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BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte BRAD JACKSON, ANTHONY HUYNH, and JOHN NGUYEN[1]

Appeal 2019-001802
Application 14/725,174
Technology Center 3700

Before JILL D. HILL, LEE L. STEPINA, and ARTHUR M. PESLAK, *Administrative Patent Judges*.

HILL, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Brad Jackson et al. ("Appellants") appeal under 35 U.S.C. § 134(a) from the Examiner's decision rejecting claims 1–24. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM-IN-PART, designating a portion of the affirmance a NEW GROUND of rejection.

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[1] Appellants identify the real party in interest as Medtronic plc. Appeal Br. 3.

BACKGROUND

Appellants' invention relates to a medical catheter. Claim 1, reproduced below, illustrates the claimed invention, with certain limitations italicized:

> 1. A catheter comprising:
> an elongated body comprising:
> an inner liner defining an inner lumen of the elongated body;
> an outer jacket; and
> a coil member positioned between at least a portion of the inner liner and the outer jacket, wherein the coil member is adhered to the inner liner with a thermoset adhesive, and *wherein the coil member and the inner liner are not adhered to the outer jacket with adhesive.*

REJECTIONS[2]

I. Claims 1–4, 6–15, 17, 18, and 20–24 stand rejected under 35 U.S.C. § 103 as unpatentable over Bose (US 2009/0030400 A1, pub. Jan. 29, 2009) and Krasnicki (US 4,676,229, iss. June 30, 1987). Final Act. 4.

II. Claims 5 and 19 stand rejected under 35 U.S.C. § 103 as unpatentable over Bose, Krasnicki, and Berg (US 5,951,495, iss. Sept. 14, 1999). Final Act. 8.

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[2] A rejection of claims 3 and 4 under 35 U.S.C. § 112(b), a rejection of claim 18 under 35 U.S.C. § 112(b), and a provisional rejection of claims 1–4, 6–15, 17, 18, and 20–24 on the ground of nonstatutory double patenting are withdrawn based on Appellants' Remarks submitted in an Amendment After Final Action ("Amendment") filed April 23, 2018. *See* Advisory Act. 2 (mailed May 18, 2018); *see also* Final Act. 3 and 9. We understand the Examiner's refusal to enter the Amendment to be based on Appellants newly added claims 25–28 and that the withdrawal of the above-noted rejections is in effect in light of Appellants' Remarks. *Id.*

III. Claim 16 stands rejected under 35 U.S.C. § 103 as unpatentable over Bose, Krasnicki, and Samson (US 6,143,013, iss. Nov. 7, 2000). Final Act. 9.

ANALYSIS

Rejection I – Claims 1–4, 6–15, 17, 18, and 20–24

The Examiner finds that Bose discloses a catheter having an inner liner, an outer jacket, and a coil member positioned between the inner liner and the outer jacket, but relies on Krasnicki to disclose a coil member that is adhered to the inner liner with a thermoset adhesive. Final Act. 4. The Examiner concludes that it would have been obvious "to modify the catheter of Bose with the adhesive of Krasnicki for the purpose of holding the coil to the inner liner when the tubing is deformed in a tight radius." *Id.* at 5 (citing Krasnicki, 3:49–53).

Claims 1–3, 6–9, 11, 13, and 15

Appellants argue claims 1–3, 6–9, 11, 13, and 15 as a group. Appeal Br. 6. We select independent claim 1 as representative. Claims 2, 3, 6–9, 11, 13, and 15 stand or fall with claim 1.

Combination Does Not Result in Claimed Catheter

Appellants argue that, because the references fail to suggest curing "Krasnicki's adhesive 37 before placing Bose's outer layer 28 over the reinforcing layer 26 and the liner 24," the Examiner has failed to establish that the proposed modification "necessarily would have resulted in ….'the coil member and the inner liner are not adhered to [an] outer jacket with adhesive,' as recited in claim 1." Appeal Br. 8. Appellants contend that the

Examiner cannot rely on inherency for this feature, because the Examiner has not established inherency. *Id.* at 9; *see also* Reply Br. 3–5. According to Appellants, to the extent that the Examiner is relying on Figure 2 of Krasnicki to support the rejection, one of ordinary skill would have included Krasnicki's filler material 34, which would not result in the catheter as recited in claim 1. Appeal Br. at 9–10.

The Examiner responds that claim 1 is an apparatus, not a method. Ans. 3. The Examiner states that, rather than relying on inherency, Krasnicki's Figure 2 shows "no adhesive on the outer layer." Ans. 4. The Examiner notes the proposed combination does not import Krasnicki's filler material with its adhesive. Ans. 5.

