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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte RICHARD T. STONE and XUAN WEI

Appeal 2017-010175
Application 13/982,159
Technology Center 3700

Before MICHELLE R. OSINSKI, SUSAN L. C. MITCHELL, and GEORGE R. HOSKINS, *Administrative Patent Judges*.

MITCHELL, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

The Appellant[1] seeks our review under 35 U.S.C. § 134(a) of the Examiner's rejections of claims 13–41 as set forth in a Final Office Action.

[1] We use the word "Appellant" to refer to "applicant" as defined in 37 C.F.R. § 1.42. Appellant identifies the real parties in interest as Medtronic, Inc. and Medtronic plc, the ultimate parent entity of Medtronic, Inc. Appeal Brief (March 13, 2017) ("Appeal Br.") 3.

Final Office Action (October 13, 2016) ("Final Act."); 37 C.F.R. § 41.31(a)(1). We have jurisdiction under 35 U.S.C. § 6(b).

The Examiner rejected the claims as unpatentable for failure to comply with the written description requirement, indefiniteness, and obviousness. Appellant argues that the claims, as properly interpreted, have adequate written description support and are not indefinite. Appellant also argues that the prior art does not disclose all the elements of the claims on appeal.

For the reasons explained below, we sustain the indefiniteness rejection concerning claims 28 and 29 and do not sustain the remaining rejections. Thus, we affirm in part.

CLAIMED SUBJECT MATTER

The claimed subject matter relates to an implantable medical device ("IMD") that produces and detects pressure waves with a portion of the IMD housing to detect a physiological state of a patient. Spec. Abst., ¶ 5. Claims 13, 24, and 36 are independent. Claim 13 is illustrative and reads as follows with particular emphasis on the claim language that is the focus of our analysis.

13. A method comprising:

> *producing a pressure wave within a patient with a portion of a device housing of an implantable medical device using an actuator element configured to contact the portion of the device housing*, wherein the *device housing encloses a processor and the actuator element*, and wherein the implantable medical device is configured to couple to an implantable medical lead;

> detecting at least one reflected pressure wave with the portion of the device housing; and
>
> determining, by the processor and based on the at least one reflected pressure wave, a physiological condition of the patient.

Appeal Br. 34.

Independent claim 24, an apparatus claim, has similar language requiring "an actuator element configured to contact a portion of the device housing to produce a pressure wave within a patient with the portion of the device housing." *Id*. at 37. Similarly, independent claim 36, also an apparatus claim, has similar language requiring a "means for producing a pressure wave within a patient with a portion of a device housing of an implantable medical device." *Id*. at 41.

EVIDENCE

The prior art on which the Examiner relies in rejecting the claims on appeal is:

Name	Reference	Date
Gerber	US 2007/0027494 A1	Feb. 1, 2007
Penner et al.	US 2004/0204744 A1	Oct. 14, 2004
Von Arx et al.	US 2006/0009818 A1	Jan. 12, 2006
Tepper et al.	US 5,524,624	June 11, 1996
Rondoni et al.	US 2007/0255176 A1	Nov. 1, 2007
Guly et al.	WO 86/06606	Nov. 20, 1986
Freudenrich	*How Ultrasound Works, printed in* http://www.physics.utoronto.ca	Feb. 1, 2001
Chua	*The Principles of Medical Ultrasound, printed in* http://www.mrcophth.com/commonultrasoundcases	Feb. 1, 2001

Name	Reference	Date
Simmons	*Medical Physics - Ultrasound, printed in* http://www.genesis.net.au	Aug. 2, 2003
Dynamic Ultrasound Group	*Fundamentals of Ultrasound Imaging, printed in* http://dynamicultrasound.org	March 11, 2007

REJECTIONS

The Final Office Action includes the following rejections:

1. Claim 39 is rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement;
2. Claims 24–35, 40, and 41 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite;
3. Claims 13–16, 19–27, and 30–41 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Gerber and at least one of Penner, Von Arx, or Tepper; and
4. Claims 17 and 28 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Gerber and at least one of Penner, Von Arx, or Tepper, and one or more of Freudenrich, Chua, Simmons, and Dynamic Ultrasound Group;
5. Claims 13–16, 19–27, and 30–41 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Rondoni, Guly, Gerber, and at least one of Penner, Von Arx, or Tepper;
6. Claims 17, 18, 28, and 29 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Rondoni, Guly, Gerber, and at least one of Penner, Von Arx, or Tepper, and one or

more of Freudenrich, Chua, Simmons, and Dynamic Ultrasound Group.

