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EXAMINER	
DEDOULIS, CHRISTINE A	

ART UNIT	PAPER NUMBER
3794	

NOTIFICATION DATE	DELIVERY MODE
10/14/2025	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 17/190,224	Applicant(s) Wright et al.	
	Examiner CHRISTINE A DEDOULIS	Art Unit 3794	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 08 July 2025.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☑ This action is **FINAL.** 2b) ☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 6-29 and 31-32 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 6-29 and 31-32 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☑ The drawing(s) filed on 02 March 2021 is/are: a)☑ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☑ Notice of References Cited (PTO-892)

2) ☐ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed July 8, 2025, has been entered and fully considered. Claims 6-29, 31 and 32 are pending. Claims 6-29 and 31 are amended. Claim 32 is newly added.

Notice of Pre-AIA or AIA Status

2. The present application is being examined under the pre-AIA first to invent provisions.

3. In the event the determination of the status of the application as subject to AIA 35 U.S.C. 102 and 103 (or as subject to pre-AIA 35 U.S.C. 102 and 103) is incorrect, any correction of the statutory basis (i.e., changing from AIA to pre-AIA) for the rejection will not be considered a new ground of rejection if the prior art relied upon, and the rationale supporting the rejection, would be the same under either status.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on nonstatutory double patenting provided the reference application or patent either is shown to be commonly owned with the examined application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. See MPEP § 717.02 for applications subject to examination under the first inventor to file provisions of the AIA as explained in MPEP § 2159. See MPEP § 2146 *et seq.* for applications not

subject to examination under the first inventor to file provisions of the AIA. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The filing of a terminal disclaimer by itself is not a complete reply to a nonstatutory double patenting (NSDP) rejection. A complete reply requires that the terminal disclaimer be accompanied by a reply requesting reconsideration of the prior Office action. Even where the NSDP rejection is provisional the reply must be complete. See MPEP § 804, subsection I.B.1. For a reply to a non-final Office action, see 37 CFR 1.111(a). For a reply to final Office action, see 37 CFR 1.113(c). A request for reconsideration while not provided for in 37 CFR 1.113(c) may be filed after final for consideration. See MPEP §§ 706.07(e) and 714.13.

The USPTO Internet website contains terminal disclaimer forms which may be used. Please visit www.uspto.gov/patent/patents-forms. The actual filing date of the application in which the form is filed determines what form (e.g., PTO/SB/25, PTO/SB/26, PTO/AIA/25, or PTO/AIA/26) should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to www.uspto.gov/patents/apply/applying-online/eterminal-disclaimer.

5. Claims 6-29, 31 and 32 are rejected on the grounds of nonstatutory double patenting as being unpatentable over claims 1-29 of U.S. Patent No. 10,966,782. Although the claims at issue are not identical, they are not patentably distinct from each other because the claims of U.S. Patent No. 10,966,782 anticipate the claims of the application. Accordingly, the application claims are not patentably distinct from the patent claims. Here, the more specific patent claims encompass the broader application claims. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific narrow invention, applicant may not obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

Claim Rejections - 35 USC § 112

The following is a quotation of 35 U.S.C. 112(b):
(b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 31 is rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor (or for applications subject to pre-AIA 35 U.S.C. 112, the applicant), regards as the invention.

7. Claim 31, line 2 recites "radiofrequency neurotomy." It is at most unclear what these terms are modifying. It appears applicant intended to recited -- radiofrequency neurotomy system -- .

8. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of pre-AIA 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries for establishing a background for determining obviousness under pre-AIA 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 6-17, 19-26, 28 and 29 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Racz et al., (hereinafter 'Racz,' U.S. Pat. No. 6,146,380) in view of Lee et al., (hereinafter 'Lee,' U.S. PGPub. No. 2007/0016183).

