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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte MICHAEL RONTAL

Appeal 2018-006904
Application 14/172,393
Technology Center 3700

Before JOHN C. KERINS, WILLIAM A. CAPP, and
GEORGE R. HOSKINS, *Administrative Patent Judges*.

HOSKINS, *Administrative Patent Judge*.

DECISION ON APPEAL

Pursuant to 35 U.S.C. § 134(a), Appellant¹ appeals from the Examiner's decision to reject claims 1–4, 8, and 14 in this application. The Board has jurisdiction over the appeal under 35 U.S.C. § 6(b).

A hearing was held on March 4, 2020. *See* Transcript (entered Mar. 18, 2020) (“Tr.”).

We REVERSE.

¹ We use the word “Appellant” to refer to “applicant” as defined in 37 C.F.R. § 1.42. Appellant identifies himself, Michael Rontal, as the real party in interest. Appeal Br. 1.

CLAIMED SUBJECT MATTER ON APPEAL

Claim 1 recites:

1. A method of irrigating the interior surface of a body cavity having an ostium connecting the interior of the cavity with an adjacent body passage, comprising:
 - inserting an inflatable balloon, in a deflated condition, through the ostium into the interior of the cavity;
 - inflating the balloon;
 - wherein the balloon contains a series of projections formed on its outer surface, and wherein the projections are adapted to contact the interior wall of the cavity when the balloon is inflated to form a passage between the exterior wall of the balloon and the interior wall of the cavity;
 - while the balloon remains inflated, introducing a fluid flow into the passage through an inflow tube extending between the exterior of the ostium and through a central passage of the balloon to an output at the end of the body cavity opposite to the ostium;
 - wherein the projections interfere with the fluid flow in such a way as to urge the fluid flow into a turbulent condition;
 - removing the fluid from the passage through an outflow tube having one end connecting to the passage at the ostium end of the passage and the other end terminating exterior of the ostium; and
 - deflating and removing the balloon.

Appeal Br. 10 (Claims App.). The other claims on appeal, claims 2–4, 8, and 14, each depend directly from claim 1. *Id.* at 10–11.

Claims 5, 10, 11, 13, and 15–20 are withdrawn from consideration. *See* Amendment (Apr. 17, 2017), 3–5.

Claims 6, 7, and 9 are canceled. *Id.* at 3.

The status of claim 12 is uncertain. Appellant identifies claim 12 as pending and on appeal. Appeal Br. 11 (Claims App.). The Final Office Action on appeal describes claim 12 as withdrawn from consideration

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(Final Act. Form PTOL-326 #5a), and accordingly does not address the merits of claim 12 (*id.* at 2–8). This uncertainty appears to have been caused by an unresolved disagreement between the Examiner and Appellant concerning a restriction requirement. *See* Restriction Requirement (entered Aug. 18, 2015); Response to Restriction Requirement (filed Aug. 25, 2015) (asserting claim 12 belongs to elected Group I, Species A); Non-Final Action (entered Oct. 28, 2015) (determining elected species A “does not include any structure that can be reasonably considered a ‘cowling’”, so claim 12 belongs to non-elected Species C). In the event of further prosecution, the Examiner and Appellant may clarify the status of claim 12.

REJECTIONS ON APPEAL

Claims 1–4 and 8 are rejected under 35 U.S.C. § 103(a) as unpatentable over Becker (US 2007/0073269 A1, pub. Mar. 29, 2007), Bacino (US 2013/0116655 A1, pub. May 9, 2013), Morriss (US 2008/0183128 A1, pub. July 31, 2008), and Makower (US 2006/0063973 A1, pub. Mar. 23, 2006). Final Act. 2–7.

Claim 14 is rejected under 35 U.S.C. § 103(a) as unpatentable over Becker, Bacino, Morriss, Makower, and Shapland (US 8,708,986 B2, iss. Apr. 29, 2014). Final Act. 8.

OPINION

A. *Obviousness over Becker, Bacino, Morriss, and Makower
(Claims 1–4 and 8)*

1. *Claim 1*

a. *Becker Disclosure*

The Examiner finds Becker discloses a method of irrigating the interior surface of a sinus cavity embodying many of the limitations of claim 1. Final Act. 3–7. Figure 12 of Becker is reproduced below.

