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BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte GREG A. WALTERS, GARY ROUBIN, MICHAEL THOMAS NISPEL, MICHAEL AUSTIN DOTSEY, and PIYUSH ARORA[1]

Appeal 2018-001340
Application 14/569,291
Technology Center 3700

Before MICHAEL L. HOELTER, JEREMY M. PLENZLER, and JEFFREY A. STEPHENS, *Administrative Patent Judges*.

HOELTER, *Administrative Patent Judge.*

DECISION ON APPEAL

STATEMENT OF THE CASE

This is a decision on appeal, under 35 U.S.C. § 134(a), from the Examiner's Final Rejection of claims 1–9, 11–13, 16–27, and 31–36. Br. 1. We have jurisdiction under 35 U.S.C. § 6(b). For the reasons explained below, we REVERSE the Examiner's rejection of these claims.

THE CLAIMED SUBJECT MATTER

The disclosed subject matter "relates generally to closing percutaneous punctures." Spec. ¶ 2. Apparatus claims 1 and 16 are

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[1] "The real party in interest is the appellant-applicant, Essential Medical Inc." Br. 1. We thus proceed on the basis that, for purposes of this appeal, Essential Medical Inc. is the "Appellant."

independent. Claim 1 is illustrative of the claims on appeal and is reproduced below.

> 1. A deployment instrument configured to seal a percutaneous puncture in a wall of an artery, the deployment instrument configured to slide along a guide wire positionable through the puncture, the deployment instrument comprising:
>
> a closure device including a toggle and a plug connected to the toggle, the toggle defining a distal surface, an opposed proximal surface, and a cavity that extends from the distal surface to the proximal surface, the cavity sized and configured to receive the guide wire so that at least the toggle is slidable along the guide wire when the guide wire is 1) received by the cavity, and 2) is positioned to extend through the percutaneous puncture;
>
> a handle member;
>
> a delivery component that is supported by the handle member and that extends relative to the handle member in a distal direction;
>
> a release component supported by the handle member and extending relative to the handle member along the delivery component in the distal direction; and
>
> an actuator supported by the handle member and operably coupled to the delivery component and the release component, the actuator configured to actuate at least one of the delivery component and the release component from a first state where the toggle is fixed between the distal end of the delivery component and the release component, into a second state where the toggle is released from between the distal end of the delivery component and the release component.

REFERENCES RELIED ON BY THE EXAMINER

Kensey et al.	US 5,282,827	Feb. 1, 1994
Nash et al.	US 5,662,681	Sept. 2, 1997
Ginn	US 2003/0078616 A1	Apr. 24, 2003

THE REJECTION ON APPEAL

Claims 1–9, 11–13, 16–27, and 31–36 are rejected under pre-AIA 35 U.S.C. § 103(a) as unpatentable over Nash (which incorporates Kensey by reference) and Ginn.

ANALYSIS

Appellant argues independent claim 1 (Br. 5–14) separate from independent claim 16 (Br. 15–17) because of their different recitations. *See* Br. 17. The Examiner rejects both independent claims employing the same rationale. Final Act. 3–4. We address these two claims as follows.

Claim 1, unlike claim 16, recites a toggle that "is slidable along the guide wire." The Examiner acknowledges that "Nash does not teach" this limitation and relies on Ginn for such teaching. Final Act. 4. The Examiner states that it would have been obvious "to add a guidewire . . . as taught by Ginn" to ensure proper sealing and easy navigation of the toggle to the proper position. Final Act. 4.

Nash discloses a toggle 32 that is navigated to the proper position within a body lumen and employed to seal a puncture from within that lumen. *See, e.g.*, Nash Abstract and Figures. The Examiner is not expressive as to why Nash needs additional structure (i.e., "add a guidewire") to achieve what is already accomplished without such additional structure.

Further, Appellant contends that "Nash-Kensey and Ginn are not capable of performing the function recited in the claims" and that "the proposed modification of Nash-Kensey with Ginn is not proper because it would destroy Nash-Kensey's principle of operation." Br. 10.

