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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/185,831	02/20/2014	Siddarth K. Shevgoor	P-10098/A	7564

71562 7590 10/18/2019

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FISHER, MELISSA L	

ART UNIT	PAPER NUMBER
1611	

NOTIFICATION DATE	DELIVERY MODE
10/18/2019	ELECTRONIC

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte SIDDARTH K. SHEVGOOR, JONATHAN KARL BURKHOLZ, HUIBIN LIU, YIPING MA, and MING ZHOU

Appeal 2018-009123
Application 14/185,831
Technology Center 1600

Before DONALD E. ADAMS, RICHARD M. LEBOVITZ, and JOHN E. SCHNEIDER, *Administrative Patent Judges*.

ADAMS, *Administrative Patent Judge*.

DECISION ON APPEAL

Pursuant to 35 U.S.C. § 134(a), Appellant[1] appeals from Examiner's decision to reject claims 1–6, 9–16, and 21–26. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM-IN-PART, however, because our rationale differs from Examiner's, we designate the affirmance a new ground of rejection under 37 C.F.R. § 41.50(b).

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[1] We use the word "Appellant" to refer to "applicant" as defined in 37 C.F.R. § 1.42. Appellant identifies the real party in interest as Becton Dickinson and Company (Appellant's July 17, 2017 Appeal Brief (Appeal Br.) 2).

STATEMENT OF THE CASE

Appellant's disclosure relates "to inserts for medical devices that are configured to elute an antimicrobial agent." Spec.[2] ¶ 1. Claims 1, 14, and 25 are representative and reproduced below:

> 1. An insert for a medical device, comprising:
>
> a body comprising a distal opening, a proximal opening, and a lumen that extends between the distal and proximal openings, wherein the body is constructed of a base material, wherein the base material comprises
>
> an *antimicrobial agent*, wherein an outer diameter of the body is larger than an inner diameter of a lumen of a medical device within which the body will be placed such that the body is *compression fit* within the lumen of the medical device, wherein the body is configured to be entirely disposed within a lumen of the medical device.

(Appeal Br. 14 (emphasis added).)

> 14. A medical device comprising:
>
> a catheter adapter comprising a proximal end, a distal end, and a lumen that extends therebetween;
>
> *an insert disposed entirely within the lumen of the catheter adapter*, wherein the insert comprises a body, wherein the body comprises a distal opening, a proximal opening, and a lumen that extends between the distal and proximal openings, wherein the body is constructed of a base material, wherein the base material comprises [*an antimicrobial agent*[3]]; and

[2] Appellant's February 20, 2014 Specification.

[3] We note that the phrase "an antimicrobial agent," present in Appellant's amendment filed December 12, 2016 was not reproduced in the text of Appellant's claim 14 as reproduced in Appellant's Appeal Brief (*see* Appellant's December 12, 2016 Amendment 4).

> *a septum* disposed within the lumen of the catheter adapter, wherein the insert is disposed adjacent the septum to secure the septum.

(*Id*. at 15 (emphasis added).)

> 25. An insert for a medical device, the insert comprising:
>
> a body comprising a distal opening, a proximal opening, and a lumen that extends between the distal and proximal openings, wherein the body is constructed of a base material, wherein the base material comprises an *antimicrobial agent*, wherein the body is configured in a shape of a tube having an inner diameter and an outer diameter, wherein *the outer diameter of the tube is constant along an entire length of the tube*.

(*Id*. at 16 (emphasis added).)

Grounds of rejection before this Panel for review:

I. Claims 1–3, 5, 6, 9–16, and 21–26 stand rejected under 35 U.S.C. § 102(a)(1) as anticipated by Grandt.[4]

II. Claims 1–6, 9–16, and 21–26 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Grandt and Potter.[5]

III. Claims 1–4 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of co-pending Application 14/606,833.

Anticipation:

ISSUE

Does the preponderance of evidence on this record support Examiner's finding that Grandt teaches Appellant's claimed invention?