10. **Regarding claim 6,** Racz discloses a radiofrequency neurotomy system for treating a patient (Figs. 1-2B), the radiofrequency neurotomy system comprising: a cannula (10, 33) that is conductive (col. 3, ll. 60-65) and comprises: a lumen (shaft 12, 34); a proximal end through which a longitudinal axis passes (Figs. 1-2B); and a distal end (Figs. 1-2B); a tip (14,38) that is conductive and is attached to the distal end of the cannula (Fig. 1; col. 4, ll. 17-23), the tip comprising: a channel that passes through the tip (see opening 46 in Fig. 2B); a transition region (see region between proximal and distal ends); a body portion (at reference numeral 14, 38) at an angle of between about 5 degrees and about 90 degrees relative to the longitudinal axis of the proximal end of the cannula (Figs. 1-2B); and a tapered portion that comprises a sharpened point at a distal end thereof that is configured to pierce the skin of the patient (col. 5, ll. 3-5, "The tip portion 38 of the shaft 34 has a distal pointed end 40, which as described above can be useful in penetrating tough tissue."), the tapered portion further comprising a fluid port in fluid communication with the channel of the tip that is configured to transfer fluid that has passed through the lumen of the cannula and through the channel of the tip (col. 8, ll. 54-57, " In the pointed-tipped needle shown in FIG. 2, the aperture or opening 46 for injecting fluids lies at the very distal end of the tip 38…").

11. Racz discloses the cannula is capable of receiving a variety of devices, including probe (22). Further, "[t]his physical relationship between the probe 22 and the shaft 12 facilitates electrical contact between the two elements." (col. 3, ll. 60-65; also see col. 5, ll. 41-51).

12. Racz, however, is silent regarding a wire port spaced from the fluid port; and a wire that is conductive and is movable through the cannula to interact with the transition region of the tip, wherein the transition region of the tip is configured to physically contact and outwardly deflect a distal end of the

wire as the distal end of the wire is advanced distally along the transition region, the wire being advanceable to a deployed position in which the distal end of the wire extends outwardly from the wire port, wherein when the wire is in the deployed position, the tip and the wire are in electrical communication so as to operate together as an expanded electrode that is configured to deliver radiofrequency energy to a nerve of the patient for treatment of pain.

13. However, in the same field of endeavor, Lee (Fig. 1) teaches a similar ablation device comprising a plurality of conductive wires (wire-like stylets 22), moveable through the cannula (16) to interact with the transition region of the tip, wherein the wire port(s) is spaced proximally from the distal most tip ([0092]). Lee teaches, "[a]s tip 24 [of stylet 22] is advanced, it bears against surface 12, which deflects it" ([0092]; [0099]; also see [0018] for deflection mechanism). As seen in Figure 1, the wire-like stylets (22) are advanceable to a deployed position in which the distal end of the wire extends outwardly from the wire port, wherein when the wire is in the deployed position, the tip and the wire are in electrical communication so as to operate together as an expanded electrode that is configured to deliver radiofrequency energy to a nerve of the patient for treatment of pain ([0092]; as broadly claimed, the ablation energy may be applied for a variety of treatments, including treatment of pain). This wire-like stylets (22) may be advanced in any desired pattern (e.g., singly or in combination), and the ablative energy can be focused at the wire-like stylets (22), such that tissue surrounding cannula (16) is substantially unaffected ([0092]), thereby increasing accuracy and control. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was filed to have modified the system as taught by Racz to include a wire port spaced from the fluid port; and a wire that is conductive and is movable through the cannula to interact with the transition region of the tip, wherein the transition region of the tip is configured to physically contact and outwardly deflect a distal end of the wire as the distal end of the wire is advanced distally along the transition region, the wire being advanceable to a deployed position in which the distal end of the wire extends outwardly from the wire port, wherein when the wire is in the deployed position, the tip and the wire are in electrical communication so as to operate together as an expanded electrode that is configured to deliver radiofrequency energy to a nerve of the

patient for treatment of pain, as taught by Lee. Doing so allows for one or more wire-like stylets to extend radially from the distal region of the cannula so as to achieve desired energy patterns and obtain a desired ablation tissue volume ([0092]; [0105]), thereby improving accuracy and control.

