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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte MARK D. WOOD and JOHN DEANE

Appeal 2020-000308
Application 15/040,943
Technology Center 3700

Before JENNIFER D. BAHR, JOHN C. KERINS, and
MICHAEL J. FITZPATRICK, *Administrative Patent Judges*.

BAHR, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Pursuant to 35 U.S.C. § 134(a), Appellant appeals from the Examiner’s decision to reject claims 1, 5, 10, 13, and 18.^{1, 2} We have jurisdiction under 35 U.S.C. § 6(b). We REVERSE.

¹ We use the word “Appellant” to refer to “applicant” as defined in 37 C.F.R. § 1.42. Appellant identifies Boston Scientific SciMed, Inc. as the real party in interest. Appeal Br. 3.

² Claims 2–4, 6, 7, 14, 15, and 19 have been canceled, and claims 8, 9, 11, 12, 16, 17, and 20 have been withdrawn from consideration. *See* Amendment After Final Office Action (filed Mar. 21, 2019, hereinafter “Amdt. After Final Act.”); Final Act. 1 (Office Action Summary).

CLAIMED SUBJECT MATTER

Appellant's invention is directed to medical devices for accessing body lumens along the biliary tree. Spec. 1:11–12. Claim 1, reproduced below, is illustrative of the claimed subject matter:

1. A dual-wire catheter system for accessing a body lumen along the biliary and/or pancreatic tract, the catheter system comprising:

a catheter shaft having a proximal end, a distal end, a first guidewire lumen defined therein, and a secondary guidewire holding structure;

wherein the first guidewire lumen extends centrally along a length of the catheter shaft;

wherein the secondary guidewire holding structure is a channel formed in and extending along a length of an outer wall of the catheter shaft, the channel having a distal end proximal of the distal end of the catheter shaft, the channel having a length and being radially open along an entirety of its length, wherein the channel distally reduces in depth;

a first guidewire disposed in the first guidewire lumen;
and

a second guidewire disposed in the secondary guidewire holding structure.

REFERENCES

The prior art relied upon by the Examiner is:

Name	Reference	Date
Wilson	US 6,221,090 B1	Apr. 24, 2001
Deal	US 2005/0059890 A1	Mar. 17, 2005
Von Oepen	US 2008/0027411 A1	Jan. 31, 2008
Brown	US 2013/0158507 A1	June 20, 2013

REJECTIONS

Claims 1, 5, 10, 13, and 18 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Brown and Von Oepen.

Claims 1, 5, 13, and 18 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Wilson and Von Oepen.

Claim 10 stands rejected under 35 U.S.C. § 103(a) as unpatentable over Wilson, Von Oepen, and Deal.

OPINION

Obviousness—Brown and Von Oepen

The Examiner finds that Brown’s catheter system comprises a secondary guidewire holding structure in the form of a channel (lumen 34), but that “Brown fails to disclose that the channel is radially open along an entirety of its length” as recited in each of Appellant’s independent claims 1, 13, and 18. Final Act. 6–7. The Examiner finds that Von Oepen teaches, in a catheter guidewire system, “a guidewire channel (20 or 21) which encompasses a discontinuity (22) such that it is radially open[,] the discontinuity running along an entire length of the channel in order to permit quick removal of a guidewire received within the channel.” *Id.* at 7 (citing Von Oepen ¶¶ 14, 15, 41, 48, 70). The Examiner then determines that it would have been obvious “to form the guidewire holding structure of Brown to include a discontinuity such that the channel is radially open along an entirety of its length, as disclosed by Von Oepen, in order to permit rapid removal of the guidewire from the catheter.” *Id.*

Appellant submits Von Oepen does not describe discontinuity 22 as “providing any feature related to the rapid, fast, or quick removal of the guidewire from the channel 20 or 21.” Appeal Br. 8. Appellant further

points out that Von Oepen describes “two methods of removing the guidewires from the channels, neither of which is described as being fast, rapid, or quick.” *Id.* (citing Von Oepen ¶¶ 70, 71). With respect to the method Von Oepen discusses in paragraph 70, Appellant argues that “the use of a secondary device or surface would appear to require an extra step and thus be slower than simply pulling the guidewire loading device proximally.” *Id.* Appellant further contends that the alternative method Von Oepen discusses in paragraph 71 “of simply pulling the guidewire loading device over the guidewire would not appear to result in the guidewire being passed through the discontinuity 22 and thus would provide no difference or advantage over the device of Brown, in which the guidewire is simply removed from the continuous lumen.” *Id.* at 8–9.

