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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte PATRICK W. KELLY

Appeal 2018-005569
Application 13/706,036
Technology Center 3700

Before MICHAEL L. HOELTER, ANNETTE R. REIMERS, and MICHAEL L. WOODS, *Administrative Patent Judges*.

WOODS, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Pursuant to 35 U.S.C. § 134(a), Appellant[1] appeals from the Examiner's decision to reject claims 1–11, 17, and 18, which constitute all the claims pending in this application. Appeal Br. 1. Claims 12–16 have been withdrawn. *Id.* 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); *see also id.* § 1.42. The Real Party in Interest is Sanford Health. Appeal Br. 1.

CLAIMED SUBJECT MATTER

Appellant's invention relates to a debranching stent graft, which includes a main body stent graft limb and a bifurcation that defines two legs. *See* Spec. Abstr.

Of the rejected claims, claim 1 is the sole independent claim. Appeal Br. (Claims App'x). We reproduce claim 1, below, with emphasis added to a particular limitation discussed in this Decision.

> 1. A debranching stent graft limb comprising:
>
> a main body stent graft limb with a bifurcation defining a first leg and a second leg,
>
> wherein the main body stent graft limb has a distal end and a proximal end;
>
> wherein the main body stent graft limb has a diameter at the proximal end in the range from about 14 mm to about 18 mm;
>
> wherein the diameter along the length of the main body stent graft limb either tapers outwardly toward the distal end or remains constant;
>
> wherein the first leg has a diameter ranging from about 8 mm to about 12 mm; wherein the second leg has a diameter ranging from about 6 mm to about 10 mm; and
>
> wherein the distance from the proximal end of the main body stent graft limb to the distal end of the first leg and the second leg is in the range from about 70 mm to about 90 mm; and
>
> *wherein the diameter of the first leg is about 2 mm greater than the diameter of the second leg;*
>
> wherein the length of the first leg and the length of the second leg are each a minimum of about 30 mm; and
>
> wherein the main body stent graft limb comprises a stent structure extending along the length of the main body stent graft limb, wherein the first leg comprises a stent structure extending along the length of the first leg and wherein the second leg comprises a stent structure extending along the length of the second leg.

Id. (emphasis and indentations added for clarity).

REFERENCES

The prior art relied upon by the Examiner is:

Name	Reference	Date
Piplani	US 5,489,295	Feb. 6, 1996
Nunez	US 6,136,022	Oct. 24, 2000
Gordon	US 6,773,456 B1	Aug. 10, 2004
Dehdashtian	US 2006/0224228 A1	Oct. 5, 2006
Ressemann	US 6,224,609 B1	May 1, 2001

REJECTIONS

1. Claims 1–4, 6, 7, 9, and 18 are rejected under 35 U.S.C. § 103(a) as unpatentable over Piplani and Nunez, with Gordon relied on as evidence. Final Act. 3.
2. Claims 5, 8, 10, and 11 are rejected under 35 U.S.C. § 103(a) as unpatentable over Piplani, Nunez, and Dehdashtian, with Gordon relied on as evidence. Final Act. 6.
3. Claim 17 is rejected under 35 U.S.C. § 103(a) as unpatentable over Piplani, Nunez, and Ressemann, with Gordon relied on as evidence. Final Act. 7.

OPINION

I. Claims 1–4, 6, 7, 9, and 18 – Unpatentable Over Piplani and Nunez

Appellant contests the rejection of claims 1–4, 6, 7, 9, and 18 collectively. *See* Appeal Br. 3–14. We select claim 1 as representative,

treating claims 2–4, 6, 7, 9, and 18 as standing or falling with representative claim 1. *See* 37 C.F.R. § 41.37(c)(1)(iv).

a. Examiner's Rejection

In rejecting claim 1, the Examiner relies on Piplani for disclosing several of the claimed features, citing its Figure 4, which we reproduce, below:

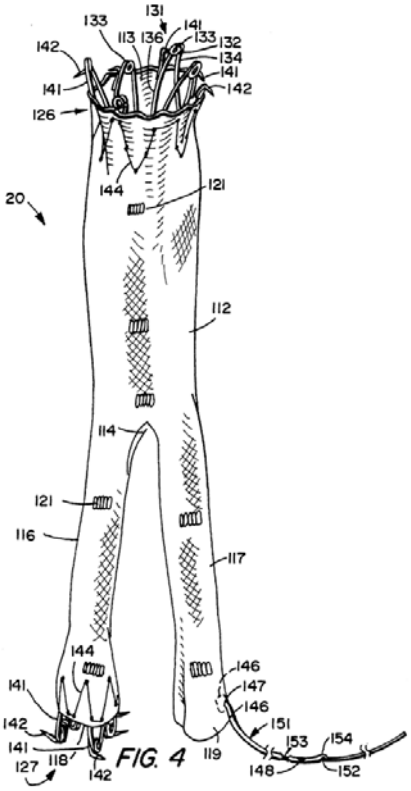

Figure 4 depicts "an enlarged perspective view of a graft having a bifurcation." Piplani, 1:53–54. The Examiner finds that Piplani discloses "a debranching stent graft limb 20 having a main body stent graft limb 12 with a bifurcation defining a first leg 116 and a second leg 117." Final Act. 3. The Examiner further finds that Figure 4 also depicts stent structure 126, 127, 163. *Id.* at 4 (*citing also* Piplani, Figs. 17–19).

The Examiner acknowledges, however, that Piplani does "not explicitly disclose the diameter of the first leg is about 2 mm greater than the diameter of the second leg." *Id.* The Examiner cites to Gordon as evidence that "blood vessels are not necessarily the same size and thus vascular grafts must use legs or graft limbs that differ." *Id.* (citing Gordon, 1:42–47). The Examiner further relies on Nunez for teaching that the diameter of a first leg is greater than a diameter of a second leg. *Id.* (citing Nunez, Fig. 16, 13:44, 46).

> In combining Piplani with Nunez, the Examiner reasons that
>
> > It would have been obvious to one of ordinary skill in the art to use a greater diameter leg for a first leg than a second leg in a bifurcated stent graft as taught by Nunez et al. with the bifurcated stent graft of Piplani et al. such that it matches the vessel specifications or dimensions, as evidenced by Gordon. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a first leg having a diameter greater than about 2mm, since it has been held that the optimization of results-effective variables, when the general conditions (Nunez teaches . . . it is known one leg is about 2mm greater in diameter than a second leg of a bifurcation) of a claim are disclosed in the prior art, is not inventive an[d] is in fact obvious to one of ordinary skill in the art.

Id. at 4–5 (citing in-part Nunez, 3:6–7).

b. Appellant's Argument

Appellant contends the rejection presenting the following arguments:

(a) "About" is explicitly defined in the Application and the recital thereof does not impact the criticality of the recited ranges. Appeal Br. 4.

(b) Criticality of the claimed ranges is demonstrated via a showing that the claimed ranges achieve unexpected results relative to the prior art ranges. *Id.* at 5.

(c) There exists a lack of motivation to combine Piplani, Nunez, and Gordon. *See* Reply Br. 2.

Appellant also submits declaration testimony from the inventor, Dr. Patrick Kelly ("Declaration"), to support its arguments. Appeal Br. 4.

We address each of Appellant's arguments separately, below.

c. Analysis

We agree with the Examiner's findings, reasoning, and analysis as set forth in the Final Office Action and Answer and adopt these as our own. We further provide additional analysis, below, to supplement the Final Office Action and Answer.

i. "About" is Defined in Specification

As to Appellant's first argument, although we agree with Appellant that the Specification defines "about" to mean +/- 5% (Appeal Br. 4), this does not identify any Examiner error.

As understood by Appellant *and the Examiner*, the Specification states, "As used herein, with respect to measurements, 'about' means +/- 5 %." Spec. 29, l. 14; *see also* Ans. 3–4 ("the relative term 'about' used for all the range of dimensions claimed and has been defined in the specification with some boundaries set forth being +/-5 %. *The examiner acknowledges the indication of boundaries set forth*" (emphasis added))).

In its Reply Brief, Appellant argues that "the Examiner fails to submit any argument or showing that application of +/- 5% would somehow enlarge Appellant's claimed ranges such that they would no longer be a narrow species relative to the genus of ranges taught by the combination of cited art." Reply Br. 2. We find Appellant's point of contention, however, to be a straw man's argument. The rejection before us does not require a showing that the +/- 5% "would somehow enlarge Appellant's claimed ranges such that they would no longer be a narrow species relative to the genus of ranges taught by the combination of cited art," and Appellant's contention otherwise does not apprise us of Examiner error.