ANALYSIS

Written Description Rejection

The Examiner determines that the limitation in claim 39 reciting "means for controlling, based on the physiological condition, the electrical stimulation therapy," is a means-plus-function limitation under 35 U.S.C. § 112 with processor 56 and processor 82 as corresponding structure described in the Specification. Final Act. 4. The Examiner further determines that there is no written description support for this limitation "because the specification fails to provide the algorithm (e.g., the necessary steps and/or flowcharts) that performs the claimed function of controlling, based on the physiological condition, the electrical stimulation therapy." *Id*. at 6.

Appellant responds that the Specification does provide such an algorithm. Appeal Br. 22–26. Appellant specifically points to paragraphs 38, 61, 71, and 110 as providing "example algorithms for 'controlling, based on [a] physiological condition, [] electrical stimulation therapy," such that sufficient detail is provided for one of skill in the art to reasonably conclude that Appellant had possession of the claimed invention. *Id*. at 23.

To satisfy the written description requirement, "the [original] specification must describe an invention understandable to that skilled artisan and show that the inventor actually invented the invention claimed." *Ariad Pharms., Inc. v. Eli Lilly & Co.,* 598 F.3d 1336, 1351 (Fed. Cir. 2010)

(en banc). "[T]he test for sufficiency is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Id*. "[T]he level of detail required to satisfy the written description requirement varies depending on the nature and scope of the claims and on the complexity and predictability of the relevant technology." *Id.* at 1351 (citing *Capon v. Eshhar*, 418 F.3d 1349, 1357–58 (Fed. Cir. 2005)).

When construing a means-plus-function limitation under 35 U.S.C. § 112, ¶ 6, the corresponding structure of a computer-implemented, means-plus-function limitation that performs a particular function, in this case processors 56 or 82, must be more than simply a general-purpose computer or microprocessor to avoid impermissible functional claiming. *Aristocrat Techs. Austl. Pty Ltd. v. Int'l Game Tech*., 521 F.3d 1328, 1333 (Fed. Cir. 2008); *see In re Katz Interactive Call Proc. Patent Litig*., 639 F.3d 1303, 1316 (Fed. Cir. 2011). That is, the specification must disclose "enough of an algorithm to provide the necessary structure under § 112" or a disclosure that can be expressed in any understandable terms, e.g., a mathematical formula, in prose, or as a flowchart. *Finisar Corp. v. The DirectTV Grp., Inc.*, 523 F.3d 1323, 1340 (Fed. Cir. 2008). Simply reciting a claimed function in the specification, and saying nothing about how the computer or processor ensures that such a function is performed, is not a sufficient disclosure for an algorithm which, by definition, must contain a sequence of steps. *Blackboard, Inc. v. Desire2Learn, Inc.*, 574 F.3d 1371, 1384 (Fed. Cir. 2009).

We agree with Appellant that sufficient detail, including the necessary steps and flowcharts, is provided for one of skill in the art to reasonably understand that Appellant had possession of the claimed subject matter including a "means for controlling, based on the physiological condition, the electrical stimulation therapy." For instance, the Specification states that the IMD controls delivery of a second electrical stimulation therapy to a patient based on a physiological condition such as bladder fullness determined by reflected pressure waves detected by a portion of the IMD housing. Spec. ¶ 38. The Specification also states that processor 56 controls therapy delivery module 64, which may be done by selectively accessing and loading stimulation therapy programs 60 to therapy delivery module 64. *Id*. ¶¶ 61, 71.

The Specification also states that the therapy program "may define a set of therapy parameters that define the electrical stimulation, e.g., pulse rate, pulse width, voltage or current amplitude, and pulse frequency," *see* Spec. ¶ 29, and describes that "the stimulation parameters for stimulation therapy programs 60 may be selected to relax bladder 12 (FIG. 1) or close or maintain internal urinary sphincter closure or urethral tone." Spec. ¶ 65. Example ranges of stimulation parameters for a first stimulation therapy program that may be applied to the sacral or pudendal nerves include frequency, amplitude, and pulse width. *Id*. ¶ 65. The Specification also describes second stimulation therapy programs "to maximize the closure of one or more of internal urinary sphincter, external urinary sphincter, and periurethral muscles . . . [and] may also be selected to minimize muscle fatigue." *Id*. ¶ 66. Example ranges of stimulation parameters for a second

stimulation therapy program are also described. *Id*. ¶ 67. The Specification also provides a specific example of a stimulation therapy program that delivers more than one set of stimulation parameters to activate fast-twitch and then slow-twitch muscle fibers. *Id*. ¶¶ 68–69.

