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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte ROBERT GORDON McRAE, MICHAEL S. MIRIZZI,
BRADY D. ESCH, ANNA GRACE PRESTEZOG,
TODD SCHOENBERGER, HALIL IBRAHIM KARABEY, and
JEFF ZALEWSKI

Appeal 2011-001198
Application 11/472,793
Technology Center 3700

Before KEN B. BARRETT, MICHELLE R. OSINSKI, and
BRADFORD E. KILE, *Administrative Patent Judges*.

OSINSKI, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Appellants¹ appeal under 35 U.S.C. § 134(a) from a final rejection of claims 1-5, 7-13, 15-20, and 30-41 under 35 U.S.C. § 103(a) as unpatentable over Edwards (US 2002/0183740 A1, pub. Dec. 5, 2002) and Balbierz (US 6,770,070 B1, iss. Aug. 3, 2004). Ans. 3-5. Claims 6, 14, and 21-29 are cancelled. App. Br. 5. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM-IN-PART.

CLAIMED SUBJECT MATTER

The claimed subject matter relates to “a method and apparatus for delivering tumescent fluids to body tissue.” Spec., para. [0002]. Claims 1, 15, and 30 are the independent claims on appeal. Claim 1 is illustrative of the claimed subject matter and is reproduced below:

1. A catheter for treating a hollow anatomical structure (HAS), said catheter comprising:
 - one or more shafts which extend away from a proximal end of said catheter toward a distal end thereof, a first shaft of said one or more shafts defining a central axis of said catheter and having an atraumatic tip on a distal end thereof to minimize injury as the catheter is advanced within an HAS;
 - an HAS constriction energy source located on said first shaft at or near said distal end of said first shaft and configured to apply energy to a wall of said HAS; and
 - a transmural fluid delivery channel separate from said HAS constriction energy source and comprising a second shaft of said one or more

¹ Appellants identify the real party in interest as Tyco Healthcare Group LP. App. Br. 3.

shafts, said second shaft being radially expandable from said central axis;

wherein a distal end of said transmural fluid delivery channel has a first position near said first shaft and said central axis and a second position radially expanded from said first shaft and said central axis, the second position allowing fluid to be injected into tissue outside of and surrounding said wall of said HAS.

ANALYSIS

Claims 1, 15, and 30

Only issues and findings of fact contested by Appellants in the Briefs will be addressed. *See Ex parte Frye*, 94 USPQ2d 1072, 1075-76 (BPAI 2010) (precedential). Appellants argue claims 1, 15, and 30 as a group. App. Br. 16-30. We select independent claim 1 as the representative claim. *See* 37 C.F.R. § 41.37(c)(1)(vii) (2011).

The Examiner found that Edwards teaches all of the limitations of claim 1 except for “directly disclos[ing] a constriction energy source located at the distal end of the first shaft” of the catheter. Ans. 3. The Examiner found that Balbierz “teaches an atraumatic tip on the distal end of a catheter comprising a constriction energy source.” *Id.* at 3-4 (citing Balbierz, figs. 9B, 9C). The Examiner concluded:

[I]t would have been obvious to a person having ordinary skill in the art at the time the invention was made to have modified the device of Edwards (the hollow space or bubble 222) with the electrode as taught by Balbierz 9B, 9C since the location and use of electrodes is very well known in the art and given an available space, a person with ordinary skill may choose to add an electrode to this area.

Id. at 4.

Appellants first contend that neither Edwards nor Balbierz teaches a first shaft having an atraumatic tip on a distal end thereof. App. Br. 17-20. In particular, Appellants contend that Edwards teaches a catheter 14 having a sharp tipped electrode 38 which is positioned near the treatment site of the prostate 6” (*Id.* at 17) and that Balbierz’s electrode probes “similarly have sharp tips on their distal ends.” (*Id.* at 18). Appellants contend that while Balbierz’s electrodes may take various shapes and geometries, including ball and hemispherical (*Id.* at 19 (citing Balbierz, 13:47-51, figs. 9A-H)), “Balbierz fails to provide any further description or discussion of the ‘ball’ and ‘hemispherical’ electrodes . . . and none of the electrodes depicted with the rest of the device are atraumatic” (*Id.* at 19 (citing Balbierz, figs. 2, 9A, 9E-H, 10-12, 14A, 16-18, 20, 21, and 24)).

