

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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RESMED CORP.,  
Petitioner,

v.

CLEVELAND MEDICAL DEVICES, INC.,  
Patent Owner.

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IPR2025-00246  
Patent 11,857,333 B1

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Before SHERIDAN K. SNEDDEN, NEIL T. POWELL, and  
CYNTHIA M. HARDMAN, *Administrative Patent Judges*.

HARDMAN, *Administrative Patent Judge*.

PRELIMINARY GUIDANCE  
PATENT OWNER'S MOTION TO AMEND  
*37 C.F.R. § 42.121(e)*

## I. INTRODUCTION

We instituted trial as to claims 15–29 of U.S. Patent No. 11,857,333 B1. Paper 12 (“Institution Decision” or “Dec.”). After institution, Patent Owner filed a Motion to Amend that is contingent on the patentability of claims 15–29. Paper 28 (“Motion” or “Mot.”). Petitioner filed an opposition to the Motion. Paper 31 (“Opposition” or “Opp.”).

In the Motion, Patent Owner requests that we provide preliminary guidance concerning the Motion in accordance with 37 C.F.R. § 42.121(a)(1)(ii). Mot. 2; *see* 37 C.F.R. § 42.121(e)(1); *see also Rules Governing Motion to Amend Practice and Procedures in Trial Proceedings under the America Invents Act before the Patent Trial and Appeal Board*, 89 Fed. Reg. 76,421 (Sept. 18, 2024) (“Final Rule”). We have considered Patent Owner’s Motion and Petitioner’s Opposition.

In this Preliminary Guidance, we provide information indicating our initial, preliminary, non-binding views on whether Patent Owner has shown a reasonable likelihood that it has satisfied the statutory and regulatory requirements associated with filing a motion to amend in an *inter partes* review and whether Petitioner establishes a reasonable likelihood that the substitute claims are unpatentable. 37 C.F.R. §§ 42.121(e)(1), (2); *see also* 35 U.S.C. § 316(d) (statutory requirements for a motion to amend); 37 C.F.R. §§ 42.121(a)(2), (a)(3), (b) (regulatory requirements and burdens for a motion to amend); *Lectrosonics, Inc. v. Zaxcom, Inc.*, IPR2018-01129, Paper 15 (PTAB Feb. 25, 2019) (precedential) (providing information and guidance regarding motions to amend). The reasonable likelihood standard we apply in this Preliminary Guidance is different from the preponderance of the evidence standard we will apply when ultimately deciding the Motion. *Compare* 37 C.F.R. § 42.121(e)(1), *with* § 42.121(d). Finally, this

preliminary guidance is not a “decision” for purposes of rehearing under 37 C.F.R. § 42.71(d). 37 C.F.R. § 42.121(e)(2).

For purposes of this Preliminary Guidance, we focus on the proposed substitute claims, and specifically on the amendments proposed in the Motion. *See* 37 C.F.R. § 42.121(e)(1); Final Rule, 89 Fed. Reg. at 76,425. We do not address the patentability of the originally challenged claims. *See id.* Moreover, in formulating our preliminary views on the Motion and Opposition, we have not considered the parties’ other substantive papers on the underlying merits of Petitioner’s challenges. We emphasize that the views expressed in this Preliminary Guidance are subject to change upon consideration of the complete record, including any revision to the Motion filed by Patent Owner. Thus, this Preliminary Guidance is not binding on the Board when rendering a final written decision or any other subsequent decision in this proceeding. 37 C.F.R. § 42.121(e)(2); *see Medytox, Inc. v. Galderma S.A.*, 71 F.4th 990, 1000 (Fed. Cir. 2023).

## II. PRELIMINARY GUIDANCE

### A. Statutory and Regulatory Requirements

Patent Owner bears the ultimate burden to show that the Motion complies with the requirements of 35 U.S.C. §§ 316(d)(1) and (3) and 37 C.F.R. §§ 42.121(a)(2), (a)(3), (b)(1), and (b)(2). 37 C.F.R. § 42.121(d)(1). For the reasons discussed below, at this stage of the proceeding and based on the current record, it appears that Patent Owner has not shown a reasonable likelihood that the Motion satisfies the statutory and regulatory requirements associated with filing a motion to amend. *See* 37 C.F.R. § 42.121(e)(1).

