

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 DR. SANDEEP CHATTERJEE IN SUPPORT OF
PETITIONER'S OPPOSITION TO PATENT OWNER'S CONTINGENT
MOTION TO AMEND AND REQUEST FOR PRELIMINARY
GUIDANCE**

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I, Sandeep Chatterjee, 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. WRITTEN DESCRIPTION

A. Legal Standard

4. I understand that to satisfy the written description requirement, the specification disclosure must clearly allow a POSITA to recognize what the inventor has claimed and demonstrate that the inventor had possession of the invention at the

time of the patent. I understand that pointing to a number of disparate disclosures in the specification from which a POSITA could have potentially created the claimed invention is insufficient to satisfy the written description requirement. And I further understand that disclosures that only render the invention obvious, that is, do not actually describe the invention, are equally insufficient to demonstrate that the inventor possessed the invention at the relevant time.

B. 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

5. In my opinion, the specification of the patent application that matured into the ’333 patent (U.S. Patent App. No. 15/641,715 (the “’715 Application,” Ex. 1002)), does not contain adequate written description support for the Substitute Claims. In particular, it is my opinion that 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” lacks written description support in the ’715 application.

6. In my opinion, none of the disclosures that PO identifies as supporting written description of the limitation do so. *See* Mot. Amd., 7 (citing “Ex. 1002 at 5:2-12, 11:17-12:1, 34:20-24, 72:25-73:18”). PO identifies no disclosure in which a cell phone of any kind has software configured to adjust the therapy administered by the PAP. Similarly, PO identifies no disclosure in the ’715 application of any

device within the system that a POSITA would have understood to be a cell phone that adjusts PAP therapy. *See* EX1002, 5:2-12 (diagnostic device transmit signals to an intermediary device (e.g., cell phone) or a treatment device/PAP); *id.*, 11:17-12:1 (method to transmit data from the sensors to a data acquisition system and a PAP, and then on to a remote monitoring station with remote programming of the PAP); *id.*, 34:20-24 (diagnostic device data (“output”) used to adjust PAP treatment); *id.*, 72:25-73:18 (remote data acquisition device and system for the transmission of PAP data to a remote server for analysis and database storage (explaining Fig. 10)).

7. For instance, PO appears to be suggesting that the function of the “data acquisition system” disclosed in the ’719 application provides written description support for a cell phone that adjusts the PAP therapy. But the data acquisition system is not disclosed as a cell phone, nor is one implied. The description the ’719 specification provides for a data acquisition system (“a single box” with several modules or “several boxes” each containing a module) would not have led a POSITA to believe that it could have been a cell phone. *See* EX1002, 21:30-22:3 (data acquisition system is “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”).¹ In any event, the data acquisition system is solely described as sending signals to the remote internet site. No device within the system is disclosed for transmitting therapeutic instructions to the PAP, let alone a subject's cell phone. *See* EX1002, 72:25-73:18.

8. In view of PO's cited disclosures, it is my opinion that the '719 application lacks adequate written description support for “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” and, thus, does not demonstrate that the inventors were in the possession of the invention.

C. 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

9. It is my opinion that U.S. Patent App. No. 11/266,899 (the “'899 Application,” Ex. 2033), the first non-provisional application in the priority chain for the '333 patent, also does not support written description 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.” PO's citations once again

¹ Indeed, the “data acquisition system” appears to be a component integrated with the PAP itself.

fail to demonstrate that the patentees had possession of a cell phone that adjusts PAP therapy. *See* Mot. Amd., 7 (citing “Ex. 2033 at 34:9-21, 38:24-39:28”).

10. For example, PO points to the '899 application at 34:9-21, but that solely describes a “remote communication system” (which can include a cell phone) that sends PAP data to a remote internet site. The passage has no written description of the remote communication system transmitting any signals to the PAP/CPAP, including signals capable of adjusting its therapy. A POSITA would not have believed the patentees to be in possession of a cell phone with software configured to adjust the PAP therapy. The same is true for the other '899 application disclosure PO cites, which describes a diagnostic device having data that can be used to adjust a treatment device/PAP. *See* EX2033, 38:24-39:28. But the diagnostic device is not disclosed as a cell phone, and a POSITA would not have recognized the diagnostic device disclosures as describing one. *See id.*; *see also* 41:11-17 and Fig. 8 (diagnostic device 441 comprising radio 436, antenna 434, microprocessor 438, data storage 440 and modem 442).

11. Accordingly, in my opinion the '899 application does not provide written description sufficient to demonstrate to a POSITA that the inventors were in the possession of an invention “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.”

IV. OBVIOUSNESS**A. Toge in view of Kumar render obvious “a subject’s cellular phone with downloadable first software” that receives a “quantified level of severity data” (claim 30.d)**

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

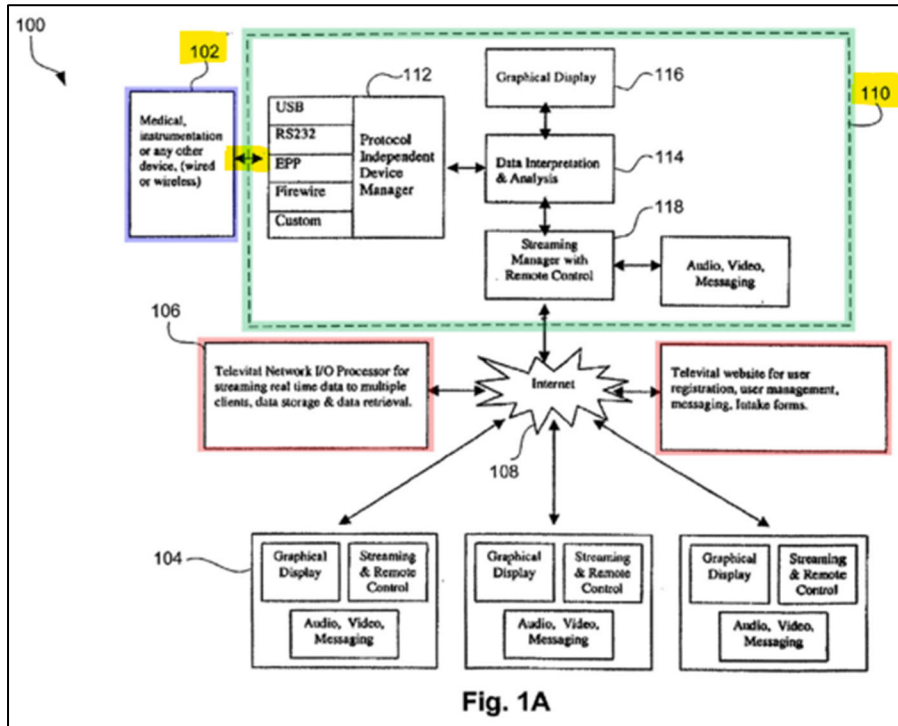
13. Toge discloses a networked PAP system in which the PAP (PAP device 2) transmits patient data to physician-side devices like a computer (physician-side computer 4) and cell phone (mobile terminal 5), as outlined in detail previously. *See* EX1044, [0008]; *see also* Pet., 9-10; Chatterjee ¶¶100-101. Kumar discloses a patient’s cellular phone (computing device 110) that downloads a first software (“the appropriate plug-in”) and allows for communication with a patient-side device (patient-side devices 102) like Toge’s PAP “for collecting data from a patient/client.” *See* EX1008, [0067], [0071]-[0075]; *see also*, Pet., 39 and Chatterjee ¶¶182-183 (describing Kumar’s disclosure of a patient-side cell phone). 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 “computing device 110, such as a ... wireless telephone”); Pet., 39; Chatterjee ¶¶182-183.

