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Medtronic, Inc. (CVG) 8200 Coral Sea Street NE. MS: MVC22 MINNEAPOLIS, MN 55112			TEMPLETON, CHRISTOPHER L	
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte ANDREA J. ASLESON, RONALD A. DRAKE,
MARK T. MARSHALL, and KELLY M. WIEN

Appeal 2019-005148
Application 14/620,410
Technology Center 3700

Before CHARLES N. GREENHUT, WILLIAM A. CAPP, and
JEREMY M. PLENZLER, *Administrative Patent Judges*.

CAPP, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Appellant¹ seeks our review under 35 U.S.C. § 134(a) of the final rejection of claims 1–3, 5–8, 10–14, 16, 17, and 22. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM IN PART.

¹ We use the word “Appellant” to refer to “applicant” as defined in 37 C.F.R. § 1.42(a). Appellant identifies Medtronic, Inc. as the Applicant and real party in interest. Appeal Br. 3.

THE INVENTION

Appellant's invention relates to surgical tools that provide access to implant medical leads. Spec. 1. Claim 1, reproduced below, is illustrative of the subject matter on appeal.

1. A medical access tool comprising:

a needle member including a proximal end, a piercing distal tip, and a lumen, the needle member extending along a longitudinal axis of the medical access tool between the proximal end thereof and the piercing distal tip thereof, the lumen extending from a proximal opening thereof at the proximal end to a distal opening thereof at the distal tip;

a coiled wire extending around the longitudinal axis of the medical access tool with a pitch, the coiled wire including a proximal segment, a distal segment, and a tissue-engaging tip, the coiled wire having an inner surface, the inner surface being spaced radially apart from an outer surface of the needle member along a length of the proximal segment, the distal segment extending distally from the proximal segment to the tissue-engaging tip, the distal tip of the needle member being recessed proximally from the tissue-engaging tip by a fixed distance equal to a length of the distal segment, and the coiled wire having a stiffness that prevents significant deformation of the pitch thereof during operation of the medical access tool, wherein the coiled wire is configured to proximally pull tissue up the coiled wire by rotating without advancing until the distal tip passively pierces the tissue without advancing; and

a junction connecting the coiled wire to the medical access tool, the junction being configured to prevent movement of the coiled wire along the longitudinal axis of the medical access tool relative to the needle member.

THE REJECTIONS

The Examiner relies upon the following as evidence in support of the rejections:

NAME	REFERENCE	DATE
Altman	US 6,416,510 B1	July 9, 2002
Ryan	US 2004/0002699 A1	Jan. 1, 2004
Rioux	US 2008/0108950 A1	May 8, 2008
Kauphusman	US 2009/0163862 A1	June 25, 2009
Gillies	US 2012/0123461 A1	May 17, 2012
Smith	US 2013/0178845 A1	July 11, 2013
Nita	US 8,690,819 B2	Apr. 8, 2014

The following rejections are before us for review:²

1. Claims 1–3, 10–12, 16, and 17 are rejected under 35 U.S.C. § 103 as being unpatentable over Altman and Gillies.
2. Claims 7, 13, and 22 are rejected under 35 U.S.C. § 103 as being unpatentable over Altman, Gillies, and Rioux.
3. Claim 5 is rejected under 35 U.S.C. § 103 as being unpatentable over Altman, Gillies, and Nita.
4. Claims 1, 8, 12, and 14 are rejected under 35 U.S.C. § 103 as being unpatentable over Ryan, Smith, and Gillies.
5. Claims 2 and 6 are rejected under 35 U.S.C. § 103 as being unpatentable over Ryan, Smith, Gillies, and Kauphusman.
6. Claim 5 is rejected under 35 U.S.C. § 103 as being unpatentable over Ryan, Smith, Gillies, Kauphusman, and Nita.

² Rejections of claims 1–8, 10, and 11 under 35 U.S.C. § 112(b) and of claim 4 under 35 U.S.C. § 103 have been withdrawn by the Examiner. Ans. 11.

