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BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte SARAH ELLEN DRILLING, JOHN C. OSLUND, MATHIAS C. GLIMSDALE, and XIAOPING GU

Appeal 2019-006617
Application 14/992,516
Technology Center 3700

Before EDWARD A. BROWN, MICHAEL L. HOELTER, and JAMES P. CALVE, *Administrative Patent Judges*.

BROWN, *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 31–56. 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. Appellant identifies the real party in interest as St. Jude Medical, Cardiology Division, Inc. Appeal Br. 1.

CLAIMED SUBJECT MATTER

Claims 31, 50, and 56 are independent claims. Claim 31, reproduced below, illustrates the claimed subject matter:

> 31. A medical device comprising:
> at least one layer of a fabric of braided strands, having proximal and distal ends and a central axis extending therebetween, the medical device having an expanded preset configuration comprising a generally frustoconical shaped portion at each end, wherein, in the expanded preset configuration, each frustoconical shaped portion comprises first and second ends and a conical portion disposed therebetween, wherein the first ends are generally planar and face one another and have a larger cross-sectional diameter than the second ends, wherein the second ends correspond to the proximal and distal ends of the medical device, wherein the medical device is configured to be constrained to a reduced configuration for delivery through a diagnostic catheter, and wherein the medical device is biased towards the expanded preset configuration such that the medical device is configured to self-expand and at least partially return, when unconstrained, towards the expanded preset configuration.

Appeal Br. 10 (Claims App.).

REJECTIONS ON APPEAL

Claims 31, 36–39, 43–52, and 56 are rejected under 35 U.S.C. § 103(a) as unpatentable over Forber (US 6,221,086 B1, issued Apr. 24, 2001) and Feller (WO 2006/034153 A2, published Mar. 30, 2006).

Claims 32–34 are rejected under 35 U.S.C. § 103(a) as unpatentable over Forber, Feller, and Soltesz (US 2006/0135947 A1, June 22, 2006).

Claim 35 is rejected under 35 U.S.C. § 103(a) as unpatentable over Forber, Feller, Soltesz, and Meng (US 2008/0033478 A1, published Feb. 7, 2008)

Claims 40–42, 53, and 54 are rejected under 35 U.S.C. § 103(a) as unpatentable over Forber, Feller, and Dao (US 2005/0075625 A1, published Apr. 7, 2005).

Claim 55 is rejected under 35 U.S.C. § 103(a) as unpatentable over Forber, Feller, and Amplatz (US 2008/0200945 A1, published Aug. 21, 2008).

ANALYSIS

Rejection of claims 31, 36–39, 43–52, and 56 over Forber and Feller

Claims 31, 36–39, 43–49

The Examiner finds that Forber discloses all limitations of claim 31 except for each frustoconical shaped portion including first ends that are generally planar and face one another. Final Act. 5 (*see* annotated Forber Figure 23). The Examiner relies on Feller as disclosing a medical device for occluding a blood vessel comprising two bulbous portions 24, 26 separated by a relatively narrow portion 28. *Id.* (citing Feller, Fig. 2). The Examiner finds that the medical device shown in Figure 2 of Feller comprises a generally frustoconical shaped portion at each end, wherein each frustoconical portion comprises first and second ends and the first ends are generally planar and face one another. *Id.* at 5, 6 (annotated Feller Figure 2). Based on these findings, the Examiner concludes that it would have been obvious to modify Forber's medical device to have the "dog bone" shape taught by Feller, as this shape is known in the art to be effective in occluding

blood vessels and this shape would still remain in contact with vessel walls if the device were canted off axis. *Id.* at 6 (citing Forber, col 5, ll. 12–16).

Appellant contends that one of ordinary skill in the art would not have modified the medical device shown in Figure 23 of Forber to have the "dog-bone" shape disclosed in Feller, as this would reduce the contact area of the occlusion device with the blood vessel. Appeal Br. 5. Appellant contends that Forber describes that the occlusion devices provide a force that resists downstream movement of the deployed device, namely:

> the frictional force generated by the device 40 pushing against the vessel wall. This frictional force is a function of the coefficient of friction between the film 32 and the vessel wall, the radial force, and the surface area of contact. [. . .] The greater the contact area, the greater the frictional force.

