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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte STEVEN J. ALLEX, DONALD GEER,
BRETT ALLYN WILLIAMS, BRADY JON HATCHER,
and TRISTAN LYNN TIESO

Appeal 2018-001068
Application 14/340,407
Technology Center 3700

Before LISA M. GUIJT, BRADLEY B. BAYAT, and
FREDERICK C. LANEY, *Administrative Patent Judges.*

LANEY, *Administrative Patent Judge.*

DECISION ON APPEAL

STATEMENT OF THE CASE

Appellant¹ appeals under 35 U.S.C. § 134(a) from the Examiner's decision (filed Feb. 4, 2016 hereinafter "Final Act.") rejecting claims 1–13.² We have jurisdiction over this appeal 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 Vector Corp., LLC, as the real party in interest. Appeal Br. 3. (filed Mar. 7, 2017).

² Claim 14 has been canceled. Appeal Br. 12.

INVENTION

Appellant's invention "relates generally to medical devices and more specifically to radiopaque catheter balloons for use with balloon catheters." Spec. ¶ 2.

Claim 1, reproduced below, is the sole independent claim and is representative of the invention.

1. A balloon for use with an intraluminal catheter, comprising:

(a) an inflation layer, consisting of a compliant polymeric cylinder having a central region ending in opposing conical regions, said cylinder defining an outer surface and an inner lumen for retention of inflation fluid;

(b) a fiber layer, consisting of at least two layers of inelastic, braided fibers disposed around the length of the inflation layer; and

(c) at least one coating layer, consisting of at least one adhesive disposed to affix the fiber layer to the inflation layer, wherein at least one adhesive penetrates the fiber layer to form the at least one coating layer,

wherein the braided fibers have a pitch with respect to one another between 65° and 75° along the central region of the balloon and a pitch with respect to one another between 35° and 45° at both conical regions of the balloon when inflated to provide the balloon with a burst pressure of 16 atmospheres or greater.

Appeal Br. 11 (Claims App.).

REJECTIONS

I. The Examiner rejected claims 1–5 and 9–13 under 35 U.S.C. § 103(a) as unpatentable over Elton (WO 2010/027998 A1;

pub. Mar. 11, 2010) and Davies, Jr. et al. (US 7,914,487 B2; iss. Mar. 29, 2011, hereinafter “Davies”).³

- II. The Examiner rejected claims 6–8 under 35 U.S.C. § 103(a) as unpatentable over Elton, Davies, and van Sloten et al. (US 2008/0228138 A1; pub. Sept. 18, 2008, hereinafter “van Sloten”).

ANALYSIS

Before we reach the Examiner’s obviousness rejections of claims 1–13, we first turn to Appellant’s argument that the Examiner’s objection to marked up Figure 5, which includes a legend showing a range of pitch angles for different portions of the balloon device shown. “[T]he kind of adverse decisions of [E]xaminers which are reviewable by the [B]oard must be those which relate, at least indirectly, to matters involving the rejection of claims.” *In re Hengehold*, 440 F.2d 1395, 1403-04 (CCPA 1971). Because the Examiner finds marked up Figure 5 introduces new matter, which is matter that is also found in the claims rejected in this appeal, we determine that it is within our purview to address the Examiner’s objection to marked up Figure 5.

The Examiner finds the Specification fails to convey to a skilled artisan that Appellant had possession of braided fibers having a pitch with respect to one another between 65° and 75° along the central region of the balloon and a pitch with respect to one another between 35° and 45° at both

³ We note that the Examiner provides a heading for this rejection that identifies 35 U.S.C. § 103, but states claims 1–5 and 9–13 are anticipated by Elton and Davies. Final Act. 4. We understand the Examiner’s reference to anticipation to be a typographical error.

conical regions of the balloon, as claim 1 recites. Final Act. 3. The Examiner asserts the written description is silent regarding the braid pitches in the central and conical regions of the claimed radiopaque balloon. *Id.* The Examiner also finds the Figures do not support a finding that Appellant was in possession of this recited limitation. *Id.* In particular, the Examiner finds that neither the originally filed Figure 5, which is a copy of a photograph of a braided fiber sheath (hereinafter “original Figure 5”), nor the subsequently submitted (filed Oct. 30, 2013) replacement Figure 5, which is a drawing of the photographed braided fiber sheath (hereinafter “replacement Figure 5”), are sufficient to evidence the braided fibers with the recited range of pitches at the central and conical regions. *Id.*

Appellant does not dispute the fact that the written description lacks any reference to using a specific range of pitches for the braided fibers at the central and conical regions of the disclosed radiopaque balloon. *See* Appeal Br. 5–6. Appellant instead relies solely on Figure 5, in either its photographic or drawing form, as evidence that the applicants possessed the claim ranges of pitch for the braided fibers. Offering the Declaration of Steven J. Alex (Appellant’s App’x D), Appellant argues both forms of Figure 5 show the recited pitch ranges for the braided fibers in the central and conical regions. *Id.*

Appellant’s expert, Mr. Alex, declares, “a skilled artisan . . . *would have been able to* determine the braided orientation including pitch angles from [the] originally filed Figure 5 . . . by conventional methods which were known and customary in the art at the time of filing.” Appeal Br. (Evidence App’x D ¶ 4) (emphasis added). Although Mr. Alex declares the pitch of the braids at central and conical regions of the balloon “*could have been*

routinely determined from originally filed Figure 5,” he does not represent that he actually took any steps to determine the pitch of the braids *from the original Figure 5*. *Id.* (Evidence App’x D, ¶ 5) (emphasis added). Mr. Alex’s conclusory remarks about what a skilled artisan “could have” done or “would have been able” to do has little, if any, evidentiary value. Therefore, Appellant has not persuasively rebutted the Examiner’s determination that original Figure 5 lacks the clarity necessary to satisfy the written description requirement for the specific range of pitch angles shown in marked up Figure 5, which a preponderance of the evidence supports.

Turning to replacement Figure 5, this illustration cannot be relied upon because there is no indication within the Specification that it was drawn to scale. *Ans. 2*; see *Hockerson-Halberstadt, Inc. v. Avia Group Int’l*, 222 F.3d 951, 956 (Fed. Cir. 2000). Although, under proper circumstances, drawings alone may provide a “written description” of an invention as required by the first paragraph of 35 U.S.C. § 112, we do not agree this case presents the proper circumstances. These are not the proper circumstances because it would require evaluating replacement Figure 5 for precise dimensional attributes, rather than approximations, and there is no dispute the written specification is devoid of any indication replacement Figure 5 is drawn to scale.⁴ Thus, relying on replacement Figure 5 on this record would be contrary to Federal Circuit precedent that “arguments based on drawings

⁴ Appellant contends that replacement Figure 5 is a “computer drawn replica” of the actual device photographed in original Figure 5. Appeal Br. 6. Even accepting this as true, it does not change the fact that Appellant does not provide any indication that the replacement Figure 5 was drawn to scale *in the written description*.

not explicitly made to scale . . . are unavailing.” *Nystrom v. Trex Co.*, 424 F.3d 1136, 1149 (Fed. Cir. 2005) (citing *Hockerson-Halberstadt, Inc.*, 222 F.3d at 956; *In re Wright*, 569 F.2d 1124, 1127 (CCPA 1977)).

However, even if the proper circumstances were present in this case and replacement Figure 5 could be relied upon, Appellant still has not shown persuasively that replacement Figure 5 shows the claimed *ranges* of angles for the braided fibers in the central and conical regions. Having considered the Alex Declaration ourselves (Evidence App’x D), marked up Figure 5 shows a range for the braid pitch in a central region and a second range for the braid pitch of the conical regions. A measurement of a braid angle at a specific point, as shown in Appendix C of the Alex Declaration, would result in a single angle, such as 67°. A measurement at a specific point of the replacement drawing cannot be relied upon for the claimed ranges of angles. Therefore, we are not persuaded the Examiner’s objection to marked up Figure 5 as introducing new matter was in error.