#### 1. Reasonable Number of Substitute Claims

A motion to amend must propose a reasonable number of substitute claims. 35 U.S.C. § 316(d)(1)(B); 37 C.F.R. § 42.121(a)(3).

Patent Owner proposes to cancel claims 17, 18, and 20, and substitute claims 15, 16, 19, and 21–29 with substitute claims 30–41. Mot 1–2, 23–27 (App. A).

Based on our review of the current record, Patent Owner has shown it proposes a reasonable number of substitute claims because it proposes a less than one-to-one substitution. *See* 37 C.F.R. § 42.121(a)(3) (“The presumption is that only one substitute claim would be needed to replace each challenged claim, and it may be rebutted by a demonstration of need.”). Petitioner does not argue otherwise. *See generally* Opp.

## 2. Respond to a Ground of Unpatentability

A motion to amend must respond to a ground of unpatentability involved in the proceeding. 37 C.F.R. § 42.121(a)(2)(i).

Patent Owner argues that it “the amendments introduce novel and nonobvious features that avoid the prior art and Petitioner’s proposed combinations.” Mot. 12; *see also id.* at 13–21 (arguing that the newly added limitations in proposed substitute independent claim 30 distinguish the claim from the teachings of Toge (Ex. 1044), Kumar (Ex. 1008), and Norman (Ex. 1059)). Petitioner argues that the substitute claims do not respond to a ground of unpatentability because “the prior art of record employed in the proposed combinations still render the Substitute Claims obvious.” Opp. 8.

We find that Patent Owner has met this requirement by amending the claims in response to the unpatentability arguments presented in the Petition. Nevertheless, below we consider whether the proposed substitute claims remain unpatentable as obvious over Toge and Kumar in connection with evaluating Petitioner’s unpatentability arguments directed to the newly-added claim limitations.

### 3. Scope of Amended Claims

A motion to amend may not enlarge the scope of the claims of the patent. 35 U.S.C. § 316(d)(3); 37 C.F.R. § 42.121(a)(2)(ii). Patent Owner’s Motion only adds narrowing limitations, and thus does not enlarge the scope of the patent claims. *See* Mot. 3–4, 23–27 (App. A). Petitioner does not argue otherwise. *See generally* Opp.

### 4. New Matter

A motion to amend may not introduce new subject matter. 35 U.S.C. § 316(d)(3); 37 C.F.R. § 42.121(a)(2)(ii). Patent Owner contends the proposed substitute claims are supported by “U.S. Patent App. No. 15/641,715 (the ‘’715 Application,’ Ex. 1002), which issued as the ’333 Patent, filed on July 5, 2017, and U.S. Patent App. No. 11/266,899 (the ‘’899 Application’), which is the first non-provisional application in the chain of priority, filed on November 4, 2005.” Mot. 4. Patent Owner provides a table of citations to the ’715 and ’899 Applications for each limitation of the proposed substitute claims. *Id.* at 5–12.

We focus here on disputed limitation 30.f,<sup>1</sup> which recites, in relevant part, “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.” Mot. 7–8, 23–24. Patent Owner cites several passages in the ’715 and ’899 Applications that allegedly disclose the requirement “that the patient’s cell phone . . . contain[s] software configured to adjust the therapy administered by the PAP or CPAP

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<sup>1</sup> For ease of reference, we refer to the claim limitations of proposed substitute claim 30 listed in Patent Owner’s table of citations as 30.preamble, 30.a, 30.b, 30.c, 30.d, 30.e, and 30.f, respectively. *See* Mot. 5–8.

device.” *Id.* at 5, 7–8 (claim chart). Petitioner argues that Patent Owner’s citations do not sufficiently disclose limitation 30.f. Opp. 2–8.