Accordingly, Appellant's first argument is not persuasive.

ii. Criticality of the Claimed Ranges and Unexpected Results

The issue is whether Appellant has shown that the claimed range—wherein the diameter of the first leg is about 2 mm greater than the diameter of the second leg—achieves unexpected results.

Prior art ranges that overlap with a claimed range create "a presumption of obviousness," which may be rebutted if the patentee, or appellant, comes forward with evidence showing, *inter alia*, that the prior art teaches away from the claimed invention or that the claimed invention achieves unexpected results. *See E.I. du Pont de Nemours & Co. v. Synvina C.V.*, 904 F.3d 996, 1006 (Fed. Cir. 2018).

Appellant contends that its "critical ranges enable the product to achieve unexpected benefits," citing its inventor declaration. Appeal Br. 5 (citing Declaration ¶ 7). Dr. Kelly—the named inventor—testifies that

"Claim 1's recited ranges are both narrower than Piplani's ranges and critical . . ., because the ranges adapt the debranching stent graft limb to be a modular docking station for other stent grafts and to permit revision procedures with fewer side effects than known up-and-over techniques." Declaration ¶ 7. Dr. Kelly further testifies that "the claimed debranching stent graft limb may be used for treatment of common iliac aneurysms that form, for example, after repair of a previous aortic aneurysm resulting in loss of seal and potential rupture of the aneurysm." *Id.* (citations omitted). Dr. Kelly contends that "[t]he combination of Piplani and Nunez results in a graft that would be used to repair the original aortic aneurysm, not the subsequent common iliac aneurysm." *Id.*

Appellant's contention that the claimed ranges are critical and achieve unexpected results are not persuasive.

The Board has broad discretion as to the weight to give to declarations offered in the course of prosecution. *See Velander v. Garner*, 348 F.3d 1359, 1371 (Fed. Cir. 2003) ("[A]ccord[ing] little weight to broad conclusory statements [in expert testimony before the Board] that it determined were unsupported by corroborating references [was] within the discretion of the trier of fact to give each item of evidence such weight as it feels appropriate."); *see also Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 294 (Fed. Cir. 1985) ("Opinion testimony rendered by experts must be given consideration, and while not controlling, generally is entitled to some weight. Lack of factual support for expert opinion going to factual determinations, however, may render the testimony of little probative value in a validity determination." (citations omitted)).

In the present case, we accord little weight to Dr. Kelly's declaration and find it insufficient to establish that the ranges of claim 1 exhibit unexpected results.

First, Dr. Kelly's declaration refers generally to the "claimed ranges," without addressing the particular claimed range that is at issue before us, namely, "wherein the diameter of the first leg is about 2 mm greater than the diameter of the second leg." *See, generally*, Declaration. We note that claim 1 recites at least six different claimed ranges:

> (1) wherein the main body stent graft limb has a diameter at the proximal end in the range from about 14 mm to about 18 mm;
> (2) wherein the first leg has a diameter ranging from about 8 mm to about 12 mm;
> (3) wherein the second leg has a diameter ranging from about 6 mm to about 10 mm
> (4) wherein the distance from the proximal end of the main body stent graft limb to the distal end of the first leg and the second leg is in the range from about 70 mm to about 90 mm;
> (5) wherein the diameter of the first leg is about 2 mm greater than the diameter of the second leg; and
> (6) wherein the length of the first leg and the length of the second leg are each a minimum of about 30 mm.

Appeal Br. (Claims App'x). Dr. Kelly's testimony is vague and we cannot discern which, if any, of the claimed ranges is critical and achieves unexpected results. We further point out that Appellant's Specification describes *at least twenty four* different embodiments, several of which having multiple sub-embodiments. *See* Spec. 3–23. Notably, most of Appellant's stent embodiments do not share the same claimed ranges as claim 1, and several include leg graft diameters that are the same. *See, e.g.*, *id.* at 10 ("wherein the first leg and the second leg each have a diameter in

the range from about 14 mm to about 16 mm"). Indeed, Appellant's Specification includes multiple embodiments with ranges that cover a wide spectrum of ranges, and nothing in the Specification or Declaration leads us to believe that the ranges recited in claim 1 are somehow "critical" or lead to unexpected results.

