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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte RICHARD S. GINN

Appeal 2018-003046
Application 13/673,898
Technology Center 3700

Before GEORGE R. HOSKINS, BRADLEY B. BAYAT, and ARTHUR M. PESLAK, *Administrative Patent Judges*.

HOSKINS, *Administrative Patent Judge*.

DECISION ON APPEAL

Pursuant to 35 U.S.C. § 134(a), Appellant[1] appeals from the Examiner's decision to reject claims 1, 2, and 47–55 in this application.[2] The Board has jurisdiction over the appeal under 35 U.S.C. § 6(b).

A hearing was held on November 14, 2019. *See* Transcript (entered Dec. 9, 2019) ("Tr.").

We AFFIRM.

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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 Transaortic Medical, Inc., as the real party in interest. Appeal Br. 2.

[2] Claims 3–46 are canceled. *See* Appeal Br. (filed July 19, 2017) 2; Claims App. (filed Aug. 9, 2017) 1.

CLAIMED SUBJECT MATTER

Claim 1 is the sole independent claim on appeal, and it recites:

1. A system for deploying a device to a distal location across a diseased vessel, comprising:

a protective sheath defining a lumen therethrough;

said sheath comprising an expandable embolic capture assembly having a collapsed configuration and an expanded configuration housed in said sheath and constrained in its collapsed configuration;

said embolic capture assembly comprising a tubular porous filter mesh having pores sized to prevent passage of embolic particles and to permit the flow of blood thereby providing an outlet for blood;

said embolic capture assembly having an open distal end in said expanded configuration comprising an inlet;

said embolic capture assembly having a hoop structure coupled to said tubular porous filter distal end;

said hoop structure being located at the distal portion of said embolic capture assembly and having a collapsed configuration and an expanded configuration, said expanded configuration being dimensioned to engage the walls of a blood vessel; and

a proximal manipulation structure coupled to said hoop structure which is capable of collapsing said hoop structure and closing the distal portion of said embolic capture assembly by the application of hoop tension to capture particles in said tubular porous filter mesh.

Claims App. 1.

PRIOR ART REFERENCES

The Examiner cites the following prior art references:

Name	**Reference**	**Date**
Kerr	US 5,941,896	Aug. 24, 1999
Clubb	US 2004/0153117 A1	Aug. 5, 2004
Agnew	US 2008/0167705 A1	July 10, 2008
Spenser	US 2009/0254169 A1	Oct. 8, 2009

Name	Reference	Date
Bortlein	US 2010/0100167 A1	Apr. 22, 2010
Angel	US 2010/0217304 A1	Aug. 26, 2010
Pah	US 2010/0305604 A1	Dec. 2, 2010

REJECTIONS ON APPEAL

Claims 1, 2, and 47–55 are rejected under 35 U.S.C. § 112(a)[3] for lack of written description. Final Act. (dated Apr. 20, 2017) 9–10. In addition, the Examiner has "objected to" to claim 55. *Id.* at 9. The reasoning for the objection is rooted in whether Appellant's Specification provides written description support for the challenged subject matter. *Id.*; Appeal Br. 5 (the objection is "really . . . that the [claimed] recitation is contrary to the specification and drawings"). We will therefore review the objection because, in effect, it is a rejection under 35 U.S.C. § 112(a). *Cf.* MPEP § 1201.

Claim 47 is rejected under 35 U.S.C. § 112(b) for indefiniteness. Final Act. 10–11; Ans. (dated Dec. 19, 2017) 2 (withdrawing indefiniteness rejection as to all other claims).

Claims 1, 2, and 51–54 are rejected under 35 U.S.C. § 103(a) as unpatentable over Pah and Clubb. Final Act. 11–12.

Claims 47 and 55 are rejected under 35 U.S.C. § 103(a) as unpatentable over Pah, Clubb, and Bortlein. Final Act. 13.

Claims 48–50 are rejected under 35 U.S.C. § 103(a) as unpatentable over Pah, Clubb, Bortlein, and Spenser. Final Act. 13–14.

[3] This application was filed on November 9, 2012, after the AIA amendments to § 112 took effect on September 16, 2012. *See* Leahy-Smith America Invents Act ("the AIA"), Pub. L. No. 112-29, § 4(e), 125 Stat. 284, 297 (2011); MPEP § 2161(I).

Claims 1, 47–50, and 55 are rejected under 35 U.S.C. § 103(a) as unpatentable over Agnew and Kerr. Final Act. 14–17.

Claims 2 and 51–54 are rejected under 35 U.S.C. § 103(a) as unpatentable over Agnew, Kerr, and Angel. Final Act. 17–18.

OPINION

A. Written Description (Claims 1, 2, and 47–55)

Claim 1 (and Claims 2 and 47–55 Via Dependencies)

The Examiner determines claim 1 fails to have written description support in Appellant's Specification, in reciting an expandable embolic capture assembly being "*housed in* said sheath." Claims App. 1 (emphasis added); Final Act. 2–3, 9–10. The Examiner finds Appellant's Specification describes the capture assembly as comprised of rail members 32, which "are part of the 'sheath' and not a separate structure as" required by the "housed in" term in claim 1. *Id.* at 3, 9–10 (citing Spec. 30:4–5). Dependent claims 2 and 47–55 are rejected on the same basis. *Id.* at 9–10.