The Examiner specifically found that Edwards teaches an atraumatic tip 198 (described as a “tapered tip portion” in paragraph [0102] and illustrated as such in Figure 14) on a distal end of shaft 196 (*Id.* at 3) and that at least Figures 9B-9C of Balbierz teach an atraumatic tip on a distal end of a catheter. *Id.* at 3-4 (citing Balbierz, figs. 9B-9C). Appellants have not provided persuasive reasoning or evidence as to why these particular findings of the Examiner are incorrect.

Appellants secondly contend that neither Edwards nor Balbierz teaches transmural fluid delivery channels having a position allowing fluid to be injected into tissue outside of and surrounding targeted tissue (*i.e.*, “outside of and surrounding said wall of said HAS” as set forth in claim 1). The Examiner found that Edwards teaches second shafts 188 (stylets) to provide transmural fluid delivery into tissue outside of and surrounding the wall of the HAS. Ans. 6 (citing Edwards, paras. [0017], [0071] and figs. 14,

4). Appellants' contentions with respect to Edwards are not persuasive because Appellants do not provide any particular reasoning or evidence as to Edwards' purported failure to teach transmural fluid delivery channels. App. Br. 20. Appellants' additional contention that Balbierz does not teach or suggest fluid channels to deliver fluid to tissue outside the targeted tissue (App. Br. 20-21) "is not persuasive because Edwards was used for this limitation" as pointed out by the Examiner. Ans. 6.²

Appellants additionally contend that the Examiner's proposed combination of Edwards and Balbierz is improper because (i) Edwards teaches away from using an electrode device within the urethra (App. Br. 22); (ii) the proposed combination does not take into account "the frustration of purpose of Edwards that would result from the combination" (*Id.* at 24); (iii) replacement of a hollow space, bubble or ultrasound transponder at the end of Edwards' stylet guide with Balbierz's electrode would "be contrary to the purpose of Edwards" as it "would increase *imprecision*" (Reply Br. 9); and (iv) the proposed combination is based on hindsight (App. Br. 29; *see also* Reply Br. 9-11). In particular, Appellants contend that the "use of an electrode device on the stylet guide of Edwards would indiscriminately destroy healthy cells in the urethra and cause the loss of some function of the prostate, which are problems Edwards cites with the prior art devices." *Id.*

² We also do not find persuasive Appellants' statements merely pointing out claim language without identifying what gaps, if any, exist between the Examiner's findings and the claim limitations. App. Br. 16-17; *See In re Lovin*, 652 F.3d 1349, 1357 (Fed. Cir. 2011) ("[T]he Board reasonably interpreted Rule 41.37 to require more substantive arguments in an appeal brief than a mere recitation of the claim elements and a naked assertion that the corresponding elements were not found in the prior art.").

at 23 (citing Edwards, para. [0009]). Appellants further contend that “there is no reason given as to why one of skill in the art would modify the delivery device to replace the hollow space, bubble, or ultrasound transponder with an electrode and convert it into a treatment device.” *Id.*

We do not find Appellants’ arguments to be persuasive. Edwards discloses that radiofrequency electrodes carried by catheters were known and used in the art for the treatment of prostate tissue in spite of Edwards’ acknowledgment of the potential destruction of healthy cells. Edwards, para. [0009]; *see also* Ans. 4 (“the location and use of electrodes is very well known in the art.”). Using an electrode on a catheter continued to be available for application of energy to targeted tissue with energy, just as Edwards taught, notwithstanding the added availability of Edwards’ apparatus for penetrating tissue for more targeted tissue destruction. *See In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994) (“A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use.”).