[4] Grandt et al., US 2007/0083188 A1, published Apr. 12, 2007.
[5] Potter, US 2008/0194707 A1, published Aug. 14, 2008.

FACTUAL FINDINGS (FF)

FF 1. Grandt discloses a "catheter having a first guidewire tube and a second guidewire tube" (Grandt ¶ 4; *see generally* Final Act.[6] 3–5).

FF 2. Grandt's Figure 1 is reproduced below:

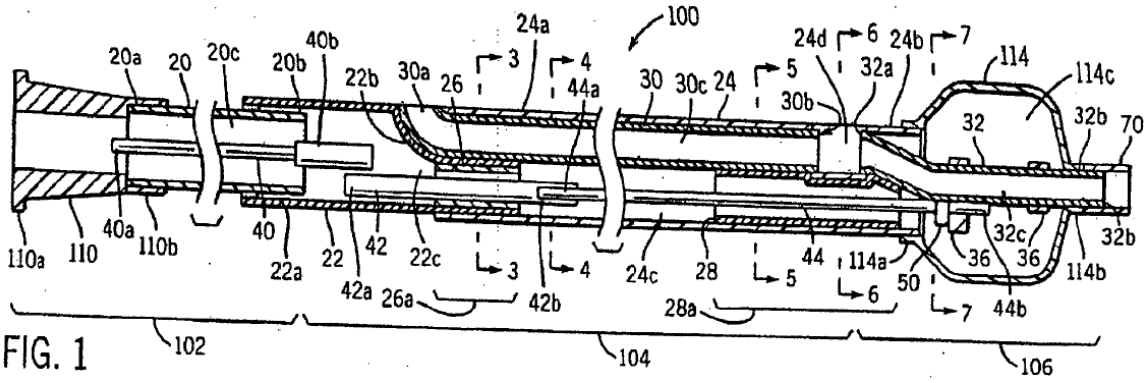

FIG. 1

Grandt's "FIG. 1 is a schematic side view of a first representative embodiment of a catheter [100] having a main body portion including a proximal section [102], intermediate section [104], and distal section [106] in accordance with Grandt's . . . invention" (Grandt ¶ 23; *see also id.* ¶ 69 ("catheter 100 has a main body portion including a proximal section 102, a distal section 106, and an intermediate section 104 disposed between the proximal and distal sections. Each section having a proximal end and a distal end" (emphasis omitted)); *see* Final Act. 3–4).

FF 3. Grandt's "catheter can further include at least two overlapping stiffening members" (Grandt ¶ 67; *see id.* ¶ 140 (Grandt's "catheter 100 can include proximal, intermediate, and distal stiffening members, 40, 42, and 44, respectively" (emphasis omitted)); *id.* ¶ 139 (Grandt's "term 'stiffening member' can include a filament, strand, wire, coil, or other member to

[6] Examiner's May 4, 2017 Final Office Action.

increase the stiffness of a section of the catheter elongate main body"); *see generally* Final Act. 3–5).

FF 4. Grandt discloses that "[a] variety of materials can be used as coatings for the stiffening member," including "antimicrobial agents" (Grandt ¶ 160; *see* Final Act. 3 and 5).

ANALYSIS

Examiner finds that Appellant's claimed invention is anticipated by Grandt (Final Act. 3–5). We are not persuaded.

Each of Appellant's independent claims 1, 14, and 25 requires that the body of the device is constructed of a base material that comprises an antimicrobial agent. We agree with Examiner that the term "'comprising', an open transitional phrase[,] . . . is inclusive or open-ended and does not exclude additional, unrecited elements or method steps" (Ans.[7] 4). We note, however, that even though the claimed base material may include additional ingredients, Appellant's claims require that the base material from which the body is constructed, as opposed to a coating material on the body, contains an antimicrobial agent.

In this regard, Examiner finds that Grandt "discloses antimicrobial agents can be utilized" as a *coating* for its stiffening members (Final Act. 3 (citing Grandt ¶ 160); *see also* FF 4). Although Grandt discloses that an antimicrobial agent may be used as a *coating* for a stiffening member (FF 4), Examiner failed to identify, and we do not find, a disclosure in Grandt of a body which is constructed of base material that comprises an antimicrobial agent (*see generally* Appeal Br. 7, 9, and 11; *see also* Reply Br. 4

[7] Examiner's November 17, 2017 Answer.

("Independent claims 14 and 25 include the same language as claim 1 requiring 'the body is constructed of a base material, wherein the base material comprises an antimicrobial agent,' and thus, Grandt . . . does not appear to teach each and every element of claims 14 and 25 for the same reasons as stated with respect to claim 1")).

In addition, we note that Appellant's claim 13 depends from and further limits the insert of Appellant's claim 1 to further comprise "a reinforcing substructure contained within the base material, the reinforcing substructure comprising a material that is different than the base material" (Appeal Br. 15). Examiner relied upon Grandt's stiffening members to meet the requirement for a reinforcing substructure as set forth in Appellant's claim 13 (*see* Final Act. 5 ("Regarding claim[] 13 . . . Grandt et al. discloses a stiffening member")). Thus, Examiner recognizes that Grandt's stiffening member is distinct from the "body" of Grandt's device and, therefore, any such antimicrobial coating on Grandt's stiffening member cannot also represent a component of the base material of Grandt's body.

CONCLUSION

The preponderance of evidence on this record fails to support Examiner's finding that Grandt teaches Appellant's claimed invention. The rejection of claims 1–3, 5, 6, 9–16, and 21–26 under 35 U.S.C. § 102(a)(1) as being anticipated by Grandt is reversed.

Obviousness:

ISSUE

Does the preponderance of evidence relied upon by Examiner support a conclusion of obviousness?

FACTUAL FINDINGS (FF)

FF 5. Grandt discloses a catheter 100 having first and second guidewire tubes, wherein the main body portion of catheter 100 includes a proximal section 102, intermediate section 104, and distal section 106 (*see* FF 1–2).

FF 6. Grandt's catheter may also include proximal, intermediate, and distal stiffening members coated with an antimicrobial agent (*see* FF 3–4).

FF 7. Grandt's Figure 4B is reproduced below:

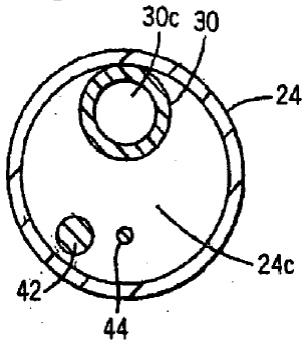

FIG. 4B

Grandt's "FIG. 4B is . . . [a] cross sectional view at line 4-4 of the catheter of FIG. 1 in accordance with . . . [Grandt's] invention," wherein "a portion of catheter 100 in which second guidewire tube 30 is disposed generally coaxially within distal tubular member 24, such that inflation lumen 24c annularly surrounds guidewire tube 30 and guidewire lumen 30c" (Grandt ¶¶ 27 and 123 (emphasis omitted); *see generally* Final Act. 3).

FF 8. Grandt discloses that "distal tubular member 24 . . . includes gap 24d along its length. Gap 24d is in fluid communication with the exterior of catheter 100" and "can be constructed by placing two circumferential slits through the wall of distal tubular member 24 to define a flap region" (Grandt ¶ 100 (emphasis omitted)); *see* Final Act. 5 (citing element 24d of Grant's Fig. 1) (Examiner finds that Grandt "discloses a septum")).

FF 9. Examiner finds that Grandt "does not teach that the antimicrobial agent comprises between 0.1 and 40% w/w of the insert" (Final Act. 6).

FF 10. Potter discloses:

> [A] medical device capable of releasing a medically active ingredient, said device including a blend of: (i) a carrier polymer or a blend of carrier polymers; (ii) a medically active ingredient; and, optionally, (iii) a water sensitive polymer for releasing said medically active ingredient in the presence of water and/or a pH sensitive polymer for releasing said medically active ingredient in the presence of a solution having a pH within a predetermined range; with the proviso that, if component (iii) is absent, the carrier polymer includes an ethylene vinyl alcohol copolymer.

(Potter, Abstract; *see also id.* ¶ 19 (Potter discloses that its "medical device is [preferably] a urinary catheter or urinary drainage bag"); *see generally* Final Act. 6.)

FF 11. Potter discloses that the "medically active ingredient may be a drug, for example a drug to control inflammation or, preferably, an antimicrobial agent" (Potter ¶ 13; *see generally* Final Act. 6).

FF 12. Potter discloses that "the blend typically comprises between about 0.1 and 20%, . . . by weight of the antimicrobial agent" (Potter ¶ 28; *see* Final act. 6).

ANALYSIS

Based on the combination of Grandt and Potter, Examiner concludes that, at the time Appellant's invention was made, it would have been prima facie obvious to prepare a medical device, as disclosed in Grandt, having a body that is constructed of a base material that comprises a blend of ingredients including an antimicrobial agent in the amount of 0.1 and 20% by weight, as set forth in Potter (*see* Final Act. 6–7; FF 5–12).

Appellant contends "that Grandt fails to teach the elements of independent claims 1, 14, and 25 [as Appellant] discussed . . . with respect to the rejection under 35 U.S.C. § 102, and that Potter fails to rectify these deficiencies" (Appeal Br. 12). Appreciating Appellant's separate arguments with respect to Appellant's independent claims 1, 14, and 25, as set forth in the rejection under 35 U.S.C. § 102, we address Appellant's contentions in the context of this obviousness rejection below.

CLAIM 1

As discussed in the above analysis under 35 U.S.C. § 102, Grandt does not teach a device having a body that is constructed of a base material that comprises an antimicrobial agent. Potter, however, makes up for this deficiency by disclosing a device, similar to Grandt's device that has a body constructed of a base material that comprises an antimicrobial agent (*see* FF 10–12). Thus, one of ordinary skill in the art would have had reason to make Grandt's body with a material comprising an antimicrobial agent as described by Potter because Grandt teaches the presence of such agent on the device's body and Potter supplies one. Final Act. 6–7. Therefore, we find that, at the time Appellant's invention was made, it would have been prima facie obvious to prepare a medical device, such as Grandt's catheter using a composition, which comprises an antimicrobial agent as taught by Potter (*see* FF 2–11). Appellant did not provide adequate evidence to the contrary. (*see* Appeal Br. 6–7).

> We recognize that Appellant's claim 1 requires that the
>
> outer diameter of the body is larger than an inner diameter of a lumen of a medical device within which the body will be placed such that the body is compression fit within the lumen of the

> medical device, wherein the body is configured to be entirely disposed within a lumen of the medical device.

(Appeal Br. 14). We agree, however, with Examiner's finding that because "[t]here is no medical device required by the instant claim," this limitation of Appellant's claim 1 is "an intended use of the claimed insert" (Ans. 5). *See Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 809 (Fed. Cir. 2002) ("[T]he patentability of apparatus or composition claims depends on the claimed structure, not on the use or purpose of that structure."); *see also Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1468 (Fed. Cir. 1990) ("[A]pparatus claims cover what a device *is*, not what a device *does*."). Therefore, we are not persuaded by Appellant's contentions regarding a body configured to be compression fit within a lumen of a medical device or a body configured to be entirely disposed within a lumen of a medical device, which, as Examiner's correctly asserts, are intended use limitations of Appellant's claimed insert (*see* Appeal Br. 7–8; *cf.* Ans. 5 (Examiner finds the foregoing limitation to represent an intended use limitation)).

CLAIM 14

The medical device of Appellant's claim 14 comprises, *inter alia*, a septum disposed within the lumen of a catheter adapter, wherein an insert is disposed adjacent to the septum to secure the septum (*see* Appeal Br. 15). To reach this limitation of Appellant's claim 14, Examiner directs attention to Grandt's element 24d (*see* FF 8). Element 24d of Grandt's device, however, represents a "gap" that "is in fluid communication with the exterior of catheter 100" and "can be constructed by placing two circumferential slits through the wall of distal tubular member 24 to define a flap region" (*id.*). Examiner failed to explain how this "gap" can be

interpreted to represent a septum (*see* Final Act. 4–5; *see also* Ans. 6–7). Therefore, we agree with Appellant's contention that "gap 24d appears to allow fluid communication with the exterior of the catheter 100 and does not appear to include a septum" (Appeal Br. 10).

CLAIM 25

As discussed above, the combination of Grandt and Potter makes obvious a device having a body that is constructed of a base material that includes an antimicrobial agent (*see* FF 5–12). Therefore, we are not persuaded by Appellant's contention to the contrary (*see* Appeal Br. 11).

CONCLUSION

The preponderance of evidence relied upon by Examiner supports a conclusion of obviousness with respect to claims 1 and 25. The rejection of claims 1 and 25 under 35 U.S.C. § 103(a) as unpatentable over the combination of Grandt and Potter is affirmed. Claims 2–6, 9–13, 21, 22, and 26 are not separately argued and fall with claims 1 and 25, respectively. We recognize, however, that our rationale for affirming the rejection of claims 1 and 25 differs from Examiners and, therefore, we designate the affirmance a new ground of rejection.

The preponderance of evidence relied upon by Examiner fails to support a conclusion of obviousness with respect to claims 14–16, 23, and 24. The rejection of claims 14–16, 23, and 24 under 35 U.S.C. § 103(a) as unpatentable over the combination of Grandt and Potter is reversed.

Provisional Obviousness-type Double Patenting:

Claims 1–4 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over

the claims of co-pending Application 14/606,833. As Examiner explains, Appellant "has provided no arguments directed to this rejection" (Ans. 9). "If a ground of rejection stated by the examiner is not addressed in appellant's brief, appellant has waived any challenge to that ground of rejection and the Board may summarily sustain it." Manual of Patent Examining Procedure § 1205.02 (Rev. 08.2017, January 2018). This provisional rejection is, therefore, summarily affirmed.

DECISION SUMMARY

In summary:

Claims Rejected	**35 U.S.C. §**	**Reference(s)/Basis**	**Affirmed**	**Reversed**	**New Ground**
1–3, 5, 6, 9–16, 21–26	102(a)(1)	Grandt		1–3, 5, 6, 9–16, 21–26	
1–6, 9–16, 21–26	103	Grandt, Potter	1–6, 9–13, 21, 22, 25, 26	14–16, 23, 24	1–6, 9–13, 21, 22, 25, 26
1–4		Provisional Obviousness-type Double Patenting	1–4		
Overall Outcome			1–6, 9–13, 21, 22, 25, 26	14–16, 23, 24	1–6, 9–13, 21, 22, 25, 26

TIME PERIOD FOR RESPONSE

This decision contains a new ground of rejection pursuant to 37 C.F.R. § 41.50(b) (effective September 13, 2004, 69 Fed. Reg. 49960 (August 12, 2004), 1286 Off. Gaz. Pat. Office 21 (September 7, 2004)). 37 C.F.R. § 41.50(b) provides "[a] new ground of rejection pursuant to this

paragraph shall not be considered final for judicial review."

37 C.F.R. § 41.50(b) also provides that the appellant, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of the appeal as to the rejected claims:

> (1) *Reopen prosecution*. Submit an appropriate amendment of the claims so rejected or new evidence relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the proceeding will be remanded to the examiner. . . .
>
> (2) *Request rehearing*. Request that the proceeding be reheard under § 41.52 by the Board upon the same record. . . .

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED-IN-PART; 37 C.F.R. § 41.50(b)