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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte RALF KAUFMANN, HARDY MUELLER, RAINER LESMEISTER, MICHAEL BRAUN, and JOHN GEIS

Appeal 2018-001205
Application 11/391,898
Technology Center 3700

Before LISA M. GUIJT, BRADLEY B. BAYAT, and PAUL J. KORNICZKY, *Administrative Patent Judges*.

GUIJT, *Administrative Patent Judge.*

DECISION ON APPEAL

STATEMENT OF THE CASE

Pursuant to 35 U.S.C. § 134(a), Appellant[1] appeals from the Examiner's decision to reject claims 1–13 and 17. We have jurisdiction under 35 U.S.C. § 6(b).

We REVERSE.

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[1] We use the word Appellant to refer to "applicant" as defined in 37 C.F.R. § 1.42(a). Appellant identifies the real party in interest as JOTEC GmbH. Appeal Br. 1.

CLAIMED SUBJECT MATTER

The claims are directed to "a delivery system with a self expanding stent for implantation into a blood vessel." Spec. ¶ 2. Sole independent claim 1, reproduced below, is illustrative of the claimed subject matter:

> 1. A delivery system with a self expanding stent for implantation into a blood vessel in the region of the aortic arch, said stent comprising a hollow cylindrical body which is radially compressed for implantation, and with a pull-back sheath which surrounds the stent and which radially compresses the stent for positioning and releasing the stent in the blood vessel in the region of the aortic arch, wherein the pull-back sheath comprises a highly flexible front section which surrounds the stent and which maintains said stent in its compressed state, and further comprises a more rigid rear section which is connected to the front section and which is designed to transmit torsional and traction forces to the front section, the front and rear sections being made from different materials, and wherein the front section consists of a woven textile tube with textile structure, the front section configured to form kinks and folds in the textile tube during delivery of the stent in the blood vessel in the region of the aortic arch, whereby the kinks and folds allow flexion movement during delivery of the stent in the blood vessel in the region of the aortic arch.

REFERENCES

The prior art relied upon by the Examiner is:

Name	Reference	Date
Fischell	US 5,976,153	Nov. 2, 1999
Colgan	US 6,520,983 B1	Feb. 18, 2003
DiCarlo	US 6,929,626 B2	Aug. 16, 2005

REJECTIONS

I. Claims 1–5, 10, and 17 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Colgan and DiCarlo.

II. Claims 1–13 and 17 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Fischell and DiCarlo.

OPINION

Rejection I

Regarding independent claim 1, the Examiner finds that Colgan discloses a sheath having a highly flexible front section and a more rigid rear section, as claimed. Final Act. 6 (citing Colgan 16:15–50, Fig. 20A). The Examiner also finds that Colgan discloses that

> it is known to include a braided, textile material [i.e., third layer 394] at the distal end because this aids in create a delivery sheath that is flexible enough to negotiate the bends, but also has sufficient strength and stiffness; In particular, the braid is stated to provide longitudinal stiffness and flexibility in the sheath.

Id. (citing Colgan 2:43–57); *see also* Colgan 17:29 (disclosing, with reference to Figure 20C, that the third layer is "a fiber braid"). The Examiner finds that "due to this flexibility" (i.e., the flexibility of third layer 394), Colgan's sheath "is configured to form kinks and folds at the distal end during delivery of the stent." Final Act. 6.

The Examiner determines that Colgan "does not teach that the front section of the catheter *consists* of a woven textile tube with a textile structure." Final Act. 6. The Examiner relies on DiCarlo for disclosing a catheter with a front, or distal, section consisting of a woven texture tube with a textile structure, as claimed, and for teaching that "the catheter is

flexible and therefore is considered to be configured to form kinks and folds." *Id.*

The Examiner reasons that it would have been obvious to modify Colgan's "catheter" so that "the distal end consists of a woven textile tube with a textile structure," as taught by DiCarlo, to provide "a lower profile" that is "more comfortable for the patient . . . while also able to resist collapse." *Id.* at 6–7 (citing DiCarlo 1:15–23, 54–56, 2:14–16). The Examiner also relies on Colgan's disclosure of "varying different parts of the woven textile sheath to modify the structural properties of the sheath" and DiCarlo's disclosure that "the woven textile tube has sufficient self-supporting rigidity to be advanced through a body lumen" and also that "modifying the materials and weave of the textile [adjusts] the structural properties." Ans. 7 (citing DiCarlo 5:46–50, 8:10–9:25).

Appellant argues, *inter alia*, that the Examiner's reasoning is "based on nothing more than the sole assumption that the proposed modification *can* be done." Appeal Br. 14–15. Appellant submits that DiCarlo's catheters are "*low-profile indwelling* tubes" and that

> the Examiner has not identified any teaching or suggestion that the low-profile textile tube is strong enough to hold any compressed stent inside or to release the stent into the small bodily lumen, or that the low-profile textile tubes (which are intended to be indwelling tubes) are designed to be withdrawn or even can be withdrawn from the small bodily lumen after the stent is released.

Appeal Br. 15–16. Appellant concludes that "the skilled artisan has no reason to combine Colgan and DiCarlo to arrive at instant claim 1." *Id.* at 15; *see also* Reply Br. 1 ("the Examiner's proposed combination fails because there is no reason for the skilled artisan to combine and/or modify

the cited references in order to arrive at the present claims with a reasonable expectation of success").

