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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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*Ex parte* ANDREW J. RIES, ERIC J. WENGREEN, JOHN E. LOVINS,  
RANDY S. ROLES, MICHAEL R. KLARDIE, and  
THOMAS I. CEBALLOS

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Appeal 2016-000674  
Application 12/410,233  
Technology Center 3700

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Before LINDA E. HORNER, LYNNE H. BROWNE, and  
GORDON D. KINDER, *Administrative Patent Judges*.

HORNER, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Andrew J. Ries et al. (Appellants)<sup>1</sup> seek our review under 35 U.S.C. § 134(a) of the Examiner’s decision rejecting claims 1–15 and 21. Final Office Action (October 24, 2014) (hereinafter “Final Act.”). Claims 16–20 and 22 are canceled. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM-IN-PART.

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<sup>1</sup> Appellants identify Medtronic, Inc. and Medtronic, plc as the real parties in interest. Appeal Brief 3 (March 27, 2015) (hereinafter “Appeal Br.”).

### CLAIMED SUBJECT MATTER

Appellants' claimed subject matter relates to "headers and setscrews for implantable medical devices." Spec. 1, ll. 4–5. Claims 1, 13, and 21 are independent. Claim 1 is representative of the subject matter on appeal and is reproduced below, with certain claim language italicized.

1. An implantable medical device (IMD) assembly having a header for coupling a lead and a setscrew for securing the lead to the header, the setscrew comprising:

a unitary metal core having:

a head portion having an engagement segment;

a shank portion having a threaded outer surface for threadedly-coupling to the header;

an insulating coating disposed over the head portion of the metal core, the insulating coating having a thickness sufficient to electrically isolate the head portion from a surrounding medium, *wherein the insulating coating is dimensioned to cover the engagement segment such that an application of torque to an external surface of the insulating coating compresses the insulating coating against the engagement segment to trigger rotational engagement of the unitary metal core;* and

a sealing member disposed over a portion of the insulating coating.

Appeal Br. 18 (Claims App.).

### REJECTIONS

The Final Office Action includes the following rejections:

1. Claims 1–6, 9, 11–15, and 21 stand rejected under 35 U.S.C. § 102(b) as anticipated by Fruland (US 2006/0247716 A1, published November 2, 2006).
2. Claim 7 stands rejected under 35 U.S.C. § 103(a) as unpatentable over Fruland.

3. Claim 8 stands rejected under 35 U.S.C. § 103(a) as unpatentable over Fruland and Bradshaw (US 5,545,188, issued August 13, 1996).
4. Claim 10 stands rejected under 35 U.S.C. § 103(a) as unpatentable over Fruland and Hall (US 2009/0318999 A1, published December 24, 2009).

## ANALYSIS

### *Rejection of claims 1–6, 9, 11–15, and 21 as anticipated by Fruland*

Appellants present arguments directed to all of the pending claims and present further arguments specifically addressing dependent claims 2–5. Appeal Br. 7–14 (addressing all claims); *id.* at 14–16 (addressing claims 2–5).<sup>2</sup> We treat claims 1, 6, 9, 11–14, and 21 as being argued as a group, and select claim 1 as representative of the group. Claims 6, 9, 11–14, and 21 stand or fall with claim 1. We separately address claims 2–5 and 15 *infra*.

### *Claim 1*

The Examiner finds that the embodiment of Figure 13 of Fruland, as informed by the detailed disclosure of the embodiment of Figure 6 of Fruland, anticipates the setscrew of the assembly of claim 1. Final Act. 2–4. Fruland describes an embodiment of a setscrew in Figures 4–6, wherein the setscrew has an internal drive interface. Final Act. 2–3; Fruland ¶¶ 30, 31. Fruland discloses that “[i]n another example, the drive is an external drive that interfaces with a socket wrench, as shown in **FIGS. 13 and 14.**” *Id.* at ¶ 30. Figure 13 depicts a screw 1300 but without the detail showing, for

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<sup>2</sup> Because claim 15 recites subject matter similar to claim 4, and the Examiner relies on the same findings as the basis for anticipation of the subject matter of both claims, we treat claims 4 and 15 together.

example, the insulative body member and the conductive shaft member, those details already having been provided in Figure 6. We understand Fruland's reference in paragraph 30 to the external drive example to mean that the screw of the external drive example is the same as the screw of the internal drive example except for the different drive interface at the top of the head of the set screw. Thus, contrary to Appellants' assertion (Appeal Br. 11), the Examiner is not relying upon a combination of two embodiments; rather, the Examiner is relying on the external drive example of Figure 13, as further described in Figure 6.

