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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte JEFFREY E. HULL and MARK A. RITCHART

Appeal 2019-000555¹
Application 13/956,221
Technology Center 3700

Before PHILLIP J. KAUFFMAN, JEREMY M. PLENZLER, and
ALYSSA A. FINAMORE, *Administrative Patent Judges*.

FINAMORE, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Pursuant to 35 U.S.C. § 134(a), Appellant² appeals from the Examiner's decision to reject claims 1–4, 6–9, 13, 14, and 21. We have jurisdiction under 35 U.S.C. § 6(b).

We affirm.

¹ We reference herein the Specification filed July 31, 2013 (“Spec.”), Final Office Action mailed April 19, 2017 (“Final Act.”), Appeal Brief filed December 18, 2017 (“Br.”), and Examiner's Answer mailed May 29, 2018 (“Ans.”).

² Appellant is the Applicant, Avenu Medical, Inc., which, according to the Appeal Brief, is the real party in interest. Br. 1.

SUBJECT MATTER ON APPEAL

The invention is directed to “a device to allow extension, elongation or repair of a previously created arteriovenous fistula between a first blood vessel and an adjacent second blood vessel.” Spec. 3:20–22. Claim 1, the sole independent claim, is representative of the claimed subject matter and reproduced below.

1. A device for elongating, extending, or repairing a tissue aperture, comprising:
 - a handle;
 - a body connected to and extending distally from the handle, comprised of a flexible material and having a primary lumen;
 - a rigid jaw member connected to and extending distally from the flexible body; a tissue cutting element disposed on the jaw member, wherein the jaw member comprises two elements, each having distal ends, wherein one of the elements is pivotable relative to the other element to create a spacing of varying sizes between the two elements at their respective distal ends;
 - a lever on the handle which moves at least one of the jaw member elements relative to the other one to increase or decrease the spacing between the distal ends of the elements, thereby opening or closing the jaws of the jaw member to a plurality of incremental positions between fully opened and fully closed to thereby achieve an optimal size extension of an aperture in tissue;
 - a wire connecting the lever to the jaw member which opens or closes the jaw member;
 - a ratcheting mechanism on said lever which applies variable incremental pressure within a range of $100 \text{ mN/mm}^2 - 500 \text{ mN/mm}^2$ to the jaw member;
 - a secondary lumen disposed in one of the jaw elements which receives a guidewire therein; and
 - a temperature sensor disposed on the rigid jaw member.

Br. 18, Claims App.

REJECTIONS

The Examiner rejects the claims on appeal as follows:

- I. claims 1, 4, 7, 8, and 14 under 35 U.S.C. § 103(a) as unpatentable over Lau³, Arp⁴, Cuny⁵, Edwards⁶, and Weaver⁷;
- II. claims 2 and 3 under 35 U.S.C. § 103(a) as unpatentable over Lau, Arp, Cuny, Edwards, Weaver, and Appling⁸;
- III. claim 6 under 35 U.S.C. § 103(a) as unpatentable over Lau, Arp, Cuny, Edwards, Weaver, and Anderson⁹;
- IV. claims 9 and 13 under 35 U.S.C. § 103(a) as unpatentable over Lau, Arp, Cuny, Edwards, Weaver, and Hausen¹⁰; and
- V. claim 21 under 35 U.S.C. § 103(a) as unpatentable over Lau, Arp, Cuny, Edwards, Weaver, Pendleton¹¹, and Gauderer¹².

ANALYSIS

Rejection I

Appellant argues claims 1, 4, 7, 8, and 14 as a group. Br. 10–14. We select independent claim 1 as representative, and the remaining claims stand or fall with independent claim 1. 37 C.F.R. § 41.37(c)(1)(iv).

³ US 2006/0217706 A1, published Sept. 28, 2006.

⁴ US 2005/0277952 A1, published Dec. 15, 2005.

⁵ US 5,626,608, issued May 6, 1997.

⁶ US 2009/0234355 A1, published Sept. 17, 2009.

⁷ US 5,571,136, issued Nov. 5, 1996.

