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SHUMAKER & SIEFFERT , P.A
1625 RADIO DRIVE , SUITE 100
WOODBURY, MN 55125

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LEE, ERICA SHENGKAI	

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rs.patents.five@medtronic.com

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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Ex parte MARTIN T. GERBER

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Appeal 2019-000700
Application 11/606,627
Technology Center 3700

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Before TONI R. SCHEINER, ERIC B. GRIMES, and JEFFREY N. FREDMAN, *Administrative Patent Judges*.

SCHEINER, *Administrative Patent Judge*.

DECISION ON APPEAL

Pursuant to 35 U.S.C. § 134(a), Appellant[1] appeals from the Examiner's decision to reject claims 1–4, 10–13, 15, 19–23, and 38. We have jurisdiction under 35 U.S.C. § 6(b).

We reverse.

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[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. of Minneapolis, Minnesota and Medtronic plc of Dublin, Ireland. Appeal Br. 3 (entered June 6, 2018).

BACKGROUND

Appellant's invention is directed to a flexible apparatus for implanting a therapy element (e.g., a neurostimulation lead) into a patient's tissue. *See* Spec. ¶¶ 6–8. According to the Specification, the apparatus comprises an introducer "configured to preferentially flex . . . more easily in a particular direction to help prevent the introducer from inadvertently flexing in a direction that may damage tissue . . . during implantation of the therapy element." *Id.* ¶ 6.

STATEMENT OF THE CASE

Claims 1–4, 10–13, 15, 19–23, and 38 are pending and on appeal. Claims 24–26, 28–32, and 35–37 have been withdrawn from consideration, and claims 5–9, 14, 16–18, 27, 33, and 34 have been cancelled. Final Act. 3. Claim 1, the sole independent claim on appeal, is representative of the subject matter on appeal and reads as follows:

> 1. An apparatus configured to facilitate implantation of a therapy element into tissue of a patient, the apparatus comprising:
>
> a dilator; and
>
> a sheath defining an inner lumen configured to interchangeably receive the dilator and the therapy element,
>
> wherein a first portion of the dilator is configured to preferentially flex in at least a first direction over at least a second direction that is different from the first direction, wherein a second portion of the dilator is configured to preferentially flex in the second direction, the dilator being configured to allow the first portion to flex in at least the first direction and the second portion to flex in the second direction at a same time, and wherein a cross-sectional shape of at least one of the first portion or the second portion of the dilator comprises an oval shape having a major axis and a minor axis, the oval shape having a first outer dimension along the major axis and a second outer dimension along the minor axis,

> wherein the first dimension is larger than the second dimension, and the at least one of the first portion or the second portion of the dilator being configured to preferentially flex about the major axis due to the respective oval shape.

Appeal Br. 18.

The following rejections under pre-AIA 35 U.S.C. § 103(a) are before us for review:

Claims 1–4, 11, 13, 19, 22, 23, and 38 as unpatentable over Mamo,[2] Kucklick,[3] and Avitall;[4]

Claim 10 as unpatentable over Mamo, Kucklick, Avitall, and Spear;[5]

Claim 12 as unpatentable over Mamo, Kucklick, Avitall, and McKay;[6]

Claim 15 as unpatentable over Mamo, Kucklick, Avitall, and Bowser;[7] and

Claims 20 and 21 as unpatentable over Mamo, Kucklick, Avitall, and Kupiecki.[8]

DISCUSSION

The Prior Art

Mamo

Mamo discloses a "minimally invasive instrument set for implanting sacral stimulation leads compris[ing] at least a needle and a dilator that are

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[2] Mamo et al., US 2002/0147485 A1, published Oct. 10, 2002.
[3] Kucklick et al., US 2005/0043682 A1, published Feb. 24, 2005.
[4] Avitall, US 5,441,483, issued Aug. 15, 1995.
[5] Spear et al., US 2002/0173785 A1, published Nov. 21, 2002.
[6] McKay, US 2008/0009823 A1, published Jan. 10, 2008.
[7] Bowser et al., US 6,419,674 B1, issued Jul. 16, 2002.
[8] Kupiecki et al., US 2003/0225425 A1, published Dec. 4, 2003.

particularly adapted to enable introduction of . . . neurostimulation lead electrode(s) in operative relation to a sacral nerve." Mamo ¶ 9.