Appellant contends "it is plain from Fig. 18G [of Appellant's Specification] that the embolic capture assembly 26 is housed in sheath 16." Appeal Br. 6.

The Examiner answers that Appellant's Figure 18G "does not clearly show" the capture assembly within the sheath. Ans. 3. The Examiner finds Appellant's Specification describes reference number 26 as an "expanded configuration" of sheath 16. *Id.* (citing Spec. 29:22–23). The Examiner concludes reference number 26 is "a portion of the sheath," so it is not housed in the sheath as required by claim 1. *Id.*

Appellant replies that Appellant's Figure 18B "shows that the obturator-jacket assembly 168 comprises the distal portion of the sheath 16," and the capture assembly is housed within assembly 168. Reply Br. 2 (citing Spec. 29:8–13)[4].

We conclude the Examiner has the better position. As described in Appellant's Specification, Figures 18B–18E illustrate "a railed *sheath* in a collapsed configuration (16)," and "*the distal portion of the railed sheath* may be allowed to become fully expanded (26)." Spec. 27:22–29:29 (emphases added). These Figures additionally show how the "collapsed railed sheath portion (16) [is] *removably coupled* to a distal obturator-jacket assembly (168)," such that removal of assembly 168 exposes portion 26 of sheath 16 so it may fully expand. *Id.* at 28:13–15 (emphasis added), 28:31–29:6. These disclosures fail to demonstrate possession of an expandable capture assembly (i.e., sheath portion 26) being "housed in" a sheath (i.e., sheath portions 16 and 26) as claimed, because sheath portion 26 is part of the sheath. Appellant's counsel conceded this point during the hearing. *See* Tr. 5:24–6:7. Although sheath portion 26 is housed in assembly 168 (Figs. 18B–18C), assembly 168 is not part of the sheath, as demonstrated by the description of assembly 168 being removably coupled to sheath portion 16 (Figs. 18B–18E, Spec. 28:3–15). Thus, we sustain the rejection of claim 1, and of claims 2 and 47–55 by virtue of depending from claim 1, as lacking written description.

[4] We have modified Appellant's citations here, and elsewhere in our decision, to refer to the pertinent disclosures in the Specification filed on November 9, 2012, rather than the corresponding disclosures in the publication of the application on May 30, 2013.

Claim 47 (and Claims 48–50 and 55 Via Dependencies)

The Examiner determines claim 47 fails to have written description support in Appellant's Specification, in reciting an "obturator having an exterior transverse dimension smaller than that of said sheath" and "surrounding said embolic capture assembly" of the sheath. Claims App. 1; Final Act. 2, 10. "Rather, the 'obturator jacket assembly' is collapsed and then pulled proximally through said 'sheath.'" *Id.* (citing Spec. 29:27–29). "There is no support for the obturator jacket assembly (168, 152) surrounding the expandable capture assembly (26) and having a smaller transverse dimension, there is only support for the obturator jacket having a smaller transverse dimension when it is pulled through the lumen." *Id.* at 2. Dependent claims 48–50 and 55 are rejected on the same basis. *Id.* at 9–10.

Appellant contends it "would not be possible" for the obturator jacket assembly to be collapsed and pulled proximally through the sheath as described in Appellant's Specification, "unless . . . the exterior cross-section of the obturator was smaller than that of the sheath." Appeal Br. 6–7.

The Examiner answers that, while Appellant's Specification states "the 'obturator assembly may be pulled proximally through the lumen of the sheath'" (Spec. 29:27–29), "there is no disclosure of the dimension of the 'obturator' in relation to the 'sheath.'" Adv. Act. (dated July 31, 2017), 2. According to the Examiner, "[t]he 'obturator' does not necessarily need to have a smaller dimension than the 'sheath' to be pulled through, since the obturator jacket is configured to be deformed." *Id.*; Ans. 4. The Examiner also cites Appellant's Figures 18B and 18D as "show[ing] the obturator jacket [168] having the same dimension at the proximal end as the sheath 16." Adv. Act. 2; Ans. 4.

We conclude Appellant has the better position. It is undisputed that obturator-jacket assembly 168 is collapsed, and then pulled proximally through sheath portion 16. *See* Spec. 29:27–29. In order for that to occur, assembly 168 must have an exterior transverse dimension smaller than that of sheath 16 as recited in claim 47, even if assembly 168 must be torn or fractured to achieve such a configuration as contemplated in the Specification. *See id.* at 29:6–24. Claim 47 does not specify that the dimension must be achieved in a pre-collapsed configuration as the Examiner appears to conclude; the claim is open to assembly 168 being collapsed to have the recited transverse dimension. Thus, we do not sustain the rejection of claim 47, and of claims 48–50 and 55 by virtue of depending from claim 47, as lacking written description.