As a result, for all of the foregoing reasons, we sustain the Examiner’s objection to marked up Figure 5.

Rejections I and II – Obviousness

In contesting obviousness Rejections I and II, Appellant groups all of the claims together. Appeal Br. 4. Like the Appellant, we select claim 1 to decide the appeal of these rejections, with claims 2–13 standing or falling with claim 66. *See* 37 C.F.R. § 41.37(c)(1)(iv) (permitting the Board to select a single claim to decide the appeal as to a single ground of rejection of a group of claims argued together).

The Examiner determines that the combined teachings of Elton and Davies discloses the combination of elements claim 1 recites, except the

specific pitch of the braided fibers in the central region to be in the range of 65–75° and the pitch in the conical regions to be in the range of 34–45°. Final Act. 4–5. The Examiner, however, finds that “Davies teaches that the pitch (braid angle A) may vary over the surface of the balloon to provide the best fit for the braided layer (column 8, lines 1-17).” *Id.* at 5. The Examiner determines the claimed ranges are not an inventive distinction over the prior art because, at most, they are the discovery of optimum or workable ranges that are within the capabilities of a skilled artisan and involve only routine skill. *Id.* at 5 (citing *In re Aller*, 220 F.2d 454, 456 (CCPA 1955)).

Appellant asserts that the Examiner is mistaken because Davies gives no direction “as to where along the balloon variations should be made” or “as to what kind of variations should be made.” Appeal Br. 8. According to Appellant, “no one reading Davies would recognize that specific pitch parameter on the conical regions as compared to the central region of the balloon should be varied.” *Id.* Appellant contends, “even if one were to experiment with variations to pitch, nothing but serendipity would produce the pitches producing the claimed burst pressures as unexpectedly discovered and claimed by Appellant.” *Id.* at 9.

Appellant’s argument is unpersuasive because it fails to undermine the Examiner’s determination that selecting “the specific pitch of the braided fibers in the central region to be in the range of 65–75° and the pitch in the conical regions to be in the range of 34–45°” is nothing more than an application of the ordinary skill possessed by an artisan. Ans. 4. Appellant does not dispute the Examiner’s finding that the combination of Elton and Davies discloses the general conditions of the device claim 1 recites. Nor does Appellant dispute that Davies evidences (*see* Davies col. 8, ll. 11–14) a

skilled artisan knew varying the pitch angles of the braided fibers “from location to location over the surface of the balloon” could enhance the fit of the braided layer over the length of the balloon. Ans. 4. Thus, the Examiner has established the pitch angles of the braided fibers at different locations of the balloon were known to be “result-effective variables.” “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” *In re Applied Materials Inc.*, 692 F.3d 1289, 1295 (Fed. Cir. 2012) (quoting *In re Aller*, 220 F.2d at 456).

Although Appellant offers attorney argument that the claimed configuration of pitch angles for the braided fibers at the central and conical regions provides “unexpected results,” such conclusory remarks without any evidentiary support have little, if any, probative value. Furthermore, the Specification does not support Appellant’s contention the claimed range of pitch angles enable the claimed burst. The Specification states, “the braided sleeve may be formed from inelastic fibers of any configuration, *e.g.*, fibers of single or multiple threads, so long as the formed braided sheath prevents radial distortion of the [inflated] balloon.” Spec. ¶ 33. Therefore, we sustain the Examiner’s obviousness rejection of claim 1, as well as claims 2–13, which fall with therewith.

CONCLUSION

The rejections of claims 1–13 under 35 U.S.C. § 103(a) are affirmed. In addition, we sustain the Examiner’s objection to marked up Figure 5 that

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includes legends to identify specific ranges of variance in the braid angles at different locations of the balloon device shown.

DECISION SUMMARY

Claims Rejected	Basis	Affirmed	Reversed
1-5, 9-13	§ 103 Elton, Davies	1-5, 9-13	
6-8	§ 103 Elton, Davies, van Sloten	6-8	
Overall Outcome		1-13	

AFFIRMED

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).