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EXAMINER
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ANTISKAY, BRIAN MICHAEL

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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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*Ex parte* JAMES V. KAUPHUSMAN, MARTIN M. GRASSE,  
ALLAN M. FUENTES, and SALOME A. GONZALEZ<sup>1</sup>

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Appeal 2017-010025  
Application 12/982,675  
Technology Center 3700

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Before JEFFREY N. FREDMAN, RYAN H. FLAX, and  
RACHEL H. TOWNSEND, *Administrative Patent Judges*.

FLAX, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision under 35 U.S.C. § 134(a) involving claims directed to an electrophysiological medical device and a system with such a device. Claims 1–26 are on appeal as rejected under 35 U.S.C. § 103. We have jurisdiction under 35 U.S.C. § 6(b).

We affirm.

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<sup>1</sup> Appellants identify the Real Party in Interest as “St. Jude Medical, Atrial Fibrillation Division, Inc.” Appeal Br. 1. Herein we reference the Specification of Dec. 30, 2012 (“Spec.”); Final Office Action of Sept. 27, 2016 (“Final Action”); Appeal Brief of Mar. 27, 2017 (“Appeal Br.”); Examiner’s Answer of May 18, 2017 (“Answer”); and Reply Brief of July 18, 2017 (“Reply Br.”).

## STATEMENT OF THE CASE

Independent claim 1 is representative and is reproduced below:

1. An electrophysiological medical device comprising:

an electrophysiological catheter-introducer comprising a tubular inner liner defining an inner surface and an outer surface, said inner surface defining an unobstructed central major lumen which extends along a longitudinal axis;

a tubular outer layer around said inner liner and in contact with said outer surface of said inner liner, wherein said tubular outer layer has an outer diameter sized to pass through human cardiac vasculature to a human heart,

a plurality of circumferentially separated minor lumens extending axially through said outer layer and in contact with said inner liner;

a braid extending through said outer layer and surrounding said unobstructed central major lumen, wherein said braid extends through a majority of the longitudinal axis of the electrophysiological catheter-introducer, and wherein each wire of said braid comprises a rectangular cross-section, and wherein the braid is configured to maintain a structural integrity of the shaft along the length of the braid and is further configured to transfer a torque along the longitudinal axis;

an electroanatomical system imaging element coupled to a distal portion of said electrophysiological catheter-introducer;

an electrical wire coupled to said electroanatomical system imaging element and extending through one of said plurality of minor lumens;

a plurality of pull wires respectively extending through other ones of said plurality of minor lumens; and

an actuator coupled to said plurality of pull wires and capable of deflecting a distal end of the electrophysiological catheter-introducer,

said electrical wire and said plurality of pull wires extending through a separate minor lumens, and the minor lumen through which said electrical wire extends being circumferentially located between minor lumens through which pull wires extend,

wherein the actuator and the unobstructed central major lumen are configured to allow a catheter to extend from a proximal end of the actuator through the unobstructed central major lumen and exit the distal end of the electrophysiological catheter-introducer.

Appeal Br. 30–31 (Claims Appendix). Independent claim 12 is directed to a system and is substantially similar to claim 1, but also recites “an electroanatomical navigation system.” *Id.* at 33–34. Claim 17 is directed to a medical device and is also substantially similar to claim 1, but recites “a torque transfer member” rather than specifically a braid. *Id.* at 35–36. Appellants do not argue these different elements to be patentable distinctions over the prior art.

The following rejections are appealed:

Claims 1, 5, 6, 10–14, 16–22, and 24–26 stand rejected under 35 U.S.C. § 103(a) over Wendlandt,<sup>2</sup> Gibson,<sup>3</sup> Cimino,<sup>4</sup> Cumming,<sup>5</sup> and Zhou.<sup>6</sup> Final Action 2.

Claims 2, 3, 7, and 23 stand rejected under 35 U.S.C. § 103(a) over Wendlandt, Gibson, Cimino, Cumming, Zhou, and Kampa.<sup>7</sup> *Id.* at 16.

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<sup>2</sup> US 6,517,477 B1 (issued Feb. 11, 2003) (“Wendlandt”).

<sup>3</sup> US 2008/0139999 A1 (published June 12, 2008) (“Gibson”).

<sup>4</sup> US 5,364,352 (issued Nov. 15, 1994) (“Cimino”).

<sup>5</sup> US 2007/0299424 A1 (published Dec. 27, 2007) (“Cumming”).

<sup>6</sup> US 2005/0043713 A1 (published Feb. 24, 2005) (“Zhou”).

<sup>7</sup> US 7,824,517 B2 (issued Nov. 2, 2010) (“Kampa”).

