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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte WILLIAM A. CARTIER, WILLIAM C. HAMILTON JR.,
JAMES J. MITCHELL, and DANIEL T. LAGOE

Appeal 2019-001973
Application 14/708,355
Technology Center 3700

Before EDWARD A. BROWN, LISA M. GUIJT, and
BRENT M. DOUGAL, *Administrative Patent Judges*.

GUIJT, *Administrative Patent Judge*.

DECISION ON APPEAL
STATEMENT OF THE CASE

Appellant¹ appeals under 35 U.S.C. § 134(a) from the Examiner's rejection of claims 19, 22–25, and 27–36.² We have jurisdiction under 35 U.S.C. § 6(b).

We REVERSE.

¹ AngioDynamics, Inc. (“Appellant”), the applicant as provided for under 37 C.F.R. § 1.46, is also identified as the real party in interest. Br. 3.

² Appeal is taken from the Final Office Action dated Oct. 19, 2017.

CLAIMED SUBJECT MATTER

Claim 19, reproduced below as the sole independent claim on appeal, is also exemplary of the subject matter on appeal. The Appeal Brief omitted the disputed claim limitation, which is inserted and emphasized below, from the Claims Appendix; this disputed limitation was added by amendment with the July 7, 2016 filing of a Request for Continued Examination. *See* Br. 14 (Claims App.).

19. A system for removing material from a hollow anatomical structure, comprising:

an outer shaft having a distal end and a proximal end;

an inner shaft having a distal end and a proximal end, the inner shaft being movable independent of the outer shaft;

a macerator element comprising a tubular extension and a shearing member, the tubular extension being affixed to a distal most end of the inner shaft and having at least one opening along a wall of the tubular extension, the shearing member comprising at least one opening along a wall of the shearing member, the shearing member being coaxially disposed and freely rotatable within the tubular extension, the opening of the tubular extension may align with the opening of the shearing member and create a path for fluid communication therethrough, [*the macerator element able to be advanced and/or retracted while the outer shaft remains stationary*];

a drive shaft coaxially disposed within a lumen of the inner shaft, the drive shaft is attached to the shearing member, the drive shaft capable of rotating the shearing member at a rate of up to 10,000 RPMs;

an aspiration force applied to an aspiration lumen situated between an inner wall of the inner shaft and an outer wall of the drive shaft, when the tubular extension opening and the shearing member opening are aligned so that the aspiration force causes the fluid to move from the outside of the macerator element to within the aspiration lumen for removal.

THE REJECTIONS

I. Claims 19, 22, 28, 31, 35, and 36 stand rejected under 35 U.S.C. § 102(b) as anticipated by Escudero (US 2009/0018567 A1; published Jan. 15, 2009).

II. Claim 23 stands rejected under 35 U.S.C. § 103(a) as unpatentable over Escudero and Kim (US 2009/0099581 A1; published Apr. 16, 2009).

III. Claim 24 stands rejected under 35 U.S.C. § 103(a) as unpatentable over Escudero.

IV. Claims 25, 29, 30, and 34 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Escudero and Goll (US 2006/0195138 A1; published Aug. 31, 2006).

V. Claim 27 stands rejected under 35 U.S.C. § 103(a) as unpatentable over Escudero and Reger (US 5,211,651; issued May 18, 1993).

VI. Claim 32 stands rejected under 35 U.S.C. § 103(a) as unpatentable over Escudero and Glines (US 2007/0239182 A1; published Oct. 11, 2007).

VII. Claim 33 stands rejected under 35 U.S.C. § 103(a) as unpatentable over Escudero, Goll, and Nool (US 2005/0004594 A1; published Jan. 6, 2005).

ANALYSIS

Rejection I

The Examiner finds that Escudero discloses the limitations of claim 19, including an inner shaft (i.e., catheter 120) movable independent of an

outer shaft (i.e., member 124), and also a macerator element (i.e., housing 104 of cutter assembly 102) comprising a tubular extension (i.e., mechanical locking ring 126) and a shearing member (i.e., cutting edges 112, 109), wherein the tubular extension (126) is affixed to a distal most end of the inner shaft (i.e., catheter 120). Final Act. 4 (citing Escudero ¶¶ 164, 170, 262, Figs. 8A, 8B, 26A, 26B); *see also* Escudero ¶ 170, Figs. 2A (mechanical locking ring 126), 8A, 8B. The Examiner also finds that the macerator element (i.e., cutter assembly 102) is able to be advanced and/or retracted while the outer shaft (i.e., member 124) remains stationary, as claimed. Final Act. 4–5.

