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EXAMINER
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte CARL D. WAHLSTRAND, JOHN E. KAST, GABRIELA C. MOLNAR, GLENNA L. CASE, LISA M. JOHANEK, and PHILLIP C. FALKNER

Appeal 2018-001987
Application 15/366,349
Technology Center 3700

Before STEVEN D.A. McCARTHY, JEREMY M. PLENZLER, and ALYSSA A. FINAMORE, *Administrative Patent Judges*.

PLENZLER, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Appellant seeks our review under 35 U.S.C. § 134(a) of the Examiner's Decision rejecting claims 21–45. We have jurisdiction under 35 U.S.C. § 6(b).

We REVERSE.

CLAIMED SUBJECT MATTER

Claims 21, 32, and 41 are independent, with claims 22–31, 33–40, and 42–45 depending from claim 21, 32, or 41. Claim 21 is reproduced below:

> 21. An introducer for introducing a medical lead into a patient, the introducer comprising:
>
> a shaft;
>
> a lumen configured to receive the medical lead;
>
> a radial component; and
>
> an arcuate component having a proximal end and a distal end, the arcuate component connected to the radial component and the radial component connected to the shaft, wherein the distal end defines a distal opening in communication with the lumen,
>
> wherein the arcuate component extends along a closed path at least 90 degrees and less than 360 degrees and is configured to tunnel a path through subcutaneous tissue,
>
> wherein the introducer is configured such that rotating the shaft results in rotation of the arcuate component to create an arcuate path through subcutaneous tissue, and
>
> wherein projecting the introducer onto a plane with a longitudinal axis of the shaft normal to the plane produces an arcuate shape defined by the arcuate component.

REJECTIONS

1. Claims 21–30, 32–39, and 41–44 are rejected under 35 U.S.C. § 102(b) as anticipated by Wijayarthna (US 4,694,838, issued Sept. 22, 1987).

2. Claims 31, 40, and 45 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Wijayarthna and Pohndorf (US 4,512,351, issued Apr. 23, 1985).

OPINION

Claims 21, 32, and 41 are each directed to "[a]n introducer for introducing a medical lead into a patient" with a "lumen configured to receive the medical lead." The introducer of claims 21 and 32 includes an "arcuate component configured to tunnel a path through subcutaneous tissue, the introducer [being] configured such that rotating the shaft results in rotation of the arcuate component to create an arcuate path through subcutaneous tissue." Claim 41 similarly recites that the arcuate component "is configured to tunnel through subcutaneous tissue." Claim 44, which depends from claim 41, recites "wherein the introducer is configured such that twisting the shaft results in rotation of the arcuate component to create an arcuate path through subcutaneous tissue."

The Examiner finds that "Wijayarthna teaches an introducer (see figure 1) *capable of being used for introducing* the medical lead into a patient" and "the introducer is *configured such* that rotating the shaft results in rotation of the arcuate component to create an arcuate path through subcutaneous tissue, see figure 1." Final Act. 3–4 (addressing claim 21); *see also id.* at 6, 8 (addressing claims 32 and 41 in same manner). In the Answer, the Examiner explains that Wijayarthna's device is "configured such that rotating the shaft results in rotation of the arcuate component to create an arcuate path through subcutaneous tissue," as recited in claims 21 and 32, because "Wijayarthna does not provide any disclosure of a reason the device is not fully capable of being used to tunnel through tissue without the use of a sheath or guidewire." Ans. 5 (explaining that the "configured to" limitations recited in the claims are simply an intended use). The

Examiner additionally determines that the "tunnel[ling]" recited in the claims does not require the introducer to create any passage. *Id.* at 4.

Appellant disputes these findings. Appeal Br. 7–12. We agree that the Examiner erred in finding these elements are disclosed by Wijayarthna.

One problem with the rejection is that the Examiner misapprehends the requirements of the "configured to" limitations recited in the claims. Those limitations do not simply recite an intended use, as the Examiner asserts. Rather, those limitations require that the apparatus "is designed or constructed to be used" in the manner recited. *In re Giannelli*, 739 F.3d 1375, 1379 (Fed. Cir. 2014). As Appellant explains, this is clear from the Specification. Appeal Br. 10 (citing Spec. ¶¶ 31, 46, 58). The Specification explains, for example, that the distal end of the introducer "may be blunt or have a sharp end to facilitate advancement of arcuate component 24 through tissue of a patient" (Spec. ¶ 33), and "the introducers or components thereof are formed from metal, alloy, or hard plastic material" (*id.* ¶ 58) so that "the distal end 29 of the arcuate component 24 [of the introducer can be] inserted through or past the skin" and "the shaft 22 [of the introducer can] be twisted about its axis . . . to cause arcuate component 24 to tunnel a semi-circular path beneath the skin 60 of the patient" (*id.* ¶ 46).

Appellant explains that "the device of Wijayarthna . . . is a device that is introduced into a patient through the use of an introducer (guidewire or sheath) and is not an introducer in the parlance of the present claims when read in light of the present specification." Appeal Br. 9 (citing Wijayarthna, 5:47–50). Appellant further explains that when describing its structure, Wijayarthna states that "[t]he tip portion forming the loop is made of a soft flexible material . . . so as to be inserted over the guidewire or positioned

within the sheath." *Id.* at 11–12 (citing Wijayarthna, 5:18–25). Appellant is correct.

The Examiner responds that "[t]he act of tunneling through tissue does not require the device to cut tissue but simply to form a passageway through the tissue, which the device of Wijayarthna would do when extended through an opening in the tissue due to its hollow cylindrical shape." Ans. 4. That is, the Examiner determines that passing Wijayarthna's catheter through an existing opening is tunneling. The Examiner, however, provides no explanation as to why that reading of the claims is consistent with Appellant's Specification. Appellant responds that it is not. Reply Br. 3–4. We agree with Appellant. As explained above, Appellant's Specification clearly describes the introducer as forming the opening (i.e., tunneling) and having the structure necessary to perform the tunneling. *See* Spec. ¶¶ 33, 46, 58. Reading the claims in the manner proposed by the Examiner would not be consistent with the Specification.

Under the proper reading of the claims, the Examiner has not established that Wijayarthna's catheter is *capable of* "tunnel[ling] . . . through subcutaneous tissue," let alone that it is designed or constructed to be used in that manner as required by the claims. The Examiner fails to explain sufficiently, for example, why the soft flexible catheter of Wijayarthna is designed or constructed to perform the recited tunneling.

Accordingly, we do not sustain the Examiner's decision to reject claims 21–45.

DECISION

We REVERSE the Examiner's decision to reject claims 21–45.

REVERSED