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.
15/724,879	10/04/2017	Zhihui Yin	101674.0076P2	5516

158673 7590 07/01/2020

BD/Rutan & Tucker, LLP
611 ANTON BLVD
SUITE 1400
COSTA MESA, CA 92626

EXAMINER	
MARCETICH, ADAM M	

ART UNIT	PAPER NUMBER
3781	

NOTIFICATION DATE	DELIVERY MODE
07/01/2020	ELECTRONIC

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.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ip.docket@bd.com
patents@rutan.com

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte ZHIHUI YIN, DAVID FISH, TOM ROBERTS, ADAM SILVER, and BRIAN CHAPMAN

Appeal 2019-006912
Application 15/724,879
Technology Center 3700

Before MICHAEL C. ASTORINO, NINA L. MEDLOCK, and AMEE A. SHAH, *Administrative Patent Judges*.

ASTORINO, *Administrative Patent Judge*.

DECISION ON APPEAL

Pursuant to 35 U.S.C. § 134(a), the Appellant[1] appeals from the Examiner's decision to reject claims 1–15.[2] We have jurisdiction under 35 U.S.C. § 6(b).

We REVERSE and enter a NEW GROUND OF REJECTION pursuant to our authority under 37 C.F.R. § 41.50(b).

---

[1] We use the word "Appellant" to refer to "applicant" as defined in 37 C.F.R. § 1.42. The Appellant identifies the real party in interest as C.R. Bard, Inc. Appeal Br. 4.

[2] Claims 16–20 have been withdrawn. Final Act. 1 (PTOL-326, Box 5a); Appeal Br. 4.

STATEMENT OF THE CASE

Claimed Subject Matter

Claims 1 and 13 are the independent claims on appeal. Claim 1, reproduced below, is illustrative of the claimed subject matter.

1. A urinary catheter, comprising:
a handle including:
a plurality of ridges designed for gripping the handle; and
one or more loops integral with the handle designed for manipulating the urinary catheter; and
a catheter shaft attached to the handle, the catheter shaft including:
a catheter tip;
a lumen; and
a plurality of eyelets proximate the catheter tip, the eyelets in fluid communication with an opening in a proximal end of the handle by way of the lumen.

Rejections

Claims 1–3, 5, 13, and 15 are rejected under 35 U.S.C. § 103 as unpatentable over Fröjd (US 2011/0060317 A1, pub. Mar. 10, 2011) and Yarger (US 5,360,414, iss. Nov. 1, 1994).

Claims 4 and 14 are rejected under 35 U.S.C. § 103 as unpatentable over Fröjd, Yarger, and Foley (US 2015/0273183 A1, pub. Oct. 1, 2015).

Claims 6–12 are rejected under 35 U.S.C. § 103 as unpatentable over Fröjd, Yarger, and Campbell et al. (US 2013/0253426 A1, pub. Sept. 26, 2013) (hereinafter "Campbell").

ANALYSIS

Independent Claim 1 and Dependent Claims 2–12

Claim 1 calls for "[a] urinary catheter" having "a catheter shaft attached to a handle," in which the catheter shaft includes "a catheter tip," "a lumen," and "a plurality of eyelets proximate the catheter tip, the eyelets in fluid communication with an opening in a proximal end of the handle by way of the lumen." Appeal Br. 30, App. A.

The Examiner finds that Fröjd teaches catheter 1 having elongated shaft 3 attached to gripping sleeve 4, in which elongated shaft 3 includes catheter insertion end 31, an open-ended internal lumen, and drainage aperture 32 proximate catheter insertion end 31, drainage aperture 32 in fluid communication with the open-ended internal lumen. Final Act. 3. The Examiner finds that Fröjd fails to teach a plurality of eyelets. *Id.* The Examiner cures this deficiency by relying on the teachings of Yarger. *Id.* at 3–4. The Examiner finds Yarger teaches catheter shaft 22 that includes holes 28a–d and that the holes correspond to "a plurality of eyelets proximate the catheter tip, the eyelets in fluid communication with the lumen." *Id.* at 4. The Examiner determines that it would have been obvious to modify Fröjd's catheter by adding a plurality of eyelets in view of Yarger's teaching. *Id.* Therefore, the modification proposed by the Examiner only modifies the catheter to add one or more eyelets proximate to the catheter tip. The modification does not alter the structure of the proximate end of Fröjd's catheter, which includes flared connector 2 and gripping sleeve 4.