⁸ US 2004/0116901 A1, published June 17, 2004.

⁹ US 2012/0059371 A1, published Mar. 8, 2012.

¹⁰ US 7,875,029 B1, issued Jan. 25, 2011.

¹¹ US 2010/0324446 A1, published Dec. 23, 2010.

¹² US 6,361,540 B1, issued Mar. 26, 2002.

The Examiner relies on Lau for disclosing most of the limitations of independent claim 1. Final Act. 3. Lau describes a welding and separating device “that is used to close off and separate side branches from a primary [blood] vessel being harvested, and also possibly to sever the primary vessel.” Lau ¶ 64. Device 30 includes modular handle unit 20 and hollow, flexible, elongated shaft or body 36, depicted in Figure 1C as extending distally from the handle. *Id.* ¶¶ 67, 68, 94, Figs. 1A–1C. Body 36 terminates at its distal end in a rigid jaw member having two distally-extending jaw elements 40, 42. *Id.* ¶ 69, Fig. 1C. Control rod 112, connected at one end to actuator or lever 44 and, at the other end, indirectly to jaw elements 40, 42, enables the lever to open or close the jaw member. *Id.* ¶¶ 69, 94, 100, Figs. 1C, 4. Second heating element 48 mounted along an inner surface of jaw element 40 acts as a tissue cutting element. *Id.* ¶¶ 71, 85, Fig. 1C.

The Examiner acknowledges Lau fails to disclose “a wire connecting the lever to the jaw member which opens or closes the jaw member” as recited in independent claim 1, and finds Arp teaches this limitation. Final Act. 3–4. Arp describes flexible endoscope clip applicator 10 including manual actuator 18 and pair of jaws 20. Arp ¶ 89, Fig. 1. Manual actuator 18 includes lever 22 and control member 36 connected to lever 22 and spring 38. *Id.* ¶ 93, Figs. 1, 3. Paragraph 98 of Arp, in particular, uses the terms “control member” and “control wire” interchangeably to describe the element labeled with reference numeral 36, thereby implying that the control member is a wire. *See also id.* ¶ 19. When lever 22 is pivoted toward the distal end of device 30, it pulls control element 36 proximally, resulting in the closing of jaw elements 20. *Id.* ¶ 95. When lever 22 is

released, spring 38 forces control member 36 distally, allowing jaw elements 20 to open. *Id.* ¶ 99. The Examiner reasons it would have been obvious to replace Lau’s control rod 112 with a wire of the sort taught by Arp “as an alternative mechanism that would [have] work[ed] equally well to grasp tissue.” Final Act. 4. The Examiner also reasons Lau’s lever 44 and control rod 112, and Arp’s lever 22, control wire 36, and spring 38, were known mechanisms for opening and closing jaw elements in medical devices. Ans. 3–4.

Appellant asserts the Examiner has failed to provide an adequate reason for combining the teachings of Lau and Arp. Br. 10–11. In particular, Appellant contends “[t]he rejection provides no guidance at all as to how or why the teachings of Arp would have been applied to this very different structure of Lau, absent reference to Appellant[’s] teachings.” *Id.* Appellant further argues “as is apparent from even a cursory review of the respective references, the respective jaw elements of each are for very different purposes.” *Id.* at 11. According to Appellant, Lau’s device must fit within the constraints of a small diameter design that is less than 5 mm and apply opening and closing forces of around 1–3 lb., whereas Arp’s device is for the much larger-scale procedure of applying clips endoscopically with approximately 17 lb. of pressure and no heating or cutting. *Id.* (citations omitted).