Claim 55 (and Claims 48–50 Via Dependencies)

As discussed above, we will review the Examiner's objection to claim 55, because in substance it is properly characterized as a rejection under 35 U.S.C. § 112(a). According to the Examiner, Appellant's Specification indicates the term "obturator jacket-like wrapper portion" in claim 55 "is meant to read 'expandable embolic capture assembly'," because "the obturator jacket-like wrapper portion is clearly not uncovered." Final Act. 9.

Appellant contends "the Examiner is wrong," because "it is *the jacket-like wrapper portion 26* of the device that is uncovered when the obturator 168 is advanced distally." Appeal Br. 5–6 (emphasis added) (citing Spec. 27:22–29, and Figs. 18B, 18C and 18D).

We conclude the Examiner has the better position. As described in Appellant's Specification, Figures 18B–18E illustrate how distal

displacement of obturator-jacket assembly 168 removes assembly 168 from sheath portion 26, thereby permitting sheath portion 26 to expand fully. Spec. 28:13–15, 28:31–29:6. Assembly 168 is uncovered both before and after that removal (Figs. 18B–18E). These disclosures fail to demonstrate possession of assembly 168 being uncovered when assembly 168 is advanced distally to be released from sheath 16, 26, as is required by claim 55. Although sheath portion 26 is uncovered when assembly 168 is advanced distally, sheath portion 26 is part of the sheath, not assembly 168. Thus, we sustain the rejection of claim 55, and of claims 48–50 by virtue of depending from claim 55, as lacking written description.

B. Indefiniteness (Claim 47)

The Examiner determines claim 47, in reciting "said obturator," is unclear and therefore indefinite. Final Act. 10–11; Ans. 2 (withdrawing portion of rejection focusing on "jacket-like wrapper portion" in claim 47). The Examiner determines there is no antecedent basis for the "said obturator" term, and "[i]t is unclear if [the term] is referring to the 'elongate obturator-jacket assembly' or a portion of the assembly." Final Act. 11.

Appellant contends there is antecedent basis for the "said obturator" term in claim 47, because claim 47 previously recites an "obturator-jacket assembly." Appeal Br. 8. The "obturator" portion of the previous term, according to Appellant, provides antecedent basis for the later-recited "said obturator." *Id.*

The Examiner answers that "the 'obturator' could be a different structure from the 'obturator-jacket assembly.'" Ans. 4.

We conclude Appellant has the better position. A person of ordinary skill in the art would understand that, where claim 47 recites "an elongate

obturator-jacket assembly," the assembly includes an obturator portion. The person further would understand that, where claim 47 later recites "said obturator," the claim is referring back to the obturator portion of the obturator-jacket assembly. Thus, we do not sustain the rejection of claim 47 as indefinite.

C. Obviousness over Pah and Clubb (Claims 1, 2, and 51–54)

Appellant argues for the patentability of claims 1, 2, and 51–54 over Pah and Clubb as a group, without arguing for any of the claims separately from the other claims. *See* Appeal Br. 8–10. We therefore select claim 1 to decide the appeal of the rejection based on obviousness over Pah and Clubb. *See* 37 C.F.R. § 41.37(c)(1)(iv) (2017).

In rejecting claim 1, the Examiner finds Pah discloses each and every claim limitation, including an expandable embolic capture assembly (i.e., filter 2 of catheter 1 as shown in Figure 5), except Pah's filter element 8 is a *film* filter rather than a *mesh* filter as claimed. Final Act. 11–12. The Examiner finds Clubb discloses a mesh filter that, like Pah's film filter element 8, is designed to capture emboli from a bloodstream. *Id*. at 12 (citing Clubb ¶ 4). The Examiner determines it would have been obvious to modify Pah's filter element 8 to be a mesh filter rather than a film filter, "because the substituted elements and their functions were known in the art and the results of the substitution would have the same predictable result of capturing emboli." *Id*.

Appellant firstly argues Pah's filter 2 is not an "embolic *capture* assembly" as required by claim 1 (emphasis added). Appeal Br. 8–10. According to Appellant, Pah's filter 2 instead is an emboli "flow-through device" because filter 2 merely inhibits emboli from entering tributary

arteries, such that the emboli continue flowing through the main artery in which filter 2 is placed. *Id.* at 8–9. In support, Appellant asserts Pah's filter 2 comprises distal portion 6 having small openings that prevent passage of emboli into the tributary arteries, and proximal portion 7 having large openings that minimize the impedance of blood flow through the main artery and therefore do not impede the passage of emboli. *Id.* (citing Pah ¶¶ 21, 22, 25, 66, 88).