Id. (citing Forber, col. 9, ll. 7–16). Therefore, Appellant asserts, one skilled in the art would not have been motivated to reduce the contact area of the device shown in Figure 23 of Forber with the reduced-diameter central portion of the dog-bone-shaped device of Feller, because this would reduce the frictional force that maintains the devices' position within a blood vessel and increase the likelihood that the device would be dislodged from its deployed position. *Id.* at 6.

The Examiner responds that, as shown in Figure 4 of Feller, the "'dog bone shape'" is capable of contacting the blood vessel along the entire length of the occlusion device. Ans. 4. The Examiner agrees with Appellant's contention that "'the contact area between the device and the vessel wall also depends on the overall size of the device relative to the overall size of the vessel.'" *Id.*; Appeal Br. 7. The Examiner disagrees, however, with Appellant's argument that the modified "dog bone" shape

would reduce the contact area of Forber's device, determining that "the [dog bone] shape is fully capable of contacting a cylindrical vessel wall along the entire length thereof if the vessel has a slightly smaller diameter than the full expandable diameter of the device." *Id.* at 5.

We agree with the Examiner that modifying Feller's device by substituting the shape shown in Figure 23 with Feller's dog bone shape would not necessarily reduce the contact area between the device and a vessel wall. Figures 3 and 4 of Feller show that the bulbous portions 24, 26, and the relatively narrow portion 28 of dog bone shape 22 are configured to contact a vessel wall in which the occlusion device is deployed.

Moreover, the Examiner points out that the surface area of contact between the device and vessel wall is only one factor that contributes to the frictional force resisting downstream movement of the occlusion device. Ans. 5. Particularly, Forber discloses that the coefficient of friction between the film (device) and a vessel wall and the radial force additionally contribute to the frictional force as the Examiner finds. *Id.* (citing Forber, col. 9, ll. 7–16). Accordingly, Forber teaches or suggests that a reduction in the contact surface area between the device and a vessel wall could be compensated by increasing the coefficient of friction and/or the radial force to provide the desired frictional force.

Appellant also disagrees with the Examiner's statement that "'[t]he dog-bone shape, ball-shape, conical shape, and tapered cylindrical shape are art-recognized functionally equivalent shapes for occlusion devices and it is obvious to substitute one known shape for another shape providing the same function to yield predictable results.'" Appeal Br. 6; Final Act. 11. Appellant contends that "one skilled in the art would recognize that

occlusion devices intended for occluding different areas of the body would likely be designed or shaped with the area to be occluded in mind." *Id.*

The Examiner responds that the device shapes taught by both Forber and Feller effectively occlude blood vessels, depending on the vessel shape each device shape is placed in. Ans. 3. The Examiner maintains that the dog-bone shape of Feller and the tapered cylindrical shape of Forber are designed for occluding different areas of the body, and one of ordinary skill in the art would recognize the interchangeability of the shapes depending on the desired use to occlude a particular vessel. *Id.*

The Examiner proposes to substitute one known element (i.e., a known occlusion device shape) with another element (i.e., another known occlusion device shape), relying on a simple substitution rationale. Ans. 3. According to this rationale, "when a patent claims a structure already known in the prior art that is altered by the mere substitution of one element for another known in the field, the combination must do more than yield a predictable result." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007) (citation omitted). Appellant does not contend that one of ordinary skill in the art would have been unable (i.e., would have lacked the requisite skill) to substitute one known element for another, or that the results of the substitution would have been unpredictable. Accordingly, Appellant does not apprise us of error in the Examiner's simple substitution rationale.

Appellant also contends that each embodiment described in Forber meets Forber's requirement/advantage of remaining in contact with the vessel wall if the device is canted off axis, and, therefore, it is unclear why one of ordinary skill in the art would have modified or substituted the shaped devices of Forber with Feller's dog-bone shape. Reply Br. 1–2.