Below we review Patent Owner’s cited support in the ’715 and ’899 Applications for limitation 30.f. We note, however, that the priority chain for the ’333 patent includes other applications in addition to the ’715 and ’899 Applications. *See* Ex. 1001, code (63). The ’899 Application “is the first nonprovisional application in the chain of priority.” Mot. 4. To gain the benefit of the filing date of this application under 35 U.S.C. § 120, Patent Owner must show that *each* application in the chain leading back to the ’899 Application “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) (quoting *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc)). Although we find that Patent Owner’s citations fail to provide adequate written description support for limitation 30.f for the reasons discussed below, Patent Owner’s showing is also flawed because Patent Owner failed to show that the cited disclosure from the ’899 Application was carried through each application to the ’715 Application (i.e., the application that led to the ’333 patent).

We now turn to analyzing Patent Owner’s cited support.

i. The ’715 Application (Ex. 1002)

Patent Owner argues that the ’715 application discloses that “the patient’s cell phone and medical provider’s remote computer contain software configured to adjust the therapy administered by the PAP or CPAP device.” Mot. 5. As support, Patent Owner cites the disclosure in the ’715 application at 5:2–12 as teaching that “the diagnostic device transmits output data to intermediary devices such as a cell phone, modem, or router,” and the disclosure at 34:20–24 as teaching that “the

clinician or the subject can adjust the therapy administered by the PAP device based on the diagnostic device's output data." *Id.*; *see also id.* at 7.

Petitioner responds that the disclosure at 5:2–12 is insufficient because it “only discloses that a diagnostic device (e.g., sensors) can transmit signals” to an “intermediary device” which can be a cell phone, but does not disclose that the intermediary device “transmit[s] any signals to a treatment device” or “adjusts the PAP/CPAP therapy.” *Opp.* 2–3 (emphasis omitted). Regarding the cited passage at 34:20–24 of the '715 Application, Petitioner asserts that it teaches that the patient can adjust the PAP/CPAP device, but it “does not disclose or suggest that it is a patient's cell phone that adjusts the treatment device.” *Opp.* 4.

We find that Petitioner has the better view of the cited disclosure in the '715 Application at 5:2–12 and 34:20–24. In short, we agree with Petitioner that neither citation “disclose[s] or suggest[s] a patient's ('subject's') cell phone is able to be configured to adjust PAP/CPAP therapy.” *Opp.* 2.

Patent Owner additionally cites the '715 Application at 72:25–73:18 as supporting limitation 30.f. *Mot.* 7–8. Patent Owner, however, fails to adequately explain the connection between the limitation 30.f and this disclosure. In the text of the Motion, Patent Owner asserts that “a subject's cell phone and remote internet site receive the subject's sleep data,” and specifically characterizes 72:25–73:18 as “disclosing the transmission of the subject's sleep data to a remote internet site hosted on a server.” *Id.* at 4–5. These assertions do not explain how the cited disclosure supports limitation 30.f.

Finally, Patent Owner cites the '715 Application at 11:17–12:1 as supporting limitation 30.f, but again fails to adequately explain the connection between the claim limitation and this disclosure. *See Mot.* 7–8. We agree with Petitioner that this passage discusses remotely programming the PAP device, but does not

disclose or describe the device or component carries out the remote programming.  
Opp. 3.

In sum, on this record, we find that Patent Owner has not adequately shown that the cited disclosure in the '715 Application demonstrates the inventors had possession of a method of treating a subject's sleep apnea "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." *See* Mot. 5–8, 23–24 (App. A). The portions of the '715 Application cited by Patent Owner describe remotely adjusting the PAP/CPAP device's settings and disclose that the subject may adjust the PAP/CPAP device, but they do not appear to disclose that software on the subject's cell phone can be used to make such adjustments.

ii. The '899 Application (Ex. 2033)

Patent Owner points to two passages in the '899 Application that it alleges provide written description support for claim limitation 30.f. Mot. 7–8. First, regarding 34:9–21, Patent Owner asserts that "a subject's cell phone and remote internet site receive the subject's sleep data," and specifically characterizes 34:9–21 as disclosing "a remote internet site for analysis." *Id.* at 4–57–8. These assertions do not explain how the cited disclosure supports the "cell phone" portion of limitation 30.f. Additionally, we agree with Petitioner that although the text at 34:9–21 "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,'" this does not disclose "a 'remote communication system' sending signals or data to adjust the PAP/CPAP therapy" or "a patient cell phone that sends signals to the PAP or adjusts PAP therapy." Opp. 6.