The Appellant argues that the Examiner's rejection fails to demonstrate how Fröjd results in a "[plurality of] eyelets in fluid

communication with an opening in a proximal end of the handle by way of the lumen," as recited in claim 1, because Fröjd does not teach that drainage aperture 32 is in fluid communication with an opening in a proximal end of gripping sleeve 4. Appeal Br. 9–12. The Appellant's argument is persuasive.

Fröjd discloses a connection between gripping sleeve 4 and flared connector 2 in which the connection is strong enough to ensure that separation does not occur between gripping sleeve 4 and flared connector 2 during normal use. Fröjd ¶¶ 11–12, 20, 41, 43. Fröjd also discloses that the gripping sleeve may be connected to the flared connector by means of a friction fit, mechanical interlocking, adhesion, or welding. *Id.*

The Examiner finds that by connecting gripping sleeve 4 and flared connector 2, "the two elements share a fluid connection with the lumen of [flared] connector 2." Final Act. 9. According to the Examiner, "[t]he assembly of griping sleeve 4 and flared connector 2 shows a lumen, which communicates with the opening at the proximal end of griping sleeve 4 at outwardly protruding flange 23 (Fig. 2)." Advisory Act. (mailed Jan. 29, 2019). Although the Examiner finds that when griping sleeve 4 and flared connector 2 are joined with welding or adhesion they become a single or an integral piece (*id.*), the Examiner does not deviate from the finding that drainage aperture 32 is in fluid communication with an opening in a proximal end of gripping sleeve 4. The Examiner explains, "claim 1 does not recite "direct" fluid communication. The catheter can be used as a standalone catheter without connecting to a further drainage tube. This will permit the lumen to communicate with the proximal ends of both the gripping sleeve and funnel[, i.e., flared connector]." Ans. 10; *see id.* at 11.

Here, the Examiner finds that the disputed claim language reads on fluid communication that is indirect between drainage aperture 32 and an opening in the proximal end of gripping sleeve 4.

The Appellant argues that the Examiner's position concerning indirect fluid communication "is untenable in the context of fluid communication, as either the eyelets are in fluid communication with the proximal opening by way of the lumen or the eyelets **are not** in fluid communication." Reply Br. 5. The Appellant's argument is persuasive.

We fail to understand how a skilled artisan would consider fluid communication as indirect because it runs counter to a primary characteristic of fluid communication, i.e., that a fluid communicates by flowing and changing shape within its container. The fluid that flows through drainage aperture 32 does not communicate, by flowing and changing shape, with the proximal end of gripping sleeve 4.

Additionally, the Examiner explains that "Fig[ure] 2 of Fr[ö]jd depicts a gap between the funnel [(flared connector 2)] and gripping sleeve [4] which will permit communication." Ans. 10. However, the Appellant argues, and we agree, that the Examiner's finding is speculative. *See* Appeal Br. 11–12; Reply Br. 6–7. First, Fröjd does not describe a gap that exists between gripping sleeve 4 and flared connector 2. Second, Fröjd discloses that flared connector 2's outwardly protruding flange 23 provides an abutment for gripping sleeve 4, which suggests that flange 23 and gripping sleeve 4 are in contact. Third, as discussed above, gripping sleeve 4 and flared connector 2 may be connected, which suggests that the proximal end of gripping sleeve 4 is not open to fluid communication. Fröjd ¶ 11–12, 20, 41, 43. Lastly, the Examiner's suggestion of fluid communication in the

depicted gap runs counter to Fröjd's design to collect fluid (i.e., urine) through flared connector 2.