Appellant’s arguments are persuasive. The method Von Oepen describes in paragraph 70 makes use of discontinuity 22 by removing the guidewires through the discontinuity formed in the proximal end of the guidewire placement device and propagating them along the length of the discontinuity until each of the guidewires is free of its respective lumen. *See* Von Oepen ¶ 70. Von Oepen teaches facilitating this propagation “by passing a secondary device over the guidewires external to the placement device or by passing a surface distally between the guidewires and the outer surface of the guidewire placement device.” *Id.* We agree with Appellant that this method of removing the guidewires does not appear to be any more rapid or quick than simply pulling the guidewire placement device proximally. Further, Brown mentions, without further detail, that “[i]n some embodiments the first and second lumens 32, 34 may be configured for rapid exchange of devices extending through the lumens 32, 34,” but gives no

indication that passing guidewires (wire guide 72), or other devices extending through lumen 34, externally of catheter 10 through a slit or discontinuity in the catheter wall proximal of side port 42 would be desirable. Brown ¶ 21. As Appellant correctly points out, the method Von Oepen describes in paragraph 71 for removing the guidewires does not make use of the discontinuity and, thus, would not provide any incentive for adding a discontinuity to the catheter wall of Brown to render lumen 34 radially open along an entirety of its length.

In light of our findings above, the Examiner’s articulated reason (i.e., “in order to permit rapid removal of the guidewire from the catheter”) for modifying Brown to include a discontinuity such that lumen 34 is radially open along an entirety of its length, as disclosed by Von Oepen, lacks rational underpinnings.

The Examiner responds by directing our attention to Wilson’s disclosure of providing guidewire lumens/channels with a radially open slit as a means of effecting “rapid exchange” by enabling guidewires to be removed laterally through the sides of the catheter. Ans. 6 (citing Wilson 16:13–16). The Examiner relies on Wilson as “an evidentiary reference which merely serves to link the phrase ‘rapid exchange’ with slits through the catheter sidewall to thereby establish the level of knowledge and understanding expected of a customary artisan.” *Id.*

Appellant acknowledges that “rapid exchange catheters were generally known,” but contends that such catheters include a slit that runs only along a short section of the lumen, and not along the entire length of the lumen. Reply Br. 2 (quoting text from Wilson 14:17–22 (disclosing a slit (not shown) extending only part of the length of first guide wire lumen 34A,

from side port 34C to just proximal of the balloon portion of the catheter)); *see also* Wilson 16:13–16 (disclosing a slit (not shown) to permit stent-positioning guide wire 41A to be unzipped from the proximal 100 cm of the catheter, thereby allowing the wire “to act as a rapid exchange wire”). Thus, Appellant submits that providing a slit to provide a “rapid exchange” feature as taught by Wilson would not result in the structure claimed. Reply Br. 2–3.

Appellant’s argument is persuasive. Wilson appears to describe a slit extending along the proximal portion of the lumen to provide a “rapid exchange-type catheter” or “rapid exchange wire,” but not a slit extending along the entire length of the lumen. *See, e.g.*, Wilson 14:17–22; 16:13–16. Thus, even if one were to follow the teachings of Wilson and provide a slit for “rapid exchange” of Brown’s guidewires, it is not apparent why a person having ordinary skill in the art would have been prompted to provide a slit along the entire length of Brown’s lumen 34 so as to result in a “channel having a length and being radially open along an entirety of its length,” as recited in Appellant’s independent claims 1, 13, and 18. *See* Appeal Br. 13, 14 (Claims App.).

The Examiner, therefore, fails to establish that the subject matter of independent claims 1, 13, and 18 would have been obvious. Accordingly, we do not sustain the rejections of claims 1, 13, and 18, or of claims 5 and 10, which depend from claim 1, as unpatentable over Brown and Von Oepen.

Obviousness—Wilson and Von Oepen

The Examiner finds that Wilson’s Figure 44 embodiment is a catheter system substantially as claimed in claims 1, 13, and 18, except that the

channel (lumen 26) forming the secondary guidewire holding structure is not radially open along an entirety of its length. Final Act. 8–9. The Examiner determines that it would have been obvious “to form the guidewire holding structure of Wilson to include a discontinuity such that the channel is radially open along an entirety of its length, as disclosed by Von Oepen, in order to permit rapid removal of the guidewire from the catheter.” *Id.* at 9.

Appellant argues that Wilson already teaches a catheter having rapid exchange features and, thus, “there is no rational reason for one of ordinary skill in the art to modify Wilson with Von Oepen as asserted by the Examiner, to permit rapid removal of the guidewire.” Appeal Br. 11. Appellant also repeats the arguments, which we find persuasive for the reasons discussed above, that Von Oepen’s discontinuity is not described as, and does not appear to be, a rapid exchange feature. *See id.*

The Examiner responds by acknowledging that Wilson discloses rapid exchange features, but not on the embodiment of Figure 44 relied on in the rejection. Ans. 14, 16. According to the Examiner, even assuming that Figure 44 of Wilson does “provide for rapid-exchange configurations, the presence of one solution does not speak as to the obviousness of modification to incorporate known, alternative solutions demonstrated by the prior art.” *Id.* at 16–17.

Appellant explains that Wilson configures the Figure 44 embodiment to provide maximum torque and teaches providing slit 144 to allow positioning guide wire 151 to bend slightly and flex into the slit as the wire encounters frictional resistance along the slope of ramp 143. Reply Br. 5 (citing Wilson 26:5–14; Fig. 47). Appellant contends that because “Wilson specifically states the slit is designed to allow the positioning wire 151 to

flex into the slit as it encounters and travels up the ramp 143 in the specifically designed torquing member 140, Wilson cannot be seen to provide any rational reason to extend the slit along the length of the catheter.” *Id.* at 5–6. Appellant also submits that by teaching a rapid exchange catheter in other embodiments and designing the embodiment illustrated in Figures 37–47 for providing maximum torque rather than as a rapid exchange catheter, “Wilson appears to have decided against making the torquing catheter one that includes rapid exchange features.” *Id.* at 6. Moreover, Appellant contends that providing a discontinuity, as taught by Von Oepen and proposed by the Examiner, along the entire length of positioning guide wire lumen 142 of Wilson would appear to render Wilson’s torquing catheter “unsuitable for its intended use as such a discontinuity would appear to allow the guide wire to exit the catheter as the catheter is torqued over the wire.” *Id.*

Appellant’s arguments are persuasive. Given the role of slit 144 in allowing positioning guide wire 151 to flex into the slit to provide a more gradual bend in the wire to relieve the bending moments in the wire, it is doubtful that a person having ordinary skill in the art would have been prompted to provide a slit along the entire length of Wilson’s positioning guide wire lumen 142 that would allow the wire to exit (i.e. be removed from) the catheter as taught by Von Oepen. *See* Von Oepen ¶ 70.

For all of the above reasons, the Examiner fails to establish that the subject matter of claims 1, 13, and 18 would have been obvious. Accordingly, we do not sustain the rejection of independent claims 1, 13, and 18, or of claim 5, which depends from claim 1, as unpatentable over Wilson and Von Oepen.

Obviousness—Wilson, Von Oepen, and Deal

The Examiner’s application of Deal does not cure the aforementioned deficiencies in the combination of Wilson and Von Oepen. *See* Final Act. 9–10 (applying Deal for its teachings of guidewire lumens extending the entire length of the catheter shaft and determining it would have been obvious to configure Wilson’s first guidewire lumen (tracking wire lumen 125) the full length of the catheter shaft). Accordingly, we do not sustain the rejection of claim 10 as unpatentable over Wilson, Von Oepen, and Deal.

DECISION SUMMARY

Claims Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
1, 5, 10, 13, 18	103(a)	Brown, Von Oepen		1, 5, 10, 13, 18
1, 5, 13, 18	103(a)	Wilson, Von Oepen		1, 5, 13, 18
10	103(a)	Wilson, Von Oepen, Deal		10
Overall Outcome				1, 5, 10, 13, 18

REVERSED