Figure 6, set forth below, depicts a flow diagram of an example technique for determining a bladder fullness state with pressure waves generated and detected by the housing of IMD 20.

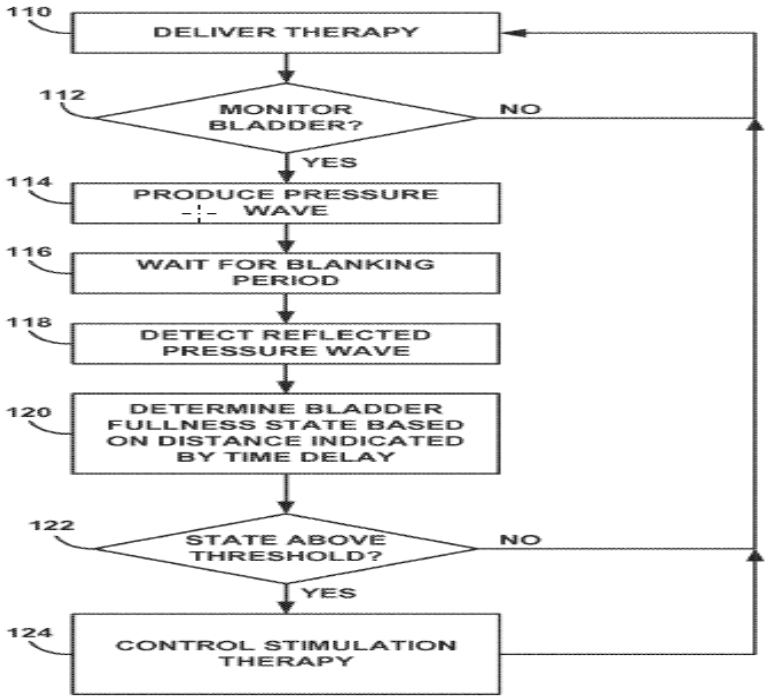

FIG. 6

In describing Figure 6 set forth above, the Specification states:

> In response to determining the determined bladder fullness state is above the fullness threshold ("YES" branch of block 122), processor 56 controls therapy delivery module 64 to deliver stimulation therapy to patient 14, where the electrical stimulation is configured to compensate for the determined

> bladder fullness state (124), e.g., to help prevent an incontinence event. Stimulation control may be in the form of adjusting a single stimulation parameter, e.g., increasing a voltage amplitude value or frequency (e.g., according to therapy adjustment instructions associated with the detected bladder fullness state in memory 58), or delivering stimulation according to a different or additional therapy program (e.g., a stimulation therapy program 60 associated with the detected bladder fullness state in memory 58), or delivering a second stimulation therapy, e.g., a "boost" to the first stimulation therapy already delivered to patient 14.

Spec. ¶ 110.

From these exemplary descriptions, we find that Appellant has provided a sufficiently fulsome description of steps in prose and the flowchart set forth in Figure 6 for one of skill in the art to reasonably understand that Appellant had possession of the claimed subject matter including a "means for controlling, based on the physiological condition, the electrical stimulation therapy."

Therefore, we do not sustain the Examiner's rejection of claim 39 as failing to comply with the written description requirement.

Indefiniteness Rejection

The Examiner rejected several claims as indefinite for failing to particularly point out and distinctly claim the subject matter of the invention. Final Act. 6–9.

We determine that a claim is indefinite "when it contains words or phrases whose meaning is unclear." *Ex parte McAward*, Case No. 2015-006416, slip op. at 11 (PTAB Aug. 25, 2017) (citing *In re Packard*, 751 F.3d 1307, 1313 (Fed. Cir. 2014) (per curiam)). In other words, "claims are

required to be cast in clear—as opposed to ambiguous, vague, indefinite—terms." *Id*. This requirement, however, does not demand unreasonable precision in drafting. *Id*. We apply this standard to the claims that the Examiner rejected as indefinite.