One of ordinary skill in the art could have predictably utilized Balbierz’s electrode tips with Edwards’ device for the application of energy to destroy prostate tissue, such that the Examiner’s reason for making the proposed combination of prior art teachings has rational underpinnings. *See KSR Int’l Co. v. Teleflex, Inc.*, 550 U.S. 398, 416 (2007) (“The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.”). While tradeoffs may be required in balancing the benefits of an electrode tip for energy application with a tip for reflecting ultrasound, such tradeoffs do not appear to be outside the level of ordinary skill. *Winner Int’l Royalty Corp. v. Wang*,

202 F.3d 1340, 1349 n. 8 (Fed. Cir. 2000) (“The fact that the motivating benefit comes at the expense of another benefit, however, should not nullify its use as a basis to modify the disclosure of one reference with the teachings of another. Instead, the benefits, both lost and gained, should be weighed against one another.”). For the foregoing reasons, we find that the Examiner did not err in concluding that the subject matter of independent claim 1 would have been obvious from the combination of Edwards and Balbierz, and we sustain the rejection of claims 1, 15, and 30 under 35 U.S.C. § 103(a).

Claims 2, 4, 5, 8-10, 16-18, 31, 33, 34, 35, 40, and 41

Claims 2, 4, 5, 8-10, 16-18, 31, 33, 34, 35, 40, and 41 depend directly or indirectly from independent claims 1, 15, or 30. Appellants’ arguments in support of the patentability of these claims solely relate to their dependency on claims 1, 15, or 30. App. Br. 30. Since we have found no deficiencies in the combination of Edwards and Balbierz with respect to claims 1, 15, and 30, we find that the Examiner did not err in concluding that the subject matter of claims 2, 4, 5, 8-10, 16-18, 31, 33, 34, 35, and 40 would have been obvious from the combination of Edwards and Balbierz, and we sustain the rejection of these claims under § 103(a).

Claims 3, 36, and 37

Claim 3 recites that the constriction energy source comprises “a resistive coil,” and claim 36 recites that the energy source is “a heating coil.” The Examiner found that a “resistive heating source [at column 14, line 30 of Balbierz] inherently comprises a resistive coil.” Ans. 4. Appellants contend that “there are many different types of resistive heating elements,

none of which are specified in *Balbierz*.” App. Br. 30; *see also Id.* at 31 (citing *Cont’l Can Co. USA v. Monsato Co.*, 948 F.2d 1264, 1268 (Fed. Cir. 1991).

The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *See In re Rijckaert*, 9 F.3d 1531 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art). “To establish inherency, the extrinsic evidence ‘must make clear that the missing descriptive matter is necessarily present in the thing described in the reference.’” *See In re Robertson*, 169 F.3d 743 (Fed. Cir. 1999) (citation omitted)). The Examiner has not pointed to any express language in *Balbierz* nor articulated sufficient facts and/or technical reasoning to support that the resistive heating source coupled to a conductive wire in *Balbierz* necessarily comprises a *coil*. Accordingly, we do not sustain the rejection of claims 3, 36, and 37 (which depends from claim 36) under 35 U.S.C. § 103(a) as unpatentable over Edwards and *Balbierz*.

Claims 7 and 13

Claim 7 recites that the “first and second shafts are coaxial.” Claim 13 recites substantially similar language as claim 7. The Examiner found that “[t]he first and second shafts [196, 188 (straight section)] were coaxial for at least some point as shown in Fig. 14 of Edwards.” Ans. 6. Appellants contend that at most Figure 14 of Edwards shows a device with three shafts, “each of which has a different axis and where none of the ax[e]s are aligned in a coaxial manner.” App. Br. 31. While the first shaft 196 and the straight

section of second shaft 188 are illustrated as having parallel axes for a portion of the length of catheter probe 186, the Examiner has not articulated sufficient facts and/or technical reasoning to support that the first shaft 196 and the straight section of second shaft 188 share a common axis, *i.e.*, are coaxial. Accordingly, we do not sustain the rejection of claims 7 and 13 under 35 U.S.C. § 103(a) as unpatentable over Edwards and Balbierz.