We agree with the Examiner's finding that filter 2 of Pah's Figure 5 captures emboli, and does not simply prevent emboli from passing through the filter. Pah does disclose, as Appellant contends, that in *some embodiments* filter 2 has smaller pores in a distal filter section 6 and larger pores in a proximal filter section 7. Pah ¶¶ 18, 21, 22, 25, 53, 58, 65, 66, 88, and Figs. 2–4. However, filter 2 of Figure 5, which is cited by the Examiner, is not such a filter. *See id.* at Fig. 5. Instead, filter 2 of Figure 5 has pores with "a roughly constant size over the entire length of the filter," which will work in the context of Figure 5 because "the filter . . . tapers gradually from distal to proximal" thereby providing "a very large filter surface." *Id.* ¶¶ 26, 82, 88, 104. Thus, in Figure 5, filter 2 "*reliably retain[s]*" embolism-causing material such as plaque and debris, so that "[w]hen the filter 2 is pulled in, the embolic material, plaque and debris filtered from the blood *remain completely* in the filter 2 and are *pulled back with it* into the catheter tube 3." *Id.* ¶¶ 15, 30, 88, 117 (emphases added).

Appellant next asserts "the removal of Pah's filter 2 by withdrawing it into catheter tube 3 would *flush emboli out of the distal end of filter 2 rather than capturing it*," "as a matter of fundamental fluid dynamics." Appeal Br. 9 (emphasis added). Appellant acknowledges the Pah disclosure quoted

above reflecting that the embolic material and debris filtered from the blood remain completely in the filter 2 (Pah ¶ 117), but asserts this disclosure "is implacably at odds with the flow-through nature of [Pah's] device which will necessarily wash the emboli which are filtered out through the 'larger openings' in the proximal section 7 and has to be considered a mis-statement by [Pah's] attorney." *Id.* at 9–10 (citing Pah ¶ 87).

The Examiner answers that the purpose of Pah's filter 4 is to capture emboli, plaque, and debris found in the blood. Ans. 4–6 (citing Pah ¶¶ 15, 30, 104, 117).

Appellant replies that, in disclosing embolic material "remain[s] completely *in the filter* 2" (Pah ¶ 117 (emphasis added)), the phrase "'in the filter' does **not mean captured by the filter**," but rather "must mean **in the bloodstream** which flows **through the filter**," because Pah discloses "substantially unimpeded flow of blood through filter 2 **and** . . . this unimpeded flow will carry embolic particles to the feet and legs." Reply Br. 3–4 (emphasis by Appellant) (citing Pah ¶¶ 22, 25, 60, 66, 92); *id*. at 4 (further citing Pah ¶¶ 7, 15, 18, 24, 88, 104).

We agree with the Examiner. Appellant's assertion that Pah's filter cannot operate as described in Pah relies solely on attorney argument, which "cannot take the place of evidence in the record." *See In re Geisler*, 116 F.3d 1465, 1470 (Fed. Cir. 1997). Appellant does not cite, and we are not aware, of any evidence in the record tending to suggest Pah's description of how filter 2 in Figure 5 operates is somehow incorrect. Thus, the evidence establishes filter 2 in Figure 5 captures embolic particles, and does not merely prevent embolic particles from entering a tributary artery as they continue to flow past the filter through a main artery. *See*, *e.g.*, Pah ¶¶ 15,

30, 104, 117. For example, as already discussed above, filter 2 in Figure 5 has pores of roughly constant size, not proximal and distal sections of differently sized pores.

Appellant finally asserts, in a new argument raised in the Reply Brief, that the Examiner errs in finding Pah discloses the limitation in claim 1 reciting "a proximal manipulation structure coupled to said hoop structure which is capable of collapsing said hoop structure and closing the distal portion of said embolic capture assembly by the application of hoop tension to capture particles in said tubular porous filter mesh." Claims App. 1; Reply Br. 5. Here, the Examiner finds Pah's filter wire 10 is a proximal manipulation structure, coupled to distal ring section 11 which is a hoop structure, such that pulling on wire 10 collapses ring section 11 to close filter 2. Final Act. 11–12 (citing Pah ¶¶ 69, 114, 117).

Appellant objects that Pah "constricts the **proximal, not the distal** portion of his filter when he removes it by pulling the filter 2, proximal section 7 first, proximally into catheter 3." Reply Br. 5 (emphasis by Appellant) (citing Pah ¶ 117). According to Appellant, "[t]here is absolutely no structure in Pah which permits constriction or closure of the distal portion of filter 6 [sic '2']." *Id.*

We are not persuaded of Examiner error. It is undisputed that Pah indicates filter 2 is retracted into catheter 3 by pulling on filter wire 10, which is connected to distal ring section 11 via end ring 9 and struts 13. *See* Pah, Fig. 5, ¶¶ 31, 67, 69, 78, 84–86, 117. Pah, therefore, discloses a proximal manipulation structure coupled to a distal hoop structure to collapse the hoop structure. Appellant's argument relies on an implicit claim construction whereby the term "coupled to" in claim 1 requires some

sort of direct connection between filter wire 10 and distal ring section 11, precluding intermediate elements such as end ring 9 and struts 13. Appellant does not cite, and we cannot find, any disclosure in Appellant's Specification that would support this narrow claim construction. *See, e.g.*, Spec. 28:27–31, 29:30–30:7, 31:1–10, Figs. 18F–18G; *In re Am. Acad. of Sci. Tech Ctr.*, 367 F.3d 1359, 1364 (Fed. Cir. 2004) (during examination of a patent application, pending claims are given their broadest reasonable construction consistent with the Specification).