A. Claim 24

The Examiner rejects claims 24–35, 40, and 41 as indefinite for failing to particularly point out and distinctly claim the subject matter of the invention because the recitation of an actuator element *or* a detector element as detecting at least one reflected pressure wave with a portion of the device housing renders claim 24 unclear as to whether a detector is required. Final Act. 6–7. The Examiner determines that claims 25 through 35 and claims 40 and 41, all of which depend on claim 24, suffer from the same defect. *Id*. at 7.

As to claim 24 and those claims which depend from claim 24, Appellant asserts that the alternative between whether an actuator or a detector element detects at least one pressure wave with a portion of the device housing is acceptable because it is clear from the Specification that an actuator element and a detector element may be a single element such that a separate detector element is absent. Appeal Br. 27 (citing Spec. ¶ 75); Reply Br. 18 (stating "claim 24 merely recites two alternatives for what element is configured to detect at least one reflected pressure wave with a portion of the device housing").

Although the detector element is not listed separately as a limitation of claim 24, it is clear from the language used by the Appellant that a detector element is not part of the apparatus as claimed in claim 24 if the

actuator element is used to detect the pressure wave as opposed to the detector element. This interpretation is supported by the Specification as pointed out by Appellant. The Specification provides:

> In other examples, actuator element 72 and detector element 74 may be a single element. Actuator element 72 and detector element 74 may be, for example, a single piezoelectric element that transforms energy between mechanical and electrical states. Accordingly, in some examples, actuator circuit 68 and detector circuit 70 may be a single electrical circuit that both produces and detects pressure waves with housing 52 of IMD 20.

Spec. ¶ 75. As Appellant has stated, "there is no question as to scope or clarity, but instead there is a clear binary pair of options." Reply Br. 18.

Therefore, we do not sustain the rejection of claims 24–35, 40, and 41 as indefinite as being unclear as to whether a detector is required.

B. Claims 28 and 29

The Examiner also finds that claims 28 and 29 have the additional problem of a recitation of "one or more circuits" where it is not clear if those circuits are part of the processor of claim 24 or a separate and distinct set of circuits. Final Act. 7–8. Appellant responds that the claims clearly state that the acoustic module comprises the claimed one or more circuits, and if the processor is a circuit, "one of ordinary skill in the art would have understood that the acoustic module may have separate circuits to perform this feature or include the processor as part of the acoustic module." Appeal Br. 28 (citing Spec. ¶¶ 71, 73).

The Examiner maintains that the processor of claim 24 and the acoustic module of claims 28 and 29 are separate and distinct elements as

evidenced by the transitional phrase "further comprising" of claims 28 and 29. Ans. 35. Specifically, the Examiner states:

> On their face, claims 28 and 29 present one or more circuits (being part of the acoustic module) as being an additive element to all the previously cited elements due to the use of the transitional phrase "further comprising". However, the specification and the Appellant's remarks indicate this is not always the case. Thus, there is a contradiction to the presentation of the claim elements and what these claim elements are intended to encompass.

Id. at 36.

Appellant replies:

> To the extent that the one or more circuits may include the processor recited in claim 24, all claim 28 recites is that the acoustic module now includes the processor. Dependent claim 28 thus would narrow the recited features as including an additional relationship between the acoustic module and the processor.

Reply Br. 20.

We agree with the Examiner that the recitation of "one or more circuits" in claims 28 and 29 is unclear. Both claims 28 and 29 depend directly from claim 24 that recites a system comprising at least an actuator element and a processor that is configured to determine a physiological condition of the patient based on a reflected pressure wave. Appeal Br. 37–38. Both dependent claims 28 and 29 recite the system of claim 24 "further comprising an acoustic module comprising at least one of the actuator element or the detector element and *one or more circuits*" configured to determine various data concerning the reflected pressure wave. *Id*. at 38.

It is unclear from the further recitation of claims 28 and 29 whether the "one or more circuits" are part of the processor of claim 24, or a separate

circuit. Appellant admits that the acoustic module may now include the processor, but that is not made clear from the language used in dependent claims 28 and 29 that just recite "one or more circuits" without defining the circuit(s)' relationship to the processor recited in claim 24.

Therefore, we sustain the rejection of claims 28 and 29 as indefinite.