Patent Owner next cites the '899 Application at 38:24–39:28, but does not explain the connection between the claim limitation and this disclosure. *See* Mot. 5, 7–8. Additionally, we agree with Petitioner that this passage “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’” and “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,’” but does not define the “diagnostic device” or disclose that it is a subject’s cell phone. Opp. 7.

In sum, on this record, we find that Patent Owner has not adequately demonstrated disclosure in the '899 Application demonstrating that the inventors had possession of a method of treating a subject’s sleep apnea “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.” *See* Mot. 5–8, 23–24 (App. A). The portions of the '899 Application cited by Patent Owner do not appear to disclose that the subject’s cell phone can be used to adjust the PAP or CPAP device.

Based on the foregoing, it appears that Patent Owner’s amendments to proposed claim 30 introduce new matter in limitation 30.f.

#### B. Petitioner’s Unpatentability Arguments

Petitioner bears the ultimate burden to show that any proposed substitute claims are unpatentable. 37 C.F.R. § 42.121(d)(2). For the reasons discussed below, at this stage of the proceeding and based on the current record,<sup>2</sup> it appears

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<sup>2</sup> We express no view on the patentability of original claims 15–29 in this Preliminary Guidance. Instead, we focus on limitations added to those claims in the Patent Owner’s Motion to Amend.

that Petitioner has shown a reasonable likelihood that proposed substitute claim 30 is unpatentable.<sup>3</sup> *See* 37 C.F.R. § 42.121(e)(1).

Petitioner argues that proposed substitute claim 30 is unpatentable as obvious over Kumar (Ex. 1008) and Toge (Ex. 1044). Opp. 8–25. Petitioner addresses limitations 30.d, 30.e, and 30.f. *Id.* We address Petitioner’s arguments regarding these claim limitations below.

1. Claim Limitation 30.d

- i. Transmitting “the collected data and/or the quantified level of severity data to a subject’s cellular phone with downloadable first software”

Petitioner argues that “[t]o 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,’” Kumar and Toge teach this subject matter. Opp. 10 (citing Pet. 18–41). Specifically, Petitioner contends that “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.” *Id.* (citing Ex. 1008 ¶¶ 72, 74–75; Pet. 39; Ex. 1072 ¶ 14). Petitioner argues that Kumar also “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.” *Id.* (citing Ex. 1008 ¶¶ 67–68, 75; Ex. 1072 ¶¶ 13, 15).

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<sup>3</sup> Petitioner’s Opposition does not include unpatentability arguments specific to proposed substitute claims 31–41. *See generally* Opp. Nor does Petitioner assert that the proposed substitute claims are unpatentable for lack of adequate written description support.

Petitioner argues a person of ordinary skill in the art “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” because 1) “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;” 2) “it would have encouraged the patient to comply with the prescribed treatment;” and 3) “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.” Opp. 11–12 (citing Ex. 1072 ¶¶ 12–19; Ex. 1071 ¶ 7).

Patent Owner contends that “Toge does not disclose the use of patient’s cell phone in its system,” and a person of ordinary skill in the art would not have been motivated to add one because “Toge is directed to the physician so there was no problem that needed solving that would have motivated this modification,” and “Toge’s PAP device includes a PAP display screen that already allows a patient to view their sleep data.” Mot. 15–16.

On this record, we find that Petitioner has the better position. We agree with Petitioner that a person of ordinary skill in the art would have been motivated to add a patient’s cell phone (from Kumar) to Toge’s system because “Toge is not solely ‘directed to the physician.’” Opp. 13. Instead, Petitioner demonstrates that Toge “contemplates the patient operating the PAP device,” and that regardless, a person of ordinary skill in the art “would have been motivated to add a patient’s cell phone to Toge’s PAP system” to increase patient convenience, engagement, and compliance. Opp. 13; Ex. 1044 ¶¶ 26, 30; Ex. 1071 ¶ 7. At this stage,

Petitioner also adequately demonstrates that a person of ordinary skill in the art “would have had the skill and a reasonable expectation of success” to combine Kumar and Toge because

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.

Opp. 13 (citing Ex. 1072 ¶ 19).

- ii. Transmitting “the collected data and/or the quantified level of severity data to a remote internet site hosted on at least one server”

Petitioner argues that Toge discloses a CPAP device wirelessly connected to a physician-side terminal device that is configured to receive treatment data.

Opp. 14 (citing Ex. 1044 ¶¶ 6, 9). Petitioner argues that “Kumar discloses ‘a remote internet site is hosted on at least one server,’” and that a person of ordinary skill in the art “would have found it obvious to implement Toge’s physician-side computer as a web server because it already receives PAP data” and because it would “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” and to “increase the convenience, diagnosis, and treatment for patients.” Opp. 14–15 (citing Ex. 1071 ¶¶ 10–14; Ex. 1072 ¶¶ 20–32; Ex. 1008 ¶ 69, 83).

Patent Owner argues that a person of ordinary skill in the art would not have modified Toge’s system with Kumar’s web server “because it would have interfered with Toge’s purpose of pushing crucial treatment data to the physician-side devices.” Mot. 17 (citing Pet. 23–25; Ex. 2032 ¶¶ 41–48); *see also id.* at 20–21; *see also id.* at 18 (arguing that “Toge’s system pushes patient data to the

doctor's computer and mobile device for analysis and without request"). According to Patent Owner, "[b]ecause data is pulled only upon request [in Petitioner's combination], Toge's purpose of pushing, without request, 'necessary' or 'crucial' [] treatment data would be interfered with." *Id.* at 21 (citing Ex. 2019, 25–26; Ex. 2020, 2–3).

On this record, we find that Petitioner has the better argument. Petitioner adequately shows that (1) Toge's purpose is not limited to "emergency action," given that Toge discloses monitoring "a patient's breathing rate and oxygen saturation levels both 'in real-time or at regular intervals;" and 2) "Kumar's networking system is, in fact, designed for the 'push' of real-time transmissions" because it discloses "real-time streaming" of data and transmission of signals in real-time. Opp. 16–17 (citing Ex. 1044 ¶¶ 7, 44, 46, 47; Ex. 1008 ¶¶ 9, 10, 14). Petitioner also demonstrates that "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" because "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." *Id.* at 17 (citing Ex. 1005 ¶¶ 92, 146; Ex. 1008 ¶ 7; Ex. 1072 ¶¶ 29–32).

At this stage, Petitioner also adequately demonstrates that a person of ordinary skill in the art "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" and

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.

Opp. 15–16.

- iii. Transmitting “the collected data and/or the quantified level of severity data . . . 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”

Petitioner contends that Kumar and Toge “disclose a ‘second processor on the at least one server’” because a person of ordinary skill in the art “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.” Opp. 17–18. Petitioner argues that “both Toge and Kumar disclose ‘a physician at a remote computer’ able to review the ‘quantified level of severity data.’” *Id.* at 18.

Patent Owner does not address these elements of limitation 30.d. *See generally* Mot.

On this record, we agree with Petitioner’s position that Kumar and Toge teach or suggest these elements of claim limitation 30.d. *See* Opp. 17–18.

## 2. Claim Limitation 30.e

Petitioner contends Patent Owner “does not dispute that the Petition establishes that Toge alone or in view of Kumar” teaches “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.” Opp. 19 (citing Mot. 15–17; Pet. 34–39).

Petitioner argues that Kumar and Toge teach “further determining therapy efficacy data with . . . the subject’s cellular phone using the first software” because “Toge discloses ‘determining the therapy efficacy data’ for the reasons described

in the Petition” and “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’).” Opp. 20.

Patent Owner does not address proposed claim limitation 30.e. *See generally* Mot.

On this record, we agree with Petitioner’s position that Kumar and Toge teach or suggest claim limitation 30.e. *See* Opp. 18–21.

3. Claim Limitation 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 . . .”)

Petitioner contends that a person of ordinary skill in the art “would have found it obvious to configure Kumar’s patient-side cell phone to adjust the PAP/CPAP therapy” because it is “the same functionality that Toge’s physician-side cell phone possesses.” Opp. 22–23. In particular, Petitioner argues that 1) “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);” 2) “Kumar discloses that the patient cell phone has downloadable software;” and 3) “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.” *Id.* at 22. Petitioner argues that the patient’s cell phone could have been used to “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.” *Id.* at 23. Alternatively, Petitioner argues that “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." *Id.*

Petitioner argues that a person of ordinary skill in the art would have incorporated these changes because 1) the patient's cell phone "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;" 2) the changes would have resulted in a "PAP system that was capable of better fine-tuning PAP/CPAP pressure" and "would have further increased patient comfort and aided in patient motivation to the use the device;" 3) "moving the screen and controls from the PAP device itself to the patient's cell phone . . . 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);" and 4) the changes would have resulted in "a smaller form factor PAP device." *Id.* at 24–25.

Petitioner contends a person of ordinary skill in the art "would have had a reasonable expectation of success in implementing a patient cell phone that adjusts the PAP/CPAP" because "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 [person of ordinary skill in the art] as evidenced by Toge's physician cell phone." *Id.* at 25.

Patent Owner contends "no asserted art in the grounds discloses a PAP/CPAP device therapy being adjusted by the patient's cell phone." Mot. 14. According to Patent Owner, "Toge's system includes physician-side computers and physician-side mobile terminals that allow physicians to review patient sleep data and respond to medical emergencies, if necessary," but "Toge's system does not include a patient's cell phone, let alone one that adjusts the PAP device." *Id.*

(citing Ex. 1044 ¶¶ 18–19, 39, 47, 54; Ex. 2032 ¶ 34). Patent Owner contends that Kumar “discloses a patient-side computing device,” but “this device simply manages the transmission of data between the patient-side medical device and the web server.” *Id.* (citing Ex. 1008 ¶¶ 18, 72, claims 5, 9).

On this record, we agree with Petitioner’s position that Kumar and Toge teach or suggest claim limitation 30.f. *See* Opp. 21–25. We agree with Petitioner that Toge teaches that “the therapy administered by the PAP or CPAP device is configured to be adjusted by . . . the remote computer of the clinician, technician, or physician,” and that the physician may use a cell phone to adjust the PAP or CPAP device. *See, e.g.,* Ex. 1044 ¶ 19. We also agree that a person of ordinary skill in the art would have been motivated to implement the same functionality in a subject’s cell phone such that “the therapy administered by the PAP or CPAP device is configured to be adjusted by the first software on the subject’s cellular phone.” *See* Opp. 21–25.

#### 4. Obviousness Conclusion

Based on the foregoing, it appears that Petitioner has shown a reasonable likelihood that Kumar and Toge would have rendered obvious the subject matter of limitations 30.d, 30.e, and 30.f in proposed substitute claim 30. We note that Patent Owner has not yet had an opportunity to respond to the arguments and evidence cited in Petitioner’s Opposition or this Preliminary Guidance. Patent Owner will have the opportunity to do so in a Reply or in a Revised Motion to Amend in this proceeding.

### III. CONCLUSION

This concludes our Preliminary Guidance. Patent Owner has the option to reply to this Preliminary Guidance *or* to file a revised motion to amend (“MTA”) by DUE DATE 3. 37 C.F.R. §§ 42.121(e)(3), (f); Paper 13. Patent Owner’s reply

or revised MTA may only respond to this Preliminary Guidance or Petitioner's Opposition and may be accompanied by new evidence (including declarations). 37 C.F.R. § 42.121(e)(3). Petitioner has the option to file a sur-reply responsive to this Preliminary Guidance, Patent Owner's reply, or Patent Owner's revised MTA but may not present new evidence in any case. 37 C.F.R. § 42.121(e)(3). Petitioner may also file a reply to the preliminary guidance in the case Patent Owner does not file a reply or revised MTA. 37 C.F.R. § 42.121(e)(4).

In addition, Patent Owner is reminded that amendments of the challenged claims may also be pursued in a separate reissue or reexamination proceeding before, during, or after an AIA trial proceeding, including subsequent to the issuance of the Final Written Decision. We draw Patent Owner's attention to the April 2019 *Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding*. See 84 Fed. Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. See 37 C.F.R. §§ 42.8(a)(3), (b)(2).

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