Claim 4 stands rejected under 35 U.S.C. § 103(a) over Wendlandt, Gibson, Cimino, Cumming, Zhou, Kampa, and Barbut.<sup>8</sup> *Id.* at 18.

Claims 8 and 9 stand rejected under 35 U.S.C. § 103(a) over Wendlandt, Gibson, Cimino, Cumming, Zhou, and Devens.<sup>9</sup> *Id.* at 18.

Claim 15 stands rejected under 35 U.S.C. § 103(a) over Wendlandt, Gibson, Cimino, Cumming, Zhou, and Beatty.<sup>10</sup> *Id.* at 19.

#### DISCUSSION

“[T]he examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a *prima facie* case of unpatentability. If that burden is met, the burden of coming forward with evidence or argument shifts to the applicant.” *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992). Arguments made by Appellants in the Appeal Brief and properly presented in the Reply Brief have been considered in this Decision; arguments not so presented in the Briefs are waived. *See* 37 C.F.R. § 41.37(c)(1)(iv) (2015); *see also Ex parte Borden*, 93 USPQ2d 1473, 1474 (BPAI 2010) (informative) (“Any bases for asserting error, whether factual or legal, that are not raised in the principal brief are waived.”).

“The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007). “[W]hen a patent claims a structure already known in the prior art that is altered by the mere substitution of one element for another known in the field, the combination must do more than yield a predictable result.” *Id.* at 416 (citing *U.S. v.*

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<sup>8</sup> US 7,468,027 B2 (issued Dec. 23, 2008) (“Barbut”).

<sup>9</sup> US 2009/0228092 A1 (published Sept. 10, 2009) (“Devens”).

<sup>10</sup> US 7,826,881 B1 (issued Nov. 2, 2010) (“Beatty”).

*Adams*, 383 U.S. 39, 50–51 (1966)). “In determining whether the subject matter of a patent claim is obvious, neither the particular motivation nor the avowed purpose of the patentee controls. What matters is the objective reach of the claim. If the claim extends to what is obvious, it is invalid under § 103.” *Id.* at 419.

The Examiner determined that claims 1, 5, 6, 10–14, 16–22, and 24–26 would have been obvious over the combination of Wendlandt, Gibson, Cimino, Cumming, and Zhou; that claims 2, 3, 7, and 23 would have been obvious over this same prior art combination also adding Kampa; further, that claim 4 would have been obvious over the initial prior art combination adding Kampa and Barbut; further that claims 8 and 9 would have been obvious over the initial prior art combination adding Devens; and finally that claim 15 would have been obvious over the initial prior art combination adding Beatty. *See* Final Action 2–22 and Answer 2–24; *see also* the prior art as cited and discussed therein, *e.g.*, Wendlandt Abstract, 1:40–45, 4:26–36, 5:1–10, 7:7: 7:52–64, 8:5–7, 15:1–7, figures 1, 2; Gibson ¶¶ 5, 7, 15, 18, 41, 43, 46, 47, 59, 67, 69, 76, figures 2A, 2B, 4, 7, 11; Cimino Abstract, 1:6–11, 1:32–48, 7:1–16, 8:29–35, figure 7; Cumming ¶¶ 5, 8, 10, 57, figures 3, 8; Zhou ¶¶ 4, 29, 30; Kampa Abstract, 1:22–37, 2:18–26, 7:13–21, 7:61–62, 8:18–21, 8:33–40, 8:45–48, 10:47–49, figure 1B; Barbut figure 6A; Devens Abstract; Beatty Abstract, figure 1. We discern no error in the Examiner’s determinations and adopt the Examiner’s findings of fact and rationale. Final Action 2–22; Answer 2–24.

Appellants focus their arguments on the individual teachings and alleged shortcomings of the Wendlandt reference, for example, that it

teaches away from its combination with the other cited prior art, that its disclosed catheter system is not sized correctly for cardiac use, and that modifying its catheter system for such a use would render it inoperable. *See* Appeal Br. 12–28. Such arguments overlook that the obviousness rejections are over combinations of prior art where Wendlandt is but one reference. “Non-obviousness cannot be established by attacking references individually where the rejection is based upon the teachings of a combination of references. . . . [The reference] must be read, not in isolation, but for what it fairly teaches in combination with the prior art as a whole.” *In re Merck & Co.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986). For this reason, Appellants’ arguments are not persuasive. However, we address Appellants’ arguments below.