The Examiner has the better position. Krasnicki only shows adhesive 37 connecting coil 33 to inner tube 31 (*see* Krasnicki, Fig. 2), and the Examiner's modification of Bose proposes to add adhesive to the coils of Bose consistent with Krasnicki. Final Act. 5. Because Bose does not have adhesive between the coil and the outer jacket, and because the modification based on Krasnicki adds adhesive only between the coil and inner liner, not between the coil and outer jacket, a preponderance of the evidence supports the Examiner's position that the coil member and inner liner are not adhered to the outer jacket with adhesive. Further, we discern no requirement or suggestion that Krasnicki's filler material be imported into Bose's structure with the adhesive.

Reasoning with Rational Underpinning

Appellants argue that, "the Examiner failed to establish a reason, with rational underpinning, for the proposed modification of Bose's catheter 12 to

include Krasnicki's adhesive 37." Appeal Br. 10. Appellants contend that that "Bose already appears to describe a catheter in which a coil is held to an inner liner." *Id.* According to Appellants, "the Examiner has not shown that a person of ordinary skill in the art would have understood Bose's outer layer 28 to [be] insufficient in holding the reinforcing layer 26 to the liner 24 'when [Bose's catheter 12] is deformed in a tight radius.'" *Id.* at 11; *see also* Reply Br. 7. Appellants assert that Bose has a different type of outer layer than that of Krasnicki, and whereas Krasnicki might require an adhesive to hold the coil to an inner liner, "the Examiner has not shown that a person of ordinary skill in the art would understood . . . the same need to hold Bose's reinforcing layer 26 to the liner 24." *Id.*; *see also* Reply Br. 8.

According to the Examiner, the Bose catheter is improved upon, because the adhesive of Krasnicki reinforces the catheter of Bose "by holding the coil to the inner liner, so that the modified catheter maintains its structure and thus function during use." Ans. 5.

Appellants' arguments are not persuasive because Bose places a coil on an inner liner (*see* Bose ¶ 18, Fig. 2A), and Krasnicki uses an adhesive to keep a coil attached to an inner liner. *See* Krasnicki, 3:49–51. Appellants do not provide persuasive arguments that adhesive is not a known material that a skilled artisan would appreciate to hold Bose's coil to the inner liner. Appellants do not persuade us that Bose adhering its coil prior to applying outer layer 28 would not provide better securement of the coil, and we are aware of no requirement Bose recognize insufficient securement by its outer layer 28 for adhesive to rationally provide an advantage in the form of additional securement. Thus, the Examiner's reasoning is supported by rational underpinnings in that the Examiner's proposed modification is "for

the purpose of holding the coil to the inner liner when the tubing is deformed in a tight radius," which comes directly from Krasnicki. *See* Final Act. 5 (citing Krasnicki, 3:49–53). Although we appreciate that Bose already appears to describe its coil being held to its inner liner, the Examiner finds that adhesive "hold[s] the coil to the inner liner when the tubing is deformed in a tight radius, which is an improvement to the Bose catheter because it reinforces the design of the Bose catheter with the adhesive of Krasnicki." Ans. 5. Because the Examiner reasoning has a rational basis, we are not persuaded that the Examiner's rejection contains error.

For these reasons explained above, we discern no error in the Examiner's findings or conclusion, and we sustain the rejection of claim 1. Claims 2, 3, 6–9, 11, 13, and 15 fall with claim 1.

Claim 4

Appellants argue that the Examiner "fails to establish that the proposed modification of Bose's catheter 12 to include Krasnicki's adhesive 37 necessarily would have resulted in an elongated body of a catheter with substantially no material present between a coil member and an outer jacket thereof." Appeal Br. 12. Appellants assert that, based on the Examiner's reliance of Figure 2 of Krasnicki, one of ordinary skill would consider that the modification includes filler material 34. *Id.* at 13.

The Examiner responds that the modification only relies on applying an adhesive 37 in Bose, not adding filler material 34. Ans. 5–6.

