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Faegre Drinker Biddle & Reath LLP - W.L. Gore 2200 Wells Fargo Center 90 South Seventh Street Minneapolis, MN 55402-3901			TEMPLETON, CHRISTOPHER L	
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte CRAIG W. IRWIN and JAMES D. SILVERMAN

Appeal 2019-006517
Application 14/639,699
Technology Center 4100

Before MICHAEL L. HOELTER, MICHELLE R. OSINSKI, and
JEREMY M. PLENZLER, *Administrative Patent Judges*.

PLENZLER, *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 1–24 and 28–30.² We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

¹ We use the word Appellant to refer to “applicant” as defined in 37 C.F.R. § 1.42(a). Appellant identifies the real party in interest as W. L. Gore & Associates, Inc. Appeal Br. 3.

² Claims 25–27, 31, and 32 are withdrawn.

CLAIMED SUBJECT MATTER³

The claims are directed to a medical device deployment system.

Claim 1, reproduced below, is illustrative of the claimed subject matter:

1. A medical device deployment system comprising:

an expandable medical device having first and second ends and having a larger deployed diameter, and a smaller compacted diameter in a delivery configuration adapted for advancement through a vasculature of a patient;

a sheath surrounding the smaller, compacted medical device, said sheath everted back over itself, wherein an outer portion of said sheath surrounds an inner portion of said sheath;

a filamentary constraining member positioned between the inner and outer portions of the sheath in the delivery configuration such that the outer portion of the sheath surrounds the constraining member from the first end to at least the second end of the medical device, the filamentary constraining member being configured to unravel while positioned between the inner and outer portions of the sheath during deployment, and the filamentary constraining member including a cord configured to be tensioned to unravel the constraining member, wherein said medical device is deployed to the larger deployed diameter by application of simultaneous actuation forces to the sheath and the cord of the filamentary constraining member.

³ Independent claim 13 recites “a second sheath being located between the inner and outer portions of the first sheath such that the outer portion of the first sheath surrounds the second sheath from the first end to at least the second end of the medical device.” Although we do not reach this claim separately to resolve the appeal, we note that it is unclear how the embodiment Appellant identifies in the Specification supports this limitation. *See* Appeal Br. 4 (referencing, e.g., Spec. ¶¶ 62, 63); *see also* Spec. ¶¶ 62, 63 (discussing the embodiment shown in Figure 17 with first sheath 26 and second sheath 96).

REFERENCES

The prior art relied upon by the Examiner is:

Name	Reference	Date
Armstrong	US 6,315,792 B1	Nov. 13, 2001
Austin	US 2005/0240254 A1	Oct. 27, 2005
Randall	US 2007/0060999 A1	Mar. 15, 2007
Koss	US 2008/0281398 A1	Nov. 13, 2008
Irwin	US 2009/0182411 A1	July 16, 2009
Papp	US 2010/0036472 A1	Feb. 11, 2010

REJECTIONS

Claims 1–24 and 28–30 are rejected under 35 U.S.C. § 112(a) as failing to comply with the written description requirement.

Claims 1–24 are rejected under 35 U.S.C. § 112(b) as being indefinite.

Claims 1–7, 9–19, 21–24, 28, and 30 are rejected under 35 U.S.C. § 103 as being unpatentable over Austin and Armstrong.

Claims 13–19 and 21–23 are rejected under 35 U.S.C. § 103 as being unpatentable over Koss, Armstrong, and Austin.

Claims 8 and 20 are rejected under 35 U.S.C. § 103 as being unpatentable over Austin, Armstrong, and Irwin.

Claim 20 is rejected under 35 U.S.C. § 103 as being unpatentable over Koss, Armstrong, Austin, and Irwin.

Claim 29 is rejected under 35 U.S.C. § 103 as being unpatentable over Austin, Armstrong, and Papp or Randall.