7. Claims 11 and 17 are rejected under 35 U.S.C. § 103 as being unpatentable over Ryan, Smith, Gillies, and Nita.

OPINION

*Unpatentability of Claims 1–3, 5, 7, 10–13, 16, 17, and 22
over Combinations Based on Altman*

We limit our discussion to the following claim language which is where the dispute between the Examiner and Appellant centers:

wherein the coiled wire is configured to proximally pull tissue up the coiled wire by rotating without advancing until the distal tip passively pierces the tissue without advancing.

Claims App.

The Examiner concludes that claims 1–3, 5, 7, 10–13, 16, 17, and 22 are unpatentable as obvious over various combinations based on the Altman reference. Final Act. 3–7. The Examiner’s rejections are predicated on a factual finding that Altman’s needle is coiled “just like” Appellant’s needle and, therefore, “is capable of pulling tissue up the coiled wire.” *Id.* at 4.

Appellant argues that Altman is designed and configured to penetrate tissue by advancing by means of rotation. Appeal Br. 11. “Through such rotation, the structure may be ‘screwed into the heart’ to travel to a target site.” *Id.*

In response, the Examiner reiterates that Altman’s needle is coiled just like Appellant’s needle and, therefore, is capable of pulling tissue up the coiled wire. Ans. 11. The Examiner finds that Altman’s coiled wire can be rotated without advancing by rotating element 102 with element 106 while the coiled wire is advanced from 106. *Id.* at 12. Alternatively, the Examiner finds that Altman’s coiled wire can be rotated without advancing by rotating element 102 while proximally pulling element 106. *Id.*

Altman is directed to a drug delivery catheter for cardiac procedures. Altman, Abstract. Altman's catheter includes a distal helical coil that engages and penetrates the myocardium. *Id.* Altman's helical coil 114 is screwed into the heart by turning coil 102 inside outer catheter body 106. *Id.* at col. 10, ll. 47–54. Fixed structure 130, on the inner wall of catheter body 106, forces helical coil 114 to advance from the distal end of the catheter when coil 102 and drug delivery tube 104 are rotated. *Id.*

The Examiner's explanation as to how Altman is allegedly configured to be capable of pulling tissue up the coiled wire is not supported by evidence or sound technical reasoning. Ans. 14. The Examiner's position that coil 102 and body 106 could be rotated simultaneously is not well taken. Altman is specifically configured so that coil 102 turns "inside of" body 106. Altman, col. 10, ll. 47–49. Thus, coil 102 rotates in relation to body 106 such that the two elements are not configured to rotate in unison.

We find similarly unpersuasive the Examiner's position that Altman's coil 114 could pull tissue without advancing by rotating element 102 and simultaneously pulling on body 106 at the same pace that the coiled wire is extended from 106. Ans. 14. As previously explained, Altman's coil turns relative to body 106. Altman, col. 10, ll. 47–49. Such turning causes the intended result of tip 132 advancing with respect to the distal end of body 106, thereby advancing into and penetrating a patient's tissue. *Id.* Essentially, the Examiner considers that a user could thwart such intended and designed advance into body tissue by pulling body 106 away from the body tissue at the same rate of motion that tip 132 is advancing distally from body 106 as coil 102 is rotated. Whether such a non-intended use is feasible for a skilled medical practitioner is a matter of pure speculation on the

Examiner's part. Here, the Examiner is proposing to operate Altman in a manner that runs counter to the manner in which it is "configured to" operate. Thus, it cannot be said to be "configured to" operate in the manner proposed by the Examiner.

The Examiner's finding that Altman is configured to pull tissue up by rotating without advancing or is at least capable of doing so is not supported by a preponderance of the evidence and, therefore, constitutes reversible error.³

The Examiner's error infects independent claims 1 and 12, as well as all claims that depend therefrom that are rejected over combinations based on Altman. Consequently, we do not sustain the Examiner's unpatentability rejections of claims 1–3, 5, 7, 10–13, 16, 17, and 22 over combinations based on Altman.