Appellants' arguments are not persuasive. Bose discloses a catheter 12 having an inner liner 24, a coil 26 surrounds liner 24, and an outer layer 28. *See* Bose ¶¶ 18 and 19. There is no material between the coil member

and the outer jacket. *Id.*, Fig. 2A. The Examiner's modification of Bose proposes to add adhesive to the coils of Bose. Final Act. 4. Fig. 2 of Krasnicki only shows adhesive 37 connecting coil 33 to inner tube 31. *See* Ans. 4. Because Bose does not have any material between the coil and the outer jacket, and the modification based on Krasnicki only adds adhesive between the coil and inner liner, lacking a reason why the adhesive and the filler material must necessarily be employed together, a preponderance of the evidence supports the Examiner's position that the Examiner's proposed combination would result in no material between the coil and the outer jacket. We, therefore, sustain the rejection of claim 4.

Claim 10

Claim 10 recites, *inter alia*, the outer jacket comprising a heat-shrinkable material that is heat shrunk over the inner liner and the coil member. The Examiner finds that Bose discloses a heat-shrinkable material and that "heat shrunk" is a product-by-process limitation that does not distinguish over the product of Bose. Final Act.6.

Appellants argue that certain terms "are capable of construction as structural limitations," and that "the phrase 'heat shrunk' would be expected to impart distinctive structural characteristics to the outer jacket (e.g., a closeness of fit between the outer jacket and the inner liner and coil member), and is capable of construction as a structural limitation," that distinguishes over Bose and Krasnicki. Appeal Br. 14, *see also* Reply Br. 9.

The Examiner responds that Bose has a closeness of fit, as illustrated in its Figures 2A and 2B. Ans. 6.

Appellants have the better position. Although Bose's Pebax® material (*see* Bose ¶ 22) could be heat-shrinkable, the Examiner has not established adequately that Figures 2A and 2B of Bose depict an outer layer that *has been* heat shrunk. The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. *In re Garnero*, 412 F.2d 276, 279 (CCPA 1979) (holding "interbonded by interfusion" to limit structure of the claimed composite and noting that terms such as "welded," "intermixed," "ground in place," "press fitted," and "etched" are capable of construction as structural limitations). Here, Appellants' Specification discloses that the application of heat causes the jacket to shrink to induce a wrapping force on the jacket. *See* Spec. ¶¶ 288, 295. Absent evidence that Bose discloses such a wrapping force, the Examiner has not established that Bose imparts the distinctive structural characteristic of a close fit jacket that is obtained by being heat shrunk as claimed.

Accordingly, we do not sustain the Examiner's rejection of claim 10.

Claim 12

Claim 12 requires that the coil member tapers from a first coil diameter to a second coil diameter. In the Final Action, the Examiner relies on paragraph 18 of Bose for this feature. Final Act. 6. Appellants argue that the portion of Bose on which the Examiner relies discloses that "'[t]he lumen may have a tapered inner diameter or a uniform inner diameter'" but Bose fails to disclose the "portion of the inner liner 24 over which the

reinforcing layer 26 is coiled (i.e., an outer surface of the inner liner 24) as being tapered in diameter." Appeal Br. 15.

Although we appreciate Appellants' position that "a thickness of an outer wall of Bose's inner liner 24 may increase as the diameter of the lumen defined by the inner liner decreases (i.e., tapers)" (Reply Br. 10), the more logical alternative is that the outer wall tapers as well. That is, of the two possible ways to manufacture a tube with tapering inner diameter, it is more likely that the outer wall would taper as well to provide a consistent wall thickness, rather than increasing the thickness of the outer wall. This is consistent with the remainder of Bose. Specifically, Figure 2A of Bose depicts inner liner 24 having a substantially constant thickness. One of ordinary skill in the art would understand a constant thickness to be preferred over a tapered inner lumen with increased wall thickness to maintain a uniform outer diameter. In addition, Bose prefers the catheter to have a "smooth taper." Bose ¶ 20, Fig. 2A. Bose achieves this by using walls that have a progressively thinner wall thickness for increased flexibility. *Id.* Having an inner liner with walls that increase in thickness as Appellants suggest runs contrary to this disclosure of Bose. A tapered outer wall is supported by a preponderance of the evidence. Since the coil surrounds the inner liner to reinforce the inner liner (Bose ¶ 18), a tapered outer wall of the inner liner would be understood by a skilled artisan to result in a coil member that tapers from a first coil diameter to a second coil diameter.

Because the thrust of the rejection of claim 12 is changed by our analysis above, we designate our affirmance of claim 12 a NEW GROUND of rejection pursuant to 37 C.F.R. § 41.50(b).

Claim 14

Claim 14 requires that the first outer diameter is about 4 French and the second outer diameter is about 3 French.

