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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte ROBERT C. FARNAN

Appeal 2015-001071
Application 12/794,847
Technology Center 3700

Before JENNIFER D. BAHR, AMANDA F. WIEKER, and
ARTHUR M. PESLAK, *Administrative Patent Judges*.

PESLAK, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Robert C. Farnan (“Appellant”) appeals under 35 U.S.C. § 134(a) from the Examiner’s decision rejecting claims 1–7, 10, 12–14, and 41–47.^{1 2} We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

¹ Appellant submits the real party in interest is CircuLite, Inc. Appeal Br. 3.

² Claim 11 is cancelled. Appeal Br. 14 (Claims App.).

THE CLAIMED SUBJECT MATTER

Claim 1, reproduced below, is illustrative of the claimed subject matter.

1. A coaxial transseptal device comprising:
 - a piercing device comprising a flexible shaft having a proximal end, a distal end, and a sharpened portion on the distal end, wherein a flexibility of the shaft of the piercing device increases distally and the shaft of the piercing device includes a helical cut section on a distal end thereof for increasing flexibility of the shaft along the distal end thereof; and
 - a coaxial guide-wire having a proximal portion, a distal portion with a distal tip, a transition joint separating the proximal portion from the distal portion, and a lumen extending within the proximal and distal portions of the guide-wire, the lumen of the guide-wire configured to receive the piercing device and to move relative thereto, the transition joint defining a location at which flexibility increases from the proximal portion to the distal portion, and the distal portion having a flexibility that further increases from the transition joint in a direction toward and to a location proximate the distal tip.

REJECTIONS

- 1) Claims 1–6, 10, 12, 13, and 41–45 are rejected under 35 U.S.C. § 103(a) as unpatentable over Kraus (US 6,641,564 B1, iss. Nov. 4, 2003) and Peters (US 2002/0038129 A1, pub. Mar. 28, 2002).
- 2) Claims 7 and 46 are rejected under 35 U.S.C. § 103(a) as unpatentable over Kraus, Peters, and Murray III (US 2004/0092867 A1, pub. May 13, 2004).

- 3) Claims 14 and 47 are rejected under 35 U.S.C. § 103(a) as unpatentable over Kraus, Peters, and Chin-Chen (US 2007/0185530 A1, pub. Aug. 9, 2007).

DISCUSSION

Rejection 1

Appellant argues claims 1–6, 10, 12, 13, and 41–45 as a group. Appeal Br. 7–11. Pursuant to 37 C.F.R. § 41.37(c)(1)(iv), we select claim 1 as representative to decide this rejection. The other claims stand or fall with claim 1.

The Examiner finds that Kraus discloses the limitations of claim 1 except that Kraus does not teach the flexibility of the guide-wire increases distally and the flexibility of the piercing device increases distally due to a helical cut. Final Act. 4; *see also* Ans. 3. The Examiner finds that Peters discloses “a flexible inner tubular member having a proximal portion and a distal portion with a distal tip and a transition joint separating the proximal and distal portions and a lumen extending therebetween.” Final Act. 4. The Examiner also finds that Peters discloses “the transition joint defines a location at which flexibility increases from the proximal portion to the distal portion . . . and the distal portion has a flexibility that further increases from the transition joint in a direction toward the distal tip to a location proximate the distal tip.” *Id.* The Examiner reasons it would have been obvious to modify Kraus’s flexible inner tubular guidewire to

have a transition joint separating the proximal portion and the distal portion of the guidewire wherein the flexibility of the distal portion increases from the transition joint in a direction toward and to a location proximate the distal tip of the distal portion using a helical

cut section, as taught by Peters, in order to increase the flexibility towards and at the distal end, as desired by Kraus, to allow more bendability to navigate the guidewire further into a vessel through the vasculature of a patient.

Id.

Appellant contends that the Examiner's finding that Kraus' dilator 120 is capable of functioning as a coaxial guide-wire is erroneous because it is well known in the art that "dilators and guide-wires have mutually exclusive purposes and functions." Appeal Br. 8. Appellant argues that the Examiner's finding that Kraus' dilator is capable of use as a guide-wire is inconsistent with *In re Giannelli*, 739 F.3d 1375 (Fed. Cir. 2014), because one of ordinary skill in the art would know that a dilator device is not a guide-wire and using a dilator as a guide-wire could have "negative consequences for a patient." Appeal Br. 8. Appellant also argues that Kraus teaches away from the use of a guide-wire because Kraus discloses an improvement to the prior art Seldinger technique (or method) for inserting a needle into the vasculature, wherein the Seldinger technique includes the use of a guide-wire. *Id.* at 7. By contrast, Appellant contends that Kraus discloses in several places that Kraus' improvement does not require a guide-wire. *Id.* at 7–8. Appellant also contends that the Examiner's finding that Peters discloses flexibility increasing from the transition joint toward the distal end is erroneous because although Peters discloses increased flexibility in the central portion, the flexibility decreases at the distal end. *Id.* at 10.

The Examiner responds that Appellant has not provided a proposed construction of the term "guide-wire" that would distinguish Kraus' dilator 120. Ans. 10. The Examiner submits that one of ordinary skill in the art

would understand that the term “guide-wire” “encompasses a long flexible device used to guide placement and positioning for a larger device or prosthesis, such as an intravascular . . . stent.” *Id.* The Examiner asserts that Kraus’ dilator 120 meets the structural and functional limitations of a guide-wire as so construed, and that Kraus’s reference to an improvement over the Seldinger technique as not requiring a guide-wire means that “Kraus does not require an *additional* guidewire because structure 120 in combination with structure 300, functions as the guidewire.” *Id.* at 11. With respect to the flexibility of Peters’ tube decreasing at the distal end, the Examiner responds that claim 1 does not require that the flexibility of the guide-wire increase to the very distal end but only “to a location proximate to the distal tip.” *Id.* at 12. The Examiner submits that Appellant’s Figure 3 discloses that Appellant’s claimed invention also exhibits decreased flexibility near its distal end in the area denoted by element 58 where spiral cuts in tube 74 and piercing device 44 are not present. *Id.* at 13.