Furthermore, Dr. Kelly testifies that the claimed ranges are critical because they "adapt the debranching stent graft limb to be a modular docking station" and "permit revision procedures with few side effects," but these assertions lack any corroborating evidence. For example, neither Appellant nor Dr. Kelly submit any evidence to persuade us that the claimed ranges unexpectedly produce revision procedures with fewer side effects, whatever those side effects may be. *See, generally,* Appeal Br.; *see also, generally,* Declaration; *see also Ashland Oil,* 776 F.2d at 294 ("Lack of factual support for expert opinion going to factual determinations, however, may render the testimony of little probative value in a validity determination").[2]

Dr. Kelly and Appellant further draw distinctions between the *techniques* for deploying the claimed stent graft and Piplani's stent graft, yet

[2] Appellant contends that the "claimed ranges are critical and result in a claimed ***structure*** that permits a wholly new revision procedure that avoids embolization of the internal iliac artery (a long felt and unmet need)." Appeal Br. 5. First, claim 1 recites a stent graft, not a method for deploying a stent graft to avoid embolization. Second, neither Appellant nor Dr. Kelly submit any evidence to establish the need for a graft structure that permits a deployment technique to avoid embolization was a persistent one that was recognized by those of ordinary skill in the art, how long that need existed in the industry, and whether any attempts and failures to meet that need were made by others in the industry.

these arguments miss the point. Claim 1 recites a stent graft, not a method for deploying one, and "[i]t is well established that the objective evidence of nonobviousness must be commensurate in scope with the claims." *In re Lindner*, 457 F.2d 506, 508 (CCPA 1972). In particular, Dr. Kelly testifies extensively about the difference between Piplani's graft employing an "up-and-over" technique, whereas "the presently claimed debranching stent graft limb . . . may be used in a top-down arm approach." *See* Declaration ¶ 6 ("Piplani's graft is deployed using an up-and-over (retrograde) technique . . . [whereas] the presently claimed debranching stent graft limb provides unexpected benefits over the combination of Piplani and Nunez in that it may be used in a top-down arm approach."). As pointed out correctly by the Examiner, "It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations." Ans. 4 (citation omitted).

In light of the deficiencies discussed above, neither Appellant nor Dr. Kelly's testimonial evidence persuade us that the claimed ranges are critical or that the claimed ranges achieve unexpected results.

iii. No Motivation to Combine

In its Reply Brief, Appellant also argues that there is no motivation to combine Piplani and Nunez. Reply Br. 2.

We find this argument unpersuasive.

As discussed above, the Examiner reasons that a skilled artisan would have combined Nunez's greater diameter first leg to Piplani's bifurcated stent graft "such that it matches the vessel specifications or dimensions, as

evidenced by Gordon." Final Act. 4. Because Gordon evinces that "the left iliac diameter and length may differ substantially from the right iliac diameter and length in the same patient and the same must be considered in sizing a graft" (Gordon, 1:41–47) and Nunez depicts a bifurcated graft with two legs of different diameters (Nunez, Fig. 16), we find that the Examiner's reasons for modifying Piplani are indeed taught by the cited art. In addition, Appellant has not explained with any specificity why a person of ordinary skill in the art would not have had an expectation of success in making the proposed modification.

iv. Summary

Accordingly, Appellant's arguments do not apprise us of Examiner error, and we affirm the rejection of claim 1 as unpatentable over Piplani and Nunez. We also affirm the rejection of claims 2–4, 6, 7, 9, and 18, which fall with claim 1.

II. Claims 5, 8, 10, 11, and 17– Unpatentable over Piplani, Nunez, and Other References

Appellant does not present separate arguments in contesting the rejection of dependent claims 5, 8, 10, and 11 under Piplani, Nunez, and Dehdashtian or the rejection of dependent claim 17 under Piplani, Nunez, and Ressemann. *See* Appeal Br. 14. For the reasons set forth above, in which we affirmed the rejection of claim 1, we also affirm the rejections of claims 5, 8, 10, 11, and 17.

CONCLUSION

The Examiner's rejections are affirmed.

DECISION SUMMARY

In summary:

Claims Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
1–4, 6, 7, 9, 18	103	Piplani, Nunez	1–4, 6, 7, 9, 18	
5, 8, 10, 11	103	Piplani, Nunez, Dehdashtian	5, 8, 10, 11	
17	103	Piplani, Nunez, Ressemann	17	
Overall Outcome			1–11, 17, 18	

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