There is merit to these concerns because Nash itself is wholly silent as to any "guide wire" and Kensey (which Nash incorporates by reference) teaches that any guide wire employed in an initial procedure is removed prior to insertion of the toggle into the patient. *See* Kensey 4:45–55; *see also* Br. 11–12. Hence, the Examiner's reason to "add a guidewire" (Final Act. 4) must be either based on hindsight (because Nash is silent on this point) or such addition would run counter to the teachings of Kensey (which removes the guide wire prior to toggle insertion). *See supra*. We thus agree with Appellant's assertion that "Nash-Kensey discloses neither the structure for receiving a guidewire nor the capability to slide along a guidewire even if one knew to do so." Br. 11. This is because "Nash-Kensey's instrument is designed to be inserted inside an *empty introducer sheath* and not inside an introducer sheath that has a guidewire in place." Br. 12. Accordingly, we are not persuaded the Examiner has provided articulated reasoning with rational underpinning to support a legal conclusion of obviousness. We do not sustain the Examiner's rejection of independent claim 1, or its dependent claims 2–9, 11–13, 31–33, and 36, as being obvious over Nash and Ginn.

In addition to the above, both independent claim 1 and 16 recite an "actuator" that is configured to actuate a "release component" from a first state to a second state. Regarding the recited "actuator," the Examiner states, "[s]ee gripping sections of device of Kensey," and regarding the "release component," the Examiner correlates this to item 104 (both Nash and Kensey identify item 104 as a "bypass tube"). Final Act. 3.

Kensey does not employ the word "grip" or "gripping," but nevertheless, we understand Kensey's "gripping sections" to be the portion of Kensey's instrument 20 that is illustrated in Figure 19 as being gripped by

the hand of a user. Within this gripping section/actuator of Kensey's instrument 20 (i.e., within luer fittings 110, 112), is a tensioning assembly, which tensions filament 34. *See* Kensey 8:40–45; 12:64–66 ("tensioner assembly described heretofore controls the force on the filament **34** during the retraction procedure"); Fig. 1. This filament 34 extends through instrument 20 and is secured to toggle 32 located (pre-deployment) within bypass tube 104.[2] *See* Kensey 8:20–22, Figs. 5, 11.

Hence, as we understand the Examiner's rejection, Nash/Kensey is relied on to teach an actuator (Kensey's "gripping sections") configured to actuate (or "cause" (claim 16)) a release component (bypass tube 104) to transition from a first state to a second state. Because, as discussed above, Kensey's gripping section/actuator is designed to control tension on filament 34, which passes into and through bypass tube 104 (filament 34 is used to position toggle 32 within a patient's artery), the Examiner does not make clear how Kensey's gripping section/actuator actuates or causes the bypass tube to translate between states as recited.[3] Instead, any movement of bypass tube 104 is due to a user's manual manipulation of instrument 20 as a whole, and is not due to any operation of Kensey's actuators as recited. *See* Kensey 8:7–13; 12:2–4 ("[t]he bypass tube **104** remains within the portion of the introducer sheath housing the hemostasis valve **28A**"); 12:50–52 ("[t]o that end the introducer sheath **28** and the instrument **20** are held together and withdrawn as a unit from the puncture"). Accordingly, the Examiner has not

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[2] For clarity, Appellant's Specification makes a distinction between a filament and a guide wire. *See* Spec. ¶¶ 41, 54, Fig. 3B.

[3] Appellant contends "the gripping section/proximal end on the instrument does not cause the bypass tube 104 to transition from [a] first state to a second state." Br. 15.

established by a preponderance of the evidence that Nash (or the Nash/Kensey combination) can be properly relied upon for disclosing the above recited limitation (Ginn is relied on for other reasons and does not cure this defect). Thus, we do not sustain the Examiner's rejection of independent claims 1 and 16, or of dependent claims 2–9, 11–13, 17–27, and 31–36.

DECISION

The Examiner's rejection of claims 1–9, 11–13, 16–27, and 31–36 is reversed.

REVERSED