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

DECLARATION OF JASON KIRKNESS, PH.D. IN SUPPORT OF PETITIONER'S OPPOSITION TO PATENT OWNER'S CONTINGENT MOTION TO AMEND AND REQUEST FOR PRELIMINARY GUIDANCE

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I, Jason Kirkness, Ph.D., declare as follows:

I. INTRODUCTION

1. I have been retained as an independent expert consultant in this proceeding regarding U.S. Patent No. 11,857,333 ("the '333 patent") (Ex. 1001).

2. My experience and qualifications and my status as an independent expert were summarized in paragraphs 2-14 of the Declaration of Dr. Sandeep Chatterjee in Support of Petition for Inter Partes Review of 11,857,333 (Ex. 1005, "Chatterjee") and, further, in my curriculum vitae (CV) (Ex. 1006).

3. I have reviewed the Contingent Motion to Amend ("Motion to Amend.") by Patent Owner ("PO"), the Declaration of Dr. Michael T. Goodrich submitted in support (Ex. 2032, "Goodrich"), Petitioner's Petition for Inter Partes Review of the '333 Patent ("Petition"), Patent Owner's Response ("POR"), the Declaration of Dr. David A. Borkholder in support (Ex. 2022, "Borkholder"), and other documents mentioned in this Declaration. I provide below my opinions to certain arguments made in PO's Contingent Motion to Amend and Dr. Goodrich's Declaration.

II. OBVIOUSNESS

A. Toge in view of Kumar disclose "a subject's cellular phone with downloadable first software" that receives a "quantified level of severity data" (claim 30.d)

4. It is my opinion that Toge in view of Kumar disclose this limitation.

5. Kumar discloses that computing device 110 may be a wireless phone or a pocket PC. EX1008, [0072]. Kumar specifically discloses a plug-in ("first software") downloaded by the cell phone (computing device 110) that allows communications with the patient-side devices (e.g., Toge's PAP device) through a wireless protocol. EX1008, [0074], [0073]. Specifically, Kumar explains that computing device 110 receives a "data stream from the client-side device" and analyzes the same, which may be displayed on a display module 116 ("display"). A POSITA would have understood that the plug-in allows the patient to access the patient's data on the computing device and display that data on the display of the computing device. *Id.*, [0018] ("[T]he engine will send the appropriate plug-in which allows the computing device to communicate with the patient-side device."). In my opinion, a POSITA would have further understood that the plug-in would be executable on the processor of the computing device ("first processor") and configured to be used by the computing device, otherwise the plug-in would not function on the computing device.

6. I have already described how Toge's transmission of a patient's tidal volume to physician devices, including a cell phone (mobile terminal 5) discloses transmitting "a quantified level of severity data" to a cell phone using a mobile network. *See* Kirkness ¶¶156-164; *id.*, ¶157 ("In my opinion, a POSITA would have understood that the calculated tidal volume represents the level of severity based on

the patient's sleep apnea symptoms during the treatment, because it represents, for example, level of airway obstruction the patient experiences during the sleep apnea treatment using the PAP device."); *id.*, ¶163 ("Toge discloses that the treatment data, including tidal volume ("the quantified level of severity data"), may be transmitted to mobile terminal 5 from PAP device 2, which is also connected to network 1, which may be a mobile network."). PO does not dispute that Toge's tidal volume represents a "quantified level of severity data" in its Motion to Amend.

7. In my opinion, a POSITA would have been motivated and found it obvious to implement a patient (subject's) "cell phone" and associated features (e.g., display) in the Toge PAP system. The cell phone-associated features would have allowed the patient to view the treatment data on the patient's personal cell phone and store such information for later viewing even when away from the PAP device. In fact, Toge already expressly describes that the doctor or other medical professionals are able to access treatment related PAP data via a mobile phone. *See* EX1044, [0019]. It would have also been beneficial for the patient to review such information, as it would have indicated how the patient responded to the treatment, encouraging the patient to comply with the prescribed treatment. Additionally, such a modification would have reduced the PAP device's form factor as the PAP device would not need to include a screen suitable for displaying data to the patient, which in turn improves the device's portability for, e.g., travel. In fact, it was known by at

least 2002 that making a smaller and less expensive PAP device that is easier to use than the prior bulky PAP devices was warranted and desirable:

> An earlier version of a PAP device was too big and expensive to go home with a patient, but it did a very good job at automatically determining how much pressure the patient needed. They could then go home on a conventional CPAP machine set at that pressure. Over time, we came up with AutoSet T, the take home device, which is much smaller and simpler for a patient to use.

EX1056, 4.

> Continuous positive airway pressure (CPAP) has undergone significant changes since being introduced to the public in 1981. The machines developed decades ago were heavy, loud, and with limited capabilities when compared to the sleek, lightweight ones today.

EX1057, 1.

8. In my opinion a POSITA would have had the skill and a reasonable expectation of success in combining the teachings of Toge and Kumar. Toge and Kumar are in the same field of art, and both relate to providing healthcare for sleep disorder. Moreover, Kumar states that "virtually any device may be easily incorporated into the system" (EX1008, [0074]) and specifically discussed devices to monitor "[s]leep apnea-hypopnea syndrome" (*id.*, [0240] – [0241]). Indeed, it was known at the time to interface a PAP device with a computing device, e.g., a cell phone via wireless communication as taught by Toge. *See* EX1044, [0019].

9. Moreover, it would have involved a combination of known technologies (PAP device that provides treatment data) according to known methods

(transmitting a "quantified level of severity data" from a PAP device to cell phone) to yield the predictable result of a system including a PAP device of improved portability, e.g., reduced form factor, and a patient cell phone that would have allowed the patient to review the associated treatment data, improving patient compliance.

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" (claim 30.d)

10. In my opinion, Toge in view of Kumar disclose this limitation.

11. Kumar discloses a telemedicine system "for network-based monitoring of physiological data." EX1008, Abstract. Figure 1A shows a system that includes a patient-side device 102, computing device 110 (like a wireless phone), and central server 106 that hosts a browser-based engine that can be accessed through web pages. *See* EX1008, [0067] ("[T]he system includes one or more patient-side devices 102 for collecting data from a patient/client, one or more provider-side devices 104, and an engine implemented on a central server 106.").

12. In my opinion a POSITA would have been motivated to incorporate Kumar's remote internet site with Toge's PAP system because it would have been beneficial for "the data [ ] [to] be stored in a secured storage device at the central server for later access, replay, and/or analysis." EX1008, [0083]. Kumar further discloses that a "storage device [on the server] may also be used to store all patient

data or information, and integrate the data, whether as raw data, trended data, or summary data, into any electronic medical records system," "allow[ing] for simultaneous storage, retrieval, print, analysis, and play back from anywhere in the world with access to the storage device." *Id.* In fact, Kumar states that such a feature is beneficial because it would have allowed a provider to seek expert consultation for clinically difficult cases, by sharing the patient history and medical test results online. *Id.* Additionally, "[t]he system may also track trends during the recording, and using artificial intelligence, predict future behaviors and physiological responses based on the habits of the particular client hooked up." *Id.*, [0084].

13. In my opinion, a POSITA would have also had a reasonable expectation of success in combining the above-discussed features with the Toge system. Kumar states that "virtually any device may be easily incorporated into the system." EX1008, [0074]. It was also well known to transmit data using wireless protocol(s) to a remote internet site that is implemented on a server, e.g., for later access of the data. In fact, Toge itself is already capable of transmitting treatment data from a PAP device to a physician/provider-side device via a communication network, e.g., the internet. *See* EX1044, [0060]-[0061]. Moreover, it would have involved a combination of known technologies (e.g., known PAP device that provides data relate to the subject's treatment through a communication network/Internet (Toge)) according to known methods (e.g., known methods of transmitting data wirelessly

from patient-side device to a remote engine implemented on an Internet server (Kumar)) to yield the predictable result of a system including an internet server-based remote engine that receives and stores data (quantified level of severity data) received from a patient-side device, e.g., the PAP device, on a server. Accordingly, the Toge-Kumar combination discloses a system including an internet server-based remote engine ("a remote internet site hosted on at least one server") capable of receiving data associated with patient treatments for "diagnostic monitoring" from a PAP device providing "sleep disorder treatment."

C. Toge in view of Kumar disclose "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" (claim 30.f)

14. In my opinion, Toge in view of Kumar render this limitation obvious.

15. As discussed previously and above (*see* ¶6 *supra*), Toge discloses a networked PAP system wherein a patient's therapy is adjusted by physician devices, including a cellular phone (mobile terminal 5), based on PAP data transmitted to the physician devices. *See* 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"); *see also* Kirkness ¶¶144, 158, 189-190.

16. It is my opinion that a POSITA would have found it obvious to configure the software on Kumar's patient cell phone to adjust the therapy administered by the PAP. Toge already discloses a cell phone (physician mobile terminal 5) having the capability to adjust PAP therapy in response to, for instance, "a quantified level of severity data" (tidal volume). In my opinion a POSITA would have found it obvious to implement that functionality (PAP adjustment) on the downloadable software of the patient's cell phone to achieve the benefits I discuss below.

17. For example, a physician who has analyzed and/or reviewed a patient's PAP data, could "mobilize" the patient's cell phone to adjust the prescription pressure for a patient's future PAP session.[1] The proximity of the patient's cell phone to the PAP device would make mobilizing the patient's cell phone to adjust the prescription pressure particularly attractive, as the patient's cell phone has the potential to do so more quickly and/or at a specified time/date in response to the physician's prior instruction compared to remotely doing so with the physician's cell phone. And in emergency situations like those described in Toge- when the tidal volume/quantified level of severity data drops below a particular threshold value- a

[1] A change in a patient's *prescription* pressure can generally only be done by a physician.

patient's cell phone could more rapidly detect ("receive") the data and more quickly instruct the PAP to increase the pressure to mitigate the patient's disordered breathing. Thus, the patient cell phone could provide the same functionality as the remote physician cell phone but perform those functions more quickly. *See* 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"). A patient cell phone analyzing PAP data would have the potential to aid the PAP in adjusting the provided pressure automatically or periodically, to address the patient's detected physiological condition(s).

18. In my opinion, a POSITA would have been motivated to incorporate a patient cell phone that adjusts PAP therapy into Toge's PAP system for at least the scenarios discussed above (*see* ¶¶4-9 *supra*), resulting in advantages like better proximity, response time, and consistency. Moreover, a patient having the ability to adjust allowable parameters on their cell phone as opposed to the PAP tremendously increases the ease and convenience for, and engagement of the patient. And because the patient could hold the cell phone in their hand, they would be able to modify permitted parameters *while connected to the PAP device* (e.g., wearing the PAP mask) in bed, and, potentially, even in the dark. Importantly, despite being attached to the PAP machine, a patient would have the ability to make these adjustments to

the PAP using their cell phone on their own, without requiring the assistance of, or waking any companions, increasing patient independence.

19. Finally, having patient data and PAP information display on a patient's cell phone instead of the PAP device itself would realize a couple of advantages. For one, a patient able to look at stored and/or analyzed PAP data on their cell phone would more frequently monitor their treatment progress, generally increasing patient engagement with their therapy. This is crucial given the number of patients who are not fully compliant- underutilizing their PAP devices and/or discounting therapeutic recommendations. And, as I have discussed previously (*see* ¶7 *supra*), off-loading the primary display from the PAP device to the cell phone would allow for the development of a PAP with a reduced or even eliminated display, making for a smaller, lighter weight, more portable, and potentially less expensive PAP device. A POSITA would have been motivated to produce a PAP device having such a decreased form factor.

20. In my opinion, a POSITA would have had a reasonable expectation of success in implementing a Kumar patient cell phone, capable of adjusting PAP therapy, in Toge's PAP system because it would have involved no more than a change in the programming (e.g., modified downloadable software), and the program would have been known to a POSITA from Toge's physician cell phone. Thus, it would have involved a combination of known technologies (e.g., known

programming to adjust the PAP (Toge)) according to known methods (e.g., known methods of transmitting data wirelessly from the patient communication device (cell phone) to the patient-side device (PAP) (Kumar)) to yield the predictable result of a system having a patient cell phone with downloadable software that adjusts the PAP therapy.

IV. CONCLUSION

21. I declare that all statements made herein of my knowledge are true, and that all statements made on information and belief are believed to be true, and that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Dated: January 14, 2026 By: 

Jason Kirkness