"[T]he dilator comprises the assembly of a dilator body and a dilator sheath that are inserted through the skin as an assembly and are separated to enable introduction of the neurostimulation lead through the dilator sheath lumen." *Id.* ¶ 11. "The dilator is adapted to be introduced over [a] needle or guide wire . . . whereupon the dilator body and guide wire are withdrawn, leaving the dilator sheath." *Id.* "The guide wire may be relatively stiff to prevent bending or may be flexible to enable a degree of bending." *Id.* ¶ 14.

Kucklick

Kucklick describes "a cannula and instrument port for use during surgical procedures." Kucklick ¶ 7. Figure 8 of Kucklick is reproduced below:

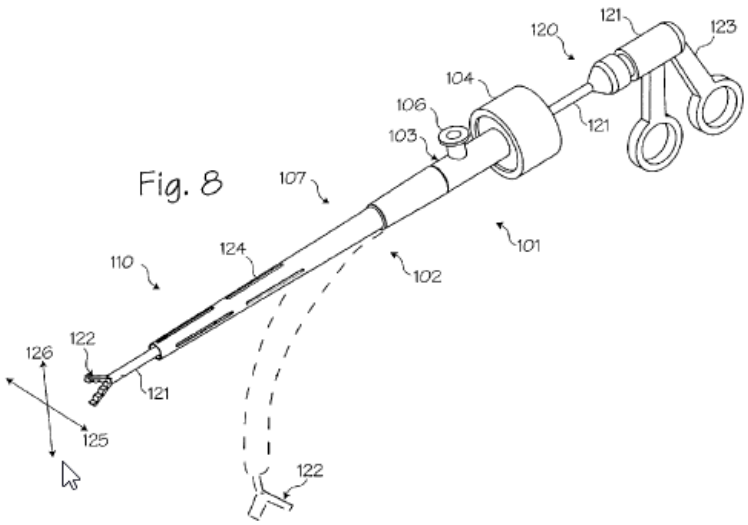

Figure 8 depicts Kucklick's instrument port 101 with distal cannula 102 and surgical clamp 120 disposed within the cannula. According to Kucklick,

"the cannula is flexible . . . [and] capable of accommodating curved, malleable or flexible instruments used during various surgical procedures." Kucklick ¶ 48. "The cannula can bend along either axis 125 or 126," and "can be made to bend preferentially along one of those two axes. For example, the cannula may be made wider along one axis, thus making the cannula preferentially bend in the direction of the other axis." *Id.* Additionally, the cannula may have slots "sized and dimensioned for preferential bending of the cannula." *Id.* Kucklick further discloses that "the instrument port's rigid tube and cannula may be provided with different cross sections to change how the cannula bends and to accommodate differently shaped instruments. For example, a cannula having an elliptical cross section is preferentially flexible on its minor axis." *Id.* ¶ 66. Kucklick teaches that the elliptical cross section "accommodates instruments having a flat, narrow shape." *Id.*

Avitall

Avitall discloses a "catheter tip with greatly increased multi-directional sharp-angle flexibility" that "affords the catheter a greater amount of 'fine tuning' by providing improved intricate or sophisticated maneuverability enabling catheter use in hard-to-reach branching vessels." Avitall 3:60–64. "This is accomplished by the provision of any of several unique catheter/sheath constructions which allow independent radical deflection of one or more longitudinally spaced or abutting shaft deflection segments disposed in the same or different directions at the behest of associated control wires." *Id.* at 3: 67–4:4.

Figure 1B of Avitall is reproduced below:

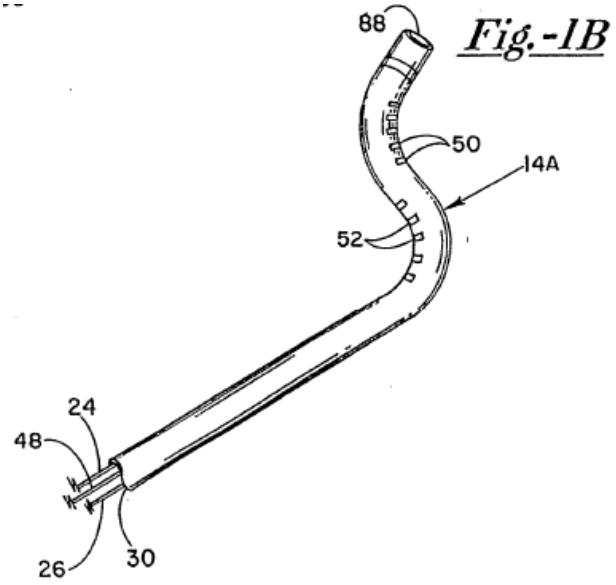

Figure 1B of Avitall depicts a catheter with "dual directioned deflection" (*id.* at 7:56–57) provided by "[a] pair of end or deflection segments . . . just proximal of the electrode . . . and each includes a series of five (5) spaced parallel lateral cuts in the form of discrete aligned notches 50 and 52 which may be any desired length or shape" (*id.* at 7:42–46). The "set of cuts 52, provided proximal to the distal set 50, may address a radially diverse direction . . . and comprise a proximal deflection segment in the flexible tip of the catheter." *Id.* at 7:51–55.

The Examiner's Rejections

The Examiner contends that the subject matter of claims 1–4, 11, 13, 19, 22, 23, and 38 would have been obvious over the combined teachings of Mamo, Kucklick, and Avitall. In particular, the Examiner finds that Mamo's implantation apparatus is configured to interchangeably receive a dilator and a neurostimulation lead (i.e., a therapy element). Non-Final Act. 4 (citing Mamo ¶¶ 11, 93, Figs. 8a–c). The Examiner acknowledges that Mamo does not disclose that "a first portion of the dilator is configured to preferentially

flex in at least a first direction over at least a second direction that is different from the first direction," or that "a second portion of the dilator is configured to preferentially flex in the second direction," at the same time. *Id.*

The Examiner turns to Kucklick for its disclosure of a mechanism for preferential flexibility, and Avitall for its disclosure of multi-directional flexibility. Non-Final Act. 4–6.

Specifically, the Examiner finds that Kucklick describes a cannula with "an elliptical cross section or [in] other words, an oval cross section," wherein the cannula "bend[s] preferentially along one of two axes 125 or 126 by being 'made wider along one axis, thus . . . preferentially bend[ing] in the direction of the other axis.'" Non-Final Act. 5 (citing Kucklick ¶ 48).

The Examiner further finds that Avitall describes an elongated medical device with "a first portion preferentially flexing in at least a first direction over at least a second direction that is different from the first direction," and a second portion "configured to preferentially flex in the second direction." Non-Final Act. 5 (citing Avitall 7:42–50). According to the Examiner, Avitall's device is "configured to allow the first portion to flex in . . . the first direction and the second portion to flex in the second direction at the same time." *Id.* (citing Avitall 7:42–8:3, Fig. 1B).

The Examiner contends it would have been obvious for one of ordinary skill in the art "to incorporate [Kucklick's] oval shaped cross-sectional design" in Mamo, "to provide preferential flexing that allows for improved intricate or sophisticated maneuverability." *Id.* (citing Kucklick ¶ 48). Moreover, the Examiner contends it would have been obvious to modify Mamo "to enable a first portion of the dilator to preferentially flex in

the at least the first direction and a second portion of the dilator to preferentially flex in the second direction different from the first direction, and at [the] same time, as taught by Avitall in order to provide multi-directional flexibility that allows for improved intricate or sophisticated maneuverability enabling use in hard-to-reach locations of the body." *Id.* at 5–6 (citing Avitall 3:60–67, 7:42–8:3).

Appellant's Arguments

Appellant contends that "a person of ordinary skill in the art would not have looked to both Avitall and Kucklick to modify Mamo's dilator to achieve preferential flexing in two portions of a dilator" (Appeal Br. 9), because "Avitall already describes a configuration that 'provides . . . multi-directional flexibility that allows for improved intricate or sophisticated maneuverability enabling use in hard-to-reach locations of the body'" (*id.*). According to Appellant, modifying Mamo according to Avitall to achieve multi-directional flexibility would not have resulted in a dilator with the elliptical cross-sections required by claim 1. *Id.* at 10. Appellant contends "[t]he Examiner failed to identify any particular reason why a person of ordinary skill in the art would also have looked to Kucklick's alleged elliptical cross-section to modify Mamo's dilator." *Id.*

