UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/971,504	12/16/2015	Phil Langston	2005.63US04	8828

24113 7590 09/26/2019

PATTERSON THUENTE PEDERSEN, P.A.
80 SOUTH 8TH STREET
4800 IDS CENTER
MINNEAPOLIS, MN 55402-2100

EXAMINER	
TOTH, KAREN E	

ART UNIT	PAPER NUMBER
3791	

MAIL DATE	DELIVERY MODE
09/26/2019	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte PHIL LANGSTON

Appeal 2019-002778
Application 14/971,504
Technology Center 3700

Before JOHN C. KERINS, MICHAEL J. FITZPATRICK, and MICHELLE R. OSINSKI, *Administrative Patent Judges*.

FITZPATRICK, *Administrative Patent Judge*.

DECISION ON APPEAL

Appellant, Phil Langston,[1] appeals under 35 U.S.C. § 134(a) from the Examiner's final decision rejecting claims 23–43 and 45–53. We have jurisdiction under 35 U.S.C. § 6(b).

We affirm in part.

[1] Appellant states that "Teleflex Incorporated and its affiliates" are additional real parties in interest by virtue of Teleflex Incorporated being an exclusive licensee of the instant Application. Appeal Br. 2.

STATEMENT OF THE CASE

The Specification

The Specification's disclosure relates generally to the field of cardiac catheters and, more specifically, to cardiac catheters for performing procedures for the testing of aortic stenosis, a condition in which the aortic valve has become narrowed and does not open normally. Spec. 1:11–17.

The Rejected Claims

Claims 23–43 and 45–53 are rejected; no other claims are pending. Final Act. 1. Independent claims 23 and 46 are illustrative and reproduced below.

> 23. A catheter comprising:
>
> a manifold portion including a first connector and a second connector; and
>
> a catheter body including,
>
> a proximal dual lumen portion including exactly two longitudinally-extending lumens, an inner lumen and a surrounding outer lumen, that share a common axis, the outer lumen surrounded by a proximal outer wall and the inner lumen surrounded by a proximal inner wall that is structured to withstand high-pressure injections; and
>
> a distal single lumen portion including an extension of the inner lumen, the single lumen portion surrounded by a distal outer wall,
>
> the first connector in fluid communication with the inner lumen and the second connector in fluid communication with the outer lumen.
>
> 46. A catheter comprising:
>
> a manifold portion including a first connector and a second connector; and a catheter body including, a proximal dual lumen portion including exactly an inner lumen and a

> surrounding outer lumen that share a common axis and at least two side holes, the inner lumen in fluid communication with the first connector, the outer lumen in fluid communication with the second connector, and the at least two side holes consecutively aligned with each other along a line that is parallel with the common axis; and
>
> a distal single lumen portion forming an extension of the inner lumen, the single lumen portion including a bend, a plurality of side holes, and a pigtail tip.

Appeal Br. 29, 33.

The Examiner's Rejections

The following rejections, all under 35 U.S.C. § 103(a), are before us for review:

1. claims 23–28 over Martin[2] and Bodicky[3] (Final Act. 2);
2. claim 29 over Martin, Bodicky, and Andrews[4] (*id.* at 3);
3. claims 30–37 over Martin, Bodicky, and Schweich[5] (*id.* at 4);
4. claims 38–43 over Martin, Bodicky, and Ladika[6] (*id.* at 7);
5. claim 45 over Martin, Bodicky, and Duffy[7] (*id.* at 8);
6. claims 46–49 and 51 over Martin '380,[8] Ladika, and Schweich (*id.* at 9);
7. claim 52 over Martin '380, Ladika, Schweich, and Duffy (*id.* at 12);

[2] US 5,976,103, issued Nov. 2, 1999 ("Martin").
[3] US 4,961,731, issued Oct. 9, 1990 ("Bodicky").
[4] US 5,865,721, issued Feb. 2, 1999 ("Andrews").
[5] US 5,782,797, issued July 21, 1998 ("Schweich").
[6] US 4,747,840, issued May 31, 1988 ("Ladika").
[7] US 6,048,332, issued Apr. 11, 2000 ("Duffy").
[8] US 5,480,380, issued Jan. 2, 1996 ("Martin '380").

8. claims 46, 47, and 51 over Aigner[9] and Ladika (*id.*);

9. claim 50 over Aigner, Ladika, and Bodicky (*id.* at 14); and

10. claim 53 over Martin, Bodicky, and Miller (*id.* at 14).

DISCUSSION

Rejections 8 and 9—Aigner as Primary Reference

Appellant does not argue against the rejection of claims 46, 47, and 51 over Aigner and Ladika or the rejection of claim 50 over Aigner, Ladika, and Bodicky. Thus, Appellant fails to apprise of error in those rejections. Rejections 8 and 9 are affirmed.

Rejections 1–5 and 10—Martin as Primary Reference

The Examiner found that Martin teaches all of the subject matter of independent claim 23 except for the proximal inner wall of the inner lumen being "structured to withstand high-pressure injections," as claimed. Final Act. 2–3 (citing Martin 3:13–27, 4:48–61, Figs. 1 and 2). The Examiner found that "Bodicky teaches forming a catheter configured to withstand high pressure injections at pressures up to 1200 pounds per square inch in order to inject a diagnostic fluid."[10] *Id.* at 3 (citing Bodicky 3:15–20). The Examiner concluded: "It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the catheter of Martin and made [sic, make] it suitable for high pressure injections, as taught by Bodicky, in order to allow its use in diagnostics." *Id.*

Appellant argues that this reason for why a person of ordinary skill in the art allegedly would have so modified Martin's catheter in view of

[9] US 4,666,426, issued May 19, 1987 ("Aigner").
[10] The cited portion of Bodicky actually recites "1000 pounds per square inch" not the 1,200 asserted by the Examiner. Bodicky 3:19–20.

Bodicky is insufficient. Appeal Br. 25–26; *see also KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007) ("requiring an apparent reason to combine the known elements in the fashion claimed by the patent at issue"); *InTouch Techs., Inc. v. VGO Commc'ns, Inc.*, 751 F.3d 1327, 1347 (Fed. Cir. 2014) (Obviousness requires "evidence that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so."). We agree with Appellant.

Martin teaches "dual lumen catheters for use in hemodialysis treatments and more particularly to a dual lumen catheter having coaxial intake and return lumens." Martin 1:13–16. Dual lumen hemodialysis catheters are preferred because they use a single incision rather than two. *Id.* at 1:26–28. Prior art needles, as well as Martin's "tip section," are inserted into veins, not arteries. *See id.* at 1:21–22 ("The earliest treatments were conducted using two needles in the same vein."), 2:40–44 ("[I]t is desirable that the tip section be sufficiently soft and pliable to permit this section to take up the local shape of a vein containing the catheter, thereby to avoid applying distorting forces to the vein and to permit prolonged access with a suitable selection of materials."). Martin does not disclose that cleaned blood is returned to a patient's vein via high pressure injections, nor would that be expected to be safe or desirable.

Bodicky "relates generally to angiographic catheters for injecting a radiopaque material or contrast medium into arteries and/or the heart, for radiological diagnostic purposes." Bodicky 1:7–10. Tubular portion 20 is constructed of a material "selected to give the catheter the desired torque and column strength necessary to push and rotate the catheter while inserting and

placing the catheter in position in the patient's heart or coronary artery or other blood vessel." *Id.* at 3:7–17. The material is "sufficiently strong to withstand high-pressure fluid injection at pressures on the order of 1000 pounds per square inch." *Id.* at 3:17–20.

The Examiner proposes that a person of ordinary skill in the art would want to make "the catheter of Martin . . . suitable for high pressure injections, as taught by Bodicky, in order to allow its use in diagnostics." Final Act. 3. But this begs the question: Why would a person of ordinary skill in the art want to convert Martin's dual lumen catheter, which is used for hemodialysis, into a diagnostics tool capable of providing high pressure fluid injection? No reason is provided by the Examiner.

On the record presented, there is not an apparent reason a person of ordinary skill in the art would have modified Martin in view of Bodicky. The lack of an apparent reason is fatal to all of Rejections 1–5 and 10.

For the foregoing reasons, we reverse Rejections 1–5 and 10.

Rejections 6 and 7—Martin '380 as Primary Reference

The Examiner found that Martin '380 teaches all of the subject matter of independent claim 46 except for the distal single lumen portion which forms an extension of the inner lumen "including a bend, a plurality of side holes, and a pigtail tip," as claimed. Final Act. 9–10 (citing Martin '380 Figs. 1, 2, 6, and 8). The Examiner found that "Ladika teaches a catheter comprising a single lumen portion with a straight section (element 26), a bend (element 20), and a pigtail portion (element 18) distal to the straight portion (see figure 1), in order to prevent the catheter from puncturing the patient's tissue. *Id.* at 10 (citing Ladika 1:60–66). The Examiner concluded: "It would have been obvious to one of ordinary skill in the art at the time the

invention was made to have made the device of Martin[ ]'380 with a distal bend and pigtail section, as taught by Ladika, in order to prevent the catheter from puncturing the patient's tissue." *Id.*

Appellant again argues insufficient rationale for combining the cited prior art features. Appeal Br. 27. And again we agree with Appellant.

Like Martin, Martin '380 "relates to dual lumen catheters for use in haemodialysis treatments and more particularly to a dual lumen catheter having intake and return lumens." Martin '380 1:5–7. The distal end of the catheter, tip portion 65, is narrow so as to be inserted into, and positioned within, a vein. *Id.* at Fig. 6, 4:2 ("tip portion 65"), 1:14–15 ("The earliest treatments were conducted using two needles in the same vein."), 1:38–40 ("As a result, no matter where the catheter may rest against a vein, some of the intake 40 openings remain patent.").

Ladika relates "to heart catheters for use in pulmonary arteriography." Ladika 1:7–8.

> The widely accepted technique for pulmonary arteriography (as it is known) is via the femoral approach wherein a catheter is first inserted into the patient's body through a vein in a lower limb and fed through the inferior vena cavae, into the right atrium of the heart, then through the tricuspid valve and into the right ventricle, then through the pulmonary semilunar valve and into the main or right or left pulmonary artery. Thereafter, the radiopaque fluid is injected through the catheter for disbursement within the selected portion of the pulmonary artery.

Id. at 1:21–31. Pigtail 18 on distal end of Ladika's catheter is used to facilitate complex maneuvering of the catheter during a femoral approach. *Id.* at 2:4–5.

The Examiner proposes that a person of ordinary skill in the art would want to make "the device of Martin '380 with a distal bend and pigtail

section, as taught by Ladika, in order to prevent the catheter from puncturing the patient's tissue." Final Act. 10. But a hemodialysis catheter is inserted merely into a vein. Martin '380 1:14–15, 1:38–40. It is not advanced into the heart or pulmonary tissue as is Ladika's pulmonary arteriography catheter.

On the record presented, there is not an apparent reason a person of ordinary skill in the art would have modified Martin '380 in view of Ladika.

Further, we agree with Appellant that incorporating Ladika's distal bend and pigtail into Martin '380 would render it "unsuitable for its intended placement within a vein and accommodating dialysis of the blood." Appeal Br. 22.

For the foregoing reasons, we reverse Rejection 6, as well as Rejection 7.

SUMMARY

Claims Rejected	Basis	Affirmed	Reversed
23–28	§103(a); Martin, Bodicky		23–28
29	§103(a); Martin, Bodicky, Andrews		29
30–37	§103(a); Martin, Bodicky, and Schweich		30–37
38–43	§103(a); Martin, Bodicky, and Ladika		38–43
45	§103(a); Martin, Bodicky, and Duffy		45
46–49, 51	§103(a); Martin ’380, Ladika, Schweich		46–49, 51
52	§103(a); Martin ’380, Ladika, Schweich, Duffy		52
46, 47, 51	§103(a); Aigner, Ladika	46, 47, 51	
50	§103(a); Aigner, Ladika, Bodicky	50	
53	§103(a); Martin, Bodicky, Miller		53
Overall Outcome		46, 47, 50, 51	23–43, 45, 48, 52

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-IN-PART