Thus, we do not sustain the Examiner's rejection of claim 1 and claims 2, 3, and 5, which depend therefrom. Additionally, the Examiner fails to rely on Foley or Campbell in any manner that would remedy the deficiency in the rejection as discussed above. Thus, we do not sustain the Examiner's rejection of claims 4 and 6–12, which depend from claim 1.

Independent Claim 13 and Dependent Claims 14 and 15

Independent claim 13 calls for a urinary catheter that includes a handle having "one or more loops integral with the handle designed for manipulating the catheter, wherein a first plane including a transverse cross-section of the handle is orthogonal to a second plane including at least one opening of the one or more loops." Appeal Br. 30, App. A.

The Examiner finds that Fröjd teaches "one or more loops integral with the handle designed for manipulating the urinary catheter." Final Act. 3 (citing Fröjd ¶ 22 ("finger holes")). However, the Examiner also finds that Fröjd is "silent whether a first plane including a transverse cross-section of the handle is orthogonal to a second plane including at least one opening of the one or more loops." *Id.* at 4. The Examiner determines:

> This limitation describes the orientation or direction of the loop, relative to the handle. Applicant's drawings show two alternatives for the loop orientation: orthogonal (Figs. 8a, 8b, 9a, 9b), and parallel (Figs. 8c, 8d). Although Fr[ö]jd does not explicitly describe the orientation of the finger loop, it would have been obvious to try one of the limited set of identified, predictable options, which include orthogonal and parallel facing loops. See MPEP 2141 (III)(E).

Id. The Examiner explains "that only a small number of viable options exist for the orientation of the finger loop," namely, a parallel, an oblique (including a range of angles), or a perpendicular arrangement with respect to the handle. *Id.* at 9–10. The Examiner then dismisses the oblique arrangement for positioning of the finger loops because it "would have made the catheter more difficult to manipulate, since an oblique loop does not correspond to the direction that a user's fingers follow" and therefore, the most favored options are the parallel and perpendicular arrangements. *Id.* at 10.

The Appellant argues that "the Examiner's fact-finding is insufficient for properly supporting a conclusion of obviousness with the obvious-to-try rationale, which, as a result, demonstrates the use of impermissible hindsight." Appeal Br. 19–22; *see* Spec. ¶¶ 76–77, 80, Figs. 8a–d, 9a, b. The Appellant contends that the "oblique orientation is not a single orientation but represents an infinite number of orientations," and one that may "make the catheter easier to manipulate by providing a handedness to the catheter." Appeal Br. 21. The Appellant's argument is persuasive.

Even if we were to agree with the Examiner that Fröjd's finger holes, which are positioned on an outwardly protruding gripping means of the gripping sleeve (*see* Fröjd ¶ 22), correspond to "one or more loops" as claimed, the number of positional arrangements of the first plane including the transverse cross-section of Fröjd's gripping sleeve to the second plane of the finger holes of Fröjd's outwardly protruding gripping means is not as limited as the Examiner's suggests. The number of orientations, as the Appellant argues, is infinite. Accordingly, the Examiner's rejection of claim 13 lacks adequate support.

Thus, we do not sustain the Examiner's rejection of claim 13 and claim 15, which depends therefrom. Additionally, the Examiner fails to rely on Foley in any manner that would remedy the deficiency in the Examiner's rejection as discussed above. Thus, we do not sustain the Examiner's rejection of claim 14, which depends from claim 13.

NEW GROUND OF REJECTION

We reject independent claim 13 and dependent claims 14 and 15 under 35 U.S.C. § 103 as being unpatentable over Fröjd, Foley, and Yarger.

Independent claim 13 recites:

> 13. A urinary catheter, comprising:
> a handle, including:
> a plurality of ridges designed for gripping the handle, and
> one or more loops integral with the handle designed for manipulating the catheter, wherein a first plane including a transverse cross-section of the handle is orthogonal to a second plane including at least one opening of the one or more loops; and
> a catheter shaft attached to the handle, the catheter shaft including:
> a catheter tip;
> a lumen; and
> a plurality of eyelets proximate the catheter tip, the eyelets in fluid communication with the lumen.

Appeal Br. 32, App. A.