OPINION

Written Description and Indefiniteness

In the Final Action, the Examiner rejects claims 1–24 and 28–30 as failing to comply with the written description requirement and claims 1–24

as indefinite. Final Act. 2. Although the Examiner's Answer does not list the written description and indefiniteness rejections, it states that "[e]very ground of rejection set forth in the Office action dated 7 September 2018 from which the appeal is taken is being maintained by the examiner except for the grounds of rejection (if any) listed under the subheading 'WITHDRAWN REJECTIONS.'" Ans. 3; *see also* 37 C.F.R. §41.39(a)(1). There are no rejections listed as withdrawn in the Examiner's Answer. Further, our review of the record does not indicate that the written description and indefiniteness rejections have been withdrawn. Accordingly, we understand these rejections to be pending.

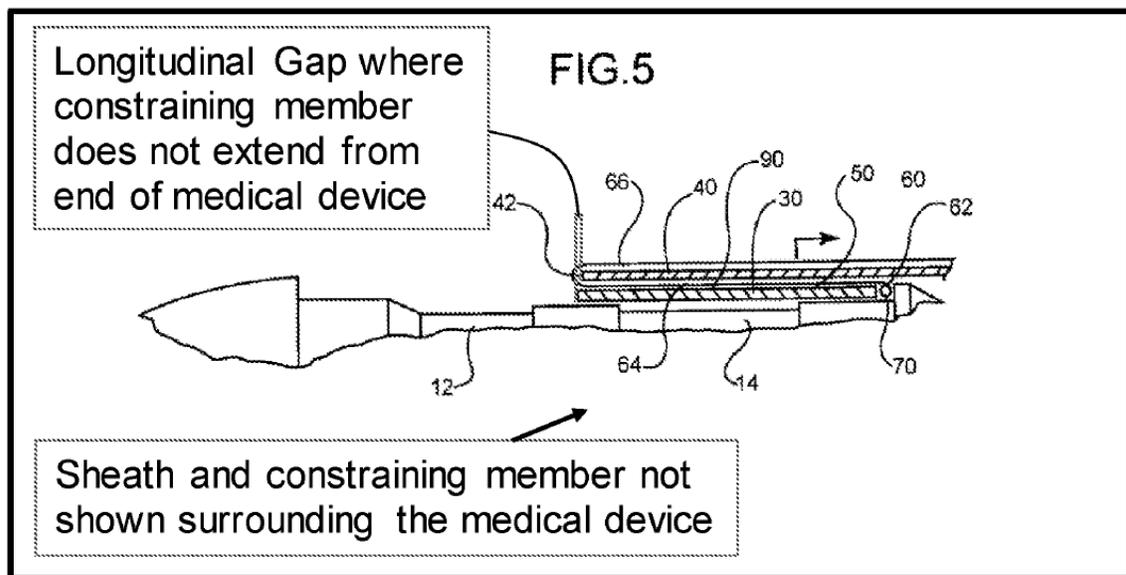
Our rules state that Appellant's "arguments shall explain why the examiner erred as to each ground of rejection contested by appellant." *See* 37 C.F.R. § 41.37(c)(1)(iv). "When the appellant fails to contest a ground of rejection to the Board . . . the PTO may affirm the rejection of the group of claims that the examiner rejected on that ground without considering the merits of those rejections." *Hyatt v. Dudas*, 551 F.3d 1307, 1314 (Fed. Cir. 2008). Accordingly, because there is no assertion of error by Appellant, we summarily affirm the Examiner's written description and indefiniteness rejections of claims 1–24 and 28–30 (written description) and claims 1–24 (indefinite).

Obviousness – Austin Rejections

Claim 1 requires "a filamentary constraining member positioned between the inner and outer portions of the sheath in the delivery configuration such that the outer portion of the sheath surrounds the constraining member from the first end to at least the second end of the medical device." The Examiner cites *Austin* as teaching this limitation.

Final Act. 4, 9; Ans. 3–4. This is the only part of the rejection disputed by Appellant. Appeal Br. 5–8; Reply Br. 2–6.