14. **Regarding claim 7**, Racz in view of Lee teach all of the limitation of the radiofrequency neurotomy system according to claim 6. In view of the prior modification Racz in view of Lee, Lee (Fig. 1) teaches wherein when the wire (22) is in the deployed position, the tip and the wire are in physical contact with each other (see Fig. 1).

15. **Regarding claim 8**, Racz in view of Lee teach all of the limitation of the radiofrequency neurotomy system according to claim 6. Racz (Figs. 1-2B) further discloses wherein the cannula (10, 33) is configured to conduct electrical signals (col. 3, ll. 60-65), wherein the cannula (10, 33) comprises insulation, and wherein the insulation is not present at a distal part of the cannula that is adjacent to the body portion of the tip (col. 4, ll. 26-28, "the straight portion 32 of the shaft 12 is at least in part electrically insulated, as indicated by the hatched area of FIG. 1.").

16. **Regarding claim 9**, Racz in view of Lee teach all of the limitation of the radiofrequency neurotomy system according to claim 6. Racz (Figs. 1-2B) further discloses wherein the tip and the wire are in electrical communication due to physical contact among the conductive components of the radiofrequency neurotomy system (col. 5, ll. 41-51, "Electrical signals from the signal generator 58 are communicated to the exposed distal tip 38 by way of contact between the probe shaft 54 and an internal lumen defined by the electrode shaft 34. If the electrode shaft 34 or cannula is a metal tube and the probe shaft 54 has a metal outer surface, then this can be accomplished simply through physical contact between the probe shaft 54 and the electrode shaft 34. When the application of therapeutic electrical signals is complete, the probe 52 is withdrawn from the cannula 33, and the electrode can then be withdrawn from the patient.").

17. **Regarding claim 10**, Racz in view of Lee teach all of the limitation of the radiofrequency neurotomy system according to claim 6. In view of the prior modification Racz in view of Lee, Lee (Fig. 1) teaches wherein the cannula (16) defines the wire port (12) (Figs. 1-2).

18. **Regarding claim 11**, Racz in view of Lee teach all of the limitation of the radiofrequency neurotomy system according to claim 6. In view of the prior modification Racz in view of Lee, Lee (Fig. 1) teaches wherein when the wire (22) is in the deployed state, the distal end of the wire that extends outwardly from the wire port is substantially straight ([0092], "stylets 22 comprises a long and straight springy wire-like member which may be housed wholly within lumen 20 of cannula 16.").

19. **Regarding claim 12**, Racz in view of Lee teach all of the limitation of the radiofrequency neurotomy system according to claim 6. In view of the prior modification Racz in view of Lee, Lee (Fig. 1) teaches wherein the distal end of the wire (22) is at an angle relative to the longitudinal axis of the cannula when the wire is in the deployed position (Fig. 1).

20. **Regarding claim 13**, Racz in view of Lee teach all of the limitation of the radiofrequency neurotomy system according to claim 6. In view of the prior modification Racz in view of Lee, Lee (Fig. 1) teaches wherein the distal end of the wire (22) is disposed away from the tip when the wire is in the deployed position (Fig. 1 illustrates distal end of wire-like stylets disposed at an angle away from tip 14, 18).

21. **Regarding claim 14,** Racz in view of Lee teach all of the limitation of the radiofrequency neurotomy system according to claim 6. Racz further discloses wherein the cannula is 16 gauge or smaller (col. 6, ll.59-62, "A further advantage of using a small-gauge spinal needle with a curved or bent distal end is that it can be accurately steered into narrow and relatively difficult-to-access portions of a patient's spine." Also see col. 8, ll. 10-15, for 10 gauge).

22. **Regarding claim 15,** Racz in view of Lee teach all of the limitation of the radiofrequency neurotomy system according to claim 6. Racz (Figs. 1-2B) discloses the fluid port at the distal most end of the canula (col. 8, ll. 54-57, " In the pointed-tipped needle shown in FIG. 2, the aperture or opening 46 for injecting fluids lies at the very distal end of the tip 38…"). In view of the prior modification Racz in view of Lee, Lee (Fig. 2) teaches wherein the wire port (at 12) is longitudinally spaced from the fluid port such that the wire port is at a proximal position relative to the fluid port.

