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Paper 46
Entered: September 17, 2014

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

RESPIRONICS, INC.,
Petitioner,

v.

ZOLL MEDICAL CORPORATION,
Patent Owner.

Case IPR2013-00322
Patent 6,681,003 B2

Before BRYAN F. MOORE, BRIAN J. MCNAMARA, and SCOTT E. KAMHOLZ, *Administrative Patent Judges.*

KAMHOLZ, *Administrative Patent Judge*.

FINAL WRITTEN DECISION
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73(b)

I. INTRODUCTION

A. Background

Petitioner Respironics, Inc. ("Respironics") filed a Petition (Paper 1, "Pet.") requesting an *inter partes* review of claims 1, 2, 4, 5, 8, 9, 16, 19, and 20 of U.S. Patent No. 6,681,003 B2 (Ex. 1001, "the '003 patent"). The Board instituted trial for the challenged claims on the ground, asserted by Respironics, of anticipation by WO 98/39061 (Ex. 1003, "Owen"). Decision to Institute (Paper 9, "Dec.") 11.

After institution of trial, Patent Owner ZOLL Medical Corporation ("Zoll") filed a Patent Owner Response (Paper 14, "Resp."). Respironics filed a Reply (Paper 20, "Reply").

Zoll also filed a contingent Motion to Amend (Paper 15). In its Motion to Amend, Zoll proposed claim 36 to substitute for patent claim 1, if claim 1 is determined to be unpatentable. Motion to Amend 1-3. Respironics filed an Opposition to the Motion to Amend (Paper 21, "Opp."). Zoll filed a Reply to the Opposition (Paper 27, "Amend Reply").

Respironics filed a Motion to Exclude certain of Zoll's evidence (Paper 31, "Pet. Motion to Exclude"). Zoll filed an Opposition (Paper 38), and Respironics filed a Reply (Paper 39).

Respironics relies upon declarations of Dr. Igor Efimov in support of its Petition (Ex. 1007), its Reply (Ex. 1011), and its Opposition to the Motion to Amend (Ex. 1021). Zoll relies upon declarations of Mr. Charles M. Gropper in support of its Response (Ex. 2006), its Motion to Amend (Ex. 2009), and its Reply to the Opposition to the Motion to Amend

(Ex. 2011). Zoll also relies on deposition testimony of Dr. Efimov (Ex. 2010). Zoll filed a Motion for Observations on Cross-Examination of Dr. Efimov (Paper 34, "Obs."), and Respironics filed a Response to the Observations (Paper 37).

Oral argument was conducted on June 26, 2014. A transcript is entered as Paper 45 ("Tr.").

The Board has jurisdiction under 35 U.S.C. § 6(c). This final written decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73.

Respironics has proved that claim 1 is unpatentable. Respironics has not proved that claims 2, 4, 5, 8, 9, 16, 19, and 20 are unpatentable.

Zoll's Motion to Amend is denied.

Respironics's Motion to Exclude Evidence is denied.

B. The '003 Patent

The '003 patent relates to a medical device worn by a patient and used to provide therapy to the patient, as well as to collect and transmit information about the patient, the device, and the patient's interaction with the device, to a remote location. Ex. 1001, Abstr. Types of data collected and transmitted include, e.g., patient medical information (*id*. at 3:1-4), device performance data (*id.* at 4:28-32), and patient compliance data (*id*. at 4:35-43). The device has a connection, such as a modem (*id.* at 3:45-50), to a communications network, such as the Internet (*id.* at 3:50-51), over which recorded data may be sent to a remote location (*id.* at 3:51-53) and instructions or upgrade software may be received (*id.* at 6:55-58).

Claims 2 and 4 are illustrative of the claimed subject matter and are reproduced below:

> 2. A method of monitoring patient medical information for the treatment of a patient, the method comprising the steps of:
>
> providing a wearable medical device for treating the patient and monitoring patient medical information;
>
> operatively connecting the medical device to the patient such that the medical device is worn by the patient;
>
> recording the patient medical information, device performance data and patient compliance data in a storage means of the medical device;
>
> operatively connecting the medical device to a communications system;
>
> transmitting the patient medical information, device performance data and patient compliance data to a health care provider by means of said communications system and recording the patient medical information, device performance data and patient compliance data in an information database, wherein said transmitting step is performed while the medical device is operatively connected to the patient for providing treatment to the patient; and
>
> providing access to the patient medical information, device performance data and patient compliance data to individuals.
>
> 4. A system for monitoring patient medical information and providing treatment to a patient, the system comprising:
>
> a wearable medical device for monitoring and storing medical parameters and treating the patient in response to a monitored medical condition, the

> medical device operatively attachable to the patient such that the medical device is worn by the patient;
>
> a communications network;
>
> means for connecting the medical device to the communication network;
>
> a patient database;
>
> means for monitoring and storing operations information of the medical device and patient compliance and use data;
>
> means for connecting the patient database to the communication network; and
>
> means for exchanging information between the medical device and the patient database, including means for transmitting the medical device operations information and the patient compliance and use data to the patient database via the communication network.