The Examiner finds the claimed diameters to be obvious over Bose's disclosed 3 French guidewire diameter, because "discovering an optimum value of a result effective variable involves only routine skill in the art." Final Act. 6 (citing *In re Boesch*, 617 F.2d 272 (CCPA 1980)).

Appellants argue that, because Bose introduces "a guidewire having a diameter of about 3 French (3 French being equal to a diameter of 0.039 inches) into the lumen 22 of the catheter 12 … Bose necessarily describes that the distal portion of the catheter 12 has an outer diameter of greater than about 3 French." Appeal Br. 16. According to Appellants, "a person of ordinary skill in the art seeking to find an 'optimum value' of the outer diameter of Bose's catheter [] would [not] have modified Bose's catheter to be unusable with [a 3 French] guidewire." *Id.* at 16–17; *see also* Reply Br. 12.

Appellants' arguments are not persuasive. As the Examiner correctly finds, Bose discloses that certain parameters "of the segments are selected such that properties of a segment are best suited for the regions of the neurovascular through which that segment of the catheter will pass during positioning and within which that segment of the catheter will be 'parked' during use." Final Act. 6 (citing Bose ¶ 19). As such, Bose recognizes that a change in size of the catheter diameter can be optimized depending on its intended use. Although Bose discloses a second guidewire that is 3 French and thus would not go through a 3 French diameter catheter, Bose discloses the second guidewire as exemplary, and also discloses that a "first guidewire

could remain in use rather than being replaced with the second guidewire." Bose ¶ 26. The first guidewire is 0.018" (Bose ¶ 26) and would be readily usable with a 3 French catheter.

Moreover, Bose discloses that the guidewire should be selected so that "it reduces the gap between the guidewire outer diameter and the delivery catheter inner diameter and thus facilitates smoother movement of the catheter/guidewire through the tortuous vascular anatomy." *Id.* Thus, Bose discloses that the diameters of both the catheter and the guidewire can be optimized, and the Examiner's reasoning for optimizing, namely, "such that properties of a segment are best suited for the regions of the vasculature through which that segment of the catheter will pass," comes directly from Bose. *See* Final Act. 6 (citing Bose ¶ 19). Because the Examiner provides a reason with a rational basis for modifying Bose to meet the claimed diameter, we are not persuaded that the rejection contains error.

Claims 17, 20–22, and 24

In support of independent claim 17, Appellants rely on essentially the same arguments as discussed above for claim 1. Appeal Br. 17–18. For the reasons set forth above, we are not persuaded that the Examiner's findings or conclusions are in error. We sustain the rejection of claim 17 for the same reasons. Claims 20–22 and 24 fall with claim 17.

Claim 18

Claim 18 depends from claim 17. Claim 18 is substantially the same as claim 4, except claim 4 recites "no material," whereas claim 18 recites "devoid of any material."

The Examiner makes similar findings to those discussed *supra* with respect to claim 4 and Appellants present similar arguments as those discussed *supra* with respect to claim 4. *See* Ans. 8; App. Br. 18–19.

Accordingly, for the reasons similar to those discussed above with respect to claim 4, we also sustain the rejection of claim 18.

Claim 23

Claim 23 depends from claim 17. Claim 23 is substantially the same as claim 12.

The Examiner makes similar findings to those discussed *supra* with respect to claim 12 and Appellants present similar arguments as those discussed *supra* with respect to claim 12. *See* Ans. 8; App. Br. 19–20.

Accordingly, for the reasons similar to those discussed above with respect to claim 12, we also sustain the rejection of claim 23. Because the thrust of the rejection of claim 12 is changed by our analysis above, we designate our affirmance of claim 23 a NEW GROUND of rejection pursuant to 37 C.F.R. § 41.50(b).

Rejection II – Claims 5 and 19

In rejecting claims 5 and 19 as unpatentable over Bose, Krasnicki, and Berg, the Examiner relies on Berg to teach "an adhesive for attaching a support member wire braid to an inner tubular member of a catheter wherein the thermoset adhesive comprises a urethane adhesive." Final Act. 8 (citing Berg, 7:48). The Examiner considers that it would have been obvious to modify the catheter of Bose and Krasnicki with Berg's adhesive "as a simple

substitution of one known element for another to obtain predictable results." *Id.*

Appellants argue that the "Examiner's reliance on a 'substitution' rationale to support the rejection" is improper, because "the Examiner failed to establish that the epoxy adhesive described by Krasnicki and the urethane adhesive described by Berg are equivalents recognized in the prior art." Appeal Br. 21.