23. **Regarding claim 16,** Racz in view of Lee teach all of the limitation of the radiofrequency neurotomy system according to claim 6. Racz further discloses comprising a fitting (hub 44, 70) proximal to the cannula that is in fluid communication with the lumen of the cannula, the fitting being configured to attach to a fluid delivery device to permit fluid from the fluid delivery device to pass into and through the lumen of the cannula when the distal end of the cannula is in the patient (col. 5, l. 52- col. 6, l. 20, "A hub 70 is a standard hypodermic needle or luer type hub, capable of connection to stylets, electrical probes, syringes, or injection tubes." Also see col. 8, ll. 45-57, for opening 46 having similar function as window 72).

24. **Regarding claim 17,** Racz in view of Lee teach all of the limitation of the radiofrequency neurotomy system according to claim 6. In view of the prior modification of Racz in view of Lee, Lee (Figs. 1-2) teaches wherein the transition region of the tip (14, 18) comprises one or more of a curved surface and a planar surface along which the wire (22) is advanced distally to achieve outward deflection (Fig. 2; [0092]).

25. **Regarding claim 19,** Racz in view of Lee teach all of the limitation of the radiofrequency neurotomy system according to claim 6. In view of the prior modification of Racz in view of Lee, Lee (Figs. 1-2) teaches wherein the tip (14, 18) and the cannula (16) are different components and a proximal portion of the tip (inner sleeve 32) is positioned within the distal end of the cannula (16).

26. **Regarding claim 20,** Racz in view of Lee teach all of the limitation of the radiofrequency neurotomy system according to claim 6. Racz further discloses wherein the proximal end of the cannula (10, 33) is cylindrical (see Figs. 1-2B).

27. **Regarding claim 21,** Racz in view of Lee teach all of the limitation of the radiofrequency neurotomy system according to claim 20. Racz further discloses wherein the body portion of the tip (at reference numeral 14, 38) is cylindrical (Figs. 1-2B).

28. **Regarding claim 22,** Racz in view of Lee teach all of the limitation of the radiofrequency neurotomy system according to claim 20. Racz further discloses wherein the body portion of the tip (at reference numeral 14, 38) is at an angle.

29. However, Racz in view of Lee are silent regarding where the angle is between about 10 degrees and about 20 degrees relative to the longitudinal axis of the cylindrical proximal end of the cannula. It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the angle as taught by Racz in view of Lee such that the angle is between about 10 degrees and about 20 degrees relative to the longitudinal axis of the cylindrical proximal end of the cannula, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

30. **Regarding claim 23,** Racz in view of Lee teach all of the limitation of the radiofrequency neurotomy system according to claim 20. Racz further discloses wherein the body portion of the tip (at reference numeral 14, 38) is at an angle.

31. However, Racz in view of Lee are silent regarding where the angle is about 10 degrees relative to the longitudinal axis of the cylindrical proximal end of the cannula. It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the angle as taught by Racz in view of Lee such that the angle is about 10 degrees relative to the longitudinal axis of the cylindrical proximal end of the cannula, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

32. **Regarding claim 24,** Racz in view of Lee teach all of the limitation of the radiofrequency neurotomy system according to claim 6. In view of the prior modification Racz in view of Lee, Lee (Fig. 1) teaches wherein when the wire (22) is in the deployed position: a first portion of the wire is proximal to the proximal end of the cannula; a second portion of the wire is in the lumen of the cannula; and a third portion of the wire extends outwardly from the wire port (see Fig. 1).

33. **Regarding claim 25,** Racz in view of Lee teach all of the limitation of the radiofrequency neurotomy system according to claim 24. In view of the prior modification Racz in view of Lee, Lee (Fig. 1) teaches further comprising a radiofrequency generator configured to supply the RF radiofrequency

energy to the expanded electrode ([0025]; [0083]-[0084]; see [0092] for electrically conductive stylets for applying RF energy).