C. Claim 36

The Examiner rejects claim 36 as indefinite because it is not clear from the Specification what structure, whether the processor or acoustic module, is intended to perform the "means for determining." Final Act. 8–9. Appellant responds that the "means for determining" could include "any structures described by the specification," such as the processor. Appeal Br. 32. The Examiner responds that this blurring of the lines between what functions are performed by the acoustic module and those performed by the processor renders the claim indefinite. Ans. 37–38.

We agree with Appellant that the fact that the Specification describes two structures that can perform the function of the "means for determining" does not render the claimed means-plus-function limitation unclear. That two structures may perform the function renders the claim broader than if the structure performing the function of the means limitation were specified in the claim, but not unclear.

Therefore, we do not sustain the rejection of claim 36 as indefinite.

D. Claim 39

Finally, the Examiner rejects claim 39 for failing to disclose a corresponding algorithm that performs the function of controlling, based on the physiological condition, the electrical stimulation therapy, the same

rationale as for the written description rejection discussed above. Final Act. 9.

For the same reasons set forth above with regard to the written description rejection of claim 39, we do not sustain the rejection of claim 39 as indefinite.

Rejection of claims 13–16, 19–27, and 30–41 over Gerber and at least one of Penner, Von Arx, or Tepper

The Examiner relies primarily on Gerber to teach the majority of the claim limitations in each independent claim. *See* Final Act. 10–12, 14–15, 18–19. Specifically, concerning the requirement of each claim of producing "a pressure wave within a patient with a portion of a device housing" of an implantable medical device, the Examiner recognizes that Gerber alone does not teach this limitation. *See, e.g., id*. at 10–12; Ans. 38–39.

The Examiner states the following:

> Gerber teaches the use of implantable ultrasound sensors (entire disclosure including paragraph 0058; FIGS. 3 and 4C; transceiver(s) 46 detects the reflected waves). It is known in the art to seal the components, including the acoustic/ultrasound sensors/transducers, in a titanium casing so as to protect the sensors/transducers and internal components from the environment (paragraphs 0035 and 0055 of Penner; paragraphs 0044-0051 and FIGS. 4-9 of Von Arx) and/or to use a titanium device housing as part of the sensor-transducer as an alternative construction of the sensor/transducer (FIG. 8 and cols. 5-6 and 12 of Tepper). It would have been obvious to one of ordinary skill in the art at the time of the invention to seal the components, including the ultrasound sensors of the combination, in a titanium or stainless steel casing so as to protect the sensors/transducers and internal components from the environment and/or to use a titanium device housing as part of the sensor/transducer since it

> is a simple substitution of one known element for another to obtain predictable results.

Final Act. 10–11.

With reference to the requirement of independent claims 13, 24, and 36 of producing "a pressure wave within a patient with a portion of a device housing," the Examiner cites to "the transceiver or the actuating unit of the transceiver produces ultrasonic waves in a housing constituted by the housing 31 of Gerber, the lead 24C of Gerber, and the titanium or stainless steel casing of the combination" and references the analysis set forth immediately above. *Id*. at 11, 14–15, 18, respectively.

Appellant asserts that the combination proposed by the Examiner is in error because "there would have been no apparent reason that would have caused one of ordinary skill in the art to modify the applied references to arrive at the claimed features." *See* Appeal Br. 7–8. For instance, Appellant states that the Examiner has not alleged that Gerber teaches producing a pressure wave within a patient *with a portion of a device housing*, much less shown how combining Gerber's system with a "titanium or stainless steel casing" as disclosed in Penner, Von Arx, or Tepper would arrive at a method that includes producing a pressure wave within a patient with a portion of a device housing, "wherein the device housing encloses a processor and the actuator element," as required by claim 13. Appeal Br. 8–9.[2]

[2] Independent claim 24 has a similar requirement that "the device housing encloses the processor and the actuator element." Appeal Br. 37. Independent claim 36 also requires that "the housing encloses a processor and at least a portion of the means for producing the pressure wave with the portion of the device housing." *Id*. at 41.

The Examiner responds that Appellant is improperly attacking the references individually because the Examiner is relying on the housing 31 of Gerber, the lead 24C of Gerber, and the titanium or stainless steel casing of the combination to teach the claimed "device housing." Ans. 38–39. The Examiner explains that:

> The housing of the combination encloses the processor because a housing part constituted by the housing part 31 of Gerber encloses the processor 32 of Gerber. This housing part 31 of Gerber is also part of the housing along with the titanium casing portion covering the sensor/transducers. There is no requirement in the claim language that the housing be a contiguous piece of material. In other words, there is nothing in the claim language to preclude the housing from being made of multiple parts. In the case of the combination, the housing has multiple parts: housing part 31 of Gerber, the lead 24C of Gerber, and the titanium or stainless steel casing portion of the combination.

Id. at 39–40.

Appellant responds that the Examiner has not provided reasoning as to why one of ordinary skill in the art would locate the transceiver that is on the distal end of sensing lead 24 of Gerber within the structure that is also described as the housing of Gerber. Reply Br. 3–4. Appellant further argues that "even if it were obvious to seal an ultrasound transceiver of Gerber with a titanium or stainless steel casing, the Examiner has not explained how the suggested combination teaches producing a pressure wave within a patient with a portion of a device housing of an implantable medical device, wherein the housing encloses the processor." *Id*. at 5. Appellant points to the references that are used by the Examiner in the rejection to show that the definition of "housing" as used by the Examiner is just too broad. *Id*. at 5–8.

Appellant concludes that:

> Appellant did not and is not making the argument that one of ordinary skill in the art [would] "simply not" cover the ultrasound sensor with a titanium or stainless steel casing. Rather, Appellant is asserting that there is no definition of a housing of an implantable medical device as would be understood by one skilled in the art that would include both housing 31 of Gerber and lead 24 of Gerber. Thus, whether or not the transceiver was independently encased in a stainless steel casing that could be defined as a housing, such a potential housing could not be the same housing as housing 31 that contains processing electronics.

Id. at 8.

We agree with Appellant that the asserted combination does not teach producing a pressure wave within a patient with *a portion of a device housing* of an implantable medical device or such a device *wherein the housing encloses the processor*. A review of the claimed subject matter and what Gerber teaches is instructive.

With regard to the claimed subject matter at issue here, the IMD detects a physiological state of a patient as follows.

> The portion of the IMD housing may be a free wall that is configured to move (e.g., oscillate) to generate pressure waves that are transmitted into adjacent fluids or tissue within a body of a patient and detect the pressure waves that were transmitted through tissue or fluid within the body. An actuator element contacts the free wall to generate pressure waves, and a detector may contact the free wall to detect wall motion. Based on the relative position of anatomical structures and bodily fluids to the IMD housing, the IMD may determine a physiological condition of a patient.

Spec. ¶ 5.

Figure 5 set forth below is a conceptual cross-sectional diagram illustrating such an IMD.

