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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte BRUNO SCHELLER and ULRICH SPECK

Appeal 2018-004242
Application 12/675,394¹
Technology Center 3700

Before PHILIP J. HOFFMANN, CYNTHIA L. MURPHY, and
ROBERT J. SILVERMAN, *Administrative Patent Judges*.

HOFFMANN, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Pursuant to 35 U.S.C. § 134(a), Appellants appeal from the Examiner's rejection of claims 20, 21, 23, 24, 26, 27, 33, 40–47, and 50–52. We have jurisdiction under 35 U.S.C. § 6(b).

We REVERSE.

¹ According to Appellants, “[t]he real party in interest . . . is Invatec Technology Center GMBH, the assignee of record, and by way of acquisition, Medtronic, Inc. and Medtronic plc . . ., the ultimate parent entity of Medtronic, Inc.” Appeal Br. 2.

According to Appellants, the “invention concerns a balloon catheter coated with at least one active substance including a distally assembled catheter balloon and an expandable protection against expansion which surrounds this[,] where the catheter balloon is on the one hand protected against premature unfolding . . .[,] and on the other hand . . . can refold itself better after dilatation has taken place.” Spec. 1. Claims 20 and 33 are the independent claims on appeal. Below, we reproduce claim 20 as illustrative of the appealed claims.

20. A balloon catheter comprising:

a catheter shaft;

a protective tube on the catheter shaft, wherein the protective tube comprises a distal end and a proximal end;

a self expanding stent located inside the protective tube;

a catheter balloon located inside the protective tube;

at least one active substance located between the catheter balloon and the protective tube;

a seal located in the protective tube proximate the distal end of the protective tube and between the protective tube and the catheter shaft, wherein the seal prevents penetration of bodily fluids between the protective tube and the catheter shaft, and wherein the seal comprises a pharmaceutical and physiologically inactive substance in solid form that is soluble in blood, wherein the seal is configured to dissolve such that blood can penetrate into the protective tube within five minutes of placement of the seal and the protective tube in blood;

the protective tube compresses the self expanding stent to protect against premature expansion of the self expanding stent and against premature loss of the at least one active substance.

REJECTIONS AND PRIOR ART

The Examiner rejects the claims as follows:

- I. Claims 20, 21, 23, 24, 26, 27, 33, 42, 44–47, and 50 under 35 U.S.C. § 103(a) as unpatentable based on Andreas (US 2004/0215312 A1, pub. Oct. 28, 2004), Stinson (US 7,004,962 B2, iss. Feb. 28, 2006), and Thompson (US 2002/0111601 A1, pub. Aug. 15, 2002);
- II. Claims 40 and 51 under 35 U.S.C. § 103(a) as unpatentable based on Andreas, Stinson, Thompson, and Lubock et al. (US 2003/0233101 A1, pub. Dec. 18, 2003) (hereinafter “Lubock”); and
- III. Claims 41, 43, and 52 under 35 U.S.C. § 103(a) as unpatentable based on Andreas, Stinson, Thompson, and McDermott et al. (WO 2007/008829 A2, pub. Jan. 18, 2007) (hereinafter “McDermott”).

ANALYSIS

Rejection I

In support of the obviousness rejection of independent claim 20, the Examiner finds that Andreas discloses most of the claim’s recitations, and further finds that although “Andreas discloses . . . a distal tip [(nosecone 28)] that forms a seal with the protective tube,” Andreas “does not disclose that the tip can be blood soluble.” Answer 3. Nonetheless, the Examiner finds that “Stinson teaches a similar system . . . , where . . . the distal tip . . . comprise[s] a blood soluble material” (*id.*), and that

it [would have been] obvious to modify the distal tip of Andreas to be dissolvable as suggested by Stinson, since such a modification allows the distal tip to degrade to a smaller size

after placement which allows the distal tip to be withdrawn through the deployable device for removal of the system (*id.* at 3–4).

Appellants argue that the Examiner errs, because there is no reason to replace Andreas’s nosecone 28 with a blood-soluble tip. Appeal Br. 7–8; *see also* Reply Br. 2–4. Based on our review, we determine that the Examiner does not provide an articulated reasoning with a rational underpinning adequate to establish that it would have been obvious to replace Andreas’s nosecone 28 with a blood-soluble tip. *See KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007). In particular, we agree with Appellants that there is no indication whether or not Andreas provides, in part with nosecone 28, “a seal to prevent penetration of bodily fluids between the sheath . . . and the shaft,” and it is not clear what might result from allowing bodily fluids from entering this space between the sheath and shaft, which presumably would occur after the blood-soluble tip dissolves. Appeal Br. 8. As Appellants further point out, in Andreas, “a distal end of the balloon member 70 is ‘bonded to an annular stop 78, which is mounted to nosecone 28.’” *Id.* (citing Andreas ¶ 51). It is not at all clear to us what may occur to multiple components of Andreas’s device, including annular stop 78 and balloon member 70, when the blood-soluble top that is used in place of Andreas’s nosecone 28 dissolves.

Thus, based on the foregoing, we do not sustain the Examiner’s rejection of independent claim 20. We also do not sustain the Examiner’s rejection of independent claim 33, which the Examiner rejects for similar reasons as claim 20. Further, we do not sustain the Examiner’s rejection of claims 21, 23, 24, 26, 27, 42, 44–47, and 50 that depend from the independent claims.

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Rejections II and III

Claims 40–43, 51, and 52 depend from independent claims 20 and 33. The Examiner does not rely on either McDermott or Lubock to remedy the above-discussed deficiency in the independent claims’ rejection. Thus, we do not sustain the rejections of claims 40–43, 51, and 52.

DECISION

We REVERSE the Examiner’s obviousness rejections of claims 20, 21, 23, 24, 26, 27, 33, 40–47, and 50–52.

REVERSED