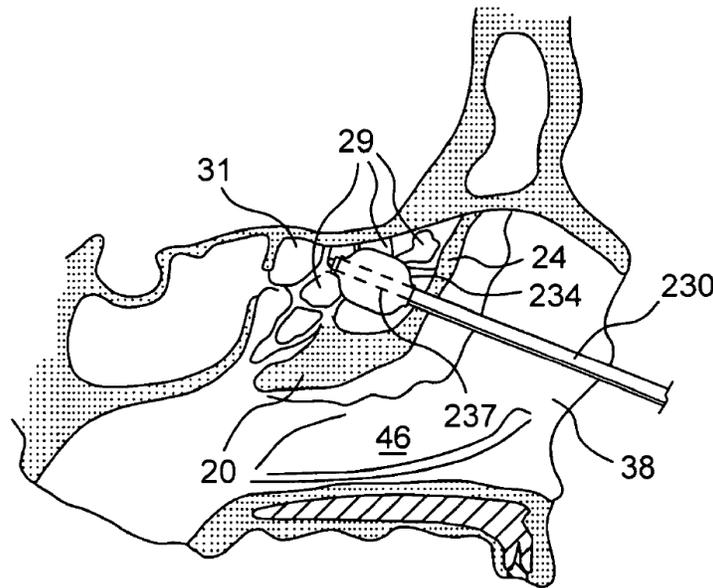


FIG. 12

Figure 12 is a schematic view of sinus balloon catheter 230, and its associated balloon 234, inserted into nasal cavity 38. Becker ¶¶ 69, 113.

The Examiner finds that, in one embodiment, balloon catheter 230 has a structure as shown in the combined disclosures of Figures 1B and 2B of Becker. Final Act. 3–4. Figure 1B of Becker is reproduced below, with our annotations added to illustrate some of the Examiner’s findings:

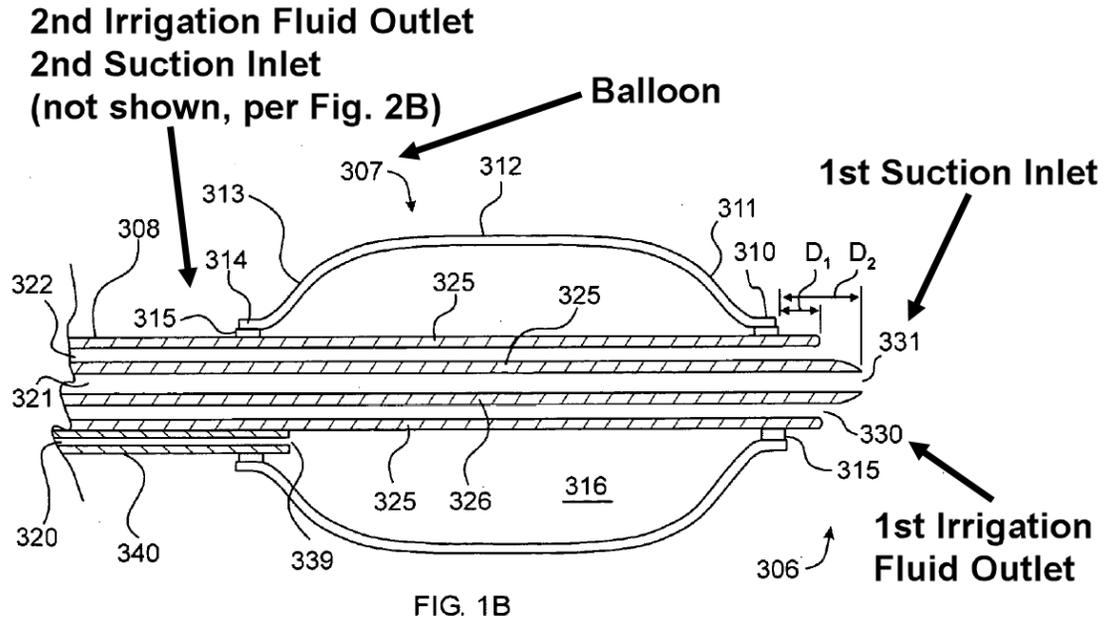


FIG. 1B

Figure 1B is a cross-sectional view of balloon 307 mounted on irrigation tube 325, which surrounds suction tube 326.² Becker ¶¶ 48, 75, 82. The coaxial tubes 325 and 326 form annular conduit 322 for providing an irrigation fluid into the sinus cavity via distal port 330, and central conduit 321 for suctioning irrigation fluid out of the sinus cavity via distal port 331. Becker ¶¶ 82–84, 88, 90. The Examiner determines it would have been obvious to include a second irrigation port for annular conduit 322 and a second suction port for central conduit 321, with both of these ports disposed proximally of balloon 307, based on Figure 2B of Becker. Final Act. 3–4; Becker, Fig. 2B, ¶¶ 95–96. Appellant does not challenge the foregoing findings on appeal.

In addition to acknowledging the foregoing unchallenged findings by the Examiner, we make the following additional findings concerning

² The “325” numeral in Figure 1B that points to the inner tube should be “326.” See Becker ¶ 82.

Becker's disclosure. Becker's ultimate medical goal is to treat sinusitis, a medical condition in which "[a]n obstruction of the narrow ducts and ostia between the paranasal sinuses and nasal cavity develops," necessitating surgery to "*restor[e] patency of the sinus ducts and ostia by enlarging the opening* and allowing mucociliary clearance of mucus from the sinus into the nose to resume." Becker ¶¶ 8–10 (emphasis added), 19–20. This is achieved by inflating Becker's balloon 234 / 307 within one or more sinus cavities to "dilate" a space or an opening, creating a permanent enlargement of the sinus cavities to facilitate ongoing drainage of mucous. *Id.* ¶¶ 36, 38, 39, 40, 41, 110, 113. We are unable to find, and the Examiner does not cite, any disclosure in Becker reflecting a use for the balloon other than forcefully inflating the balloon to rearrange sinus tissue, thereby creating enlarged cavities within the sinus. In particular, Becker does not disclose inflating the balloon for the purpose of irrigating a sinus cavity.

At the same time, Becker does disclose using its balloon catheter to irrigate a sinus cavity, as found by the Examiner and discussed above. The irrigation is described as a beneficial adjunct to Becker's treatment of sinusitis, because the irrigation permits the surgeon to suction blood, mucus, pus, and other material away from the sinus cavity, enabling "less obstructed use of an endoscope which greatly facilitates the surgeon visualizing the balloon catheter and the patient tissues in performance of the [sinusitis treating] procedure." *Id.* ¶¶ 21, 28, 37.

The Examiner and Appellant dispute whether Becker discloses performing the irrigation while the balloon is inflated, or deflated. The Examiner's position is that "Becker strongly implies" irrigation is performed while the balloon is inflated. Final Act. 5–6, 8–9 (citing Becker,

¶ 62 (Fig. 5), ¶ 64 (Fig. 7), ¶ 68 (Fig. 11), ¶ 69 (Fig. 12), claims 31, 32, 34, 52). Appellant’s position is that Becker discloses irrigation is performed while the balloon is deflated. Appeal Br. 3–4 (citing Becker ¶¶ 101, 110–117). For purposes of the present decision, we assume, without deciding, that the Examiner has the better position here, so Becker discloses performing irrigation while the balloon is inflated.

The Examiner further finds “Becker fails to disclose that the balloon contains a series of projections formed on its outer surface” to contact the interior wall of a sinus cavity when the balloon is inflated, and thereby form a passage between the exterior wall of the balloon and the interior wall of the cavity, as is required by claim 1. Final Act. 6. The Examiner nonetheless finds “the topography of the balloon surface of Becker, *even without projections*, creates” the claimed passage when the balloon is inflated, and fluid will necessarily flow through the passage. Ans. 5–6 (emphasis added) (annotating a modified representation of Becker’s Figure 3B for illustration). In support, the Examiner determines “the balloon consumes empty space of the sinus cavity which creates a virtual passage of reduced dimensions” between the balloon and the sinus cavity wall. *Id.* (citing Becker, Figs. 12 & 14).

Appellant argues a preponderance of the evidence does not support the Examiner’s finding that there is a passage between Becker’s balloon and the sinus cavity wall when the balloon is inflated. Reply Br. 2–3. We agree. As discussed above, the only purpose Becker discloses for inflating a balloon is to dilate a patient’s sinus cavity by forcefully rearranging tissue via interaction with the inflated balloon. To perform this function, Becker inflates its balloon at a high pressure, “between about 1 and 17 bars, and

most typically about 9 bars (atmospheres).” Becker ¶ 110; *id.* ¶¶ 111–117. We disagree with the Examiner’s finding that inflating a balloon at such a high pressure, so that the balloon may encounter sinus cavity tissue and rearrange it in a permanent fashion to enlarge the sinus cavity, will result in passages being formed between the inflated balloon and the cavity. Instead, we find that under such conditions, no passages will be formed between the smooth outer surface of the balloon (*id.* at Figs. 1A, 1B, 2B, 12, 15) and the sinus cavity walls encountered by the balloon when it is inflated.

Given Becker’s failure to disclose protrusions on its balloon, the Examiner turns to Bacino for the obviousness of modifying Becker’s balloon to have projections, as we discuss next.

b. Bacino Disclosure, and Obviousness of Modifying Becker’s Balloon to Have Projections in Light of Bacino

The Examiner finds Bacino discloses a balloon configuration that is “useful for a variety of applications including . . . treating the nasal sinuses.” Final Act. 4, 10 (citing Bacino ¶ 157). Further according to the Examiner, Bacino discloses several “balloons having various forms of surface projections/protrusions.” *Id.* Figure 2B(3) of Bacino is representative of Bacino’s disclosure in this regard, and is reproduced below.

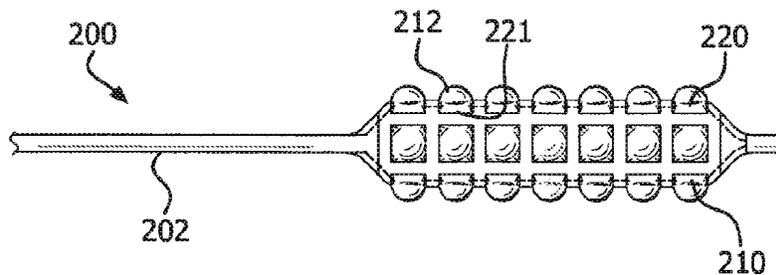


FIG. 2B(3)

Figure 2B(3) is a side view of balloon assembly 200, comprising catheter 202, template 220, and balloon 210 in an inflated state. Bacino ¶¶ 19, 59–60. Template 220 has apertures 221 so that inflation of balloon 210 forms protrusions 212. *Id.* ¶¶ 59–61.

The Examiner finds Bacino discloses protrusions 212 are useful “to help retain the balloon [210] within the cavity of interest, providing a [scraping] function, and directing fluid flow about the balloon.” Final Act. 4, 10 (citing Bacino ¶¶ 78, 94, 103). The Examiner therefore determines it would have been obvious to add projections to Becker’s balloon, as disclosed by Bacino, to: (a) help retain and anchor Becker’s balloon in place when inflated; (b) direct the flow of medicament within the sinus cavity; and/or (c) improve the disruption of debris from the sinus cavity walls with a scraping action. *Id.* at 4, 10–11; Ans. 4, 5, 8, 11, 17–18. The Examiner takes the position that, when Becker’s balloon is modified to have projections for those reasons, and the balloon is inflated to contact the sinus cavity walls and irrigation is begun, “the balloon topography will *necessarily* form a passage within the sinus cavity between the balloon surface and the cavity wall,” leading from Becker’s distal irrigation port to Becker’s proximal suction port. Ans. 5 (emphasis added), 6–8 (annotating a modified representation of Becker’s Figure 3B for illustration), 11, 12, 15.

Appellant presents several arguments in opposition, two of which we determine are persuasive. The first is that a preponderance of the evidence does not establish a rational basis for modifying Becker’s balloon to have protrusions, in light of Bacino. Appeal Br. 2–5; Reply Br. 1–2, 4. The second is that a preponderance of the evidence does not support the Examiner’s finding that adding projections to Becker’s balloon will

necessarily form fluid flow passages between the exterior wall of the balloon and the interior wall of the cavity when Becker's balloon is inflated. Appeal Br. 3–5, 6; Reply Br. 1, 2–3, 5–7. We discuss each in turn.

Concerning the obviousness rationale, the Examiner cites Bacino's paragraphs 78, 94, and 103 as disclosing the usefulness of balloon protrusions. Paragraph 78 pertinently indicates balloon projections may be used to scrape a lesion or a thrombus.³ Paragraph 94 pertinently indicates balloon projections may “be used to perform thrombectomy”⁴ or “Percutaneous Transluminal Angioplasty.”⁵ Paragraph 103 provides that, if therapeutic agent 808 is provided between balloon 810 and its surrounding template 820 having apertures 821 (Bacino ¶ 102, Fig. 8), then when balloon 810 is inflated to form protrusions through apertures 821, the “therapeutic agent can be conveyed beyond aperture by protrusion and be directed to a surrounding tissue and/or a localized portion of the body” (*id.* ¶ 103). Further, therapeutic agent 808 “can be in a solid or viscous form to maintain location within aperture” before the balloon is inflated. *Id.*

We find very little support in those disclosures for the Examiner's conclusion that it would have been obvious to modify Becker's balloon to have protrusions. The cited Bacino disclosures do not, for example, describe

³ A thrombus is a “fibrinous clot that forms in and obstructs a blood vessel, or that forms in one of the chambers of the heart.” www.dictionary.com/browse/thrombus (accessed Mar. 7, 2020).

⁴ A thrombectomy is the “surgical removal of a blood clot from a blood vessel.” www.dictionary.com/browse/thrombectomy (accessed Mar. 7, 2020).