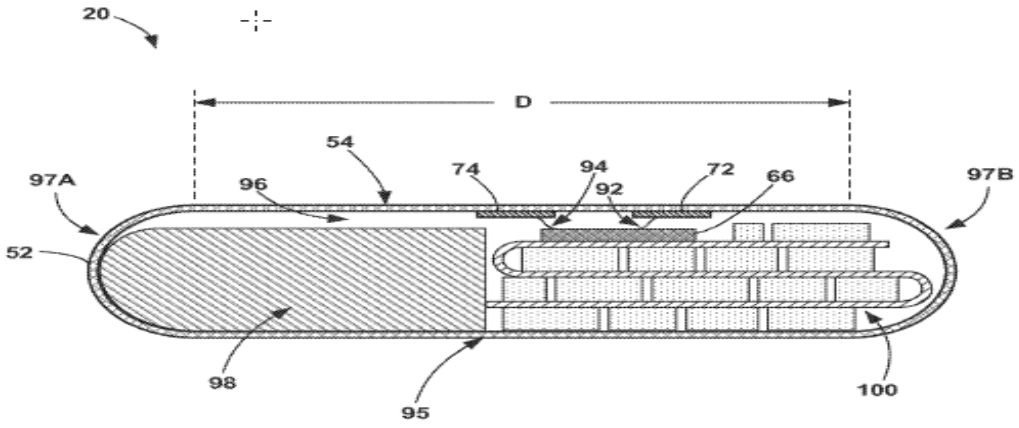

FIG. 5

As shown in Figure 5 above, IMD 20 has outer housing 52, battery 98, operational circuitry 100, acoustic module 66, actuator element 72, detector element 74, and connector ribbons 92 and 94. *Id*. ¶ 99. Operational circuitry 100 may include processor 56. *Id*. Outer housing 52 has free wall 54, a portion of housing 52 that is designed to move (e.g., vibrate or oscillate) relative to other portions of housing 52, as well as relative to battery 98 and operational circuity 100. *Id*. ¶ 100. Housing 52 may be made of a single material such as biocompatible materials like metal alloys (e.g., stainless steel or titanium alloys), or any combination of materials such as a ceramic composite for free wall 54, while the balance of housing 52 is a titanium alloy. *Id*. ¶ 105. Housing 52 may also be "any variety of shapes and sizes configured to implant IMD 20 at specific locations within patient 14." *Id*.

The operation of free wall 54 of housing 52 is further described as follows.

> Few, if any (e.g., sometimes none), rigid components are attached or mounted to free wall 54, thereby permitting free wall 54 freedom of motion to vibrate. Free space 96 is the volume of space within housing 52 adjacent to free wall 54 that allows free wall 54 to move in relation to the rest of housing 52. Free space 96 may be a vacuum or filled with air, filled with a gas mixture, or filled with an inert single gas. Although free space 96 may be of any volume, the distance between the inside surface of free wall 54 and other components is at least large enough to allow free wall 54 to move enough to produce the pressure waves of the desired frequency or to receive the reflected pressure waves. In the example shown in FIG. 5, the curved side walls of housing 52 provide a relatively stiff support structure for free wall 54.
>
> Actuator element 72 and detector element 74 contact free wall 54 either directly or indirectly (e.g., via an intervening adhesive or other intervening component). Acoustic module 66 is electrically coupled to actuator element 72 via conductive ribbon 92 and detector element 74 via conductive ribbon 94 passing through free space 96. . . . [A]ctuator element 72 is configured to produce pressure waves by causing motion of free wall 54 (e.g., oscillations of free wall 54). The produced pressure waves are transmitted away from free wall 54 and IMD 20. At least some of the transmitted pressure waves that reflect off of anatomical structures or other changes in medium density traverse back through patient 14 to contact free wall 54. The contact made by the reflected pressure waves causes vibration or motion in free wall 54. Detector element 74 contacting free wall 54 is configured to detect these vibrations or motions and converts them to electrical signals with which acoustic module 66 may determine a bladder fullness state of patient 14.

Id. ¶¶ 100–101.

Gerber, on the other hand, describes a device that provides transmembrane sensing of internal bladder conditions by implanting a sensing device outside the bladder, but using a sensor deployed within the

bladder on the end of a lead extending from the sensing device that penetrates the bladder wall. Gerber ¶¶ 5, 20–21. Gerber's Figure 3, shown below, depicts such a device.

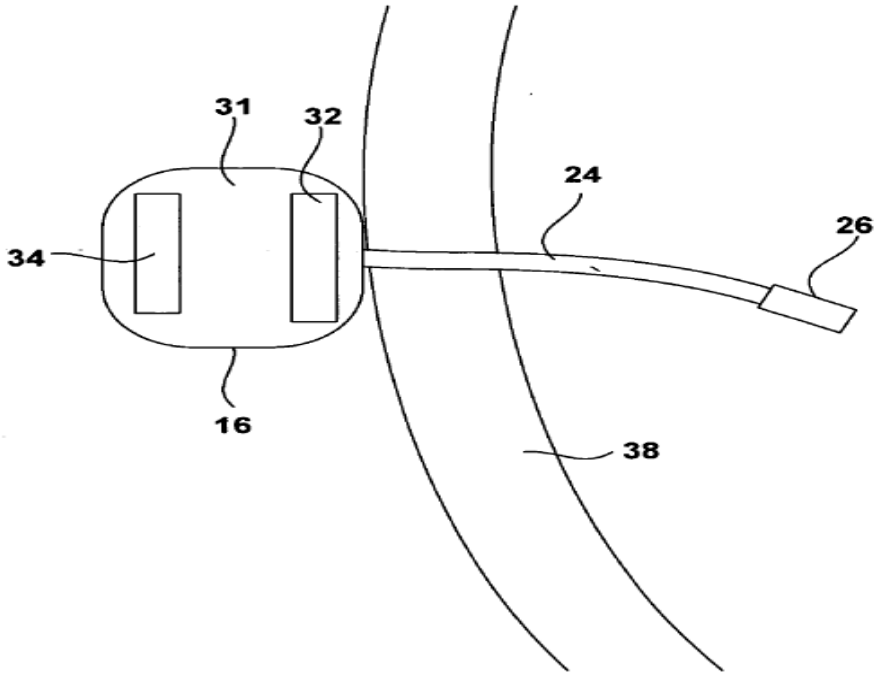

FIG. 3

> As shown in FIG. 3 [above], sensing device 16 includes a device housing 31 and sensing lead 24 that extends from the housing through bladder wall 38 and into bladder 14. The distal end of sensing lead 24 carries sensor 26. Device housing 31 includes a circuit board 32 carrying sensing circuitry which is electronically coupled to sensor 26, as well as a power source 34.

Id. ¶ 24.

The Examiner determines that one of skill in the art would view Gerber as teaching the claimed device housing from Gerber's housing 31 and lead 24 that penetrates the bladder wall with sensor 26 mounted on the distal end of lead 24. The Examiner then combines Gerber's alleged device

housing teaching with Penner and Von Arx's teachings of encasing vulnerable components in a titanium casing to protect them from the environment and the teaching of Tepper that such a casing may be used as the sensor-transducer. We agree with Appellant that one of skill in the art would not make these leaps from these teachings to arrive at the claimed invention.

We do not agree that one of skill in the art would view housing 31 and lead 24 of Gerber as the claimed device housing. In reviewing the claimed subject matter in light of the Specification, it is clear that the device housing of the claimed IMD would not be considered as including a lead that extends from the device with a sensor on the proximal end of that lead. The sensing of the physiological conditions of the bladder are performed by the claimed subject matter by producing pressure waves from the housing itself as shown by example in Appellant's Figure 5, as set forth and described above, and not by a sensor mounted on the distal end of a lead that extends from the housing. Although we acknowledge that the Specification states that the housing may be a variety of shapes, we agree with Appellant that one of skill in the art in reviewing Gerber would not include lead 24 as part of the claimed device housing. To read the device housing of the claimed subject matter as including such a lead would strain the meaning of "device housing" as used in the claimed subject matter and also as shown in Gerber, Penner, Von Arx, and Tepper that all use "device housing" in a consistent manner as the Specification of the claimed subject matter at issue here.

Therefore, we do not sustain the Examiner's rejection of claims 13–16, 19–27, and 30–41 over Gerber and at least one of Penner, Von Arx, and Tepper.

Remaining Obviousness Rejections of claims 13–41

In the remaining obviousness rejections, the Examiner relies on the same finding that the claimed "housing" for "producing a pressure wave within a patient with a portion of a device housing" is taught by housing 31 of Gerber, the lead 24C of Gerber, and the titanium or stainless steel casing of the combination of Penner, Von Arx, or Tepper with Gerber. *See* Final Act. 20–23; Pre-appeal Conference Dec. 6–9; Ans. 45–47.

For the same reasons discussed above, we do not sustain the remaining rejections under 35 U.S.C. § 103(a) of claims 13–41.

DECISION

The decision of the Examiner rejecting claims 28 and 29 as indefinite is affirmed. The remaining rejections are reversed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a). *See* 37 C.F.R. § 1.136(a)(1)(iv).

CONCLUSION

In summary:

Claims Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
39	112, first paragraph (pre-AIA)	Written Description		39
24–35, 40, 41	112, second paragraph (pre-AIA)	Indefiniteness	28, 29	24–27, 30–35, 40, 41
13–16, 19–27, 30–41	103	Gerber, Penner, Von Arx, Tepper		13–16, 19–27, 30–41
17, 28	103	Gerber, Penner, Von Arx, Tepper, Freudenrich, Chua, Simmons, Dynamic Ultrasound Group		17, 28
13–16, 19–27, 30–41	103	Rondoni, Guly, Gerber, Penner, Von Arx, Tepper		13–16, 19–27, 30–41
17, 18, 28, 29	103	Rondoni, Guly, Gerber, Penner, Von Arx, Tepper, Freudenrich, Chua, Simmons, Dynamic Ultrasound Group		17, 18, 28, 29
Overall Outcome			28, 29	13–27, 30–41

AFFIRMED IN PART