“The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art.” *In re Keller*, 642 F.2d 413, 425 (CCPA 1981) (citations omitted). Furthermore,

“when a patent claims a structure already known in the prior art that is altered by the mere substitution of one element for another known in the field, the combination must do more than yield a predictable result.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007). Even if Arp’s mechanism for opening and closing the jaw elements could not be physically incorporated into Lau’s device, Appellant does not address the Examiner’s determination that Lau’s lever 44 and control rod 112, on one hand, and Arp’s lever 22, control wire 36, and spring 38, on the other, were known mechanisms for opening and closing jaw elements in medical devices. Ans. 3–4. Appellant, therefore, does not apprise us of error in the Examiner’s determination that it would have been obvious to substitute Lau’s mechanism for opening and closing jaw elements for the corresponding mechanism in Arp. *Id.*

The Examiner also acknowledges Lau fails to describe “a ratcheting mechanism on said lever,” as recited in independent claim 1, and finds Cuny teaches this limitation. Final Act. 3–4. Cuny teaches endoscopic grasping apparatus 10. Cuny 4:55–58. Apparatus 10 includes fixed handle 16, pivotal control handle 18, and jaw elements 46, 48. *Id.* at 4:58–60, 5:41–43. Elongated rod 42 connects pivotal control handle 18, at one end, to elements 46, 48, at the other. *Id.* 5:65–6:6, Fig. 3. When pivotal control handle 18 is pressed toward fixed handle 16, proximal movement of elongated rod 42 causes jaw elements 46, 48 to close. *Id.* 4:55–67, 5:41–6:6, Fig. 2. In addition, apparatus 10 has pivotally mounted trigger 20 which, in turn, includes mating lock member 32. When pivotal control handle 18 is pressed toward fixed handle 16, teeth 36 projecting from member 32 engage mating teeth 30 projecting from arcuate section 26 of pivotal control

handle 18. If the pressure on the pivotal control handle 16 is released, engagement between teeth 30, 36 locks handles 16, 18 in position until trigger 20 is pressed. *Id.* at 4:61–63, 5:5–24, 6:7–26, Fig. 2.

The Examiner reasons it would have been obvious to provide Lau’s device with a ratcheting mechanism as taught by Cuny “to position the forceps jaws at incremental locations to better position the jaws on tissue.” Final Act. 4 (citing Cuny 1:20–36). The Examiner further reasons having a ratchet for incremental jaw positions “would help to better position the jaws on tissue, by applying consistent pressure on the tissue without having to have the user manually apply the same pressure and fatiguing the hand.” Ans. 4; *see also* Cuny 1:29–36.

Appellant argues one of ordinary skill in the art would not have had reason to add a ratcheting mechanism to Lau’s device because Lau’s device is designed to weld and separate a vessel grasped between its jaw elements. Br. 12. According to Appellant, a surgeon using the device would have no need to lock the device and free his or her hands for other tasks, as described in Cuny. *Id.*; *see also* Cuny 1:29–44, 3:45–52.

“[I]f a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill.” *KSR*, 550 U.S. at 417. Locking mechanisms, such as a ratchet, are known to provide the benefit of holding jaw members in place. Cuny 1:37–41. Given Lau’s device requires a user to outstretch his or her thumb and apply pressure to lever 44 through frictional engagement between the thumb and thumb pad 144 to manipulate the jaw members (Lau ¶ 100, Fig. 1C), Lau’s device would have been

improved by the addition of a ratcheting mechanism to hold the jaw members in place. Ans. 4.

Appellant also argues Cuny's device is "bulky and unwieldy in the context of constructing the kind of compact instrument necessary for the application intended by Lau." Br. 12. As set forth above, however, bodily incorporation is not the standard for obviousness. *In re Keller*, 642 F.2d at 425. Moreover, the Examiner correctly finds that Cuny's ratcheting mechanism is designed to be positioned on the handle, and, as such, is not subject to the size constraints applicable to those structures that must enter the patient to weld and separate vessels. Ans. 4. For these reasons, Appellant does not apprise us of error in the Examiner's reason for the combining the teachings Lau and Cuny.