⁵ An angioplasty is “the repair of a blood vessel, as by inserting a balloon-tipped catheter to unclog it” www.dictionary.com/browse/angioplasty (accessed Mar. 7, 2020).

protrusions as being useful to retain a balloon within a cavity of interest. Instead, the disclosed use of balloon projections to scrape foreign matter away from a surface suggests the opposite: moving the balloon across the surface. As to fluid flow, there is no rational relationship between Bacino's disclosure of using the expansion of an inflating balloon through template apertures to deliver a therapeutic agent to localized vessel walls, and Becker's disclosure of providing an irrigating fluid to spurt and swirl within a nasal cavity to wash away mucous and blood, to establish the obviousness of using balloon projections in Becker to aid fluid flow. The Examiner's determinations of obviousness in the foregoing regards appear to be based on a hindsight desire to reach the claimed invention, rather than the disclosures of Becker and Bacino.

There may be a rational relationship between Bacino's disclosure of using balloon projections to scrape foreign matter away from a surface, and Becker's goal of irrigating a nasal cavity to wash away mucous and blood. *See, e.g.,* Ans. 10 ("an ordinary artisan would reasonably recognize and appreciate that providing irrigant during a dilation step would provide for a compounded effect of the various mucus and debris disrupting features of the device/method as modified"). However, this leads us to the second reason why we cannot sustain the present rejection.

We determine that even if it would have been obvious to add projections to Becker's balloon, a preponderance of the evidence does not support the Examiner's finding that this will necessarily lead to the irrigation method recited in claim 1. As discussed above, we have assumed for this decision that Becker discloses performing irrigation while the balloon is inflated. However, also as discussed above, the only purpose Becker

discloses for inflating a balloon is to dilate a patient's sinus cavity by forcefully rearranging tissue via interaction with the inflated balloon. To perform this function, Becker inflates its balloon at a high pressure, "between about 1 and 17 bars, and most typically about 9 bars (atmospheres)." Becker ¶ 110. At such a high pressure, given the inherently pliable nature of an inflatable balloon, we disagree with the Examiner's finding that fluid-flow passages will necessarily result between the inflated balloon and the sinus cavity walls. Instead, we find that under such conditions, no passages will be formed between the outer surface of the balloon and the sinus cavity walls encountered by the balloon when it is inflated, even if Becker's balloon is modified to have protrusions.

For the foregoing reasons, we determine a preponderance of the evidence does not support the Examiner's determination that the combination of Becker and Bacino would lead to a method of irrigating a body cavity by inflating a balloon so that projections on the balloon contact the cavity wall to form a passage, and introducing a fluid flow into the passage, as recited in claim 1.

c. Morris and Makower Disclosures

The Examiner's reliance on Morriss and Makower does not address the foregoing deficiencies of Becker and Bacino. Morriss is cited for the obviousness of using a turbulent fluid flow to irrigate a sinus cavity, not for the obviousness of forming a fluid flow passage between an inflated balloon and the cavity walls. *See* Final Act. 4–5. Makower is cited for the obviousness of performing irrigation while a balloon is inflated, not for the

obviousness of forming a fluid flow passage between an inflated balloon and the cavity walls. *See id.* at 6–7.

d. Conclusion as to Claim 1

We do not sustain the Examiner’s rejection of claim 1 as having been obvious over Becker, Bacino, Morriss, and Makower.

2. Claims 2–4 and 8

The Examiner’s additional consideration of claims 2–4 and 8 does not cure the deficiencies concerning their common parent claim 1 noted above. *See Final Act.* 3–7. Therefore, for the reasons provided above concerning claim 1, we do not sustain the rejection of claims 2–4 and 8 as having been obvious over Becker, Bacino, Morriss, and Makower.

B. Obviousness over Becker, Bacino, Morriss, Makower, and Shapland (Claim 14)

The Examiner’s additional consideration of claim 14, and of Shapland, does not cure the deficiencies concerning the parent claim 1 noted above. *See Final Act.* 8. Therefore, for the reasons provided above concerning claim 1, we do not sustain the rejection of claim 14 as having been obvious over Becker, Bacino, Morriss, Makower, and Shapland.

CONCLUSION

In summary, we reverse each of the rejections on appeal, as summarized in the following table:

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Claim(s) Rejected	35 U.S.C. §	References	Affirmed	Reversed
1-4, 8	103	Becker, Bacino, Morriss, Makower		1-4, 8
14	103	Becker, Bacino, Morriss, Makower, Shapland		14
Overall Outcome				1-4, 8, 14

REVERSED