This contention is unpersuasive. First, Forber discloses that "*[t]he ball-like shape offers an advantage over a single disk* in that the ball-like shape *may cant* off the axis of the blood vessel and the outside of the ball-like shape will remain in contact with the vessel wall." *See Forber*, col. 5, ll. 11–15 (emphasis added). This description refers to an advantage of the ball-shaped structure 20 shown in Figure 1 of Forber. *See id.* at col. 4, ll. 60–64, Fig. 1. This description does not, however, indicate that this advantage is a requirement of all embodiments disclosed in Forber. Second, even if, in Forber, the occlusion device shown in Figure 23 provides the same advantage as the ball-shaped structure 20 shown in Figure 1, the Examiner determines that the modified occlusion device would provide this same advantage as well. Final Act. 6; Ans. 4. Indeed, Figure 4 of Feller illustrates the "dog bone" shape aligned with the vessel axis without canting.

Appellant also contends that paragraph 60 of the published application, US 2016/0151075 A[2] describes "*two* planes of occlusion configured to be provided by the subject matter of independent claims 31 and 56," whereas "Feller merely indicates that 'the 'dog bone' occlusion device 22 will typically provide a satisfactory occlusive effect in the applications of Figs. 3 and 4 if *either one* of the bulbous portions 24 and 26 acts as a plug.'" Reply Br. 2 (citing Feller ¶ 42).

This contention is not persuasive. First, claim 31 does not recite that the medical device provides two planes of occlusion. Unclaimed limitations cannot, however, be relied upon for patentability. *In re Self*, 671 F.2d 1344,

[2] Paragraph 60 of the published application corresponds to page 11, lines 8–18, of the present Specification.

1348 (CCPA 1982). Second, Appellant has not identified any structural or functional limitation recited in claim 31 that the Examiner's proposed combination of Forber and Feller would lack.

For the above reasons, we sustain the rejection of claim 31 and dependent claims 36–39 and 43–49 as unpatentable over Forber and Feller.

Claims 50–52

Claim 50 incorporates by reference all limitations of claim 31. Appeal Br. 12–13 (Claims App.). Appellant relies on the dependency of claim 50 from claim 31 for patentability. *Id.* at 7. Accordingly, we sustain the rejection of claim 50, and claims 51 and 52 depending therefrom, as unpatentable over Forber and Feller for the same reasons as discussed for claim 31.

Claim 56

Appellant relies on the same argument presented for claim 31 for patentability of independent claim 56. Appeal Br. 4–7. Accordingly, we sustain the rejection of claim 56 as unpatentable over Forber and Feller for the same reasons as discussed for claim 31.

Rejection of claims 32–34 over Forber, Feller, and Soltesz
Rejection of claim 35 over Forber, Feller, Soltesz, and Meng
Rejection of claims 40–42, 53, and 54 over Forber, Feller, and Dao
Rejection of claim 55 over Forber, Feller, and Amplatz

Claims 32–35, 40–42, and 53–55 depend directly or indirectly from claim 31 or 50. Appellant relies solely on the argument presented for claim 31 for the patentability of these dependent claims. Appeal Br. 8.

Accordingly, we sustain the rejections of claims 32–35, 40–42, and 53–55 for the same reasons as discussed for claim 31.

Non-statutory double patenting

Appellant does not contest the rejection of claims 31–56 on the ground of non-statutory double patenting. Thus, we sustain this rejection.

DECISION SUMMARY

In summary:

Claim(s) Rejected	**35 U.S.C. §**	**Reference(s)/Basis**	**Affirmed**	**Reversed**
31, 36–39, 43–52, 56	103(a)	Forber, Feller	31, 36–39, 43–52, 56	
32–34	103(a)	Forber, Feller, Soltesz	32–34	
35	103(a)	Forber, Feller, Soltesz, Meng	35	
40–42, 53, 54	103(a)	Forber, Feller, Dao	40–42, 53, 54	
55	103(a)	Forber, Feller, Amplatz	55	
31–56		Non-statutory double patenting	31–56	
Overall Outcome			31–56	

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