34. **Regarding claim 26,** Racz in view of Lee teach all of the limitation of the radiofrequency neurotomy system according to claim 25. In view of the prior modification Racz in view of Lee, Lee (Fig. 1) teaches wherein the wire and the tip are configured to disperse the RF radiofrequency energy over a larger volume than would be possible by the tip alone (see [0092] for application of ablative energy to stylets 22 and tip 14, 18; [0092]; [0105]; as broadly claimed, the stylets may be deployed in any pattern, such that the reach of the stylets would be greater than the tip alone, thereby dispersing the RF radiofrequency energy over a larger volume than would be possible by the tip alone).

35. **Regarding claim 28,** Racz (Figs. 1-2B) discloses a radiofrequency neurotomy system for treating a patient, the radiofrequency neurotomy system comprising: a needle (col. 8, l. 45 for sharp needle) comprising: a proximal end; a distal end at a first angle of between about 5 degrees and about 90 degrees relative to the proximal end (Figs. 1-2B); a cannula (10, 33) that comprises a lumen (shaft 12, 34); a tip (14, 38) connected to the cannula (10, 33), the tip being configured to pierce the skin of the patient (col. 5, ll. 3-5, "The tip portion 38 of the shaft 34 has a distal pointed end 40, which as described above can be useful in penetrating tough tissue."), the tip comprising: a channel that extends through the tip (see opening 46 in Fig. 2B); a fluid port that is in fluid communication with the channel (col. 8, ll. 54-57, " In the pointed-tipped needle shown in FIG. 2, the aperture or opening 46 for injecting fluids lies at the very distal end of the tip 38…")., and a transition region (see region between proximal and distal ends).

36. Racz discloses the cannula is capable of receiving a variety of devices, including probe (22). Further, "[t]his physical relationship between the probe 22 and the shaft 12 facilitates electrical contact between the two elements." (col. 3, ll. 60-65).

37. Racz, however, is silent regarding a wire port at a position proximal to the fluid port; and a wire movable through the cannula to interact with the transition region of the tip, wherein the transition region is configured to outwardly deflect a distal end of the wire due to physical contact as the distal end of the wire is advanced distally along the transition region while the wire is being moved to a deployed position

wherein, when the wire is in the deployed position, the tip and the wire are in electrical communication so as to operate together as an expanded electrode that is configured to deliver radiofrequency energy to a target nerve of the patient.

38. However, in the same field of endeavor, Lee (Fig. 1) teaches a similar ablation device comprising a plurality of conductive wires (wire-like stylets 22), moveable through the cannula (16) to interact with the transition region of the tip, wherein the wire port(s) is spaced proximally from the distal most tip ([0092]). Lee teaches, "[a]s tip 24 [of stylet 22] is advanced, it bears against surface 12, which deflects it" ([0092]; [0099]; also see [0018] for deflection mechanism). As seen in Figure 1, the wire-like stylets (22) are advanceable to a deployed position in which the distal end of the wire extends outwardly from the wire port, wherein when the wire is in the deployed position, the tip and the wire are in electrical communication so as to operate together as an expanded electrode that is configured to deliver radiofrequency energy to a nerve of the patient for treatment of pain ([0092]; as broadly claimed, the ablation energy may be applied for a variety of treatments, including treatment of pain). This wire-like stylets (22) may be advanced in any desired pattern (e.g., singly or in combination), and the ablative energy can be focused at the wire-like stylets (22), such that tissue surrounding cannula (16) is substantially unaffected ([0092]), thereby increasing accuracy and control. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was filed to have modified the system as taught by Racz to include a wire port at a position proximal to the fluid port; and a wire movable through the cannula to interact with the transition region of the tip, wherein the transition region is configured to outwardly deflect a distal end of the wire due to physical contact as the distal end of the wire is advanced distally along the transition region while the wire is being moved to a deployed position wherein, when the wire is in the deployed position, the tip and the wire are in electrical communication so as to operate together as an expanded electrode that is configured to deliver radiofrequency energy to a target nerve of the patient, as taught by Lee. Doing so allows for one or more wire-like stylets to extend radially from the distal region of the cannula so as to achieve desired energy patterns and obtain a desired ablation tissue volume ([0092]; [0105]), thereby improving accuracy and control.

