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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte HIDENORI TANABE and TAKAO ANZAI

Appeal 2017-002062
Application 14/033,717
Technology Center 3700

Before MICHAEL C. ASTORINO, BENJAMIN D. M. WOOD, and PHILIP J. HOFFMANN, *Administrative Patent Judges*.

WOOD, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Appellants appeal under 35 U.S.C. § 134(a) from a rejection of claims 1–9. An oral hearing in accordance with 37 C.F.R. § 41.47 was held on October 23, 2018. We have jurisdiction under 35 U.S.C. § 6(b).

We reverse.

THE INVENTION

The claims are directed to a catheter assembly. Sole independent claim 1, reproduced below, is illustrative of the claimed subject matter:

> 1. A catheter assembly comprising:
>
> a hollow catheter;
>
> a catheter hub fixed onto a base end portion of the catheter, the catheter hub having an internal passage communicating with an inside of the catheter;
>
> a needle disposed in the catheter;
>
> a needle hub fixed to a base end portion of the needle, the needle hub being connectable to a base end side of the catheter hub;
>
> a valve element positioned to block the internal passage of the catheter hub, the valve element including a tubular portion, and an opening and closing portion configured to be opened and closed, the opening and closing portion comprising at least one slit;
>
> an operation member including a tubular body, the operation member being configured such that an opening portion of the operation member is insertable into the opening and closing portion to cause the base end side and a tip side of the catheter hub to communicate with each other;
>
> a communication unit comprising at least one of a hole and a groove, the communication unit being disposed on at least one of (i) an inner periphery portion of the catheter hub where the valve

element is positioned, and (ii) a peripheral edge portion of the valve element, wherein the communication unit is configured to allow the base end side and the tip side of the catheter hub to communicate with each other; and

a sealing member including a tubular body, the sealing member being disposed at a base end side of the valve element and being configured to allow the passage of air and prohibit the passage of liquid,

wherein the sealing member includes an extending portion that extends into the tubular portion of the valve element.

REFERENCES

Yamamoto	US 5,242,411	Sept. 7, 1993
Rosen	US 5,980,492	Nov. 9, 1999
Basta	US 2005/0043684 A1	Feb. 24, 2005
Hammarsten	US 2007/0196414 A1	Aug. 23, 2007
Stout	US 2010/0204648 A1	Aug. 12, 2010

REJECTIONS

Claims 1, 2, and 7–9 are rejected under pre-AIA 35 U.S.C. § 103(a) as unpatentable over Stout, Basta, and Hammarsten.

Claims 3 and 4 are rejected under pre-AIA 35 U.S.C. § 103(a) as unpatentable over Stout, Basta, Hammarsten, and Yamamoto.

Claims 5 and 6 are rejected under pre-AIA 35 U.S.C. § 103(a) as unpatentable over Stout, Basta, Hammarsten, Rosen, and Yamamoto.

ANALYSIS

Claims 1, 2, and 7–9—Unpatentable over Stout, Basta, and Hammarsten

The Examiner finds that Stout teaches most of the limitations of claim 1. Final Act. 6 (citing Stout ¶¶ 61, 85, 87, 95, Figs. 5A, 9, 12). In particular, the Examiner finds that Stout's septum 356 corresponds to the

claimed valve element, and grooves 60, 70 correspond to the claimed communication unit. The Examiner acknowledges, however, that Stout does not teach the claimed sealing member. *Id.* The Examiner finds that Basta's support member 144 corresponds to the sealing member disposed at a base end side of the valve element, the sealing member including an extending portion that extends into the tubular portion of a valve element. *Id.* at 6–7 (citing Basta, Fig. 2). The Examiner asserts that one of ordinary skill in the art would have combined Stout and Basta's sealing member to "bias the seal to a most distal position within the passage way." *Id.* at 7 (citing Basta ¶ 26). Acknowledging that the combination of Basta and Stout does not teach the sealing member being configured to allow the passage of air and prohibit the passage of liquid, the Examiner relies on Hammarsten for that teaching. *Id.* Hammarsten teaches a stopper made from carboxymethyl-saturated foam rubber, a material that is air permeable when dry but becomes liquid-impermeable when exposed to blood. Hammarsten, Abstract, Fig. 2. The Examiner determines that it would have been obvious for one of ordinary skill in the art to make Basta's support member from the Hammarsten's carboxymethyl-saturated foam rubber, "in order to stop all flow of blood out of the IV catheter during cannulation." *Id.* (citing Hammarsten ¶ 37).

Appellants argue, *inter alia*, that there would have been no reason for one of ordinary skill in the art to use Hammarsten's material to make Basta's support member for use in Stout's device because Stout's septum 356 is coated with a hydrophobic or polymer swelling material and therefore is already configured to prohibit the passage of fluid. App. Br. 6. Appellants further argue that if Basta's support member—made from Hammarsten's

material—was used in Stout's device, once it contacts blood it "would expand into the spaces around the septum activator 380 of Stout, thus ***preventing the septum activator 380 from being able to open the septum 356***." *Id.* at 8. Appellants also assert that if this support member would modified to be softer to avoid this problem, it would be unable to provide the required support. *Id.*

The Examiner does not dispute that a support member made from Hammarsten's material might, when in contact with blood, expand enough to make it impossible to open septum 356. Instead, the Examiner asserts that it is "within the general skill of a worker in the art at the time the invention was made to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice." Ans. 9. According to the Examiner, "[o]ne of ordinary skill in the art will be motivated to make the sealing member of Basta modified by the material disclosed by Hammarsten to be soft enough to allow the septum activator to open the septum but still provide enough support." *Id.*

In Stout's catheter assembly, the septum activator opens a pathway through the septum to enable the free flow of fluid through the catheter assembly. Stout ¶ 13. It would have been unlikely for one of ordinary skill to have modified Stout's device in a way that might have interfered with this capability and, as noted above, the Examiner does not dispute that making the support member from carboxymethyl-saturated foam rubber might have done so. Further, the Examiner's suggestion that one of ordinary skill in the art would have made Hammarsten's material "soft enough" to avoid this problem assumes, without evidence, that it was known how to do so. In the absence of such evidence, we consider this suggestion to be speculative.

Accordingly, we are not persuaded that one of ordinary skill in the art would have made Hammarsten's material softer as a matter of "design choice," and we do not sustain this rejection.

The Remaining Rejections

The Examiner's remaining rejections rely on the erroneous finding that one of ordinary skill in the art would have used Hammarsten's material to make Basta's support member for use in Stout's catheter assembly. The Examiner does not rely on any of the additional references to cure the deficiency. Accordingly, for the reasons discussed above, we do not sustain the Examiner's rejections of claims 3–6 as unpatentable over Stout, Basta, Hammarsten, and additional references.

DECISION

For the above reasons, the Examiner's rejection of claims 1–9 is reversed.

REVERSED