For the following reasons, we sustain the rejection. We initially note that Appellant does not provide any evidence or persuasive technical reasoning to support the argument that one of ordinary skill in the art would understand that a dilator is not a coaxial guide-wire or otherwise offer evidence of relevant differences between a dilator and a coaxial guide-wire. Nor does Appellant provide any evidence or persuasive technical reasoning to support the argument that using a dilator as a coaxial guide-wire could have negative consequences for a patient. *See* Appeal Br. 8.

The Specification describes “radial tip 80 [of coaxial guide-wire 46] can be used to *dilate* the puncture created by the piercing device 44 through intra-atrial septum 22 to a diameter that is similar to the outer diameter of

the coaxial guide-wire 46.” Spec. ¶ 46 (emphasis added); *see also* Fig. 7C. Therefore, Appellant’s argument that Kraus’s dilator 120 cannot be used as a coaxial guide-wire is not consistent with the description in the Specification that the tip of Appellant’s coaxial guide-wire dilates a puncture created by the piercing device. Appellant’s argument that the Examiner’s finding that Kraus’s dilator 120 is capable of acting as a coaxial guide-wire is insufficient in view of *In re Giannelli* is also unavailing. In *Giannelli*, the Court of Appeals for the Federal Circuit determined the meaning of “an input assembly . . . adapted to be moved . . . by a pulling force.” *Giannelli*, 739 F.3d at 1376 (emphasis added). The Federal Circuit noted that “adapted to” can be construed to mean “configured to” or alternatively “capable of.” *Id.* at 1379. Nonetheless, the Federal Circuit held that “adapted to,” in that case, should be construed as designed or constructed to be moved by a pulling force, not merely capable of being moved by a pulling force, because the specification disclosed moving the input assembly by a pulling force only. *Id.* at 1379. Here, unlike *Giannelli*, the Specification discloses the tip of the coaxial guide-wire dilates the opening in the intra-atrial septum created by the piercing device, and, thus, is consistent with Kraus’ dilator 120. Finally, Appellant’s argument that Kraus teaches away from the use of a guide-wire is premised on the unsupported argument that one of ordinary skill in the art “would not conclude that dilator 120 is a coaxial guide wire.” Appeal Br. 7. The teaching away argument is not persuasive because of the description in Appellant’s Specification that the tip of Appellant’s coaxial guide-wire dilates the puncture. Spec. ¶ 46. For the foregoing reasons, Appellant’s contention that the recited “coaxial guide-wire” does not read on Kraus’ dilator 120 is not persuasive.

Peters discloses tube 34 having a central region 66 beginning at a transition zone near uncut portion 34 wherein central region 66 contains cut segments 40 that increase the flexibility of tube 34 toward its distal end in the direction of cutting member 36. *See* Peters ¶ 38, Fig. 4. Appellant attempts to distinguish Peters by arguing that Peters discloses decreased flexibility toward the distal end beginning in the region noted by reference numeral 67 in Figure 4 where the pitch of helical cuts 40 is decreased. Appeal Br. 10; *see* Peters, Fig. 4. The Specification describes that spiral cuts 76 in tube 74 “provide a flexibility that increases distally.” Spec. ¶ 37. Appellant’s piercing device 44 contains spiral cuts 82 to increase flexibility in the distal direction. *Id.* ¶ 38. Appellant’s Figures 3 and 4 illustrate that spiral cuts 76 in tube 74 and spiral cuts 82 in piercing device 44 end prior to the distal tip 80 in the area denoted by reference numeral 58 indicating decreased flexibility near the distal end as in Peters. *Id.*, Figs. 3, 4. Appellant’s argument is not persuasive in light of this disclosure in the Specification and because claim 1 does not preclude the distal portion from having decreased flexibility near the distal end but rather recites that the flexibility of the distal portion of the guide wire “further increases from the transition joint . . . to a location proximate the distal tip.”

Appellant, thus, fails to persuasively apprise us of error in the Examiner’s factual findings or rationale, quoted above, for the combination of Kraus and Peters, which we determine to be reasonable and supported by rational underpinnings. *See KSR Int’l Co. v Teleflex Inc.*, 550 US 398, 416 (2007) (“The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.”).

We, thus, sustain the rejection of claims 1–6, 10, 12–13, and 41–45 under 35 U.S.C. § 103(a).

Rejections 2 and 3

Claims 7 and 46 are dependent on claim 1 and claim 42 respectively. Appeal Br. 13, 16 (Claims App.). The Examiner rejects claims 7 and 46 as unpatentable over Kraus, Peters, and Murray III. Final Act. 9. Appellant relies on the same arguments for patentability set forth above for claim 1. Appeal Br. 11. We sustain the rejection of claims 7 and 46 for the same reasons set forth above with respect to claim 1.

Claims 14 and 47 are dependent on claim 1 and claim 42 respectively. Appeal Br. 15, 16 (Claims App.). The Examiner rejects claims 14 and 47 as unpatentable over Kraus, Peters, and Chin-Chen. Final Act. 10. Appellant relies on the same arguments for patentability set forth above for claim 1. Appeal Br. 11. We sustain the rejection of claims 14 and 47 for the same reasons set forth above with respect to claim 1.

DECISION

The Examiner's decision rejecting claims 1–7, 10, 12–14, and 41–47 is affirmed.

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