*Unpatentability of Claims 1, 8, 12, and 14
over Ryan, Smith, and Gillies*

Claims 1 and 8

Appellant argues claims 1 and 8 as a group. Appeal Br. 30. We select claim 1 as representative. *See* 37 C.F.R. § 41.37(c)(1)(iv).

The Examiner finds that Ryan discloses the invention substantially as claimed except for a lumen, for which the Examiner relies on Smith. Final Act. 7–8. The Examiner further finds that Ryan is capable of pulling tissue as claimed and that Gillies specifically teaches that it was known to

³ In the Answer, the Examiner, for the first time, alleges that claims 1–3, 10–12, 16, and 17 are anticipated by Altman under 35 U.S.C. § 102(a)(1). Ans. 3. We do not sustain the Examiner's alternative Section 102 rejection for essentially the same reasons discussed herein regarding erroneous findings of fact with respect to whether Altman is configured to pull tissue as claimed.

configure and use a coiled wire to proximally pull tissue by rotating the wire without advancing until distal tip (106) passively pierces the tissue. *Id.* at 8. The Examiner concludes that it would have been obvious to a person of ordinary skill in the art at the time of the invention to combine the teachings of Ryan, Smith, and Gillies to achieve the claimed invention. *Id.* at 9. According to the Examiner, a person of ordinary skill in the art would have done this to access anatomical spaces. *Id.*

Appellant argues that the prior art fails to disclose a coiled wire that is configured to proximally pull tissue up the coiled wire by rotating without advancing until the distal tip passively pierces the tissue without advancing as recited in claim 1. Appeal Br. 31. Appellant argues that the intended purpose of Ryan is screwing a probe into a resistant tissue mass using a helical needle. *Id.* at 32. Appellant argues that using Ryan in a manner as taught by Gillies to pull tissue up a helical tine would frustrate the intended purpose of Ryan. *Id.* at 33.

In response, the Examiner notes that Appellant fails to disclose any structure other than the coiled shape that can pull tissue up the coiled wire. Ans. 16. The Examiner infers that Ryan is configured to proximally pull tissue up the coiled wire by rotating without advancing since it has a coiled shape similar to that of Appellant. *Id.*

The coiled wire of Ryan is coiled just like Appellant's, and thus is capable of pulling tissue up the coiled wire. Appellant has not disclosed any structure other than the coiled shape that can pull tissue up the coiled wire; thus the coiled wire of Ryan is configured to proximally pull tissue up the coiled wire by rotating without advancing since it has a coiled shape. *Id.* at 17.

In reply, Appellant directs our attention to the “junction” recited in claim 1 as structure that enables the coiled wire to pull tissue without advancing as claimed. Reply Br. 11.

Ryan is directed to a helical needle that is attached to a surgical probe to aid in the insertion of the probe into a tissue mass. Ryan, Abstract. Ryan features probe 10 that includes needle like element 14 with a distal end 16 that is surrounded by helical needle 12. *Id.* ¶ 26, Fig. 1. Distal end 16 of needle-like element 14 is terminated by a sharp tip 24 for entering a tissue mass 28. *Id.* The proximal end 20 of needle-like element 14 includes a handle member 32 having a pair of opposing turning tabs 34a, 34b attached to the exterior wall surface 22 for rotating helical needle 12 and probe 10. *Id.* Tip 46 of helical needle 12 is spaced longitudinally and distally from tip 24 of needle-like element 14. *Id.*

The proximal end of Ryan’s helical needle 12 is attached to needle-like element 14 at attachment section 48. *Id.* ¶ 27, Fig. 1. Attachment section 48 of helical needle 12 is affixed to the elongated shaft section 18 of element 14 such that helical needle 12 and needle-like element 14 cannot be moved in a rotational or axial direction independently of each other. *Id.* ¶ 28, Fig 1.

