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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/791,368	03/08/2013	Grayson Morris	050623.01596	1615
45159	7590	10/31/2016	EXAMINER	
SQUIRE PB (Abbott) 275 BATTERY STREET, SUITE 2600 SAN FRANCISCO, CA 94111-3356			EDWARDS, LAURA ESTELE	
			ART UNIT	PAPER NUMBER
			1717	
			NOTIFICATION DATE	DELIVERY MODE
			10/31/2016	ELECTRONIC

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte ADVANCED CARDIOVASCULAR SYSTEMS, INC.

Appeal 2015-004380
Application 13/791,368
Technology Center 1700

Before LINDA M. GAUDETTE, MICHELLE N. ANKENBRAND, and
CHRISTOPHER L. OGDEN, *Administrative Patent Judges*.

GAUDETTE, *Administrative Patent Judge*.

DECISION ON APPEAL

Appellant¹ appeals under 35 U.S.C. § 134(a) from the Examiner's decision² finally rejecting claims 1, 3–11, and 13 under pre-AIA 35 U.S.C. § 103(a) as unpatentable over Leidner et al. (US 6,056,993, issued May 2, 2000 (“Leidner”)) in view of McBride-Sakal (US 2003/0109837 A1, published June 12, 2003 (“McBride”)). We have jurisdiction under 35 U.S.C. § 6(b).

We REVERSE.

The invention relates to a stent coating apparatus that utilizes a brush assembly for applying a coating to an abluminal (outer) stent surface. Specification filed Mar. 8, 2013 (“Spec.”), 1 (Technical Field). Coatings applied to stents include polymeric carriers impregnated with a drug or a therapeutic substance. *Id.* at 2. According to the Specification, in known apparatuses used for coating stents, the coatings are applied via dipping or spraying the coating onto the stent. *Id.* A major drawback of known stent coating techniques is that the coating is applied to both inner and outer surfaces of the stent. *Id.* The coating on the luminal (inner) stent surface can have a detrimental impact on the stent's deliverability and the coating's mechanical integrity. *See id.* at 2–3. “Moreover,

¹ Appellant identifies the real party in interest as Abbott Cardiovascular Systems, Inc. Appeal Brief filed November 12, 2014 (“App. Br.”), 1.

² Examiner's Answer mailed December 26, 2014 (“Ans.”), 2 (restating the rejection to take into account Appellant's amendments after final). *See also* Final Office Action mailed Mar. 11, 2014 (“Final Act.”); Advisory Action mailed May 28, 2014 (stating that the obviousness-type double patenting rejection is overcome by Appellant's filing of a terminal disclaimer on May 12, 2014); Advisory Action mailed June 25, 2014 (entering Appellant's June 11, 2014 after-final amendment cancelling claim 2 and amending claim 1 to include the limitations of cancelled claim 2); Advisory Action mailed December 2, 2014 (entering Appellant's November 11, 2014 after-final amendment to correct the claim dependencies and cancel claim 12, and withdrawing the rejection under 35 U.S.C. § 112, second paragraph).

from a therapeutic standpoint, the therapeutic agents on an inner surface of the stent get washed away by the blood flow and typically can provide for an insignificant therapeutic effect.” *Id.* at 2. The inventive stent coating apparatus is said to overcome the drawbacks associated with the prior art coating apparatuses by utilizing a brush assembly to dispense the coating, thereby enabling selective coating of stent surfaces and minimizing the formation of defects. *Id.* at 3.

Claim 1, the sole independent claim on appeal, is reproduced below:

1. A stent coating apparatus comprising:
 - a brush assembly including a plurality of fibers;
 - a stent support configured to carry a stent at a position in which the stent is in contact with the plurality of fibers; and
 - a dispensing mechanism configured to dispense a coating composition to the plurality of fibers, wherein the dispensing mechanism includes a hollow dispensing needle configured to dispense the coating composition to the plurality of fibers.

Reply Brief filed Feb. 26, 2016 (“Reply Br.”) (Claims Appendix).³

The Examiner makes the following findings in support of the rejection of claims 1, 3–11, and 13:

Leidner discloses a stent coating apparatus that includes a hollow needle dispensing tip (38/39) configured to dispense a coating material. Ans. 2 (citing Leidner 6:28–39, 62–64). “Leidner discloses that a contact type applicator, [fiber/bristle] brush assembly, can be used in the apparatus to apply coating material.” *Id.* (citing Leidner 14:42–47). Leidner does not disclose explicitly the use of the hollow needle to dispense/supply fluid to the fibers/bristles of the brush assembly. *Id.* at 3. McBride discloses an apparatus comprising a brush assembly

³ Appellant submitted a new Claims Appendix with the Reply Brief, noting the Claims Appendix to the Appeal Brief contained a typographical error. Reply Br. 2.

mounted to the end of a hollow shaft through which a coating material (i.e., a cleaning material or medication) is supplied for application to a stent. *Id.* (citing McBride ¶¶ 33–35, 46–48).

Based on the above findings, the Examiner concludes that at the time of Appellant’s invention, “[i]t would have been obvious to one of ordinary skill in the art to provide a brush assembly as taught by McBride in fluid communication with the needle tip [outlet] of the Leidner coating applicator in order to effect an [internal] fluid supplied contact type applicator in brush form.” *Id.*

Appellant argues the Examiner’s findings are not supported by the evidence and are insufficient to provide a reason why one of ordinary skill in the art would have included a brush assembly on Leidner’s needle dispensing tip. *See* App. Br. 5–8. Appellant notes that Leidner’s needle and Leidner’s brush assembly are used for two entirely different purposes. Reply Br. 5; *see also* App. Br. 5–6. Specifically, Leidner describes the brush as one several alternative means of coating a mandrel with a water soluble coating that facilitates removal of a subsequently formed prosthesis. Reply Br. 5 (citing Leidner 14:42–47); *see also* App. Br. 5. Leidner describes the needle as being used to deposit fibrous material on the mandrel when forming a tubular prosthesis (e.g., a stent). Reply Br. 4 (citing Leidner 5:24–29, 60–62; 6:1–4, 25–32); *see also* App. Br. 5–6. Appellant disagrees with the Examiner’s finding that McBride discloses an apparatus that can be used to apply a coating material. App. Br. 6. Appellant argues McBride describes an apparatus having a brush that is used solely on an implanted stent for removal of biofilm or other occluding material. *Id.* Appellant acknowledges that during use of the apparatus, McBride describes pumping an irrigation solution containing an antibiotic to the brush to facilitate the cleaning operation, but argue there is no description of using the brush to apply a coating of the antibiotic or the

cleaning materials. *Id.*; *see also* Reply Br. 4. Appellant thus maintains neither Leidner nor McBride provides an apparent reason to modify Leidner's apparatus to use a combination of a needle and a brush. *Id.* at 8.

In response to Appellant's arguments, the Examiner asserts that "[i]n light of all the teachings of both Leidner and McBride, one skilled in the art would find it convenient and useful to fluid supply a brush assembly to apply coating material including medicine or antibiotic to surface(s) of the stent." Ans. 6–7. We are persuaded by Appellant's arguments in the Appeal and Reply Briefs, however, that the evidence on the record before us does not support the Examiner's finding that one of ordinary skill in the art would have had a reason to include a brush assembly on Leidner's needle dispensing tip.

In sum, Appellant has argued persuasively that the Examiner relies on improper hindsight reconstruction to supply a reason or suggestion for modifying Leidner's apparatus to achieve an apparatus as recited in the claims. Accordingly, the Examiner's decision to reject claims 1, 3–11, and 13 is:

REVERSED