Fröjd discloses a urinary catheter having a handle (gripping sleeve 4) and a catheter shaft (elongated shaft 3). Fröjd ¶¶ 1, 37, 41, Figs. 1–3. Fröjd's handle (gripping sleeve 4) includes a plurality of ridges designed for gripping the handle (outwardly facing corrugations 42). *Id.* ¶ 45. Fröjd

discloses that "[t]he gripping sleeve may also be provided with outwardly protruding gripping means, such as wings (not shown)" and that "[o]ther types of protruding parts, such as . . . finger holes . . . are also feasible." *Id.* ¶ 22. However, Fröjd's gripping sleeve, which has a protruding part with finger holes, does not correspond to the claimed "one or more loops integral with the handle designed for manipulating the catheter, wherein a first plane including a transverse cross-section of the handle is orthogonal to a second plane including at least one opening of the one or more loops," as recited in claim 13.

Foley teaches a urinary catheter with adapter assembly 150" having large finger loop 154", which is integrally formed on the outer surface of drainage funnel 142" making it easy to control even for users with limited manual dexterity. Foley ¶ 47, Figs. 6D–E; *see id.* at Figs. 6F–G (large finger loops 254", 354"); *see also id.* ¶ 36 ("drainage funnel 42 may be grasped with one hand to extend the urine discharge sleeve 34 as indicated by the arrow in FIG. 2." (emphasis omitted)), Figs. 6I, J. Foley's large finger loop corresponds to the claimed "one or more loops integral with the handle designed for manipulating the catheter, wherein a first plane including a transverse cross-section of the handle is orthogonal to a second plane including at least one opening of the one or more loops." It would have been obvious to one having ordinary skill in the art at the time the invention was filed to modify Fröjd's gripping sleeve in view of Foley's teaching of a large finger loop in order to make it easier for a user with limited manual dexterity to control and/or manipulate the catheter.

Claim 13 recites "a catheter shaft attached to the handle." Appeal Br. 32, App. A. Although the claim calls for a physical attachment between

the catheter shaft and the handle, the claim does not require a specific type of attachment, e.g., direct or indirect. *See also Ullstrand v. Coons*, 147 F.2d 698, 700 (CCPA 1945) ("It is clear that the accepted definition of the term 'connected' is restricted to neither a direct nor an indirect connection, and the term is therefore applicable to an indirect connection.").

Fröjd's catheter shaft (elongated shaft 3) is indirectly attached to handle (guiding sleeve 4) through flared connector 2. *See* Fröjd ¶ 39 ("flared connector 2 may be connected to the elongate shaft 3 by means of welding, adhesion or the like, or form an integrated part of the elongate shaft" (emphasis omitted)); ¶ 20 ("the gripping sleeve may be connected to the flared connector by means of at least one of welding and adhesion"); *see also id.* ¶¶ 11–12, 43. Fröjd's catheter shaft (elongated shaft 3) includes a catheter tip (rounded tip 33), a lumen ("open-ended internal lumen (not shown)"), and an eyelet (drainage aperture 32) proximate catheter tip 33 in which the eyelet (drainage aperture 32) is in communication with the lumen (open-ended internal lumen). *See id.* Fröjd ¶¶ 37–38, Figs. 1–3. However, Fröjd's catheter shaft does not include "a plurality of eyelets," as required by claim 13.

Yarger teaches a catheter shaft (tubular section 22) having a plurality of eyelets (hole sets 28a–b, 28c–d) proximate a catheter tip (distal tip end 31), the eyelets (hole sets 28a–b, 28c–d) in fluid communication with a lumen (inside diameter 30). Yarger, Figs. 1, 2, col. 5, ll. 36–44, col. 5, l. 64–col. 6, l. 4. It would have been obvious to one having ordinary skill in the art at the time the invention was filed to modify Fröjd's catheter shaft to have a plurality of eyelets proximate the catheter tip in view of Foley's teaching of having more than one drainage opening for passing urine

through a catheter tube in case one or more holes become occluded (*see id.* at col. 6, ll. 9–13).