II. DISCUSSION

A. Claim Construction

In an *inter partes* review, claim terms in an unexpired patent are interpreted according to their broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,766 (Aug. 14, 2012). Claim terms are given their ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). Any special definition for a claim term must be set forth in the specification with reasonable clarity, deliberateness, and precision. *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

A limitation using the term "means for" creates a rebuttable presumption that the drafter intended to invoke 35 U.S.C. § 112 ¶ 6.[1] *Personalized Media Commc'ns. LLC v. Int'l Trade Comm'n,* 161 F.3d 696, 703-04 (Fed. Cir. 1998). When construing a means-plus-function limitation under 35 U.S.C. § 112 ¶ 6, we first must identify the claimed function, and then we look to the specification to identify the corresponding structure that performs the claimed function. *Medical Instrumentation & Diagnostics Corp. v. Elekta AB*, 344 F.3d 1205, 1210 (Fed. Cir. 2003); *Cardiac Pacemakers, Inc. v. St. Jude Med., Inc.*, 296 F.3d 1106, 1119 (Fed. Cir. 2002). With respect to the second step, "structure disclosed in the specification is 'corresponding' structure only if the specification or prosecution history clearly links or associates that structure to the function recited in the claim." *Golight, Inc. v. Wal-Mart Stores Inc.*, 355 F.3d 1327, 1334 (Fed. Cir. 2004) (citations and quotation marks omitted).

1. "patient compliance data" and "patient compliance and use data"

Respironics argued, in its Petition, that "patient compliance data" and "patient compliance and use data" both should be construed as "data related to patient use." Pet. 5 (citing Ex. 1007 ¶¶ 17-19).

Respironics's initial construction did not accord sufficient weight to the term "compliance." Although Respironics and its expert, Dr. Efimov,

[1] Section 4(c) of the AIA re-designated 35 U.S.C. § 112 ¶ 6, as 35 U.S.C. § 112(f). Because the '003 patent has a filing date before September 16, 2012 (effective date of the statute), we will refer to the pre-AIA version of 35 U.S.C. § 112.

cite numerous passages in the ’003 patent, none of these passages serves to define “patient compliance [and use] data” in a manner that justifies disregarding that term. Although the ’003 patent does describe patient compliance data as relating to whether the patient is using the device improperly, or at all (Ex. 1001, 5:49-52), it is used within the context of assessing whether the patient is following (i.e., complying with) instructions. To construe the terms as encompassing any data related to patient use is, therefore, unreasonably broad.

We determined, for purposes of instituting *inter partes* review, that the broadest reasonable construction of “patient compliance [and use] data,” in light of the Specification of the ’003 patent, is “data indicating whether a patient has followed instructions for use.” Dec. 7 (citing Ex. 1001, 4:39-43). Respironics has since indicated that it does not contest this construction. Reply 1-2; Paper 44, 2; Tr. 6:4-5.

Zoll argues that “patient compliance data” should be construed as “data quantifying an extent to which a patient correctly follows instructions,” based both on how the term would be understood by one of ordinary skill in the art, and also on how the term is used in the ’003 patent. Resp. 3, 5-14.

We have considered Zoll’s arguments and evidence but determine that neither the use of the term “patient compliance [and use] data” in the ’003 patent, nor its understanding by one of ordinary skill in the art, justifies Zoll’s argument that the broadest reasonable construction should be constrained to require that the data quantify the extent to which a patient correctly follows instructions. In short, although Zoll shows that patient

compliance data *may* be quantitative, Zoll does not explain why patient compliance data *must* be quantitative.

For these reasons, we maintain our initial determination that the terms are properly construed to mean "data indicating whether a patient has followed instructions for use."

2. Means-plus-function limitations

Respironics argues that several limitations are to be construed as mean-plus-function limitations, in accordance with 35 U.S.C. § 112 ¶ 6, and proposes constructions for those terms. Pet. 7-11 (Table). We adopted Respironics's proposed constructions for purposes of instituting *inter partes* review. Dec. 8. Zoll does not contest the applicability of § 112 ¶ 6 to these limitations, and does not contest most of the proposed constructions.

We focus our analysis on the "means for monitoring and storing" limitation in claims 4 and 19. Claim 4 recites: "means for monitoring and storing operations information of the medical device and patient compliance and use data." Claim 19 recites: "means for monitoring and storing patient medical parameters, device performance data and patient compliance data." Respironics argues that the structures disclosed in the '003 patent as performing the "monitoring" and "storing" functions are a medical device and a memory. Pet. 8. Zoll does not contest this structural correspondence. We maintain our determination that these limitations invoke 35 U.S.C. § 112 ¶ 6, and that the structures corresponding to each of these limitations are a medical device and a memory.

We have considered the parties' arguments and evidence concerning the other means-plus-function limitations, but we determine that express construction of these limitations is not material to this decision.

3. "Personnel"

Zoll proposes construing "personnel," in claim 16, as "the body of persons employed by or active in an organization, business, or service." Resp. 4. Respironics opposes this construction. Reply 8-9. We determine that express construction of this term is not material to this decision.

B. Anticipation of Claims 1, 2, 4, 5, 8, 9, 16, 19, and 20 by Owen

We instituted review based on Respironics's contention that Owen anticipates claims 1, 2, 4, 5, 8, 9, 16, 19, and 20 under 35 U.S.C. § 102(b) (2010).

1. Overview of Owen

Owen discloses wearable defibrillator 10. Ex. 1003, Abstr. The defibrillator may be provided as a belt that can be worn around the waist or chest. *Id.* at 30:30-31.[2] The device includes electrodes that are used to monitor the patient and to deliver energy to the patient. *Id.* at 5:19-21. The device also includes a visual indicator that displays, e.g., statements indicating that the patient has been wearing the device "for greater than a recommended period of time." *Id.* at 31:24-32. The defibrillator also includes a response button, which the user can push in response to an

[2] All references to Owen use the page numbers as published, not the exhibit page numbers applied by Respironics.

instruction from the device to respond. *Id.* at 33:13-15. The defibrillator also may include another button, which the user can push in order to cause the defibrillator to record a cardiac event. *Id.* at 33:15-19. The response button may serve both purposes, so that a user may push it in response to an instruction, to trigger a recording, or both. *Id.* at 33:19-22.

The defibrillator includes data memory logging block 57 that stores all information provided to, or transmitted from, the defibrillator, including both operational and patient information. *Id.* at 35:9-10, 36:18-20. Patient information includes, e.g., the patient's electrocardiogram, messages displayed on the visual indicator, and "information concerning patient interaction with the defibrillator." *Id.* at 35:11–12, 17-18 (quotation). The interaction information concerns, "e.g., if and when the patient has pressed the response button." *Id.* at 35:18-19. The device also includes a base station that is connected to the defibrillator. *Id.* at 31:11-12. The base station includes an external interface over which information is exchanged with a remote location, such as a central repository or doctor's office. *Id.* at 64:2-5. The external interface may include a modem or a network connection. *Id.* at 65:14-15. The operational and patient information stored in data memory logging block 57 may be transmitted from the defibrillator to the central repository and stored there. *Id.* at 14:3-4, 65:10-18. Information stored in the central repository is available for analysis using, e.g., a computer in communication with the central repository. *Id.* at 14:6-9. Data may be received by the defibrillator from the remote location over the external interface, including instructions that reprogram the defibrillator. *Id.* at 68:17-18. The defibrillator also may transmit information to personal

computer 6 or 201 while a patient wears the defibrillator. *Id.* at 13:24-26, 31:18-21, 77:17-20, 79:9-11, Fig. 2.

2. Analysis

a. Claim 1

Respironics presents arguments concerning anticipation of claim 1 by Owen on pages 11-13 of the Petition, supported by paragraphs 34-40 of Dr. Efimov's initial declaration (Ex. 1007). Zoll directs no argument to claim 1 in its Response, or in subsequent papers. Tr. 56:20–57:1.

Claim 1 recites:

> 1. A method of monitoring patient medical information for the treatment of a patient, the method comprising the steps of:
>
> providing a wearable medical device for monitoring patient medical information and treating the patient in response to a monitored medical condition;
>
> operatively connecting the medical device to the patient such that the medical device is worn by the patient;
>
> recording the patient medical information in a storage means of the medical device;
>
> operatively connecting the medical device to a communications system;
>
> transmitting the patient medical information to a health care provider by means of said communications system and recording the patient medical information in an information database; and
>
> providing access to the patient medical information to individuals.

Respironics argues that Owen meets claim 1 because it discloses providing a wearable defibrillator to a patient that also monitors the patient's electrocardiogram, records the electrocardiogram in memory, connects to a communication system to send the recorded information over an external data link, stores the sent information in a central repository, and makes the stored data available to health care providers for review. Pet. 12-13 (citing Ex. 1003, Abstr., 1:9-13, 4:31–5:2, 5:19-23, 5:23–6:14, 6:29–7:6, 7:11-19, 8:2-12, 14:2-12, 30:21-31, 31:8-21, 34:15-16, 35:9–36:20, 64:2-16, Figs. 1-2); Ex. 1007 ¶¶ 34-40.

Upon consideration of Respironics's arguments and evidence, we are persuaded that a preponderance of the evidence supports its contention that claim 1 is unpatentable under 35 U.S.C. § 102(b) as anticipated by Owen. As summarized above in section II.B.1, Owen discloses a method in which a patient wears a device that can both monitor the patient and deliver defibrillation therapy while being worn. Ex. 1003, 5:19-21. The device stores recorded medical information, such as an electrocardiogram, in memory, and transmits that information over a communication network to a database for review by individuals. *Id.* at 14:3-9, 35:9-10, 36:18-20. This evidence demonstrates that all limitations of claim 1 were disclosed by Owen, in the claimed arrangement. We determine, consequently, that Owen anticipates the subject matter of claim 1.

b. Claim 2

Respironics presents arguments concerning anticipation of claim 2 by Owen on pages 11-16 of the Petition, supported by paragraphs 34-39 and

41-49 of Dr. Efimov's initial declaration (Ex. 1007). Claim 2 is reproduced above at page 4.

We focus our analysis on the claim limitation "patient compliance data." Claim 2 requires that patient compliance data be recorded in a storage means of the medical device, transmitted to a health care provider, recorded in an information database, and made accessible to individuals.

In its Petition, Respironics cites a lengthy paragraph in Owen as providing disclosure of patient compliance data, as well as several other limitations. Pet. 14 (claim chart) (citing Ex. 1003, 35:9–36:20). This paragraph describes "data logging memory block 57" and lists many types of information that are stored in it. Ex. 1003, 35:9–36:20. Respironics quotes from this list several types of information, including "the patient's [electrocardiogram,]" "information concerning patient interaction with the defibrillator," "operational errors" of the defibrillator, and patient parameters, such as information indicating "whether the electrodes are not attached, or are improperly attached" to the patient. Pet. 14. Respironics does not identify in the Petition which of these types of information constitute patient compliance data, but Dr. Efimov cites information concerning electrode placement and "information concerning patient interaction with the defibrillator" when addressing patient compliance data. Ex. 1007 ¶ 44, final sentence. Respironics also cites "information relating to a plurality of patients that use the type of defibrillator" when discussing information that is recorded in an information database. Pet. 15 (claim chart) (citing Ex. 1003, 8:5-6).

Zoll argues that none of the types of information Respironics cites as being "patient compliance data" are so. Resp. 14-20. We address each type of information in turn.

(1) "whether the electrodes are not attached, or are improperly attached"

Zoll argues that information indicating whether the electrodes are not attached or improperly attached is not "patient compliance data," because Owen does not disclose instructing the patient on the correct way to attach the electrodes, and also because improper attachment may simply reflect passive loosening, as opposed to the patient's failure to follow instructions. Resp. 18-20 (citing Ex. 2006 ¶ 40). We agree with Zoll. Respironics has not identified where Owen discloses instructing the patient on the correct placement of the electrodes. Respironics also has not explained how information indicating electrode detachment or incorrect attachment necessarily reflects the patient's failure to follow instructions, regardless of whether Owen discloses instructing the patient on electrode placement.

(2) "information concerning patient interaction with the defibrillator"

In its Petition, Respironics does not specify what types of "information concerning patient interaction with the defibrillator" it considers to constitute "patient compliance data." In our decision instituting *inter partes* review, we cited disclosure in Owen that information logged in memory block 57 includes an indication of "if and when the patient has pressed the response button." Dec. 8 (citing Ex. 1003, 35:18-19). The patient may push the response button in response to the verbal message

"PLEASE RESPOND" given by the defibrillator to the patient. Ex. 1003, 33:13-15. Respironics argues that the button-push information constitutes "patient compliance data." Reply 10; Tr. 9:22–10:3. Respironics also argues that a statement indicating that the patient has been wearing the electrode harness for "greater than a recommended period of time" constitutes "patient compliance data." Reply 10-11 (citing Ex. 1003, 31:24-32). According to Respironics, Owen discloses displaying this statement on the defibrillator's visual display, and "displayed messages" are among the types of information stored in, and transmitted from, memory block 57. Reply 10 (citing Ex. 1003, 35:9-10).

(a) Button push

Zoll argues that the information indicating whether and when the patient pushed the response button is not "patient compliance data" as we construe that term, because nothing in Owen indicates whether the button push was in response to the verbal instruction "PLEASE RESPOND." Resp. 15-17. According to Zoll, Owen does not disclose storing any information concerning *when* a prompt to push the button was issued to the patient. Tr. 52:7-11. Without information about when a prompt was issued, argues Zoll, information about when the patient pushed the button does not provide any indication about whether the patient followed an instruction. *Id.*

In reply, Respironics argues that when a patient pushes the button in response to the "PLEASE RESPOND" verbal instruction, the patient has followed an instruction, and the data indicating that the button was pushed is indicative of the patient's compliance with the instruction. Reply 10.

We agree with Zoll that information indicating whether and when the patient pushed the response button does not constitute "patient compliance data." Although Owen discloses that verbal messages may correspond to messages displayed on the visual indicator (Ex. 1003, 32:19-20), and that displayed messages are stored in the memory block (*id.* at 35:17), Respironics does not identify disclosure that Owen records the time at which the verbal prompt is given to the patient. Respironics thus has not explained how Owen provides sufficient context for one to be able to determine whether a prompt preceded a particular button push. Without this context, the information recorded upon the pushing of the button is insufficient to distinguish a prompted button push from an unprompted button push or an accidental one. There is no assurance that every, or indeed *any*, recorded button push was performed in response to an instruction. Button-push information recorded in the memory block is not usable as patient compliance data, because there is no way to know that it indicates whether the patient followed instructions. Because it cannot be known whether the button-push data reflects patient compliance, we determine that it does not constitute "patient compliance data."

(b) "wear time" message

In its Motion for Observations, Zoll cites testimony in which Dr. Efimov acknowledges that Owen does not disclose that the patient is told how long to wear the harness. Obs. 12 (citing Ex. 2010, 116:6-21). The testimony is as follows:

> Q. . . . In rendering your opinions in this matter, you have not identified anything in Owen

> that would identify to the user, or to anyone, the actual wear time of the device, right?
>
> MS. DEFRANCO: Objection. Scope and relevance.
>
> A. I can look again. (Witness reviews document.) Yeah. I didn't find this particular clarification, but I did find other examples where it's more clarified, but not what exactly the amount of time patient will be instructed to wear the harness.

Ex. 2010, 116:8-21. Respironics acknowledges that Owen does not disclose communicating the recommended wear time to the patient, other than by displaying the statement that the wear time has been exceeded.

Tr. 22:18-23.

We are not persuaded that the "wear time" statement constitutes "patient compliance data," because Respironics has not shown that Owen discloses telling the patient what the recommended wear time is. Without evidence that that patient had been told not to wear the harness longer than a recommended period of time, information that the patient exceeded this time cannot be said to indicate whether the patient followed instructions for use.

(3) "information relating to a plurality of patients that use the type of defibrillator"

Respironics cites this type of information when addressing what information is recorded in the information database. Pet. 15. It is not clear whether Respironics is citing it as an example of "patient compliance data" or one of the other data types recited in the claim—patient medical information or device performance data. Respironics does not make any

plausible arguments, or cite any credible evidence, to explain how "information relating to a plurality of patients that use the type of defibrillator" constitutes "patient compliance data." We are not persuaded, consequently, that this type of information is "patient compliance data."

(4) Analysis

Anticipation is a question of fact and requires a showing of strict identity between the claimed subject matter and the disclosure of a single reference. *Trintec Indus., Inc. v. Top-U.S.A. Corp.*, 295 F.3d 1292, 1296 (Fed. Cir. 2002) (noting "strict identity required of the test for novelty"). To anticipate the subject matter of a claim, a single reference must disclose all limitations in the claimed arrangement. *Wm. Wrigley Jr. Co. v. Cadbury Adams USA LLC*, 683 F.3d 1356, 1361 (Fed. Cir. 2012). It is not enough to show that a reference is "substantially the same" as the claimed subject matter. *Jamesbury Corp. v. Litton Indus. Prods.*, 756 F.2d 1556, 1560 (Fed. Cir. 1985), *overruled on other grounds, A.C. Aukerman Co. v. R.L. Chaides Constr. Co.*, 960 F.2d 1020 (Fed. Cir. 1992) (*en banc*). Rather, it must be shown that the claim at issue encompasses subject matter fully disclosed by a single reference. *In re Skvorecz*, 580 F.3d 1262, 1266 (Fed. Cir. 2009).

Respironics has not shown that Owen discloses "patient compliance data," as we have construed that term—a construction that Respironics expressly does not contest. *See* Tr. 6:4-5; Paper 44, 2. We reach this conclusion because the evidence Respironics has put forward, as discussed above, does not persuade us that any of the data that Owen records or transmits is indicative of whether the patient has followed instructions for

use. A preponderance of evidence does not emerge, consequently, to show that Owen discloses every limitation of claim 2 in the claimed arrangement. For these reasons, we determine that Respironics has not proved that Owen anticipates the subject matter of claim 2.

c. Claims 4, 5, 8, 9, 16, 19, and 20

Independent claims 4 and 19 are directed to systems for monitoring patient medical information and providing treatment to a patient. Claim 4 recites the limitation "patient compliance and use data" within the "means for monitoring and storing" and "means for exchanging" limitations. Ex. 1001, 10:66-67, 11:6. Claim 19 similarly recites "patient compliance data" as part of "means for monitoring and storing" and "means for exchanging" limitations. As discussed above in section II.A.2, we construe the "means for monitoring and storing" limitations as invoking 35 U.S.C. § 112 ¶ 6 and as corresponding to a medical device and a memory.

As discussed above in section II.A.1, we construe "patient compliance and use data" identically to "patient compliance data," i.e., as "data indicating whether a patient has followed instructions for use." Claim 19 and its dependent claim 20 recite "patient compliance data."

For reasons discussed above in connection to claim 2, we have determined that Respironics has failed to show that Owen discloses "patient compliance [and use] data." It follows that Respironics has failed also to show that Owen discloses structure that performs the recited functions involving "patient compliance [and use] data." Although it is undisputed that Owen discloses a medical device (defibrillator 10) and a memory (data

logging memory block 57), Respironics has not shown that Owen discloses these structures in the context of performing any operations on "patient compliance [and use] data." Respironics has not shown, therefore, that Owen meets the means-plus-function limitations that recite functions involving "patient compliance [and use] data." *See Fresenius USA, Inc. v. Baxter Int'l, Inc.*, 582 F.3d 1288, 1300 (Fed. Cir. 2009) (disclosure in the prior art of a particular structure, without discussion of that structure in the context of the claimed function, does not meet a means-plus-function limitation).

A preponderance of evidence does not emerge, consequently, to show that Owen discloses every limitation of claims 4 and 19 in the claimed arrangements. For these reasons, we determine that Respironics has not proved that Owen anticipates the subject matter of claims 4 and 19, as well as dependent claims 5, 8, 9, 16, and 20.

III. MOTION TO AMEND

A. Zoll's Burden

An *inter partes* review is neither a patent examination proceeding nor a patent reexamination proceeding. The proposed substitute claims, in a motion to amend, are not entered automatically and then subjected to examination. Rather, the substitute claims will be added directly to the patent, without examination, if the patent owner's motion to amend claims is granted. The patent owner is not rebutting a rejection in an Office Action, as though this proceeding were a patent examination or a patent reexamination. Instead, the patent owner bears the burden of proof in demonstrating

adequate written description support and patentability of the proposed substitute claims over the prior art, and thus entitlement to add these proposed substitute claims to its patent. 37 C.F.R. §§ 42.20(c); 42.121(b).

B. Proposed Claim

Zoll proposes claim 36 as a substitute for claim 1. Proposed claim 36 is reproduced below, with additions relative to claim 1 underlined and deletions in brackets:

> 36. A method of monitoring patient medical information for the treatment of a patient, the method comprising the steps of:
>
> providing, at a remote location, a wearable medical device for monitoring and collecting information including patient medical information and data indicative of patient compliance, and treating the patient in response to a monitored medical condition;
>
> providing, at a central host location, a searchable information database that (i) stores patient medical information and data indicative of patient compliance for a plurality of different patients, and (ii) is internet-accessible simultaneously by a plurality of authorized individuals at different locations;
>
> at the remote location, operatively connecting the medical device to the patient such that the medical device is worn by the patient;
>
> at the remote location, recording the collected information that includes the patient medical information and the data indicative of patient compliance in a storage means of the medical device, wherein the data indicative of patient

compliance includes a quantitative measure of time that the medical device was worn by the patient;

at the remote location, operatively connecting the medical device to a communications system;

transmitting the collected information that includes the patient medical information and the data indicative of patient compliance from the remote location to the central host location accessible to a health care provider by means of said communications system and recording the patient medical information and the data indicative of patient compliance in [[an]] the searchable information database; [[and]]

at the central host location, providing simultaneous internet access to the patient medical information and the data indicative of patient compliance stored in the searchable information database to the plurality of authorized individuals at different locations remote from the central host location;

at the central host location, receiving medical device update data corresponding to a treatment adjustment specified by an authorized individual that, remotely and via the internet access, has reviewed information stored in the searchable information database that relates to the patient wearing the medical device; and

at the central host location, making the received medical device update data available for upload to the medical device at the remote location when the medical device next communicates with the central host location.

Motion to Amend 1-2.

C. *Written Description*

Zoll's entire discussion of the written description support for proposed claim 36 in its Motion to Amend is reproduced below:

> Support for the amendment may be found in the '003 patent, whose disclosure matches the filed application (e.g., at 2:17-18, 2:24-30, 2:37-45, 2:58-62, 3:1-8, 3:50-53, 3:55-4:28, 4:32-63, 5:28-59, 6:33-45, 6:62-7:4, 7:17-22, 8:10-15, 8:66-9:20, 9:33-35, 9:38-53, and Fig. 6. EX 1001) and in U.S. Provisional 60/157,881 (EX 1010) to which the '003 patent claims priority (e.g., 3:7-10, 3:13-16, 3:21-4:3, 4:11-14, 4:17-22, 6:4-6, 6:7-7:9, 7:12-19, 8:9-9:6, 10:9-16, 11:5-11, 11:19-22, 13:14-18, 15:4-17, and Fig. 6).

Motion to Amend 4. Zoll's expert, Mr. Gropper, does not address written description support in his declaration that accompanies the Motion to Amend. *See* Ex. 2009. Respironics argues, in opposition, that Zoll failed to identify the written description support for proposed claim 36, both to the level of detail required, and with regard to support for every limitation in the provisional application of which Zoll claims the benefit. Opp. 1-2. Zoll asserts, in reply, that the discussion of written description support in its Motion to Amend was sufficient such that a person of ordinary skill would have understood that the inventors had possession of the subject matter of proposed claim 36. Amend Reply 2 (citing Ex. 2011 ¶ 23). Zoll also submitted a more detailed listing of support for the limitations of proposed claim 36 in the provisional application with Mr. Gropper's declaration that

accompanies Zoll's Reply in support of its Motion to Amend. Ex. 2011 ¶ 23.

We agree with Respironics that Zoll has not made a sufficient showing of written description support for proposed claim 36 to demonstrate its entitlement to the proposed claim. Zoll's string citations amount to little more than an invitation to us (and to Respironics, and to the public) to peruse the cited evidence and piece together a coherent argument for them. This we will not do; it is the province of advocacy. *See Stampa v. Jackson*, 78 USPQ2d 1567, 1571 (BPAI 2005) (quoting *Ernst Haas Studio, Inc. v. Palm Press, Inc.*, 164 F.3d 110, 111-12 (2d Cir. 1999) ("Appellant's Brief is at best an invitation to the court to scour the record, research any legal theory that comes to mind, and serve generally as an advocate for appellant. We decline the invitation.")).

This shortcoming in Zoll's motion is particularly acute because Zoll proposes extensive modifications relative to claim 1. Zoll seeks to add hundreds of words to claim 1, more than tripling its length. Yet Zoll offers only a string of citations to the '003 patent and to the underlying provisional application as evidence showing written description support. So extensive a modification of the claim requires a more detailed showing of how each limitation of the proposed claim not only is disclosed in the original and benefit applications, but also is disclosed in combination with all of the other claim limitations. *See Novozymes A/S v. DuPont Nutrition Biosciences APS*, 723 F.3d 1336, 1349 (Fed. Cir. 2013) (claim is considered as an "integrated whole" when assessing written description).

Zoll's Reply in support of its Motion to Amend seeks to remedy the problem, but it is too little, too late. A Reply affords the moving party an opportunity to refute arguments and evidence advanced by the opposing party, not an opportunity to improve its position. 37 C.F.R. § 42.23(b); Office Patent Trial Practice Guide, 77 Fed. Reg. at 48,767 ("[A] reply that raises a new issue or belatedly presents evidence will not be considered and may be returned. . . . Examples . . . include new evidence necessary to make out a *prima facie* case for the patentability . . . of [a] . . . proposed substitute claim, and new evidence that could have been presented in a prior filing.").

The new evidence by Mr. Gropper is offered to bolster Zoll's motion, not to refute argument or evidence by Respironics that the claim lacks adequate written description support. Zoll does not explain why it could not have presented Mr. Gropper's Reply evidence with its motion.[3] Zoll has not shown why this late evidence should be considered.

But even if we set aside the procedural infirmities with Zoll's evidence, we do not find that the reply evidence is sufficient to meet Zoll's burden of proof. Mr. Gropper opines that a person of ordinary skill in the art would have appreciated that the inventors had possession of the subject matter of claim 36, but he does not explain adequately the factual basis on which he reaches that conclusion. At best, he provides a claim chart

[3] Nor is that evidence even properly presented in the Reply; instead, it is relegated to the declaration. For example, the claim chart with citations to the provisional application is not reproduced in the Reply. Zoll effectively seeks to circumvent the Reply page limit by doing this.

purporting to show disclosure of each limitation of proposed claim 36 in Zoll's provisional application. But he does not explain how each cited passage from the provisional application supports adequately the corresponding claim limitation, nor does Mr. Gropper explain how the cited passages from the provisional application, dispersed throughout the specification and figures, demonstrate possession of the claimed subject matter as an "integrated whole." *See Novozymes*, 723 F.3d at 1349.

We do not conclude that Zoll's proposed claim 36 lacks the support of adequate written description. Instead, we conclude that Zoll has not come forward with sufficient evidence to demonstrate that claim 36 has the required support. We do not reach the issue of whether Zoll has shown patentability over the prior art of proposed claim 36.

For these reasons, we deny Zoll's Motion to Amend.

IV. MOTION TO EXCLUDE EVIDENCE

Respironics seeks to exclude portions of the testimony Zoll elicited from Dr. Efimov during cross-examination on the basis of scope and relevance. Pet. Motion to Exclude 1. Respironics cites numerous passages from the transcript of Dr. Efimov's deposition in its motion. *Id.* at 1, 3 n.1, 4, 5, 6 nn.4-5. Some of these citations are marked "[b]y way of example," implying that they are not exhaustive lists of passages sought to be excluded. *See id.* at 6 nn.4-5.

We will not engage in guesswork, or scour the record, to determine what other evidence Respironics seeks to exclude in addition to the

"examples." Accordingly, we regard Respironics's motion as being directed against only those passages identified with pinpoint citations in the motion.

The only portion of Dr. Efimov's deposition testimony that we rely upon in reaching our final decision in the proceeding is page 116, lines 6-21. *See* section II.B.2.b(2)(b), *supra.* Respironics does not cite this portion, however, in its Motion to Exclude Evidence. Consequently, we do not construe Respironics's Motion to Exclude Evidence as being directed against this passage.

Respironics also makes blanket requests to exclude all evidence it objected to as irrelevant or exceeding scope. Pet. Motion to Exclude 6-7. As noted above, however, we are not going to scour the deposition transcript to locate every scope and relevance objection. Respironics *did* object timely to Dr. Efimov's testimony in the passage noted above. Ex. 2010, 116:13-14. But Respironics provides no discussion of this passage in its motion, or any credible explanation as to how or why it is irrelevant or exceeds scope. We are not going to evaluate the propriety of Respironics's objections in the absence of a particularized and detailed showing by Respironics to establish that the evidence is inadmissible. Such blanket requests rarely amount to a satisfactory showing that the moving party is entitled to the harsh remedy of exclusion. *See* 37 C.F.R. § 42.20(c).

For these reasons, we deny Respironics's Motion to Exclude Evidence.

V. CONCLUSION

Respironics has proved, by a preponderance of the evidence, that claim 1 of the '003 patent is unpatentable as anticipated by Owen. Respironics has not proved that claims 2, 4, 5, 8, 9, 16, 19, and 20 are unpatentable as anticipated by Owen. Zoll has not proved that proposed claim 36 is patentable.

VI. ORDER

For the reasons given, it is

ORDERED that claim 1 of U.S. Patent No. 6,681,003 B2 is determined to be UNPATENTABLE;

FURTHER ORDERED that claims 2, 4, 5, 8, 9, 16, 19, and 20 of U.S. Patent No. 6,681,003 B2 are not determined to be unpatentable;

FURTHER ORDERED that Zoll's Motion to Amend is *denied*; and

FURTHER ORDERED that Respironics's Motion to Exclude Evidence is *denied*.

This is a final decision. Parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

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