39. **Regarding claim 29,** Racz (Figs. 1-2B) discloses a radiofrequency neurotomy system for treating a patient, the radiofrequency neurotomy system comprising: a cannula (10, 33) that comprises: a proximal end through which a longitudinal axis passes (Figs. 1-2B); and a distal end; a tip (14, 38) attached to the distal end of the cannula (Figs. 1-2B), the tip comprising: a channel that passes through the tip (see opening 46 in Fig. 2B); a transition region (see region between proximal and distal ends); a body portion at the distal end of the cannula that is at an angle of between about 5 degrees and about 90 degrees relative to the longitudinal axis of the proximal end of the cannula (Figs. 1-2B) and a tapered portion that comprises a sharpened point at a distal end thereof that is configured to pierce the skin of the patient (col. 5, ll. 3-5, "The tip portion 38 of the shaft 34 has a distal pointed end 40, which as described above can be useful in penetrating tough tissue."), the tapered portion further comprising a first port configured to transfer fluid (46), the first port being in fluid communication with the channel (Fig. 2B) (col. 8, ll. 54-57, " In the pointed-tipped needle shown in FIG. 2, the aperture or opening 46 for injecting fluids lies at the very distal end of the tip 38…").

40. Racz discloses the cannula is capable of receiving a variety of devices, including probe (22). Further, "[t]his physical relationship between the probe 22 and the shaft 12 facilitates electrical contact between the two elements." (col. 3, ll. 60-65).

41. Racz, however, is silent regarding a second port spaced from the first port; and a wire movable relative to the cannula to a deployed position, wherein as the wire is moved to the deployed position, a distal end of the wire is deflected outwardly due to physical contact between the distal end of the wire and the transition region of the tip, and wherein, when the wire is in the deployed position, the tip and the wire are in electrical communication so as to operate together as an expanded electrode that is configured to deliver radiofrequency energy to a nerve of the patient for treatment of pain.

42. However, in the same field of endeavor, Lee (Fig. 1) teaches a similar ablation device comprising a plurality of conductive wires (wire-like stylets 22), moveable through the cannula (16) to interact with the transition region of the tip, wherein the wire port(s) (i.e., second port) is spaced proximally from the distal most tip ([0092]). Lee teaches, "[a]s tip 24 [of stylet 22] is advanced, it bears against surface 12,

which deflects it" ([0092]; [0099]; also see [0018] for deflection mechanism). As seen in Figure 1, the wire-like stylets (22) are advanceable to a deployed position in which the distal end of the wire extends outwardly from the wire port, wherein when the wire is in the deployed position, the tip and the wire are in electrical communication so as to operate together as an expanded electrode that is configured to deliver radiofrequency energy to a nerve of the patient for treatment of pain ([0092]; as broadly claimed, the ablation energy may be applied for a variety of treatments, including treatment of pain). This wire-like stylets (22) may be advanced in any desired pattern (e.g., singly or in combination), and the ablative energy can be focused at the wire-like stylets (22), such that tissue surrounding cannula (16) is substantially unaffected ([0092]), thereby increasing accuracy and control. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was filed to have modified the system as taught by Racz to include a second port spaced from the first port; and a wire movable relative to the cannula to a deployed position, wherein as the wire is moved to the deployed position, a distal end of the wire is deflected outwardly due to physical contact between the distal end of the wire and the transition region of the tip, and wherein, when the wire is in the deployed position, the tip and the wire are in electrical communication so as to operate together as an expanded electrode that is configured to deliver radiofrequency energy to a nerve of the patient for treatment of pain, as taught by Lee. Doing so allows for one or more wire-like stylets to extend radially from the distal region of the cannula so as to achieve desired energy patterns and obtain a desired ablation tissue volume ([0092]; [0105]), thereby improving accuracy and control.

43. Claim 27 and 32 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Racz in view of Lee as applied to claims 6 and 24 above, and further in view of Epstein et al., (hereinafter 'Epstein,' U.S. Pat. No. 8,241,276).

44. **Regarding claim 27,** Racz in view of Lee teach all of the limitation of the radiofrequency neurotomy system according to claim 6. Racz discloses the transition region comprises one or more of a curved surface and a planar surface (see region between proximal and distal ends). In view of the prior modification of Racz in view of Lee, Lee teaches the distal end of the wire (22) is at an angle relative to

the longitudinal axis (Fig. 1), is disposed away from the tip (Fig. 1), and is substantially straight when the wire is in the deployed position ([0092], "stylets 22 comprises a long and straight springy wire-like member which may be housed wholly within lumen 20 of cannula 16."); the wire port (at 12) is longitudinally spaced from the fluid port such that the wire port is at a proximal position relative to the fluid port (Fig. 1; the wire port is at a proximal position relative to the tip 14, 18, thereby meeting this limitation of the claim in view of Racz); a proximal portion of the tip (inner sleeve 32) is positioned within the distal end of the cannula (16); and when the wire (22) is in the deployed position: a first portion of the wire is proximal to the proximal end of the cannula; a second portion of the wire is in the lumen of the cannula; and a third portion of the wire extends outwardly from the wire port (Fig. 1).

45. Racz in view of Lee are silent regarding the wire is configured to act as a thermocouple for measuring temperature.

46. However, in the same field of endeavor, Epstein (Fig. 4) teaches a similar system comprising a plurality of "hypotube stylets [that] contain thermocouples which are used to measure the temperature of ablated tissue, thus ensuring that the tissue will be raised to the correct temperature for a sufficient period of time to ablate tissue resulting in the creation of necrotic tissue which may be absorbed by the body." (col. 6, ll. 5-11; also see col. 8, ll. 2-7 for "wire thermocouple 57, which performs the function of measuring the temperature of the ablated tissue."). Therefore, it would have been obvious to one having ordinary skill in the art to have modified the system as taught by Racz in view of Lee to include the wire is configured to act as a thermocouple for measuring temperature, as taught by Epstein, in order to provide feedback and ensure the tissue will be raised to the correct temperature for the desired effect (col. 6, ll. 5-11; also see col. 8, ll. 2-7), thereby increasing accuracy, control and safety.

47. **Regarding claim 32,** Racz in view of Lee teach all of the limitation of the radiofrequency neurotomy system according to claim 24, but are silent regarding wherein the wire is configured to act as a thermocouple for measuring temperature.

48. However, in the same field of endeavor, Epstein (Fig. 4) teaches a similar system comprising a plurality of "hypotube stylets [that] contain thermocouples which are used to measure the temperature of

ablated tissue, thus ensuring that the tissue will be raised to the correct temperature for a sufficient period of time to ablate tissue resulting in the creation of necrotic tissue which may be absorbed by the body." (col. 6, ll. 5-11; also see col. 8, ll. 2-7 for "wire thermocouple 57, which performs the function of measuring the temperature of the ablated tissue."). Therefore, it would have been obvious to one having ordinary skill in the art to have modified the system as taught by Racz in view of Lee to include the wire is configured to act as a thermocouple for measuring temperature, as taught by Epstein, in order to provide feedback and ensure the tissue will be raised to the correct temperature for the desired effect (col. 6, ll. 5-11; also see col. 8, ll. 2-7), thereby increasing accuracy, control and safety.

49. Claim 31 is rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Tullis et al., (hereinafter 'Tullis,' U.S. Pat. No. 7,918,852) in view of Lee.