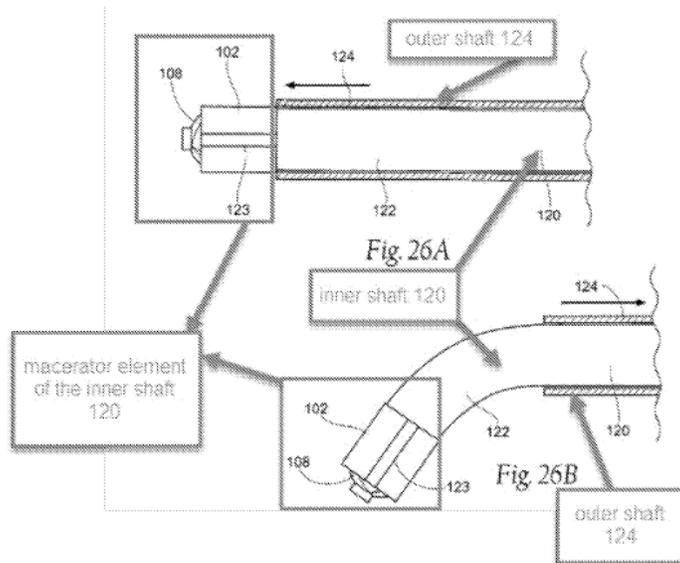
Appellant argues that Escudero fails to disclose that “the macerator element is able to be advance[d] and/or retracted while the outer shaft remains stationary,” as expressly recited in claim 19. Br. 10. Appellant submits that the Examiner’s findings relative to Escudero are speculative and also that the Examiner improperly relies on hindsight reasoning. *Id.* In support, Appellant submits that paragraph 262 of Escudero discloses that “it is the member 124 [i.e. the “outer shaft”] that is advanced and retracted relative to the flexible distal portion 122 and macerator.” *Id.* at 11. Appellant concludes that the Examiner “incorrectly equate[s] the advancement and retraction of the sheath 124 with the claimed stationery outer shaft,” which is contrary to claim 19, “which states that the macerator element is able to be advanced and/or retracted ***while the outer shaft remains stationary.***” *Id.*

The Examiner determines that the disputed claim limitation is “functional language,” which “does not impose any structural limitation on the claim.” Ans. 2. Alternatively, the Examiner determines that, “even

though it is not the method that is disclosed by Escudero,” Escudero’s macerator element (i.e., cutter assembly 102) of inner shaft (i.e., catheter 120) is capable of being advanced and/or retracted while the outer shaft remains stationery, “if one so desires to do so.” *Id.* at 2–3. Specifically, the Examiner determines that

if the user held the outer shaft stationary in one hand, the use[r] could use the other hand to grab the macerator at the distal tip and push or pull it within the sheath. There is no structure along the length of the shaft or along or within the handle that would preclude one from being able to perform this function.

Id. at 3. The Examiner provides annotations of Figures 26A and 26B.



Figures 26A and 26B of Escudero depict “side views of the flexible distal portion of the catheter having an adjustable flexible distal length,” wherein the Examiner has identified member 124 as corresponding to claimed outer shaft, catheter 120 as corresponding to the claimed inner shaft, and cutting assembly 102 (including cutter 108 and counterweight 123) as corresponding to the claimed macerator element. Escudero ¶ 112, Figs. 26A, 26B.

First, the claim limitation requiring the macerator element to be able to advance and/or retract while the outer shaft remains stationary is a structural limitation defining a physical relationship between the macerator element and the outer shaft. Thus, the Examiner's construction of the disputed claim limitation as "functional language" and not a structural limitation is not supported. *See* Ans. 2. Second, we agree with Appellant that Escudero fails to disclose this required physical relationship between member 124 (i.e., the outer shaft) and housing 104 and cutter assembly 102 (i.e., the macerator element).

In particular, Escudero discloses that, with reference to Figures 26A and 26B,

[t]he length of the flexible distal portion **122** (or a predefined portion) may be controlled, i.e., adjusted by including a member **124** either inside or outside the catheter **120**, or both inside and outside the catheter. The member **124** may comprise an axially adjustable sheath, wire, or guidewire, for example, the member **124** having a stiffness greater than the flexible distal portion. . . . [W]hen the sheath **124** is advanced distally, its added stiffness reduces the flexibility of the flexible distal portion **122**. When the sheath **124** is retracted proximally, the length of the flexible distal portion may be increased relative to the portion the sheath **124** was retracted

Escudero ¶ 262. Thus, as argued by Appellant, Escudero discloses that member 124, which corresponds to the claimed outer shaft according to the Examiner's findings *supra*, is axially movable relative to catheter 120, including housing 104 and cutter assembly 102 (i.e., the macerator element). Escudero is silent as to whether the construction of Escudero's system (including, for example, any connection between member 124 and handle 200) would allow member 124 to be held stationary, while housing 104 and

cutter assembly 102 are advanced and/or retracted relative to member 124. Thus, we agree with Appellant that the Examiner's finding is speculative.

To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either expressly or inherently. *Blue Calypso, LLC v. Groupon, Inc.*, 815 F.3d 1331, 1341 (Fed. Cir. 2016).

Accordingly, we do not sustain the Examiner's rejection of independent claim 19, and claims 22, 28, 31, 35, and 36.

Rejections II–VII

The Examiner's reliance on the following references in the rejection of the dependent claims fails to cure the deficiencies in the Examiner's rejection of independent claim 19 *supra*: (i) Kim for disclosing a balloon (Final Act. 7); (ii) Goll for disclosing an expandable basket having multiple arms, and also embolic protection and expandable wire filters (*id.* at 8–10); (iii) Reger for disclosing a distal protection device securely attached and immovably connected to the inner shaft (*id.* at 10–11); (iv) Nool for disclosing a cover made of permeable material; and (iv) Escudero for further disclosing collars (*id.* at 8).

Accordingly, we also do not sustain the Examiner's rejections of claims 23–25, 27, 29, 30, and 32–34.

DECISION

The Examiner's decision rejecting claims 19, 22–25, and 27–36 is reversed.

REVERSED