The Examiner further acknowledges Lau fails to describe "a ratcheting mechanism on said lever which applies variable incremental pressure within a range of 100 mN/mm² – 500 mN/mm² to the jaw member," as recited in independent claim 1, and turns to Edwards. Final Act. 3–4. Edwards describes a bipolar forceps device including jaw elements 13, 14 for grasping and holding tissue 32 during cutting and sealing operations. Edwards ¶¶ 24, 25. Edwards teaches that jaw elements 13, 14 should maintain a gripping force between 0.5 MPa and 1.0 MPa during a sealing operation. *Id.* ¶¶ 12, 30. The Examiner finds the range 0.5 MPa to 1.0 MPa corresponds to the range 500 mN/mm² to 1.0 N/mm², which touches the recited range of 100 mN/mm² to 500 mN/mm². Final Act. 4. The Examiner reasons it would have been obvious to modify the ratcheting mechanism added to Lau's device to "appl[y] variable incremental pressure within a range of 100 mN/mm² – 500 mN/mm² to the jaw member," as

recited in independent claim 1, because discovering optimal or workable ranges would have involved only routine skill in the art. *Id.* (citing *In re Aller*, 220 F.2d 454, 456 (CCPA 1955)).

Appellant argues:

substituting the spring-biased jaw members of Edwards into the heavily and arbitrarily modified Lau system would have led one skilled in the art to adopt the anvil and spring-biased support member 24 of Edwards, rather than the ratcheting system of Cuny, absent reference to Appellant's disclosure, since Cuny's ratcheting mechanism is concerned with locking the jaws in position to free up the surgeon's hands, rather than to apply a specified pressure to the tissue during a heating and cutting operation.

Br. 13. The Examiner, however, is not proposing to add Edwards's spring-biased jaw members to Lau. Rather, the Examiner relies on Edwards's teachings regarding the gripping force to be applied to tissue during welding or sealing operations as evidence that the range of gripping pressures recited in independent claim 1 would have been obvious.

Ans. 5–6. Furthermore, “our case law does not require that a particular combination must be the preferred, or the most desirable, combination described in the prior art in order to provide motivation for the current invention.” *In re Fulton*, 391 F.3d 1195, 1200 (Fed. Cir. 2004).

Finally, the Examiner acknowledges Lau fails to describe “a secondary lumen disposed in one of the jaw elements which receives a guidewire therein,” as recited in independent claim 1, and finds Weaver discloses this limitation. Final Act. 3–4. Weaver describes forceps assembly 10 including forceps 14 mounted on thin, flexible guide wire 12 for easy and rapid movement through a patient's vasculature.

Weaver 3:25–31, 5:37–44, Fig. 1. Forceps 14 includes jaw elements 20, 22.

Id. at 3:32–45, Figs. 1–2. Jaw element 20 defines longitudinally-extending lumen 28 for mounting jaw element 20 on guidewire 12. *Id.* at 3:46–51, Fig. 2. The Examiner reasons it would have been obvious to modify one of Lau’s jaw elements 40, 42 so as to have a secondary lumen to “help the forceps to access a target area within tissue with the help of [the] guidewire.” Final Act. 4–5.

Appellant argues that the reason articulated by the Examiner would not have motivated one of ordinary skill in the art to modify a welding and separating device such as Lau’s because Weaver applies the teaching to a forceps assembly. Br. 13. The argument is not persuasive of error. As the Examiner correctly explains, Weaver’s forceps assembly, like Lau’s welding and separating device, clamps tissue between relatively pivotable jaw elements. Ans. 5. The reason the Examiner articulates as to why the addition of a secondary lumen would have been obvious applies equally to a forceps assembly, such as that taught by Weaver, and a welding and separating device, such as Lau’s.

In view of the foregoing, Appellant does not apprise us of error in the Examiner’s rejection of independent claim 1. We, therefore, sustain the rejection of independent claim 1, with claims 4, 7, 8, and 14 falling therewith.

Rejections II–V

For claims 2, 3, 6, 9, 13, and 21, Appellant relies on the arguments for independent claim 1. Br. 14–16. For the reasons discussed above, these arguments do not apprise us of error, and we similarly sustain the rejections of claims 2, 3, 6, 9, 13, and 21.

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DECISION

The Examiner's decision to reject claims 1–4, 6–9, 13, 14, and 21 is affirmed.

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).

AFFIRMED