50. **Regarding claim 31**, Tullis (Fig. 2) discloses a radiofrequency neurotomy system for treating a patient, the radiofrequency neurotomy comprising: a cannula (28) comprising a proximal end, a distal end, a lumen (cannula 28 has a tubular body 29 having a lumen); a tip (not labeled of needle 34) secured to the distal end (58) of the cannula (28) (when inserted into the cannula), the tip being configured to pierce the skin of the patient (col. 5, ll. 41-43, cannula 28 is best suited to pierce and penetrate skin and tissue; further, a needle would necessarily be capable of piercing the skin of a patient), the tip (not labeled) comprising a proximal portion that is inserted into the lumen of the cannula (28) and a distal portion that extends beyond the distal end of the cannula (see col. 5, ll. 32-34, for needle 34 is inserted in the cannula 28 to function as the conduit for introducing a drug), the tip (not labeled) comprising a channel that extends through the tip (i.e., for fluid delivery) and a fluid port that is spaced longitudinally from the wire port (at the distal most tip of needle 34), the tip further comprising a transition region (Fig. 2).

51. Tullis is silent regarding the wire port and a wire movable through the cannula, wherein the transition region of the tip is configured to physically contact and deflect outwardly a distal end of the wire through the wire port of the cannula as the wire is advanced distally to a deployed position, wherein, when the wire is in the deployed position, the tip and the wire are in electrical communication so as to

operate together as an expanded electrode that is configured to deliver radiofrequency energy to a nerve of the patient for treatment of pain.

52. However, in the same field of endeavor, Lee (Fig. 1) teaches a similar ablation device comprising a plurality of conductive wires (wire-like stylets 22), moveable through the cannula (16) to interact with the transition region of the tip, wherein the wire port(s) (i.e., second port) is spaced proximally from the distal most tip ([0092]). Lee teaches, "[a]s tip 24 [of stylet 22] is advanced, it bears against surface 12, which deflects it" ([0092]; [0099]; also see [0018] for deflection mechanism). As seen in Figure 1, the wire-like stylets (22) are advanced distally to a deployed position, wherein, when the wire is in the deployed position, the tip and the wire are in electrical communication so as to operate together as an expanded electrode that is configured to deliver radiofrequency energy to a nerve of the patient for treatment of pain ([0092]; as broadly claimed, the ablation energy may be applied for a variety of treatments, including treatment of pain). This wire-like stylets (22) may be advanced in any desired pattern (e.g., singly or in combination), and the ablative energy can be focused at the wire-like stylets (22), such that tissue surrounding cannula (16) is substantially unaffected ([0092]), thereby increasing accuracy and control. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was filed to have modified the system as taught by Tullis to include the wire port and a wire movable through the cannula, wherein the transition region of the tip is configured to physically contact and deflect outwardly a distal end of the wire through the wire port of the cannula as the wire is advanced distally to a deployed position, wherein, when the wire is in the deployed position, the tip and the wire are in electrical communication so as to operate together as an expanded electrode that is configured to deliver radiofrequency energy to a nerve of the patient for treatment of pain, as taught by Lee. Doing so allows for one or more wire-like stylets to extend radially from the distal region of the cannula so as to achieve desired energy patterns and obtain a desired ablation tissue volume ([0092]; [0105]), thereby improving accuracy and control.

Response to Arguments

53. Applicant's arguments with respect to claim(s) 6-31 have been considered but are moot because the amendments have necessitated a new ground of rejection.

54. Applicant argues (p. 13-14), "Tullis, Dahla, and Young cannot properly be combined in the manner proposed in the Office Action due to, for example, substantial differences among the devices and systems disclosed in these references." Applicant specifically focuses on Young; however, these arguments are moot in view of the prior art set forth above.

55. No further arguments have been set forth regarding the dependent claims.

56. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any nonprovisional extension fee (37 CFR 1.17(a)) pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

57. Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTINE A DEDOULIS whose telephone number is (571)272-2459. The examiner can normally be reached M-F, 8am to 5pm.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached at 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/C.A.D./
Examiner, Art Unit 3794

/LINDA C DVORAK/
Primary Examiner, Art Unit 3794