The Examiner responds that DiCarlo is in Appellant's field of endeavor. Ans. 8.

Colgan discloses, with reference to Figures 20A–C, an outer sheath 382 having "variable properties," such that "the outer sheath 382 must be flexible enough to negotiate the bends, but have sufficient strength and stiffness." Colgan 17:21–23. Thus, Colgan discloses that "outer sheath 382 is formed of a plurality of layers," including inner layer 390, second layer 392, third layer 394, and fourth layer 398. *Id.* at 17:24–36. Colgan discloses "[the] fourth layer 398, an outer layer, of the outer sheath 382 material properties vary as it goes from the proximal end to the distal end." *Id.* at 17:33–36. DiCarlo discloses "a percutaneously or orifically pushable and placeable catheter, drainage tube or stent, such as a ureteral stent, having a textile body fluid contacting surface or a textile body lumen contacting surface" (DiCarlo 1:9–13), which has the advantage of a lower profile that is more comfortable for the patient (*see id.* at 1:15–24 (disclosing that polymeric tubes with high profiles undesirably cause patient discomfort)). We understand the Examiner's proposed modification to be the replacement, in the entirety, of Colgan's front, or distal, section of outer sheath 382 (which is comprised of four layers—the third of which is a fiber, or textile, braid) to arrive at the claimed invention, such that the front, or distal, section of Colgan's outer sheath 382 is made solely from a textile tube, as disclosed in DiCarlo, for the purpose of providing a low profile sheath that is more comfortable for the patient.

We are persuaded by Appellant's argument that the advantages disclosed in DiCarlo, namely, a low profile, *in-dwelling* stent for patient comfort, does not support the Examiner's modification to the front, or distal, section of Colgan's sheath, which itself is a stent delivery system that is removed from the patient after deployment of the stent. In other words, the Examiner has not provided sufficient reasoning that patient comfort resulting from a low profile is applicable to a sheath, which is not in-dwelling as with DiCarlo's stent, but which is removed from the patient. The Examiner's determination that DiCarlo is in Appellant's field of endeavor does not cure the deficiency in the Examiner's reasoning.

Accordingly, we do not sustain the Examiner's rejection of independent claim 1, and claims 2–5, 10, and 17 depending therefrom.

Rejection II

Regarding independent claim 1, the Examiner finds, *inter alia*, that Fischell discloses a sheath having a highly flexible front section (i.e., 36) and a more rigid rear section (i.e., 32, 34), as claimed. Final Act. 7 (citing Fischell Fig. 1); *see also* Fischell 4:65–5:6 (disclosing sheath 30 having "a thin-walled metal tube 32 for most of its length," wherein "the distal end of the tube 32 is joined to the proximal end of a flexible tube 34," and further, that "[a] thin-walled, highly flexible, tube 36 is fixedly attached at its proximal end to the distal end of the flexible tube 34"). Final Act. 7. The Examiner also finds that "[d]ue to the flexibility of the distal end," Fishchell's sheath is "configured to form kinks and folds at the distal end during delivery of the stent," as claimed. *Id.*

The Examiner determines that Fischell does not disclose that "the front section *consists* of a woven, textile tube." Final Act. 8. Similar to

Rejection I *supra*, the Examiner relies on DiCarlo for disclosing a catheter with a front, or distal, section consisting of a woven texture tube with a textile structure, as claimed, and for teaching that "the catheter is flexible and therefore is configured to form kinks and folds." *Id.*

The Examiner reasons that it would have been obvious to modify Fischell's "catheter" so that "the distal end consists of a woven textile tube with a textile structure," as taught by DiCarlo, to provide "a lower profile" that is "more comfortable for the patient . . . while also able to resist collapse." *Id.* at 6–7 (citing DiCarlo 1:15–23, 54–56, 2:14–16).

Similar to Rejection I, Appellant argues that "[e]ven assuming DiCarlo does offer the alleged advantages, there is still no reason[] for the skilled artisan to modify Fischell in order to arrive at the present claims with a reasonable expectation of success." Appeal Br. 20–21.

Again we are persuaded by Appellant's argument that the advantages disclosed in DiCarlo, namely, a low profile, *in-dwelling* stent for patient comfort, does not support the Examiner's modification to the front, or distal, section of Fischell's sheath, which itself is a stent delivery system that is removed from the patient after deployment of the stent. In other words, the Examiner has not provided sufficient reasoning that patient comfort due to a low profile is applicable to a sheath, which is not in-dwelling as with DiCarlo's stent, but which is removed from the patient.

Accordingly, we do not sustain the Examiner's rejection of independent claim 1 and claims 2–13 and 17 depending therefrom.

CONCLUSION

The Examiner's rejection of claims 1–5, 10, and 17 under 35 U.S.C. § 103(a) as unpatentable over Colgan and DiCarlo is REVERSED.

The Examiner's rejection of claims 1–13 and 17 under 35 U.S.C. § 103(a) as unpatentable over Fischell and DiCarlo is REVERSED.

DECISION SUMMARY

In summary:

Claims Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
1–5, 10, 17	103(a)	Colgan, DiCarlo		1–5, 10, 17
1–13, 17	103(a)	Fischell, DiCarlo		1–13, 17
Overall Outcome				1–13, 17

REVERSED