The Examiner finds that portion 600 corresponds to the claimed insulating coating. Final Act. 3. Appellants contend that this reading of Fruland is contrary to Fruland's description of element 600 as a "head piece." Appeal Br. 9. We find no error in the Examiner's reading of the elements of claim 1 onto Fruland's setscrew. Fruland's conductive shaft member 605 is a unitary metal core having a head portion with an engagement segment and a shank portion with a threaded outer surface. Fruland's insulative head piece 600 is disposed over the upper surface of shaft member 605 and thus over the head portion of the metal core, and has a thickness sufficient to electrically isolate the head portion from a surrounding medium. Final Act. 2-3. Simply because Fruland calls this insulative portion by a different name does not distinguish this portion of the setscrew structurally from the claimed insulating coating.

Appellants further argue that "rotation by a wrench positioned within the drive interface 210 . . . will create rotation of the head piece 600 along a first axis" and "would not result in compression of the insulating coating against the engagement segment as is required by the claims." Appeal

Br. 9–10. This argument is directed to the internal drive example of Figure 6, rather than the external drive example of Figure 13, on which we understand the Examiner to have relied.

As to the external drive example of Figure 13, Appellants “do[] not dispute that Fruland’s setscrew . . . has an external drive.” Appeal Br. 12. Appellants argue, however, that “the structure of Fruland’s setscrew will cause an indirect transfer of the torque that is applied to the head 600 to the shaft (thereby placing the head under sheer [sic, shear] stress).” *Id.* (arguing that the “drive portion is not configured to interact with the shaft” and that “wrench 1325 . . . interfaces with the head 1300”). We agree with Appellants’ characterization of the interaction of wrench 1325 with the head piece of screw 1300. We fail to see, however, how the lack of direct engagement of wrench 1325 with shaft member of screw 1300 distinguishes the claimed structure from screw 1300. The claims call for the insulating coating to be dimensioned to cover the engagement segment such that an application of torque to an external surface of the insulating coating compresses the insulating coating against the engagement segment to trigger rotational engagement of the unitary metal core. Thus, the claim language calls for an indirect rotational engagement of the metal core via the insulating coating.

Appellants argue that even in the external drive configuration, in which “[t]he wrench 1325 would presumably be placed over the head piece of a setscrew having a similar construction as the setscrew of FIG. 6,” “there is no reasonable interpretation of Fruland that would yield a disclosure that this torque force applied from wrench 1325 at the apex of the head piece would compress the actual engagement segment – shown in FIG. 6 as

features 610, 615.” Appeal Br. 13. The Examiner responds that features 610 and 615 (engagement segment) “define an opening which is filled with polymer when the shaft is molded into the head 600” and, thus:

the polymer of the head piece 600 would be dimensioned to be pressed against the protruding surface so that an application of torque to the insulating head piece 600 would compress the insulating head piece against the protruding member surfaces of shaft member 605 to trigger rotational engagement of the shaft member.

Ans. 7 (emphasis omitted). For the reasons that follow, we agree with the Examiner’s finding that the claimed torque transfer, including compression of the insulating coating against the engagement segment, occurs in the setscrew of Fruland.