In the Answer, the Examiner finds that “Figure 5 of Austin teaches an outer portion of a sheath 66 surrounding a constraining member (second sheath) 40 from the first end to at least the second end of the medical device 30 (Fig. 5).” Ans. 3. Appellant provides an annotated view of Austin’s Figure 5, reproduced below, and responds that “the element analogized to a constraining member (Element 40 in Fig. 5 of *Austin*) does not surround the medical device (Element 30 in FIG. 5 of *Austin*) from the first end to at least the second end.” Reply Br. 3.



The Figure reproduced above is Austin’s Figure 5, which depicts “a partial enlarged view of [a stent delivery system having a rolling membrane] depicted during retraction of the membrane and sheath” (Austin ¶ 28), with the addition of Appellant’s annotations indicating the alleged shortcomings in the Examiner’s findings (Reply Br. 3). One annotation indicates a “Longitudinal Gap where constraining member does not extend from end of

medical device.” The other annotation asserts that “Sheath and constraining member not shown surrounding the medical device.”

Appellant’s contentions are not commensurate with the scope of claim 1. Claim 1 requires that the “filamentary constraining member [is] positioned between the inner and outer portions of the sheath in the delivery configuration,” but says nothing about the longitudinal extent of that “filamentary constraining member.” Rather, it is the “outer portion of the sheath [that] surrounds the constraining member [and extends] from the first end to at least the second end of the medical device.” There is no dispute that Austin’s sheath 66 surrounds Austin’s “constraining member” (sheath 40) or that sheath 66 extends from first end to at least the second end of Austin’s “medical device” (stent 30).

Moreover, Austin’s Figure 5 “depict[s] . . . retraction of the membrane and sheath subsequent to the depiction in F[igure] 4.” Austin ¶ 28. Further, and immediately before reaching the position shown in Figure 5, both outer region (sheath) 66 and retaining sheath (constraining member) 40 would extend from the first end to the second end of stent (medical device) 30.

Regarding Appellant’s annotation of Austin’s Figure 5 above that asserts “Sheath and constraining member not shown surrounding the medical device,” that, too, is unpersuasive. As explained above, Figure 5 is a partial, temporal view, of the device depicted in Austin’s Figure 1. We have no reason to believe that sheaths 40, 66 do not surround the circumference of stent 30 in the state of the device shown in Figure 5. Nor is there any meaningful dispute from Appellant in this regard.

Because we agree that Figure 5 depicts the claim limitation at issue, we need not reach Appellant's additional contentions related to the Examiner's alternate/additional reliance on Austin's other Figures.

For at least the reasons set forth above, we are not apprised of error in the rejection of claim 1. Although addressing claims 13 and 28 under a separate heading, Appellant simply relies on the unpersuasive arguments presented for claim 1 for the patentability of those claims. Appeal Br. 8. Appellant does not address specifically claims 2–12, 14–24, 29, and 30. *See* Appeal Br. 5–8.

Obviousness – Koss Rejections

Because we affirm the Examiner's decision to reject claims 2–24 and 28–30 based on the combined teachings of Austin as the primary reference and various other references, we need not reach the Examiner's rejection of a subset of those claims based on the combined teachings of Koss and various other references.

CONCLUSION

The Examiner's rejections under 35 U.S.C. § 112 and those based on the combined teachings of Austin as the primary reference with various other references are affirmed. We do not reach the rejections based on the teachings of Koss combined with various other references.

DECISION SUMMARY

In summary:

Claims Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
1-24, 28-30	112(a)	Written Description	1-24, 28-30	
1-24	112(b)	Indefiniteness	1-24	
1-7, 9-19, 21-24, 28, 30	103	Austin, Armstrong	1-7, 9-19, 21-24, 28, 30	
13-19, 21-23	103	Koss, Armstrong, Austin ⁴		
8, 20	103	Austin, Armstrong, Irwin	8, 20	
20	103	Koss, Armstrong, Austin, Irwin ⁵		
29	103	Austin, Armstrong, Papp or Randall	29	
Overall Outcome			1-24, 28-30	

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). *See* 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED

⁴ As explained above, we do not reach this rejection.

⁵ As explained above, we do not reach this rejection.