Appellants argue “Wendlandt teaches away from an unobstructed central major lumen as adding additional components to the introducer system would increase the thickness of the tubular catheter and lessen the diameter of the working channel.” Appeal Br. 13. Appellants cite Wendlandt’s discussion of the disadvantages of the art’s small working channels at column 1, lines 53–58, as support for this contention. *Id.* at 13–14.

Appellants’ argument is not persuasive. Wendlandt very clearly shows and teaches “an unobstructed central major lumen” as claimed. *See, e.g.*, Wendlandt Figs. 1 and 2 (element 10). Furthermore, Wendlandt notes, in the portion of its specification just after that referenced by Appellants, that, in addition to the drawback of a working channel being small as compared to the overall diameter of the endoscope, additional disadvantages are caused

by “space [in the lumen being] taken up by . . . mechanisms,” leaving a “very small area . . . for other tools to be introduced through the endoscope.” *Id.* at 1:53–60. Thus, besides being concerned with ameliorating the small working channel problem of the prior art, Wendlandt discloses, *as an objective*, an endoscope lumen that is unobstructed, as claimed. Furthermore, even were Appellants’ position regarding Wendlandt’s central lumen correct, which it is not, the other cited prior art references, e.g., Gibson (Fig. 2B), Cumming (Fig. 3), Zhou (Fig. 2), Kampa (Fig. 1B), Barbut (Fig. 6A), and Devens (Figs. 3, 4), disclose such “an unobstructed central major lumen” as claimed.

Appellants also argue that adding additional components outside the central lumen of Wendlandt’s catheter would directly impede Wendlandt’s objective of having a large lumen within the endoscope, and that Wendlandt “is specifically placing the components within the working channel to maximize the size of the working channel.” Appeal Br. 14–15. Appellants contend adding components outside the central lumen would “negate the stated purpose of Wendlandt.” *Id.* at 15–16.

Appellants’ arguments are not persuasive. Wendlandt discloses having components around the perimeter of its relatively large, central lumen, for example, a coil to maintain its cross sectional shape, a vision chip (12), a light source (14), an accessory (14) such as an irrigator, a flexible braid or mesh (37), propulsion mechanization, and several wires (30, 38). *See* Wendlandt Figure 1 and portions cited *supra*. Thus, it is apparent that having components around the perimeter of its central lumen would not be contrary to the Wendlandt’s objectives. Moreover, the other cited prior art

references, e.g., Gibson (Figs. 2B, 11), Cimino (Fig. 7), Cumming (Figs. 3, 4), and Kampa (Fig. 1B), disclose a main, central lumen surrounded by secondary lumens carrying various things such as wires and electrodes, demonstrating that this arrangement is a known, even common, option in the prior art.

Appellants argue that “modifying Wendlandt as discussed within the Office action . . . would render the endoscope of Wendlandt inoperable for its intended purpose.” *Id.* at 16. Here, Appellants’ argument’s focus is that “[n]othing within Wendlandt discloses how a combined wall thickness of 12 mm (36 French) and an equally large central lumen can be reduced to the size discussed herein to allow the endoscope to still operate as intended.” Appeal Br. 16. In a somewhat similar vein, Appellants argue that the claims require “said tubular outer layer has an outer diameter sized to pass through human cardiac vasculature to a human heart,” and Wendlandt’s disclosed device having a diameter of 14 mm or 20 mm is too large. Appeal Br. 17–21.

These arguments are not persuasive. Wendlandt expressly invites the skilled artisan to scale its endoscope/catheter device to fit within blood vessels, as follows:

As indicated, the-catheter introducer system of the present invention could be used to navigate within body cavities other than the GI tract. For example, air passages or blood vessels could be explored using this system. For blood vessels, it would be necessary to reduce the size of the apparatus, and preferably to only use the steering section, to avoid interference with blood flow through the vessel. For example, an outer diameter of the device would have to be less than about 2 mm.

Wendlandt 14:66–15:7. Moreover, the other cited prior art references disclose using their catheters for cardiac vasculature navigation. *See* cited portions *supra*. Thus, we conclude that Wendlandt and the other cited prior art references teach and suggest an operable catheter device, sized as claimed, would have been obvious and within the level of skill in the art.

For the reasons set forth above, we are unpersuaded that the Examiner erred in presenting a case for obviousness. Appellants present the same arguments for all rejections and claims, contending that no other cited prior art makes up for the alleged shortcomings of Wendlandt; an argument we have found unpersuasive. *See* Appeal Br. 22–28. Thus, all claims fall with claim 1 for the reasons set forth above. The balance of evidence on appeal favors the Examiner’s position.

#### SUMMARY

The obviousness rejections under 35 U.S.C. § 103 are each affirmed.

#### TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED