribed treatment. Kirkness Opp. ¶7. Additionally, having PAP data on a patient’s cell phone would have allowed the patient to store the information for later viewing even when away from the PAP device such that the data would be available for viewing anytime, further encouraging patient engagement. *Id.*; Chatterjee Opp. ¶18. Patient data stored solely on the PAP device would not have been easily accessible by the patient at any time or place. *Id.* Finally, such a modification could have reduced the PAP device’s form factor, as it could have eliminated the need for a PAP/CPAP screen that would have displayed data to the patient, which in turn would have improved the device’s portability and/or resulted in a smaller and less expensive device. *Id.*

A POSITA would have had the skill and a reasonable expectation of success in implementing a patient cell phone as it would have involved the combination of a known technology (e.g., cell phone already implemented in the Toge-Kumar system as a physician-side cell phone) according to known methods (e.g., methods of transmitting data between the physician-side cell phone and the PAP/CPAP) to yield the predictable result of a PAP/CPAP system with a patient's cell phone that receives a quantified level of security data. Chatterjee Opp. ¶¶19.

PO argues that “a POSITA would not have been motivated to add a patient's cell phone to Toge's system because Toge is directed to the physician so there was no problem that needed solving that would have motivated this modification.” Mot. Amd., 15. To begin with, Toge is not solely “directed to the physician.” *Id.* Toge contemplates the patient operating the PAP device. *See* EX1044, [0026] (control/input “device 28 [is] operated by *the patient or* the physician” using “input buttons, and input terminals”); *id.*, [0030] (“transmission can be initiated *if the patient operates the input device 28* to request transmission”). Regardless, any POSITA would have been motivated to add a patient's cell phone to Toge's PAP system for the benefit of the patients, given that PAP therapy compliance is persistent issue. *See* Kirkness Opp. ¶7. Allowing patients to easily view their treatment data anytime and anywhere would increase patient engagement and compliance. *See supra*; *see also* Kirkness Opp. ¶7. Further, adding a patient's cell

phone to Toge's PAP system would allow for display of the patient's PAP data on the patient's cell phone, thereby allowing for a smaller form factor PAP device, without the traditional screen and controls. Kirkness Opp. ¶7; Chatterjee Opp. ¶18.

(b) Toge in view of Kumar disclose “a remote internet site hosted on at least one server” that receives a “quantified level of severity data”

Toge in view of Kumar render obvious this limitation. Kirkness Opp. ¶¶10-13; Chatterjee Opp. ¶¶20-32.

Toge discloses that its remote monitoring method includes a CPAP device “connected to a relay device and a physician-side terminal device via a wireless or wired communication network” and that the “physician-side terminal device is configured to receive all or part of the treatment data transmitted from the relay device.” EX1044, [0006]. Toge further discloses that “communication network 1 may be any of a public telephone network, the Internet, a mobile communication network, or a dedicated line network; alternatively, it may also be a combination of these networks.” EX1044, [0009]. In light of the above, it would have been obvious to a POSITA to utilize a “remote internet site” to receive the data related to the subject's treatment and the treatment's efficacy (e.g., Toge's tidal volume, “a quantified level of severity data”) from Toge's wireless PAP on the physician side devices of Toge. Kirkness Opp. ¶¶10-14; Chatterjee Opp. ¶¶20-28.

Kumar discloses “a remote internet site is hosted on at least one server”

("browser-based engine hosted on a central server"). *See* Pet., 23-29 (discussing Kumar's disclosure of the similar "remote station" term); Chatterjee Opp. ¶¶20-28; *see also* EX1008, [0069] ("engine/central server"). Additionally, a POSITA would have found it obvious to implement Toge's physician-side computer as a web server because it already receives PAP data and a POSITA would have known that internet content resides on a web server. *See* Chatterjee Opp. ¶26.

A POSITA would have been motivated to implement Kumar's remote engine/central server in Toge's PAP system to enable Toge's PAP to also wirelessly transmit data (e.g., a quantified level of severity data) to the remote server for storage, review, and data organization. Chatterjee Opp. ¶¶22, 24-25. In fact, Kumar discloses "data may be stored" "at the central server for later access, replay, and/or analysis" "from anywhere in the world with access." EX1008, [0083]. Hence, the remote server would increase the convenience, diagnosis, and treatment for patients. Chatterjee Opp. ¶¶27-32; Kirkness Opp. ¶12.

Moreover, a POSITA would have had a reasonable expectation of success in implementing a remote internet site hosted on at least one server, because it was well-known how to transmit data using wireless protocol(s) to a remote internet site. Thus, it would have involved a combination of known technologies (e.g., known PAP device that provides a quantified level of severity data (Toge) according to known methods (e.g., known methods of transmitting data wirelessly from patient-

side device to a remote engine on the internet (Kumar)) to yield the predictable result of a remote internet site hosted on a server Chatterjee Opp. ¶28; Kirkness Opp. ¶13.

PO argues that Toge in view of Kumar would not have rendered this limitation obvious because “Kumar’s web server would interfere with Toge’s purpose” to “push ‘necessary’ or ‘crucial’ data to physician-side devices so that physicians can monitor their patients and take emergency action when needed.” Mot. Amd., 20-21. PO erroneously insists that “[i]n the client/server-model,” “[b]ecause data is pulled only upon request, Toge’s purpose of pushing, without request, ‘necessary’ or ‘crucial’ treatment data would be interfered with.” Mot. Amd., 21. PO is mistaken for at least a couple of reasons. First, “emergency action” is not the only purpose of Toge, which is broader. For instance, Toge’s system monitors a patient’s breathing rate and oxygen saturation levels both “in real-time or at regular intervals” such that “physicians can also know the real-time or *periodic condition* of the patient.” EX1044, [0044], [0047] (emphasis added). Thus, in Toge, PAP data can be stored in the memory of the PAP device and be later transmitted or transmitted in “real-time.” See EX1044, [0007], [0046]. Second, Kumar’s networking system is, in fact, designed for the “push” of real-time transmissions that PO alleges its implementation would “interfere with.” For example, like Toge, Kumar describes “*real-time streaming*” of data “from a patient/client to a health care provider” and a telemedicine networking system that allows the “*transmission] [of] signals in real-*

time” in addition to “providing *treatment in real-time* to the patient.” EX1008, [0009], [0010], [0014]; *see also* Pet., 36, 42.

Dr. Chatterjee confirms the ability of Kumar's system to transmit patient data in real-time, for use in emergency situations, for example. EX1005 ¶¶92 (“an internet-based software system capable of streaming in real-time' health-related data” could “*help identify medical emergencies*”); *see also id.* ¶¶146; EX1008, [0007]. Thus, PO's conclusion that patient data could only be accessed from Kumar's web-based engine upon “request” is erroneous. Chatterjee Opp. ¶¶29-32. Put simply, even in a pull system, data would be effectively “pushed” in real-time. Chatterjee Opp. ¶30. Alternatively, the remote internet site/physician device could be implemented to continuously query the server for new data, making it functionally equivalent to a “push” system. Chatterjee Opp. ¶31. Accordingly, implementing Kumar's remote internet site in Toge's PAP system would not have “interfered” with any of the purposes of Toge's PAP system or dissuaded a POSITA from combining Toge with Kumar.

(c) Toge in view of Kumar disclose a “second processor on the at least one server” and “a physician at a remote computer”

Toge in view of Kumar also disclose a “second processor on the at least one server.” A POSITA would have understood Kumar's browser-based engine (remote internet site)/central server to contain a processor to analyze the data transmitted and

stored therein. *See* Pet., 33; Chatterjee ¶167; Chatterjee Opp. ¶¶33-35.

Finally, both Toge and Kumar disclose “a physician at a remote computer” able to review the “quantified level of severity data.” *See* Pet., 32-33. Toge discloses that physicians “can access the transmitted data using the *physician-side computer 4.*” EX1044, [0018] (emphasis added). Kumar similarly discloses a provider-side device that allows a physician/provider to “receiv[e] data from the patient-side device” (e.g., a “quantified level of severity data”) to “monitor the patient[], ... perform[] analysis, [and] diagnos[e] the patient.” EX1008, [0078]; Chatterjee Opp. ¶¶36-37. Kumar further discloses that the provider-side device “can be any type of computing device, such as a computer.” EX1008, [0072]; Chatterjee Opp. ¶¶36-37.

B. Toge in view of Kumar render obvious the limitations of Substitute Claim 30.e and 30.f

1. Toge in view of Kumar render obvious a patient's cell phone with downloadable software that receives and displays a patient's sleep data

- (a) **Substitute Claim 30.e (amended claim 15.e)**
“further determining therapy efficacy data with either the processor of the PAP or CPAP device, the second processor configured with a second software stored on a computer readable medium at the at least one server, or the subject's cellular phone using the first software further provided to receive and display

the quantified level of severity data and/or therapy efficacy data to the subject”⁴

PO does not dispute that the Petition establishes that Toge alone or in view of Kumar disclose “further determining therapy efficacy data with ... the second processor configured with a second software stored on a computer readable medium at the at least one server ... further provided to receive and display the quantified level of severity data...”. *See* Mot. Amd., 15-17; Pet., 34-39. PO argues that “Toge in view of Kumar does not teach the claimed features of a patient’s cell phone with downloadable first software receiving and displaying sleep data.” Mot. Amd., 15-17. To the extent PO’s argument is directed to the limitation of Substitute Claim 30.e, the claim does not require Petitioners to demonstrate that the Toge-Kumar combination discloses “a patient’s cell phone with downloadable first software receiving and displaying sleep data.” *Id.* Substitute Claim 30 recites that therapy efficacy data can be determined by “*either*”: 1) “the processor of the PAP or CPAP device,” 2) “the second processor configured with a second software stored on a computer readable medium at the at least one server,” *or* 3) “the subject’s cellular phone using the first software.” *See* Mot. Amd., 24 (emphasis added). The Petition

⁴ Given the alternative language recited in limitation [30.e], Petitioner color codes the step to identify the language it addresses and again highlights the matter added by amendment.

established that Toge in view of Kumar discloses the second configuration (“the second processor configured with a second software stored on a computer readable medium at the at least one server”). *See* Pet., 34-39 (discussing claim 15.e.1). No more is required to demonstrate that Substitute Claim 30.e is obvious. *See In re Cuozzo Speed Techs., LLC*, 793 F.3d 1268, 1281 (Fed. Cir. 2015) (confirming that only one embodiment of a claim need be obvious to render the entire claim obvious).

Regardless, Toge in view of Kumar also disclose “further determining therapy efficacy data with ... the subject’s cellular phone using the first software ... further provided to receive and display the quantified level of severity data...”. Toge discloses “determining the therapy efficacy data” for the reasons described in the Petition. *See* Pet., 34-35 (“A POSITA would have understood that the data for adjusting mode settings/parameters corresponds to the claimed “therapy efficacy data”). PO does not dispute this. As discussed above, Kumar discloses a patient cell phone (computing device 110) equipped with a “plug-in” (downloadable software) (together “the subject’s cellular phone using the first software”). *See* IV.A.1.a *supra*. Kumar further discloses that computing device 110 (“subject’s cellular phone”) performs data analysis using data interpretation and analysis module 114 and *can display the data on display module 116 of the device*. *See* EX1008, [0075]; Fig. 1A; Chatterjee Opp. ¶38.