14. Regarding the “first software,” a “plug-in” is a software module that allows for the customization of computer programs. *See also* EX1008, [0074], claim 5 (“the computing device receiving a software module for managing communication

with the at least one patient-side device from the engine”). The cell phone processor would execute the code from the plug-in to allow communication and display. The code must also be configured to use on the operating system of the phone to display data. This can be done through plug-in code that talks directly to the operating system, or through code that talks to a program already installed on the phone, such as a web browser. As Kumar explicitly discloses that “the engine will send the appropriate plug-in which allows the computer device to communicate with the patient-side device” (EX1008, [0018]), a POSITA would have understood that the plug-in (first software) would have been downloaded onto the patient’s cell phone (computing device 110) and configured to be used by the cell phone’s processor such that the plug-in would have been executable to receive and display data. *See also* EX1049 (WO0145014 “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”).

15. The patient’s cell phone (computing device 110) receives data from a patient-side device like Toge’s PAP, using a wireless protocol (wide area network (WAN)). *See* EX1008, [0067] (the devices “are connected to a wide area network (WAN) **108** such as the Internet, intranet, or extranet”); *see also id.*, [0068], [0075],

Fig. 1A (showing data transmission between patient-side device 102 and computing device 110).



EX1008, Fig. 1A, annotated.

PO also agrees with me here that Kumar's patient cell phone communicates with the patient-side device. *See* Mot. Amd., 14-15 ("Kumar discloses a patient-side computing device" that "manages the transmission of data between the patient-side medical device and the web server").

16. As I have discussed previously, Toge discloses tidal volume as a "quantified level of severity data," because it is a detected, numerical value indicative of whether a patient's breathing is weak enough to warrant "emergency measures." *See* EX1044, [0038]-[0039], [0055]; *see also* Chatterjee ¶¶121-122.

And as discussed above (*see* ¶13 *supra*), Toge discloses that PAP data like tidal volume (“quantified level of severity data”) are transmitted to other (physician) devices, including a cell phone. Based on the foregoing disclosures of Kumar that computing device 110 receives data from patient-side device 102, a POSITA would have understood that Toge’s “quantified level of severity data” (tidal volume) would have been transmitted from Toge’s PAP (patient-side device 102) to a patient’s cell phone (computing device 110).

17. A POSITA would have found it obvious and been motivated to configure Toge’s PAP system to include a patient cell phone like Kumar’s capable of receiving a “quantified level of severity data” from the PAP. Toge discloses a cell phone (mobile terminal 5) that receives “a quantified level of severity data,” and Kumar discloses a patient cell phone that receives PAP data that would have included a quantified level of severity data. *See* ¶¶13-16 *supra*. The cellular phones disclosed in Toge and Kumar would have been structurally and functional similar (if not identical from a functionality perspective) and would have been able to perform the same or similar functions. Even if, for some unlikely reason, Kumar’s patient cell phone differed from Toge’s cell phone in an ability to receive a “quantified level of severity data,” in particular, a POSITA could have easily modified or adapted Kumar’s patient cell phone (hardware or software) to do so. For instance, a POSITA would have been able to design software, preferably downloadable software,

executable on a patient's cell phone, capable of receiving a quantified level of severity data. For example, well-known Bluetooth and other API software could readily be used by a POSITA to create and/or configure software that can implement data communications with another device, like the patient's PAP.

18. A POSITA also would have been motivated to incorporate into Toge's PAP system a patient cell phone like that of Kumar's which receives PAP data ("quantified level of severity data"). Like the physician cell phone used by providers to access patient data in Toge, a patient cell phone would have allowed a patient to easily and quickly access their PAP data, and do so any time or any place, an advantage unavailable when PAP data is only accessible to the patient on the PAP device itself. Moreover, moving patient data display to a patient's cell phone would have minimized or dispensed with the need for the existing display screen on the PAP device itself, which would have resulted in either a smaller display screen or its complete elimination. In either case, the PAP device would have advantageously been smaller, more portable, and less expensive.

19. Additionally, a POSITA would have had a reasonable expectation of success in configuring Toge's PAP system to include a patient cell phone that receives PAP data, as it would have involved the use of known technologies (e.g., the cell phone already implemented in the Toge-Kumar system as a physician-side cell phone) with known approaches (e.g., transmission of data between a cell phone

and the PAP/CPAP) to yield the predictable result of a PAP system that includes a patient cell phone that receives a patient's PAP data (e.g., "quantified level of severity data").

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)

20. In my opinion, Toge in view of Kumar disclose this limitation. A POSITA would have also been motivated and found it obvious to implement the "remote internet site hosted on at least one server" disclosed in Kumar in the Toge PAP system.

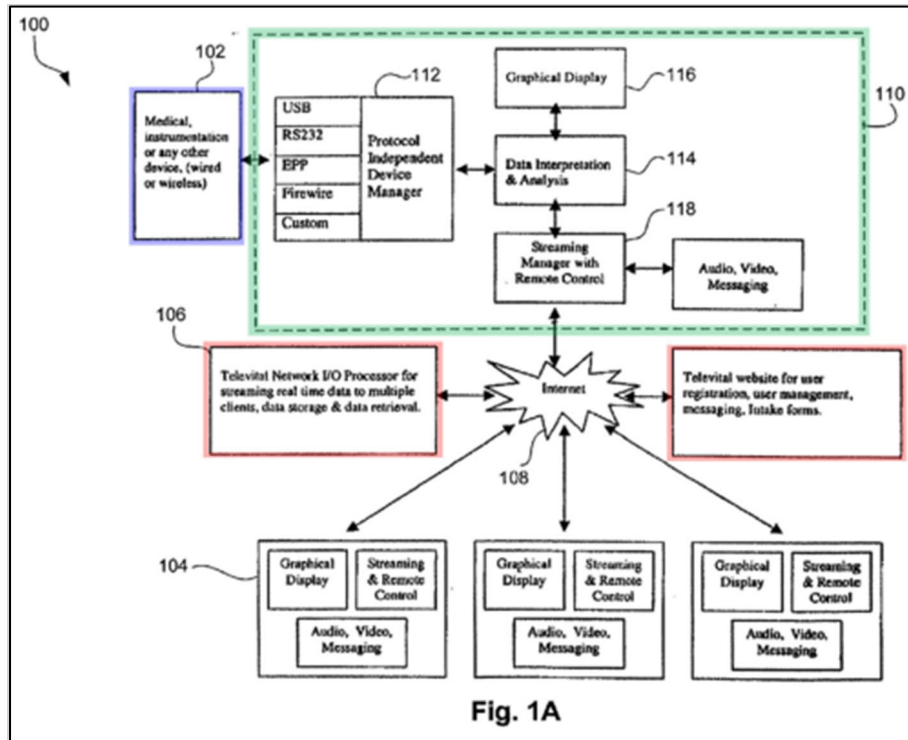
21. Toge discloses a remote monitoring method in which a CPAP device is "connected to a relay device and a physician-side terminal device via a wireless or wired communication network" and, further, that the "physician-side terminal device is configured to receive all or part of the treatment data transmitted from the relay device." Ex. 1044, [0006]. "[C]ommunication 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]. As discussed above, Toge further discloses that PAP treatment data like tidal volume ("a quantified level of severity data") is transmitted from the PAP to network 1 and then to physician side devices. *See supra* ¶¶13, 16.

22. Kumar discloses a remote internet site, and specifically, a browser-based engine for receiving data from the patient-side device. Kumar describes “at least one patient-side device for collecting data from a patient/client, a provider-side device, and an engine, each coupled to the WAN,” such as the internet. *See* EX1008, [0011]. Kumar discloses that the engine receives the data from the patient-side device where it “may receive the data from the patient-side device and transmit the raw or processed data to the provider-side device, may store the data for later transmission to the provider-side device, etc.” *Id.*, [0081]. Kumar further discloses that “[b]y receiving data from the patient-side device, a provider is able to monitor the patient’s physiology for research, keeping track of documentation, performing analysis, managing and maintaining records, diagnosing the patient, providing treatment in real-time to the patient, etc.” *Id.*, [0078].

23. Kumar explains that “the entire system runs in the context of an Internet browser.” EX1008, [0086]; *see also* [0087] (“The system may be implemented using Apache web server, MySql on Linux, Oracle on Linux, Java servlets, Applets HTML, JavaScript, Java, C+, Microsoft's .NET etc. Note also that the server may be implemented on the Internet, intranet, or an extranet.”). A physician, or provider can access the browser-based engine through a login screen, *Id.*, [0089]; Fig. 2. Kumar further discloses that the “patient’s real-physiological data” can be viewed through web pages, like those depicted in Figures 7 and 8. EX1008, [0092]-[0093];

see also Fig. 6. A POSITA would have understood that the web pages serve as a graphical user interface to access the data sent to the browser-based engine.

24. Specifically, the system includes “patient-side device(s) **102** for collecting data from a patient/client, provider-side devices **104**, and an engine implemented on a central server **106**,” where the “devices and engine are connected to a wide area network (WAN) **108** such as the Internet.” EX1008, [0067]. “The system allows for the real-time streaming of raw, interpreted, and/or processed physiological data as well as textual/audio/video data from a patient to a health care provider.” *Id.*; *see also id.*, [0068]. Kumar also discloses that the engine “may receive the data from the patient-side device and transmit the raw or processed data to the provider-side device” and “may store the data for later transmission to the provider-side device, etc.” *Id.*, [0081], [0082]. Kumar also discloses that the patient-side device may communicate through a wireless interface and may communicate over the Internet. *Id.*, [0013]. As such, Kumar discloses a “remote internet site.”



EX1008, Fig. 1A, annotated.

25. Kumar explains that “the data may be stored in a secured storage device at the central server for later access, replay, and/or analysis” (“a remote internet site hosted on at least one server”). EX1008, [0083]. Kumar further explains that this feature beneficially allows access anywhere around the world: “The storage device 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.* Kumar further explains that such a feature is beneficial since it “allows a provider to seek

expert consultation for clinically difficult cases, by sharing the patient history and medical test results online.” *Id.*

26. In another configuration, a POSITA would have understood that the physician-side computer of Toge could have been implemented as a “remote internet site hosted on at least one server” using the implementation details taught by Kumar. A POSITA would have understood that if data could be transmitted through the Internet to and from the physician-side computer, the physician-side computer would have been implemented as a web server since internet content lives on a web server. Accordingly, it would have been well within the skill of a POSITA to host data on the physician-side computer as a web server to allow others to access the data through the Internet.

27. In my opinion, a POSITA would have been motivated to implement Kumar's browser-based engine in Toge's PAP system to enable the PAP device to wirelessly transmit to the remote engine data associated the patient's treatment, including a quantified level of severity data generated that could be provided, e.g., for review/display. A remote internet site hosted on a server would provide broad access to data collection and analysis. *See* EX1008, [0083] (“the data may be stored in a secured storage device at the central server for later access, replay, and/or analysis” “allow[ing] for [the] simultaneous storage, retrieval, print, analysis, and play back from anywhere in the world with access to the storage device”). Kumar

also teaches “[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]. This would have allowed physicians and providers to better leverage data and perform analyses to find patterns that they may not have been able to identify without a large set of data by using the data collected at the physician-side computer implemented as a central server as taught by Kumar.

28. A POSITA would have had a reasonable expectation of success in implementing a remote internet site hosted on at least one server. It was well known to transmit data using wireless protocol(s) to a remote internet site, e.g., for later access of the data. Moreover, 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.

29. Both PO and Dr. Goodrich argue that implementation of “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; Goodrich ¶¶46-48. I disagree.

30. In my opinion, incorporation of Kumar's web-based engine (remote internet site) into Toge's PAP system would have still enabled the PAP to "push" data to physician-side devices as needed. To begin with, Dr. Goodrich does not explain why the system would necessarily require the web clients to "pull" the information. Goodrich ¶¶44, 48. There is nothing about the implementation of Kumar's web server preventing Toge's PAP from pushing data as soon as it is received. And where the physician-side computer and the web server are on one machine, the physician would receive the data at the same time as the web server, communicating the data to the physician even more quickly.

31. But even if the web clients could only "pull" information, the design of the system could always be implemented in a way to address emergency situations. If the server identifies an emergency, the server could automatically push out such data, using mechanisms that had been well known to a POSITA for years. For example, a push system could be implemented using standard WebSockets, a well-known concept and technology typically used to implement push notifications. Further, when active, the remote internet site/physician's web client could continuously query the server to see if new data had been received. Increasing the "pull" frequency in such a manner would achieve functionality akin to a "push" protocol.

32. In addition, I do not find Toge's "purpose" to be limited to "pushing, without request, 'necessary' or 'crucial' treatment data." Mot. Amd., 20-21; Goodrich ¶¶46-48. For example, Toge states that PAP data can be collected and saved for later transmission, demonstrating that all of Toge's PAP data are not immediately "pushed" to the physician devices. *See, e.g., id.*, [0007] ("memory means for storing treatment data obtained by the treatment data acquisition means").

C. Toge in view of Kumar disclose a "second processor on the at least one server" (claim 30.d)

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

34. As discussed above, Kumar discloses a "remote internet site hosted by at least one server" (browser-based engine/central server). *See* ¶¶20-32 *supra*. Kumar further discloses a "network I/O processor running the engine" for "streaming device data" ("quantified level of severity data") and for "data storage and retrieval." EX1008, [0082]. The data stored at the central server was available for "later ... analysis." EX1008, [0017], [0083]; *see also id.*, [0075] ("data interpretation and analysis module 114 is used to interpret the data stream from the client-side device, perform mathematical analysis" and "generate statistics"). A POSITA would have understood that the processor of the browser-based engine/server would have been implemented to analyze the transmitted and/or stored data. *See* Chatterjee ¶167.

35. In the configuration in which Toge's physician-side computer is implemented as a web server, a POSITA would have well understood that the computer/server included a processor ("second processor") in order to perform the disclosed "analysis" of data like the "quantified level of severity data." *See* EX1044, [0016]-[0018].

D. Toge alone or in view of Kumar disclose "a physician at a remote computer" who reviews the quantified level of severity data (claim 30.d)

36. Toge alone or in view of Kumar discloses "a physician at a remote computer" who "review[s]" the "quantified level of severity data." Toge explicitly discloses that a physician "can access the transmitted [PAP] data using the physician-side computer 4." EX1044, [0018]. As discussed above (*see* ¶13, 16 *supra*), Toge discloses that data (e.g., tidal volume) is a "quantified level of severity data" that would be reviewed by a physician. *See* Pet., 33; Chatterjee ¶162.

37. Toge in view of Kumar also disclose the limitation. Kumar describes a provider (physician) "receiving data from the patient-side device" (Toge's "quantified level of severity data") to "monitor the patient's physiology" by "performing analysis, ... diagnosing the patient, [and] providing treatment in real-time to the patient." EX1008, [0078]. Kumar further discloses that "the provider-side device can be any type of computing device, such as a computer." *Id.*, [0072].

E. Toge in view of Kumar disclose “the subject’s cellular phone using the first software ... further provided to receive and display the quantified level of severity data...” (claim 30.e)

38. As discussed above, Kumar discloses a subject’s (patient’s) cell phone (computing device 110) equipped with a “plug-in” (downloadable software) (together “the subject’s cellular phone using the first software”). *See* ¶¶12-19 *supra*. Kumar also discloses that the patient’s cell phone (computing device 110) can analyze the PAP/patient data (Toge’s “quantified level of severity data”) using data interpretation and analysis module 114 and display that data using display module 116. *See* EX1008, [0075] (“The data interpretation and analysis module 114 is used to interpret the data stream from the client-side device,” and that “data may be displayed graphically on the display module 116”); *see also* Fig. 1A (illustrating data interpretation and analysis module 114 and graphical display module 116 integrated with computing device 110) below.

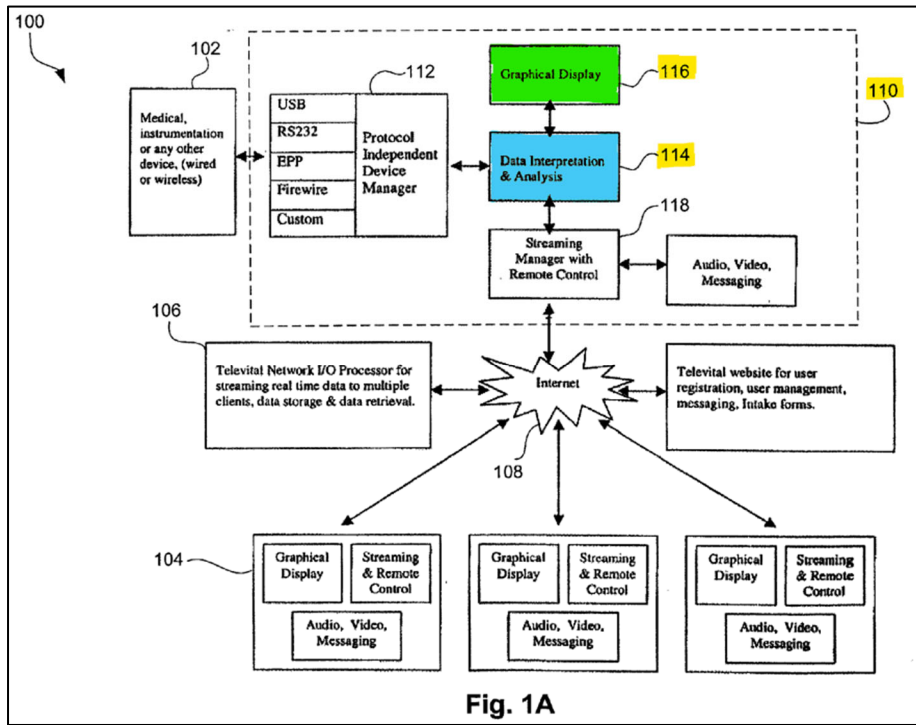


Fig. 1A

EX1008, Fig. 1A, annotated.

39. PO and Dr. Goodrich again argue that a POSITA would not have been motivated to add a patient’s cell phone to Toge’s PAP system because it would have been unnecessary (*see* Mot. Amd., 15-17; Goodrich ¶¶37-40), I have discussed above why I disagree with their assertions. *See supra* ¶¶17-19. PO and Dr. Goodrich also allege that a POSITA would not have been motivated to add a patient’s cell phone to display PAP data because “Toge’s PAP device includes a PAP display screen that already allows a patient to view their sleep data” making the cell phone display “completely unnecessary.” Mot. Amd., 16-17; Goodrich ¶39. I, again, disagree. As discussed above (*see* ¶¶18-19 *supra*), display of patient PAP data on their cellular phones would have had several advantages, including potentially

eliminating on-PAP display, resulting in a smaller, less expensive device, and added convenience for patient viewing.

F. Toge in view of Kumar render obvious “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)

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

41. As I discussed above, Toge in view of Kumar disclose a patient cell phone that can communicate with the PAP device. *See* ¶¶13, 15 *supra*. Kumar discloses that transmission between the patient cell phone and PAP is bi-directional, running from the PAP to the cell phone and from the cell phone to the PAP. *See* EX1008, [0072] (“the computing device [110] establishes a two-way communication with a vast array of client-side devices, including but not limited to medical and/or biofeedback devices, holter monitors, telemetry units, data acquisition units, etc.”); *see also* Fig. 1A (showing two-way communication between patient side device 102 (PAP) and communication device 110 (cell phone)). Because Kumar discloses that the computing device 110 and the patient-side device have “two-way” communications, a POSITA would have understood that the computing device 110 (cell phone) and the patient-side device 102 (PAP device) could transmit directly from one device to the other.

42. Toge discloses that physician-side devices like the physician cell phone (mobile terminal 5) can remotely adjust a patient’s PAP therapy based on that

patient's PAP data, including tidal volume (e.g., "quantified level of severity data"). See EX1044, [0019] ("the mobile terminal 5 [can be operated] to set the necessary data ... for the positive pressure artificial respiration assisting device 2"); *id.*, [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.*, [0039] ("if there is a decreasing trend in the tidal volume F_a , emergency measures, such as adjusting the prescription pressure to a higher level can be taken remotely from the physician-side [] mobile terminal 5").

43. In my opinion, a POSITA would have found it obvious to configure Kumar's patient-side cell phone to adjust the PAP therapy. As discussed above, Toge already discloses a cell phone with the required functionality, that is, the ability to adjust the PAP therapy. A POSITA would have found it obvious to configure the software downloadable on the patient cell phone disclosed in Kumar to adjust the PAP therapy, giving it the same capability as Toge's physician-side cell phone to "set the necessary data" or "adjust the prescription pressure" of the PAP. See EX1044, [0019], [0039].

44. A patient cell phone having an ability to adjust the PAP therapy in view of their PAP data could be used in the Toge-Kumar PAP system in a number of ways. For example, after reviewing PAP therapy data, a physician could, from a physician device (e.g., computer or PDA), transmit instructions to the patient cell

phone to adjust the PAP therapy (e.g., prescription pressure) when the patient is next undergoing PAP therapy. *See, e.g.*, EX1044, [0019], [0027] (PAP “settings can also be configured via communication network 1 through the physician-side computer 4”). Also, in an emergency situation, for instance, a patient’s cell phone could include software that responds when the “quantified level of severity data” falls below a threshold value, adjusting the PAP therapy (e.g., pressure) appropriately to remedy the situation. In fact, this is similar to the capability of Toge’s physician cell phone. *See, e.g.*, EX1044, [0039] (“a decreasing trend in the tidal volume Fa, [could trigger] emergency measures, such as adjusting the prescription pressure to a higher level, [which] can be taken ... [by] mobile terminal 5”).

45. In my opinion, a POSITA would have been motivated to modify the software on the patient cell phone to enable the cell phone to adjust the patient’s PAP therapy for several reasons. For one, the proximity of the patient’s cell phone to the PAP device itself, compared to the remote location of any physician devices, would have allowed the cell phone to more quickly make therapy adjustments in, for instance, emergency situations. In addition, a patient cell phone used to display the patient’s PAP data/information in lieu of display on the PAP device would have allowed a patient to adjust permitted PAP parameters while in bed and attached to the PAP device on their own, because the patient is able to hold the cell phone in their hand. Doing so with the PAP display and buttons would have been difficult

and cumbersome for a patient connected to the device. Moreover, moving the display screen and controls from the PAP device to a patient cell phone would have resulted in a smaller form factor for the PAP device, a design that a POSITA would have desired to increase device portability and decrease its footprint and expense.

46. 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, and this programming would have already been known to a POSITA as evidenced by the same or similar programming on Toge's physician-side cell phone. In my opinion, then, a POSITA would have had a reasonable expectation of success in implementing in Toge's PAP system Kumar's patient cell phone configured to adjust the PAP/CPAP therapy.

V. CONCLUSION

47. 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:



Sandeep Chatterjee