Appellant further contends the Examiner has failed to provide evidence suggesting that it would have been obvious to use "an elliptical cross-section when it was desired to have two different directions of preferential flex" (Reply Br. 2), and "has failed to even explain how the two different directions of preferential flex are allegedly achieved using an elliptical cross-section" (*id.* at 2–3). Appellant emphasizes that "a stated advantage of the elliptical cross section of Kucklick is that the 'cannula also

accommodates instruments having a flat, narrow shape'" (*id.* at 3), but "[a] flat narrow instrument aligned with one of the elliptical cross sections would seem to not then be aligned with the other elliptical cross sections" (*id.*). Finally, Appellant contends "[i]n the absence of any suggestion otherwise and without reliance on hindsight, the skilled artisan would have simply used the solutions discussed in Avitall, which are specifically designed for preferential bending in multiple directions." *Id.*

Analysis

Having considered the evidence and arguments of record, we are not persuaded that the Examiner has established that the teachings of Kucklick and Avitall would have given one of ordinary skill in the art a reason to modify Mamo's device in the manner required by claim 1. In particular, we are not persuaded that the prior art relied on would have led one of skill in the art to modify Mamo to have two portions configured to preferentially flex in two different directions, where *at least one portion of preferential flex is provided by an elliptical cross section*.

As discussed above, Kucklick discloses that an elliptical cross section provides preferential (i.e., directional) flexibility (Kucklick ¶ 66), while Avitall discloses that one or more segments of different "directioned deflection" can be provided by "spaced parallel lateral cuts in the form of discrete aligned notches" (Avitall, 7:44–45). We agree with Appellant's reasoned assertion that a flat narrow instrument aligned with one elliptical cross section would not then be aligned with another elliptical cross section oriented in a different direction. Thus, we are not persuaded that the Examiner has established that it would have been obvious for one of ordinary skill in the art to reconfigure Mamo's therapy element to

preferentially flex in two different directions, where both regions of preferential flex comprise an oval shape having a major axis and a minor axis (i.e., corresponding to Kucklick's elliptical cross-section). Nor has the Examiner explained why the prior art would have led one of ordinary skill in the art to provide two portions of preferential flex using two different techniques—e.g., one portion with Kucklick's elliptical cross section and another portion with Avitall's spaced parallel lateral cuts—when Avitall already provides two different directions of flex using a single technique. Thus, we are not persuaded that the Examiner has established that it would have been obvious for one of ordinary skill in the art to reconfigure Mamo's therapy element to preferentially flex in two different directions, with at least one region of preferential flex comprising an oval shape having a major axis and a minor axis, configured to flex about the major axis, and another region of preferential flex comprising spaced lateral cuts.

For the reasons discussed above, Appellant persuades us that the Examiner has not established that Claim 1 would have been obvious over the combined teachings of Mamo, Kucklick, and Avitall. We, therefore, reverse the Examiner's rejection of claim 1, as well as claims 2–4, 11, 13, 19, 22, 23, and 38, which depend from claim 1.

The Remaining Rejections

The underlying basis of the remaining rejections of claims 10, 12, 15, 20, and 21, which depend directly or indirectly from claim 1, is the Examiner's proposed combination of the teachings of Mamo, Kucklick, and Avitall. As discussed above, the Examiner has not established that Claim 1 would have been obvious over the combined teachings of Mamo, Kucklick, and Avitall. None of the additional references cited by the Examiner—

Spear, McKay, Bowser, and Kupiecki—remedies this deficiency.

Accordingly, the remaining obviousness rejections are reversed as well.

CONCLUSION

In summary:

Claims Rejected	35 U.S.C. §	Reference(s)/ Basis	Affirmed	Reversed
1–4, 11, 13, 19, 22, 23, 38	103(a)	Mamo, Kucklick, Avitall		1–4, 11, 13, 19, 22, 23, 38
10	103(a)	Mamo, Kucklick, Avitall, Spear		10
12	103(a)	Mamo, Kucklick, Avitall, McKay		12
15	103(a)	Mamo, Kucklick, Avitall, Bowser		15
20, 21	103(a)	Mamo, Kucklick, Avitall, Kupiecki		20, 21
Overall Outcome				1–4, 10–13, 15, 19–23, 38

REVERSED