For the foregoing reasons, we sustain the rejection of claims 1, 2, and 51–54 as having been obvious over Pah and Clubb.

D. Obviousness over Pah, Clubb, and Bortlein (Claims 47 and 55)

In rejecting claim 47 as having been obvious over Pah, Clubb, and Bortlein, the Examiner relies solely on Bortlein as disclosing the subject matter added by claim 47 to its parent claim 1. Final Act. 13. The Examiner finds Bortlein's Figures 3A and 3B disclose catheter 114 having an obturator-jacket assembly (i.e., distal sheath portion 132) removably coupled to a distal end of a sheath (i.e., proximal sheath portion 134) and having a distal tip (i.e., tapered section 138) and a jacket-like wrapper portion (i.e., the portion of distal sheath portion 132 surrounding medical device 112). *Id.*; *see* Bortlein ¶¶ 27–28. According to the Examiner, Bortlein's obturator "has a dimension relative to said sheath to allow the obturator to be withdrawn proximally through the lumen of sheath," as required by claim 47. Final Act. 13 (citing Bortlein, Figs. 3D–3G).

Appellant argues, in part, that Bortlein fails to disclose an obturator "being capable of being withdrawn proximally through the lumen in said sheath," as recited in claim 47. Appeal Br. 12–13. Appellant asserts

Bortlein's distal sheath portion 132 is not such an obturator, because it "cannot be removed through" Bortlein's proximal sheath portion 134. *Id*.

The Examiner answers that "the features upon which Appellant relies (i.e., the obturator being removed through the sheath) are not recited in" claim 47. Ans. 7–8.

We conclude Appellant has the better position. Claim 47 pertinently recites "*said obturator* having an exterior transverse dimension smaller than that of said sheath and *being capable of being withdrawn proximally through the lumen in said sheath*." Claims App. 1 (emphases added). Thus, in order to sustain the Examiner's rejection, Bortlein's distal sheath portion 132 must at least be capable of being withdrawn proximally through the lumen of proximal sheath portion 134.

The evidence of record does not support such a finding. Bortlein indicates proximal section 148 of distal sheath portion 132 collapses inwardly toward inner tube 122. Bortlein ¶ 30, Figs. 3A & 3D. Then Bortlein's assembly is repositioned so that distal sheath portion 132 encloses hub 126 of central tube 124. *Id.* ¶ 31, Figs. 3A & 3D–3F. "*With this arrangement*, a smoother and lower profile is created for withdrawing the catheter through the medical device 112 in the proximal direction 170, as shown in" Figures 3F and 3G. *Id.* ¶ 31 (emphasis added). At best, this disclosure establishes that a small part of distal sheath portion 132 may be received within the lumen of proximal sheath portion 134. *Id.* at Fig. 3G. This disclosure does not establish that distal sheath portion 132 is capable of "being *withdrawn* proximally *through*" the lumen of proximal sheath portion 134, as is required by claim 47 (emphases added).

For the foregoing reasons, we do not sustain the rejection of claim 47 and claim 55 depending therefrom, as having been obvious over Pah, Clubb, and Bortlein.

E. Obviousness over Pah, Clubb, Bortlein, and Spenser (Claims 48–50)

In rejecting claims 48–50 as having been obvious over Pah, Clubb, Bortlein, and Spenser, the Examiner relies solely on Bortlein as disclosing the subject matter recited in claim 47, from which each of claims 48–50 depend. Final Act. 13–14; Claims App. 1–2 (claims 49 and 50 each depend from claim 48, which depends from claim 55, which depends from claim 47). As discussed above, a preponderance of the evidence does not support the Examiner's finding that Bortlein discloses the subject matter recited in claim 47. Therefore, we do not sustain the rejection of claims 48–50 as having been obvious over Pah, Clubb, Bortlein, and Spenser.

F. Obviousness over Agnew and Kerr (Claims 1, 47–50, and 55)

Claim 1

In rejecting claim 1, the Examiner finds Agnew's Figure 1 discloses each and every claim limitation, including a sheath (i.e., outer member 12) comprising an expandable embolic capture assembly with a filter (i.e., prosthesis 24), except Agnew does not disclose a *mesh* filter, or a collapsible hoop structure located at the distal end of the filter, as claimed. Final Act. 14–15 (citing Agnew ¶¶ 8, 26).

The Examiner finds Kerr discloses a mesh filter that, like Agnew's filter, is designed to capture emboli from a bloodstream. *Id.* at 15 (citing Kerr, 5:61–62, 7:22–25). The Examiner determines it would have been

obvious to modify Agnew's filter to be a mesh filter as in Kerr, "because the substituted elements and their functions were known in the art and the results of the substitution would have the same predictable result of capturing emboli." *Id.*

The Examiner finds Kerr also discloses an "embolic capture assembly having a hoop structure (hoop of guidewire 220 . . .) coupled to the porous filter distal end and having a collapsed configuration and an expanded configuration being dimensioned to engage the walls of a blood vessel." *Id.* at 15 (citing Kerr, Figs. 11–12, 9:1–2, 9:10–15). The Examiner finds Kerr discloses "a proximal manipulation structure (guidewire 212) coupled to" the hoop structure, and capable of collapsing the hoop structure by application of hoop tension. *Id.* at 15–16 (citing Kerr, 9:26–27, 9:33–37). The Examiner determines it would have been obvious to modify Agnew's filter to include Kerr's hoop structure coupled to a proximal manipulation structure, "to more effectively trap and remove emboli." *Id.* at 16.

Appellant firstly argues Agnew "has no meaningful disclosure of an embolic capture assembly or of any kind of embolic protection device." Appeal Br. 14. According to Appellant, Agnew's "passing reference . . . to an 'embolic protection device'" is "so brief and ephemeral as to be meaningless," and "provides no evidence of which, if any, of the many types of embolic protection devices [Agnew] has in mind." *Id.* at 14–15. Appellant also asserts Agnew's embolic protection device "would include flow-through devices such as that of Pah and would not be embolic capture devices as explained with regard to Pah." *Id.* at 14.

The Examiner answers that a person of ordinary skill in the art "would know what an 'embolic protection device' is [in Agnew] without further

description." Ans. 9 (citing Agnew ¶ 26). Further according to the Examiner, the evidence does not support Appellant's contention that Agnew's embolic protection device is a flow-through device, and "it is known that an 'embolic protection device' is for capturing emboli." Final Act. 2; Ans. 9. The Examiner also finds Kerr's filter mesh "would have the result of the capturing emboli, since the particles would be prevented from flowing through the mesh openings." *Id.*

We determine the Examiner does not err in finding that the combination of Agnew and Kerr discloses an embolic capture assembly. It is undisputed that Agnew discloses deploying "self-expanding prosthesis 24" which may be a "filter" or an "embolic protection device," among other options. Agnew ¶ 26. The only concrete issue raised by Appellant is whether such a device would "capture" embolic materials, as recited in claim 1. Here, the Examiner relies on the "fine-mesh net" filter structure that the Examiner proposes to adapt from Kerr's disclosure into Agnew's structure, which we agree would operate to "capture" embolic particles. *See* Final Act. 15; Ans. 9; Kerr, Fig. 12, 5:61–62, 7:22–25, 8:52–55. A person of ordinary skill in the art, when desiring to implement Agnew's prosthesis 24 as an embolic protection device as expressly contemplated by Agnew, would naturally consider using Kerr's fine nesh-met filter structure that is disclosed as capturing embolic particles, even if Agnew does not provide any details on specific filter structures that are useful in protecting against embolic particles. *See*, *e.g.*, *In re Merck & Co.*, 800 F.2d 1091 (Fed. Cir. 1986) (nonobviousness is not established by attacking references individually when unpatentability is predicated upon a combination of prior art disclosures).

Appellant next argues "[t]here is no way" Kerr's structure "could be incorporated into the dual sheath delivery structure of Agnew without major reconstruction of Agnew," so there is no motivation to attempt the Examiner's proposed combination. Appeal Br. 15. Appellant particularly contends Kerr's embolic capture device "is complex and requires a specialized guide wire structure which also serves as a support for a filter." *Id*. Appellant also points out that Agnew's prosthesis 24 "is housed **inside** sheath 12," whereas Kerr's filter 200 is "mounted on the **outside** of catheter 206." Reply Br. 6 (emphases by Appellant).

The Examiner answers that the proposed modification to Agnew would include only Kerr's mesh filter, and hoop structure with a pull wire. Final Act. 7 (citing Agnew, Fig. 3); Ans. 9. The Examiner determines a person of ordinary skill in the art "would understand how to combine the references for a predictable result, considering it would only require adding the [cited] features of Kerr to Agnew," and not the bodily incorporation of Kerr's structure into Agnew's device. Ans. 9–10.

We determine a preponderance of the evidence supports the Examiner's determination of obviousness here. Appellant's opposition rests largely on the premise that the bodily incorporation of Kerr's entire filter structure within Agnew's prosthesis 24 would be difficult. However, the test for obviousness is not whether the features of one reference (such as Kerr) may be bodily incorporated into the structure of the other reference (such as Agnew), but rather is "what the combined teachings of the references would have suggested to those of ordinary skill in the art." *In re Keller*, 642 F.2d 413, 425 (CCPA 1981)). "A person of ordinary skill is also a person of ordinary creativity, not an automaton." *KSR Int'l Co. v. Teleflex Inc.*,

550 U.S. 398, 421 (2007). In this case, we agree with the Examiner that a person of ordinary skill in the art would have been capable of adapting Kerr's mesh filter, and hoop structure with a pull wire for removal, within Agnew's prosthesis 24, which is deployed from the inside of a delivery sheath, not the outside of a delivery sheath as in Kerr. *See, e.g.*, Agnew, Figs. 1–4, ¶¶ 42–44.

Appellant finally argues Kerr's Figures 11–12 "show that filter 200 is mounted on the surface of catheter 202," not "housed in" the catheter sheath as recited in claim 1, so the combination does not lead to the claimed invention. Appeal Br. 15 (emphasis by Appellant) (citing Kerr, 8:42–9:37). Instead, according to Appellant, the combination "would result in the filter of Kerr being mounted on the exterior of the device of Agnew." *Id.*; Reply Br. 7. This argument is not persuasive because, as discussed above, Agnew's prosthesis 24 is deployed from the inside of a delivery sheath. *See, e.g., Merck, supra*.

For the foregoing reasons, we sustain the rejection of claim 1 as having been obvious over Agnew and Kerr.

Claim 47

In rejecting claim 47 as having been obvious over Agnew and Kerr, the Examiner cites Agnew as disclosing an obturator-jacket assembly (i.e., cap 30) having a jacket-like wrapper portion (i.e., the portion of outer member 12 with tear line 48 that covers prosthesis 24) removably coupled to the distal end of a sheath. Final Act. 8, 16 (citing Agnew, Figs. 1–2, ¶ 8).

Appellant argues the Examiner errs in relying on "element 40" in Agnew as being the "obturator" of claim 47, because "element 40 is a 'channel' and not a closure device." Appeal Br. 15. This argument is not

persuasive, because the Examiner relies on Agnew's cap 30 as being an obturator, not Agnew's channel 40. *See* Final Act. 8, 16; Ans. 10. Thus, we sustain the rejection of claim 47 as having been obvious over Agnew and Kerr.

Claims 48–50 and 55

The Appeal Brief does not present additional argument against the rejection of claims 48–50 and 55 as having been obvious over Agnew and Kerr. *See* Appeal Br. 14–15. Appellant's counsel presented new arguments concerning claims 48 and 55 at the oral hearing, which we refuse to consider as untimely presented. *See* Tr. 2:19–4:2, 10:1–11:16; 37 C.F.R. § 41.47(e) (2017). We therefore sustain this rejection, for the reasons provided above in connection with parent claims 1 and 47. *See* 37 C.F.R. § 41.37(c)(1)(iv) (2017).

G. Obviousness over Agnew, Kerr, and Angel (Claims 2 and 51–54)

Claims 2 and 53

Claim 2 recites: "The system of claim 1, wherein said embolic capture assembly comprises rail members coupled to said hoop structure and which are configured to expand when said hoop expands." Claims App. 1.

The Examiner determines "Agnew as modified by Kerr . . . is silent regarding the embolic capture assembly comprising *rail members* coupled to the hoop structure and which are configured to expand when the hoop expands." Final Act. 17 (emphasis added), 8. The Examiner then cites Angel as "teach[ing] *a filter element having a wire circumference distal end* for the purpose of capturing and retaining embolic material." *Id.* (emphasis added) (citing Angel ¶ 73, Fig. 20). The Examiner concludes it would have

been obvious "to have modified the filter of Agnew as modified by Kerr to *include the structure of the filter of Angel* in order to facilitate additional apposition between the filter member and the vascular wall." *Id.* (emphasis added) (citing Angel ¶ 79).

Appellant opposes the Examiner's rejection of claim 2. *See* Appeal Br. 16–17.

We conclude that we cannot sustain the foregoing rejection of claim 2. The Examiner expressly determines that Agnew and Kerr do not disclose the claimed "rail members," but then does not establish such a disclosure to be present in Angel, or anywhere else in the prior art. *See* Final Act. 8–9, 17. Instead, the rejection cites Angel as disclosing "a wire circumference distal end," which appears to relate to the hoop structure of claim 1, not the rail members of claim 2. *Id.*; Ans. 10–11. This is confusing, because the Examiner has already relied on Kerr as disclosing the hoop structure of claim 1. Final Act. 15–16 (analysis of claim 1), 17 ("Agnew as modified by Kerr discloses the claimed invention as set forth in claim 1"). Thus, it is not clear exactly what structure(s) are being added to Kerr from Angel to result in the invention of claim 2, especially the "rail members." In that regard, both Kerr and Angel disclose structures which might be considered "rail members" coupled to a hoop structure. *See* Kerr, Fig. 12; Angel, Fig. 20. This begs the question: what structure(s) in Angel correspond to the "rail members" that the Examiner expressly finds to be absent in Kerr, and exactly how does the combination lead to claim 2? Those questions are not answered by the rejection.

Due to this lack of clarity, we cannot sustain the rejection of claim 2, and of claim 53 which depends from claim 2, as having been obvious over Agnew, Kerr, and Angel.

Claims 51, 52, and 54

Claims 51, 52, and 54 each specify particular characteristics of the "hoop structure" initially recited in their parent claim 1. Claims App. 2. The Examiner cites Angel's Figure 20 as disclosing a hoop structure having the specified characteristics. Final Act. 17–18 (citing Angel ¶¶ 17, 73, 90). We reproduce Angel's Figure 20 here:

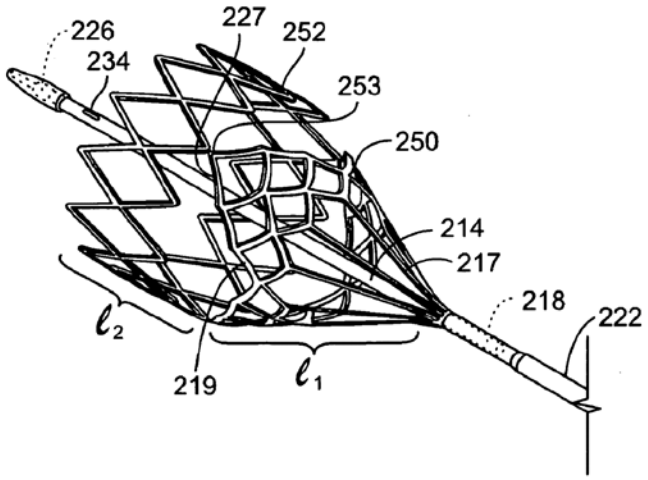

FIG. 20

Figure 20 is a perspective view of a filter in an expanded state. Angel ¶¶ 39, 75, 79. As described in Angel, the filter "is formed of plural interconnected structural elements." *Id.* ¶ 76. First structural members 217 extend along the longitudinal axis of the filter. *Id.* Second structural members 219 extend from first structural members 217 to "form at least two successive zigzag structures . . . about the circumference of the filter," defining a "lattice-like pattern." *Id.* Circumferential ring member 252 extends from apices 227 of second members 219. *Id.* ¶ 79.

Claim 51 specifies "a plurality of hoops." Claims App. 2. The Examiner finds Angel's filter has "a plurality of hoops (struts at distal end of filter 250 and the circumferential ring 252, see Fig. 20 of Angel)." Final Act. 17; *id.* at 8–9; Ans. 10–11. Appellant objects that "there are no 'hoop structures' in the filter of Angel," in part because second structural members 219 "form a 'lattice-like pattern' which pattern is not and cannot be considered to be a hoop." Appeal Br. 16. We agree with Appellant. At best, Angel's circumferential ring 252 forms one hoop, not a plurality of hoops as required by claim 51. Angel's second structural members 219, meanwhile, form a complicated lattice structure that the Examiner does not adequately explain, and we do not see, how this structure can reasonably be construed as a hoop. Thus, we do not sustain the rejection of claim 51 as having been obvious over Agnew, Kerr, and Angel.

Claim 52 depends from claim 51, and specifies that the "plurality of hoops are inter-coupled by struts having a zig-zag configuration." Claims App. 2. The Examiner finds that, in Angel's filter, "the plurality of hoops are inter-coupled by struts having a zig-zag configuration (see Fig. 20 of Angel)." Final Act. 18; *id.* at 8–9; Ans. 10–11. For the reasons provided above in connection with claim 51, we do not sustain the Examiner's finding that Angel discloses a plurality of hoops. In addition, it is not clear, and the Examiner does not explain, how Angel's Figure 20 discloses *both* a plurality of hoop structures *and* inter-coupling struts having a zig-zag configuration. Thus, we do not sustain the rejection of claim 52 as having been obvious over Agnew, Kerr, and Angel.

Claim 54 specifies that the "hoop structure comprises nitinol." Claims App. 2. The Examiner finds "Angel further teaches *the rail members*

and hoop structure comprise nitinol." Final Act. 18 (emphasis added) (citing Angel ¶ 8). We disagree with this finding. The cited disclosure indicates only that "[r]ecovery nitinol filters" were known in the prior art. Angel ¶ 8. It does not indicate that nitinol is an appropriate material for forming Angel's filters, such as the filter illustrated in Figure 20. *Id.* Further, the Examiner does not provide any reasoning to bridge this gap in the Angel disclosure, by establishing a rational basis for why it would have been obvious to make the filter of Angel's Figure 20 out of nitinol. *See* Final Act. 18. Thus, we do not sustain the rejection of claim 54 as having been obvious over Agnew, Kerr, and Angel.

CONCLUSION

In summary:

Claim(s) Rejected	**35 U.S.C. §**	**Basis / References**	**Affirmed**	**Reversed**
1, 2, 47–55	112(a)	Written Description	1, 2, 47–55	
47–50, 55	112(a)	Written Description		47–50, 55
48–50, 55	112(a)	Written Description	48–50, 55	
47	112(b)	Indefiniteness		47
1, 2, 51–54	103(a)	Pah, Clubb	1, 2, 51–54	
47, 55	103(a)	Pah, Clubb, Bortlein		47, 55
48–50	103(a)	Pah, Clubb, Bortlein, Spenser		48–50
1, 47–50, 55	103(a)	Agnew, Kerr	1, 47–50, 55	
2, 51–54	103(a)	Agnew, Kerr, Angel		2, 51–54
Overall Outcome			1, 2, 47–55	

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED