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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte LAWRENCE J. GERRANS and ERHAN H. GUNDAY

Appeal 2018-007012
Application 14/748,810
Technology Center 3700

Before ANNETTE R. REIMERS, BRANDON J. WARNER, and
BRENT M. DOUGAL, *Administrative Patent Judges*.

WARNER, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Pursuant to 35 U.S.C. § 134(a), Appellant¹ appeals from the Examiner's decision to reject claims 1–23, which are all the pending claims. Appeal Br. 1, 2. We have jurisdiction over the appeal under 35 U.S.C. § 6(b).

We AFFIRM IN PART.

¹ We use the word “Appellant” to refer to the “applicant” as defined in 37 C.F.R. § 1.42. Appellant identifies the real party in interest as Sanovas Intellectual Property, LLC. Appeal Br. 2.

CLAIMED SUBJECT MATTER

Appellant's disclosed invention "relates to methods and systems for delivering therapeutic and/or diagnostic agents to specific cellular locations within and adjacent to bodily tissues and cavities," and more specifically "relates to a method and system of localized delivery of diagnostic and/or therapeutic agents to nasal cavities and tissues via a nested balloon catheter."

Spec. ¶ 1. Claim 1, reproduced below with emphasis added, is the sole independent claim and is representative of the subject matter on appeal.

1. *A method of localized delivery of a therapeutic and/or diagnostic agent to nasal tissue or cavities, comprising the steps of:*

inserting a catheter into a nasal cavity, said catheter comprising

an outer balloon having a wall with at least one opening therethrough and an inner surface; and

an inner balloon at least partially disposed in said outer balloon, said inner balloon at least partially enclosing an inflation chamber and having an outer surface defining a space between the outer surface of said inner balloon and the inner surface of said outer balloon;

supplying the therapeutic and/or diagnostic agent to the space between the outer surface of said inner balloon and the inner surface of said outer balloon via a first lumen of said catheter; and

inflating said inner balloon by supplying fluid to the inflation chamber via a second lumen of said catheter to urge the therapeutic and/or diagnostic agent out of the at least one opening in the wall of said outer balloon and into nasal tissue.

EVIDENCE

The Examiner relies on the following evidence in rejecting the claims on appeal:

Vigil	US 5,336,234	Aug. 9, 1994
Shah	US 2005/0015047 A1	Jan. 20, 2005
Willard	US 2005/0107741 A1	May 19, 2005
Chang	US 2006/0004323 A1	Jan. 5, 2006
Zadno-Azizi	US 2006/0200074 A1	Sept. 7, 2006
Schon	US 2007/0198047 A1	Aug. 23, 2007
Broker	US 2009/0054922 A1	Feb. 26, 2009
Makower	US 2009/0187098 A1	July 23, 2009
Rahimsobhani	US 2009/0240199 A1	Sept. 24, 2009
Boatman	US 2009/0254064 A1	Oct. 8, 2009
Diamant	US 2011/0082483 A1	Apr. 7, 2011
Ogle	US 2011/0218517 A1	Sept. 8, 2011
Thielen	US 2011/0264039 A1	Oct. 27, 2011
Gerrans	US 9,186,485 B2	Nov. 17, 2015

REJECTIONS

The following rejections are before us for review:

- I. Claims 1, 2, 9, 12–14, and 18–22 stand rejected on the basis of obviousness-type double patenting as being unpatentable over claims 34–43 of Gerrans in view of Shah. Final Act. 4–11.
- II. Claims 1, 2, 7, 8, 13, 14, and 18 stand rejected under 35 U.S.C. § 103 as being unpatentable over Boatman and Shah. *Id.* at 12–18.

- III. Claim 3 stands rejected under 35 U.S.C. § 103 as being unpatentable over Boatman, Shah, and Rahimsobhani. *Id.* at 18–19.
- IV. Claims 4–6, and 11 stand rejected under 35 U.S.C. § 103 as being unpatentable over Boatman, Shah, and Chang. *Id.* at 19–22.
- V. Claim 9 stands rejected under 35 U.S.C. § 103 as being unpatentable over Boatman, Shah, and Broker. *Id.* at 22.
- VI. Claims 10 and 19 stand rejected under 35 U.S.C. § 103 as being unpatentable over Boatman, Shah, and Makower. *Id.* at 22–24.
- VII. Claim 12 stands rejected under 35 U.S.C. § 103 as being unpatentable over Boatman, Shah, and Schon. *Id.* at 24–25.
- VIII. Claims 15 and 16 stand rejected under 35 U.S.C. § 103 as being unpatentable over Boatman, Shah, and Willard. *Id.* at 26–27.
- IX. Claim 17 stands rejected under 35 U.S.C. § 103 as being unpatentable over Boatman, Shah, and Vigil. *Id.* at 28.
- X. Claim 20 stands rejected under 35 U.S.C. § 103 as being unpatentable over Boatman, Shah, and Zadno-Azizi. *Id.* at 28–31.
- XI. Claim 21 stands rejected under 35 U.S.C. § 103 as being unpatentable over Boatman, Shah, and Thielen. *Id.* at 31–32.
- XII. Claim 22 stands rejected under 35 U.S.C. § 103 as being unpatentable over Boatman, Shah, Thielen, and Diamant. *Id.* at 32.
- XIII. Claim 23 stands rejected under 35 U.S.C. § 103 as being unpatentable over Boatman, Shah, and Ogle. *Id.* at 32–33.

ANALYSIS

Rejection I – Double Patenting

Appellant does not address the double patenting rejection in the Appeal Brief. *See* Appeal Br. 6–12; *see also id.* at 3–6 (omitting this rejection from the grounds listed to be reviewed on appeal). Therefore, we summarily sustain the obviousness-type double patenting rejection of claims 1, 2, 9, 12–14, and 18–22. *See* MPEP § 1205.02 (An appellant may, of course, choose not to present arguments or rely upon particular evidence as to certain claim rejections; however, such arguments and evidence are waived for purposes of the appeal and the Board may summarily sustain any grounds of rejections not argued.); *see also In re Berger*, 279 F.3d 975 (Fed. Cir. 2002) (confirming same).

Rejections II–XIII – Obviousness over Cited Prior Art

All the claims recite a “*method of localized delivery of a therapeutic and/or diagnostic agent to nasal tissue or cavities*” that includes the steps of “*inserting a catheter into a nasal cavity*,” where the catheter has a perforated outer balloon, an inner balloon, and a space therebetween, “*supplying the therapeutic and/or diagnostic agent to [that] space*,” and “*inflating [the] inner balloon . . . to urge the therapeutic and/or diagnostic agent out of the at least one opening in the wall of said outer balloon and into nasal tissue.*” Appeal Br., Claims App. (emphasis added). In other words, as highlighted by these emphasized limitations, the claims are directed to a particular method of delivering an agent to an area of the body using a catheter; they are not directed solely to the structure of the catheter itself. *See* Appeal Br. 7–9.

For all the obviousness rejections on appeal, the Examiner relies on a base combination of Boatman and Shah to render obvious the claimed method. *See* Final Act. 12–33. In particular, the Examiner finds that Boatman discloses a multiple-balloon catheter having a perforated outer balloon, referred to as a “weeping balloon catheter,” which includes the recited catheter structure, but which is disclosed for use in a method of delivering an agent into a body vessel (described in Boatman as being any body passage lumen that conducts fluid, such as blood vessels, esophageal, intestinal, biliary, urethral, and ureteral passages). Final Act. 12–14 (citing Boatman ¶¶ 2, 33, Fig. 7A). Critically, with respect to the method claimed, the Examiner acknowledges that Boatman “fails to specifically disclose a method of localized delivery of a therapeutic and/or diagnostic agent *to nasal tissue or cavities.*” Final Act. 14 (emphasis added).

The Examiner then turns to Shah, which teaches an inflatable dual-balloon catheter *for applying pressure* to a body cavity as a way to control bleeding or hemorrhage therein.² Final Act. 14 (citing Shah, ¶¶ 8, 10, 34). Shah’s pressure-applying catheter is admittedly broadly disclosed as being useful for controlling bleeding in various body cavities, including a nasal cavity. *See* Appeal Br. 10–11; Shaw ¶ 10. From these teachings, all the

² Although the Examiner accurately notes that Shah mentions delivery of an agent to a body cavity (*see* Final Act. 14; Ans. 3), Appellant is correct that Shah does so only in the context of coating or covering the external surface of the outer balloon (*see* Appeal Br. 10–11 (citing Shah, ¶ 34)) rather than by passing any agent through the wall of the outer balloon as required in the claimed method, as Shah’s wall would need to contain the pressure acting against the body cavity. In other words, we agree with Appellant that Shah teaches locations and uses of a different type of dual-balloon catheter than in Boatman. *See* Reply Br. 2–3.

Examiner’s art rejections are premised on modifying Boatman’s method of delivering an agent via a weeping balloon catheter “to specifically nasal tissue or cavities, as taught by Shah, *for the purpose of applying pressure in the cavity* to reduce or eliminate bleeding.” Final Act. 14 (emphasis added).

Appellant persuasively argues that the Examiner’s rejections do not provide an adequately supported reason why a person of ordinary skill in the art would have modified Boatman in view of Shah to arrive at the method of the claimed invention. *See* Appeal Br. 6, 8–11; Reply Br. 2–3. We agree that the Examiner’s stated reason—to apply pressure in the nasal cavity (Final Act. 14; Ans. 3)—lacks a rational underpinning in that Shah’s teaching of use in a nasal cavity is only in the context of a pressure-applying catheter; it does not provide any relevant teaching that would suggest using another type of catheter in the nasal cavity, much less a weeping balloon catheter as in Boatman.³ Moreover, we question whether the Examiner’s stated rejections, all premised on a combination of Boatman and Shah, would achieve the claimed method—by using a multi-balloon catheter to “apply pressure,” such as to reduce bleeding, it is unclear how an agent could also be urged out of at least one opening in the wall of the outer balloon as the claims require.

³ We note that the Examiner’s ultimate conclusion of obviousness (essentially that Boatman’s method of delivering an agent via a weeping balloon catheter could be used to deliver an agent to nasal tissue) may find objective support somewhere, but it is not from Shah. As we limit our review to the rejections presented on appeal, we leave it to the Examiner to reconsider whether there would have been an objective reason in the art to apply Boatman’s teachings for such an application to nasal tissue.

Rejections based on obviousness must rest on a factual basis; in making such a rejection, the Examiner has the initial burden of supplying the requisite factual basis and may not, because of doubts that the invention is patentable, resort to speculation, unfounded assumptions, or hindsight reconstruction to supply deficiencies in the factual basis. *See In re Warner*, 379 F.2d 1011, 1017 (CCPA 1967). Here, absent improper hindsight reconstruction, we do not see a sufficiently articulated explanation, based on an objective rational underpinning, as to why one of ordinary skill in the art would have been led to modify the location of Boatman's weeping balloon catheter application to treat the nasal cavity by applying pressure, as stated in the rejections. No adequate reason for such modification is otherwise evident from the record.

The Examiner's reliance on the remaining references of record is for teaching additional claimed features, but not in a way that would cure the fundamental deficiency in the base combination of Boatman and Shah discussed above. *See* Final Act. 18–33.

Accordingly, based on the record before us, the Examiner has not met the burden of establishing a proper case of obviousness. Thus, we do not sustain the obviousness rejections of claims 1–23.

DECISION

We AFFIRM the Examiner's uncontested double patenting rejection of claims 1, 2, 9, 12–14, and 18–22.

We REVERSE the Examiner's obviousness rejections of claims 1–23 based on the cited art.

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).

CONCLUSION

In summary:

Claim(s) Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
1, 2, 9, 12–14, 18–22		Obviousness-Type Double Patenting	1, 2, 9, 12–14, 18–22	
1, 2, 7, 8, 13, 14, 18	103	Boatman, Shah		1, 2, 7, 8, 13, 14, 18
3	103	Boatman, Shah, Rahimsobhani		3
4–6, 11	103	Boatman, Shah, Chang		4–6, 11
9	103	Boatman, Shah, Broker		9
10, 19	103	Boatman, Shah, Makower		10, 19
12	103	Boatman, Shah, Schon		12
15, 16	103	Boatman, Shah, Willard		15, 16
17	103	Boatman, Shah, Vigil		17
20	103	Boatman, Shah, Zadno-Azizi		20
21	103	Boatman, Shah, Thielen		21
22	103	Boatman, Shah, Thielen, Diamant		22
23	103	Boatman, Shah, Ogle		23
Overall Outcome			1, 2, 9, 12–14, 18–22	3–8, 10, 11, 15–17, 23

AFFIRMED IN PART