Claims 11 and 19

Claims 11 and 19 recite that the “fluid delivery channel comprises at least one perforating jet.” The Examiner found that the central fluid supply lumen of Edwards as modified with Balbierz’s jets 23 “could be at various pressures and with the combination, the jets 23 of Balbi[er]z would discharge the fluid at such a high pressure as to perforate the walls to allow for several locations of fluid delivery rather than just through the needle end as shown in Edwards Fig. 4.” Ans. 7. Appellants contend that “[t]here is no indication that the ports or aperture openings [23] in Balbierz are perforating jets.” App. Br. 32 (quoting Balbierz, col. 15, ll. 18-19). Appellants contend in particular that perforating jets would “likely [and undesirably] inflict damage on the lung tissue that could not easily be sealed by Balbierz’s electrode device.” *Id.* (citing Balbierz, col. 3, ll. 1-6, 58-65).

We do not find Appellants’ arguments relating to Balbierz to be convincing since the Examiner’s rejection is based on the modification of Edwards’ device with Balbierz’s ports/apertures, coupled with an increase in the pressure of the fluid supply. Ans. 7. Edwards specifically contemplates “penetrat[ion] [of] body tissues for medical purposes such as . . . fluid substance delivery” (Edwards, para. [0002]), and the Examiner’s articulated

reasoning to arrive at the claimed subject matter has a rational underpinning. *See KSR*, 550 U.S. at 418.

For the foregoing reasons, we find that the Examiner did not err in concluding that the subject matter of claims 11 and 19 would have been obvious from the combination of Edwards and Balbierz, and we sustain the rejection of claims 11 and 19 under 35 U.S.C. § 103(a).

Claims 12, 20, 38, and 39

Claims 12 and 20 recite the catheter “further comprising a source of *tumescent* fluid which is in fluid communication with said fluid delivery channel.” (Emphasis added.) Claims 38 and 39 recite the catheter “further comprising a pressurized source of *tumescent* fluid that is in fluid communication with said fluid delivery channel.” (Emphasis added.) The Examiner found that Edwards teaches a fluid delivery port in communication with a source of tumescent fluid. Ans. 4 (citing Edwards, para. [0017]). Appellants contend that mere reference to a “treatment fluid supply lumen” in paragraph [0017] of Edwards “does not teach or suggest ‘a source of tumescent fluid.’” App. Br. 33-34.

The Examiner’s rejection does not map the claim elements of “a source of tumescent fluid” and “a pressurized source of tumescent fluid” to corresponding elements in the references or provide reasoning with rational underpinning to show how the references would have led one of ordinary skill in the art to the claimed subject matter involving tumescent fluid. Accordingly, we do not sustain the rejection of claims 12, 20, 38, and 39 under 35 U.S.C. § 103(a) as unpatentable over Edwards and Balbierz.

Claim 32

Claim 32 recites that the “fluid delivery channel extends through said energy source.” The Examiner found that Balbierz teaches “fluid delivery channels 23 [that] extend through the energy source 18 of Balbierz.” Ans. 5 (citing Balbierz, fig. 20); *see also* Final Rej., mailed Oct. 20, 2009, at 4. Appellants contend only that “a prima facie case of obviousness has not been established” because “the teachings of the claim[] [32] are never addressed.” App. Br. 33. Appellants have not provided persuasive reasoning or evidence as to why the particular finding of the Examiner is incorrect. For the foregoing reasons, we find that the Examiner did not err in concluding that the subject matter of claim 32 would have been obvious from the combination of Edwards and Balbierz, and we sustain the rejection of claim 32 under 35 U.S.C. § 103(a).

DECISION

The Examiner’s rejection of claims 1, 2, 4, 5, 8-12, 15-20, 30-35, 40, and 41 under 35 U.S.C. § 103(a) is AFFIRMED.

The Examiner’s rejection of claims 3, 7, 12, 13, 20, 36, and 37-39 under 35 U.S.C. § 103(a) is REVERSED.

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

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