PO argues that a POSITA would not have been motivated to add a patient cell

phone to the Toge system, but this is refuted *supra*. See IV.A.1.a. PO also argues that in having a display on the PAP machine, “Toge’s system already independently operates effectively for its purpose,” making a patient’s cell phone with a display function “completely unnecessary.” Mot. Amd., 16-17. As also discussed above, however, display of a patient’s treatment data on their own cellular device could have eliminated the need for a PAP display component, resulting in a more portable, smaller, less expensive PAP device. See IV.A.1.a *supra*; see also Kirkness Opp. ¶7; Chatterjee ¶¶18-19, 39. A POSITA would have known that it would have been beneficial for the patient to review such information through the patient’s own device. *Id.* But even if, as PO argues, the PAP and cell phone displays were simply duplicative, it would not have eliminated the motivation to combine the references. See *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1165 (Fed. Cir. 2006) (“[A] given course of action often has simultaneous advantages and disadvantages, and this does not necessarily obviate a motivation to combine”).

2. Toge in view of Kumar render obvious a patient’s cell phone that adjusts the PAP/CPAP therapy

- (a) Substitute Claim 30.f**
“wherein the therapy administered by the PAP or CPAP device is configured to be adjusted by the first software on the subject’s cellular phone and the remote computer of the clinician, technician, or physician based on the wirelessly transmitted collected data, quantified level of severity data, or the therapy efficacy data.”

PO agrees that the Petition establishes that Kumar discloses a communication device 102 (patient's cell phone) that can communicate with the patient-side device 110 (PAP/CPAP). *See* Mot. Amd., 14-15; *see also* Pet., 39-40 (“Kumar discloses that a patient-side device may establish [] ‘a two-way communication’ with a computing device 110, e.g., a ‘wireless phone’”). And, as discussed above, Kumar discloses that the patient cell phone has downloadable software. *See* IV.A.1.a *supra*. PO also does not dispute that Toge discloses a networked PAP system in which PAP data are transmitted to a physician's cell phone and remote computer, and that, based on the data, the physician can direct the cell phone to remotely adjust the PAP therapy. *See* Pet., 18-19 (“Toge discloses that the treatment data, including tidal volume (‘the quantified level of severity data’), is transmitted to mobile terminal 5 from PAP device 2, which is also connected to network 1, e.g., a mobile network” and further that the “care provider may operate the mobile terminal 5 to “set the necessary data...for [PAP] device 2.”); EX1044, [0027] (“The prescription pressure and minute breathing rate (as well as mode settings) values (prescription values)” “can also be configured via communication network 1 through ... mobile terminal 5”); *id.*, [0038] (“adjusting the prescription pressure to a higher level can be taken remotely from the physician-side [] mobile terminal 5”).

In view of the foregoing disclosures, a POSITA would have found it obvious to configure Kumar's patient-side cell phone to adjust the PAP/CPAP therapy.

Chatterjee Opp. ¶¶39-46; Kirkness Opp. ¶¶14-20. Thus, in the Toge-Kumar system described (Pet., 6-41), a POSITA would have found it obvious to configure the downloadable software on Kumar's patient cell phone ("first software on the subject's cell phone") (*see supra*) to "set the necessary data...for the [PAP] device 2" and/or "adjust the prescription pressure" (adjust the PAP/CPAP therapy), the same functionality that Toge's physician-side cell phone possesses. Chatterjee Opp. ¶¶40-46; Kirkness Opp. ¶16. Given the disclosure of the very same functionality in Toge's physician-side cell phone, a POSITA would have found it obvious to modify the software of Kumar's patient cell phone to similarly adjust the PAP/CPAP therapy. Chatterjee Opp. ¶¶43-46; Kirkness Opp. ¶16.

The patient's cell phone could have been utilized to, for instance, adjust the PAP/CPAP therapy after a physician (who has, e.g., analyzed/reviewed the PAP data) "mobilize[s]" the patient's cell phone by transmitting instructions (e.g., prescription pressure) from the physician's computer to the patient's cell phone. *See* Pet., 19; EX1044, [0019], [0027] (PAP "settings can also be configured via communication network 1 through the physician-side computer 4"); Chatterjee Opp. ¶44. Alternatively, Kumar's patient cell phone, like Toge's physician cell phone, could be alerted when the "quantified level of severity data" exceeds or falls below a threshold value and appropriately adjust the PAP/CPAP therapy (e.g., air pressure) to remedy the situation. *See* Pet., 16, 19, 49 ("Toge discloses 'send[ing] an alert to

... the mobile terminal 5, marking the situation as an emergency ... when the tidal volume falls below certain threshold value(s)); EX1044, [0039] (“[I]f there is a decreasing trend in the tidal volume Fa, emergency measures, such as adjusting the prescription pressure to a higher level, can be taken ... [by] mobile terminal 5”). Chatterjee Opp. ¶44; Kirkness Opp. ¶17.

A POSITA would have been motivated to modify the software on Toge's cell phone to adjust PAP/CPAP therapy (e.g., air pressure). Kirkness Opp. ¶18; Chatterjee Opp. ¶¶45-46. It would have been beneficial to adjust the PAP/CPAP with the patient's cell phone, which, generally would have been more proximate to the PAP/CPAP device and, consequently, better able to make therapy adjustments more quickly than remote physician-side devices. Kirkness Opp. ¶18; Chatterjee Opp. ¶45. A faster response time would have been advantageous in, for example, emergency situations like those described in Toge and Kumar. Kirkness Opp. ¶¶17-18; Chatterjee Opp. ¶45; *see also* Pet., 18-19, 41-42, 49; EX1044, [0007], [0044]; EX1008, [0016]. A patient cell phone could also more easily assist the PAP in automatically or periodically adjusting the patient's air pressure to “ensure the PAP therapy is properly tailored to the patient's current condition.” *See* EX1059 (Norman), [0024]; Pet., 62-63; Kirkness Opp. ¶17. Incorporating a patient cell phone into the Toge-Kumar PAP system that was capable of better fine-tuning PAP/CPAP pressure would have further increased patient comfort and aided in patient

motivation to the use the device. Kirkness Opp. ¶17.

Additionally, moving the screen and controls from the PAP device itself to the patient's cell phone would have also motivated a POSITA to make the modification. It would have allowed the patient to adjust allowable PAP parameters from their phone while in bed connected to the device (prior to or during treatment). Chatterjee Opp. ¶45; Kirkness Opp. ¶19. And, as discussed *supra* (see IV.A.1.a; IV.B.1.a), moving the display from the PAP to the phone would have been further supported by a POSITA's desire for a smaller form factor PAP device. Chatterjee Opp. ¶¶18-19, 39; Kirkness Opp. ¶¶7, 19.

A POSITA would have had a reasonable expectation of success in implementing a patient cell phone that adjusts the PAP/CPAP, as the modification of the downloadable software on Kumar's patient cell phone would have simply been a change of programming (e.g., updated downloadable software), and this programming would have already been known to a POSITA as evidenced by Toge's physician cell phone. Chatterjee Opp. ¶46; Kirkness Opp. ¶20. Given this, a POSITA would have had a reasonable expectation of success in implementing Kumar's patient cell phone in the Toge PAP system configured to adjust the PAP/CPAP therapy. Chatterjee Opp. ¶46; Kirkness Opp. ¶¶14-20.

V. CONCLUSION

The Board should deny PO's contingent motion to amend.

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CERTIFICATE OF SERVICE

I hereby certify that on January 14, 2026, a true and correct copy of the foregoing **PETITIONER'S OPPOSITION TO PATENT OWNER'S CONTINGENT MOTION TO AMEND AND REQUEST FOR PRELIMINARY GUIDANCE** is being served by electronic mail on Patent Owner's counsel of record listed below, pursuant to its Mandatory Notices:

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