Although this rejection of claim 13 is a new ground of rejection, one of the Appellant's arguments is pertinent to the current rejection. The Appellant argues that Fröjd's "gripping sleeve 4 is intended as an aftermarket accessory for user modification of a standard catheter" and "not intended to be permanently fixed to the connector 2." Appeal Br. 16; *see* Reply Br. 8. Additionally, the Appellant argues "[e]ven when the gripping sleeve 4 is fixed to the connector 2 in accordance with Fr[ö]jd, the gripping sleeve 4 is attached to the connector 2 – not the elongated shaft 3." Appeal Br. 16. The Appellant's argument is not persuasive. As discussed above, Fröjd's elongated shaft 3 (catheter shaft) is indirectly attached to a guiding sleeve 4 (handle) through flared connector 2.

Claim 14, depends directly from claim 13, and recites "wherein the one or more loops are respectively one or more rings, each attached to the handle by a tab extension of the handle." Appeal Br. 32, App. A. The rejection of claim 13 includes a modification of Fröjd's gripping sleeve in view of Foley's teaching of a large finger loop. Foley's large finger loop is shown as a ring and is attached to a handle by a tab extension of the handle. *See* Foley ¶ 47, Figs. 6D–E; *see id.* at Figs. 6F–G (large finger loops 254", 354"). Accordingly, the modification of Fröjd's gripping sleeve in view of Foley's teaching results in the subject matter of claim 14.

Claim 15, depends directly from claim 13, and recites "wherein the plurality of eyelets include at least two pairs of staggered eyelets staggered along a length of the catheter shaft and offset by about 90 degrees around the catheter shaft in a non-overlapping configuration." Appeal Br. 32, App. A.

The rejection of claim 13 includes a modification of Fröjd's catheter shaft in view of Yarger's teaching of plurality of eyelets (hole sets 28a–b, 28c–d). *Supra*. Yarger's plurality of eyelets "include at least two pairs of staggered eyelets staggered along a length of the catheter shaft and offset by about 90 degrees around the catheter shaft in a non-overlapping configuration," as recited in claim 15. *See* Yarger, Figs. 1, 2, col. 5, ll. 36–44, col. 5, l. 64–col. 6, l. 4. Accordingly, the modification of Fröjd's catheter shaft in view of Yarger's teaching results in the subject matter of claim 15.

CONCLUSION

We REVERSE the Examiner's rejection of claims 1–3, 5, 13, and 15 under 35 U.S.C. § 103 as being unpatentable over Fröjd and Yarger.

We REVERSE the Examiner's rejection of claims 4 and 14 under 35 U.S.C. § 103 as being unpatentable over Fröjd, Yarger, and Foley.

We REVERSE the Examiner's rejection of claims 6–12 under 35 U.S.C. § 103 as being unpatentable over Fröjd, Yarger, and Campbell.

We enter a NEW GROUND OF REJECTION of claims 13–15 under 35 U.S.C. § 103 as being unpatentable over Fröjd, Foley, and Yarger.

37 C.F.R. § 41.50(b) provides "[a] new ground of rejection pursuant to this paragraph shall not be considered final for judicial review."

37 C.F.R. § 41.50(b) also provides that the Appellant, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of the appeal as to the rejected claims:

> (1) *Reopen prosecution.* Submit an appropriate amendment of the claims so rejected or new Evidence relating to the claims so rejected, or both, and have the matter

> reconsidered by the examiner, in which event the prosecution will be remanded to the examiner. . . .
>
> (2) *Request rehearing*. Request that the proceeding be reheard under § 41.52 by the Board upon the same Record.

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

In summary:

Claims Rejected	35 U.S.C. §	References/ Basis	Affirmed	Reversed	New Ground
1–3, 5, 13, 15	103	Fröjd, Yarger		1–3, 5, 13, 15	
4, 14	103	Fröjd, Yarger, Foley		4, 14	
6–12	103	Fröjd, Yarger, Campbell		6–12	
	103	Fröjd, Foley, Yarger			13–15
Overall Outcome				1–15	13–15

REVERSED; 37 C.F.R. § 41.50(b)