The above referenced disclosure from paragraph 28 of Ryan effectively refutes Appellant’s argument that the “junction” recited in Appellant’s claim 1 structurally differentiates Ryan from the claimed invention. Attachment section 48 of Ryan corresponds to Appellant’s claimed juncture. *See* Appellant’s Fig. 3A.

We agree with the Examiner’s position that Ryan is capable of pulling tissue as claimed. Although Ryan’s primary purpose is to advance into

tissue mass in a screw-like manner, such does not negate the fact that it is capable of being used for other purposes. “A reference may be read for all that it teaches, including uses beyond its primary purpose.” *In re Mouttet*, 686 F.3d 1322, 1331 (Fed. Cir. 2012), citing *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 418–421 (2007). “It is well settled that the recitation of a new intended use for an old product does not make a claim to that old product patentable.” *In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997).

In view of the foregoing discussion, we determine the Examiner’s findings of fact are supported by a preponderance of the evidence and that the Examiner’s legal conclusion of unpatentability is well-founded. We sustain the Examiner’s unpatentability rejection of claims 1 and 8 over Ryan, Smith, and Gillies.

Claims 12 and 14

Appellant argues independent claim 12 and claim 14 that depends therefrom as a group. Appeal Br. 35–39. We select claim 12 as representative. 37 C.F.R. § 41.37(c)(1)(iv).

In traversing the rejection, Appellant raises the same argument about the helical coil pulling tissue that we considered and found unpersuasive with respect to claim 1 and find equally unpersuasive here. Appeal Br. 36.

Appellant next argues that the prior art fails to disclose or suggest a proximal end of the needle lumen being configured to engage with a connector of a syringe assembly as claimed. *Id.* In response, the Examiner directs our attention to elements 40, 42, and 44 of Smith as allegedly corresponding to Appellant’s needle element. Ans. 19. In reply, Appellant argues that the proximal end of element 42 is always encased with actuator

element 44 and, therefore, would not be configured to engage with a connector of a syringe assembly. Reply Br. 14.

Smith discloses an integrated catheter assembly. Smith, Abstract. Smith's tool 40 includes needle 42 that allows injections of fluids, drugs, and further can apply suction. *Id.* ¶¶ 24–25. Actuator 44 has a Luer-type fitting that allows passage of fluids for injection. *Id.*

Having considered the competing positions of Appellant and the Examiner, we find the Examiner's position more persuasive. Smith's disclosure of a Luer-type fitting that allows passage fluids for injection satisfies the disputed claim language regarding a lumen in fluid communication with an interior of a barrel of a syringe assembly. We sustain the Examiner's unpatentability rejection of claims 12 and 14 over Ryan, Smith, and Gillies.

*Unpatentability of Claims 2, 5, 6, 11, and 17
Over Combinations Based on Ryan, Smith, and Gillies*

In traversing these grounds of rejection, Appellant relies solely on arguments that we previously considered and found unpersuasive with respect to either claim 1 and/or claim 12 and find equally unpersuasive here. Appeal Br. 40–42. We sustain the Examiner's unpatentability rejections of claims 2, 5, 6, 11, and 17 over combinations based on Ryan, Smith, and Gillies.

CONCLUSION

Claims Rejected	§	References	Aff'd	Rev'd
1-3, 10-12, 16, 17	103	Altman, Gillies		1-3, 10-12, 16, 17
7, 13, 22	103	Altman, Gillies, Riox		7, 13, 22
5	103	Altman, Gillies, Nita		5
1, 8, 12, 14	103	Ryan, Smith, Gillies	1, 8, 12, 14	
2, 6	103	Ryan, Smith, Gillies, Kauphusman	2, 6	
5	103	Ryan, Smith, Gillies, Kauphusman, Nita	5	
11, 17		Ryan, Smith, Gillies, Nita	11, 17	
Overall Outcome			1, 2, 5, 6, 8, 11, 12, 14, 17	3, 7, 10, 13, 16, 22

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

AFFIRMED IN PART