Fruland discloses that “insulative head piece 600 is molded over a shaft member 605” and that “shaft member 605 includes features 610, 615 that transmit torque from the head 600 to the shaft member 605.” Fruland ¶ 31. Just as in the embodiment of Figure 7, in which protruding surfaces 725, 730, 735, 740, 745, 750, 755, and 760 “define an opening which is filled with polymer when the shaft is molded into the head” (*id.* at ¶ 32),<sup>3</sup> in

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<sup>3</sup> The Examiner refers to Figure 7 as an alternative embodiment that also anticipates the claimed setscrew. Final Act. 3 (citing protruding members 705, 710, 715, 720 and paragraph 32). In other words, we understand the Examiner to find that the external drive embodiment of Figure 13 having either the structure of Figure 6 or Figure 7 anticipates the claimed subject matter. Contrary to Appellants’ assertion (Reply Br. 2), the Examiner did not cite the teachings of Figure 7 for the first time in the Examiner’s Answer. The Examiner clearly cited paragraph 32 in the Final Action for the disclosure that the protruding surfaces “are arranged to transmit torque from an overmolded head to the shaft member” and “the surfaces define an opening which is filled with polymer when the shaft is molded into the head 600.” Final Act. 3; *see also* Advisory Action 3–5 (January 29, 2015). For

the embodiment of Figure 6, the protruding surfaces of protruding members 610 and 615 define an opening which is filled with polymer when the head is molded over the shaft 605 (*id.*, Fig. 6). In this case, application of torque to the external surface of the insulating coating causes the insulating coating within this opening to be compressed against the protruding surfaces of features 610, 615 that define the opening in the top of shaft member 605. This compression of the coating in the region of the opening triggers rotational engagement of the unitary metal core. The claim does not require that application of torque to an external surface of the insulating coating compresses the insulating coating against any particular surface of the engagement segment. As such, we find that the compression of the insulating coating in the region of the opening in Fruland's setscrew meets the claim language as written. We find no error in the Examiner's determination that Fruland's structure anticipates claim 1. Accordingly, we sustain the rejection of claim 1, and claims 6, 9, 11–14, and 21 which fall with claim 1, as anticipated by Fruland.

*Claim 2*

Claim 2 depends from claim 1 and recites “the setscrew further comprises a necked region disposed between the head portion and the shank portion.” Appeal Br. 18 (Claims App.). Appellants contend that the basis for the Examiner's “arbitrary selection” of the necked region as “being located generally at the location just above the threaded section of the shank 605 and below the head 600” is “unclear.” Appeal Br. 16. Appellants mischaracterize the Examiner's finding. The Examiner states, “The

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the same reasons discussed with regard to Figure 6, we likewise agree with the Examiner's findings as to the embodiment of Figure 7.



Examiner considers the region between the shank portion and head portion *of the shaft* as the necked region.” Final Act. 4 (emphasis added) (providing an annotated Figure 6 of Fruland labeling the “neck portion” as the section between the head portion (features 610, 615) and the threaded region of shaft 605).

The Examiner properly turned to Appellants’ Specification for an understanding of the claimed “necked region.” Ans. 8–9. The Specification describes that “[n]ecked region 235 is formed between head portion 220 and shank 210 and has a narrower diameter than head 220.” Spec. 7, ll. 2–3. We agree with the Examiner’s finding that the region of Fruland’s shaft 605 that lies between the head portion (features 610, 615) and the threaded portion meets the description of a necked region as provided in Appellants’ Specification. Specifically, the portion of shaft 605 identified by the Examiner is formed between head portion (features 610, 615) and the threaded portion of shaft 605 and is narrower than the diameter of the head portion (features 610, 615). As such, we find no error in the Examiner’s determination that Fruland anticipates claim 2. Accordingly, we sustain the rejection of claim 2 as anticipated by Fruland.

*Claim 3*

Claim 3 depends from claim 2 and recites “the sealing member is coupled to the necked region.” Appeal Br. 18 (Claims App.). The Examiner finds that “the raised ribs are the sealing members coupled to the necked region as seen in [F]igure 6.” Final Act. 4. Appellants contend that claim 3 calls for the sealing member to be a separate element from the insulating coating, and Fruland does not disclose a separate sealing member because “in Fruland, the raised ribs are part and parcel of the head 600.” Appeal

Br. 16. We disagree with Appellants' interpretation of the language of claim 3. The "coupled to" language of claim 3 requires that the sealing member is separate from the *necked region*. Fruland's raised ribs 226, 227 are separate from the necked region of shaft member 605. We see no language in claim 3, and Appellants have not pointed us to specific language of the claim, that requires the sealing member to be a separate element from the insulating coating.<sup>4</sup> As such, we find no error in the Examiner's determination that Fruland anticipates claim 3. Accordingly, we sustain the rejection of claim 3 as anticipated by Fruland.

*Claims 4 and 15*

Claim 4 depends from claim 1 and recites "the setscrew further comprises a reinforcement sleeve disposed over a part of the insulating coating." Appeal Br. 18 (Claims App.). Claim 15 depends from claim 13 and recites "means for reinforcing disposed on the setscrew." *Id.* at 20. The Examiner finds that Fruland's disclosure of a non-conductive sleeve anticipates the claimed reinforcement sleeve and means for reinforcing. Final Act. 4, 6 (citing Fig. 2, sleeve 105, Fig. 8, sleeve 835, Fig. 11, sleeve 1105, Fig. 12, sleeve 1210). Appellants argue that the identified sleeves of Fruland are "disposed adjacent a length of the bore into which Fruland's setscrew is inserted" and are not "disposed over the insulating coating of the setscrew." Appeal Br. 15. Fruland discloses use of a sleeve with internal drive setscrew embodiments and discloses that the sleeve includes an

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<sup>4</sup> Claim 1 recites "a sealing member disposed over a portion of the insulating coating." Appeal Br. 18 (Claims App.). We do not interpret "disposed over" to require that the sealing member be a separate element from the insulating coating, and Appellants do not make this argument as to claim 1. Fruland's ribs 226, 227 are disposed over the remainder of head portion 600.

opening through which a wrench can be inserted and engaged with a driver interface on the screw. Fruland ¶ 24. Fruland does not disclose a sleeve for use in the external drive embodiment of Figure 13. Because the rejection of claims 4 and 15 is based on anticipation by the external drive embodiment shown in Figure 13 of Fruland, we do not sustain the rejection of claims 4 and 15 based on a disclosure of sleeves used in other internal drive embodiments.

*Claim 5*

Claim 5 depends from claim 1 and recites “the setscrew further comprises a guiding surface disposed proximate an apex of the head portion.” Appeal Br. 18 (Claims App.). The Examiner “consider[s] the top surface of setscrew 1300 as a guiding surface.” Final Act. 5. Appellants argue that because Figure 13 of Fruland does not even depict the top surface of the setscrew 1300, the Examiner’s reliance on this Figure of Fruland is “pure conjecture.” Appeal Br. 14–15. We agree with Appellants that the Examiner has not shown anticipation of the subject matter of claim 5 by a preponderance of the evidence.

Appellants’ Specification describes that “[t]he apex of tool interface 300 may be configured to be a guiding surface such that it facilitates the position of torque wrench 302 over the setscrew 200” and that in an example, the apex is “dome-shape.” Spec. 8, ll. 8–11. Fruland describes Figure 13 as a cross-section view of setscrew 1300. Fruland ¶ 18. Fruland does not provide any other view of setscrew 1300 and does not describe where the cross-section view of Figure 13 is taken. As such, we cannot find by a preponderance of the evidence, based on the depiction of setscrew 1300 in Figure 13, that Fruland’s setscrew has a guiding surface “disposed

proximate an apex of the head portion” as recited in claim 5. Accordingly, we do not sustain the rejection of claim 5 as anticipated by Fruland.

*Remaining Grounds of Rejection Based on Obviousness*

Appellants do not present additional arguments to allege error in the Examiner’s rejections of dependent claims 7, 8, and 10. Appeal Br. 7–14. For the reasons discussed above, we find no error in the Examiner’s rejection of claim 1 based on Fruland. For these same reasons, we likewise sustain the rejections under 35 U.S.C. § 103(a) of claim 7 as unpatentable over Fruland, claim 8 as unpatentable over Fruland and Bradshaw, and claim 10 as unpatentable over Fruland and Hall.

DECISION

We affirm the decision of the Examiner rejecting claims 1–3, 6, 9, 11–14, and 21.

We reverse the decision of the Examiner rejecting claims 4, 5, and 15.

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).

AFFIRMED-IN-PART