Appellants' arguments are not persuasive. Krasnicki discloses using an epoxy cement to bond a stainless steel wire to a tubular substrate in a catheter. *See* Krasnicki 3:49–51. The Examiner provides evidence that Krasnicki's epoxy cement is a thermoset adhesive (*see* Final Act. 4–5), which Appellants do not dispute. Berg teaches UV- and heat-cured urethane adhesives 68 (*see* Berg, 7:48) for bonding a stainless steel wire 56 to a tubular member 50 (*see* Berg, 7:2–6, Fig. 7). As such, both Krasnicki and Berg teach adhesives that are suitable to bond a stainless steel wire to a catheter's tubular member.

In a similar vein, the predecessor to the Federal Circuit found that when two prior art references "teach a method for separating caffeine from oil, it would have been prima facie obvious to substitute one method for the other. Express suggestion to substitute one equivalent for another need not be present to render such substitution obvious." *In re Fout*, 675 F.2d 297, 301 (CCPA 1982). Further, it is obvious to substitute one known element or method for another to obtain predictable results. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007). The Examiner has established that Krasnicki's and Berg's adhesives are suitable to bond a stainless steel wire to a tubular member of a catheter. Appellants have not explained why

Krasnicki's and Berg's adhesives are other than known alternatives, or why the substitution of Krasnicki's adhesive with that of Berg would achieve unpredictable results. We therefore are not persuaded by Appellants' argument.

Accordingly, we sustain the rejection of claims 5 and 19.

Rejection III – Claim 16

Claim 16 requires that the coil member comprises a nickel titanium alloy.

The Examiner relies on Samson for this limitation and considers that it would have been obvious "to modify the coil material of Bose [] with the nickel titanium alloy of Samson for the purpose of resistance to plastic deformation upon physical strain." Final Act. 9 (citing Samson, 8:20–21).

Appellants argue that the Examiner fails "to establish a reason, with rational underpinning, for why a person of ordinary skill in the art would have sought to modify Bose's reinforcing layer 26 to include a nickel titanium alloy." Appeal Br. 22–23. According to Appellants, Bose's reinforcing layer 26 is formed from stainless steel or platinum, to provide enhanced kink resistance, pushability, and torqueability, and "[t]he Examiner failed to establish that a person of ordinary skill in the art would have understood there to have been a need to modify Bose's reinforcing layer 26," as the Examiner suggests. *Id.* at 23.

In response, the Examiner notes that "resistance to plastic deformation upon physical strain, [] is an improvement to the Bose catheter because it reinforces the design of the Bose catheter with nickel titanium alloy of

Samson, so that the modified catheter maintains its structure and thus function during use." Ans. 9.

Appellants' arguments are not persuasive. Bose and Samson use a coil or braid to reinforce an inner liner, and both materials are suitable for such reinforcement. *See* Bose ¶ 18; Fig. 2A; Samson 10:47–49; Fig. 2. Appellants do not provide persuasive arguments that nickel titanium alloy is not a known material that a skilled artisan would appreciate would be employed as the material for Bose's coil, or regarding unpredictable results. Moreover, the Examiner's reasoning is supported by rational underpinnings in that the Examiner's proposed modification is "for the purpose of resistance to plastic deformation upon physical strain," which comes directly from Samson. *See* Final Act. 9 (citing Samson, 8:20–21). Although we appreciate that Bose prefers a coil of stainless steel or platinum, the Examiner finds that the nickel titanium alloy "for the purpose of resistance to plastic deformation upon physical strain, [] is an improvement to the Bose catheter because it reinforces the design of the Bose catheter." Ans. 9. Because the Examiner provides a reason with a rational basis for combining Samson with Bose, we are not persuaded that the Examiner's rejection is in error.

We, therefore, sustain the rejection of claim 16.

DECISION

We AFFIRM the Examiner's rejection of claims 1–4, 6–9, 11–15, 17, 18, and 20–24 as unpatentable over Bose and Krasnicki, designating the affirmance of claims 12 and 23 a NEW GROUND of rejection, and we

REVERSE the Examiner's rejection of claim 10 as unpatentable over Bose and Krasnicki.

We AFFIRM the Examiner's rejection of claims 5 and 19 as unpatentable over Bose, Krasnicki, and Berg.

We AFFIRM the Examiner's rejection of claim 16 as unpatentable over Bose, Krasnicki, and Samson.

FINALITY OF DECISION

This decision contains new grounds of rejection pursuant to 37 C.F.R. § 41.50(b). 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 Appellants, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new grounds 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. . . .

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