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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte THERESA HERMEL-DAVIDOCK and LISA LIM

Appeal 2019-002611
Application 14/805,620
Technology Center 1700

Before ADRIENE LEPIANE HANLON, LINDA M. GAUDETTE, and
JEFFREY B. ROBERTSON, *Administrative Patent Judges*.

ROBERTSON, *Administrative Patent Judge*.

DECISION ON APPEAL¹

STATEMENT OF THE CASE

Pursuant to 35 U.S.C. § 134(a), Appellant² appeals from the
Examiner’s decision to reject claims 1, 10, 11, 15–18, 21, and 23–27. *See*
Appeal Br. 9–16. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

¹ This Decision includes citations to the following documents:
Specification filed July 22, 2015 (“Spec.”); Final Office Action mailed May
7, 2018 (“Final Act.”); Appeal Brief filed October 29, 2018 (“Appeal Br.”);
Examiner’s Answer mailed December 12, 2018 (“Ans.”); and Reply Brief
filed February 12, 2019 (“Reply Br.”).

² 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 Becton,
Dickinson, and Company. Appeal Br. 3.

CLAIMED SUBJECT MATTER

Appellant states the invention relates to a polymer resin composition including a chemically attached lubricant structure, which may be used to produce a self-lubricating medical device. Spec. ¶ 2. In particular, the Specification states the polymer resin composition is a self-lubricating polyurethane resin with a lubricant chemically attached within the polyurethane resin. *Id.* ¶ 6. Claim 1, reproduced below, is illustrative of the claimed subject matter (Appeal Br. 25, Claims Appendix):

1. A self-lubricating polyurethane comprising a reaction product of:

a diisocyanate selected from the group consisting of 4,4-diphenyl methane diisocyanate (MDI), toluene diisocyanate (TDI), isophorone diisocyanate (IPDI), and methylene bis (4-cyclohexyl isocyanate) (HMDI); and

a diol mixture containing:

a short chain diol selected from the group consisting of ethylene glycol, 1,3-propylene glycol, 1,4-butane diol, neopentyl glycol, and alicyclic glycols having up to 10 carbon atoms,

a long chain polyether diol comprising poly(tetramethylene ether) glycol, and

a diol-containing lubricant comprising polydimethylsiloxane diol;

the diol-containing lubricant being incorporated into a backbone formed by the diisocyanate and the diol mixture;

wherein the diol-containing lubricant is present in an amount ranging from about 1 to about 3 weight percent of the polyurethane; and

the polyurethane comprises a weight average molecular weight (M_w) in the range of from about 60,000 g/mol to 115,000 g/mol, and a number average molecular weight (M_n) in the range of from about 30,000 g/mol to 50,000 g/mol.

REFERENCE

The prior art relied upon by the Examiner is:

Name	Reference	Date
Meijs et al. hereinafter "Meijs"	US 2003/0018156 A1	January 23, 2003

REJECTION³

The Examiner rejected claims 1, 10, 11, 15–18, 21, and 23–27 under 35 U.S.C. § 103 as obvious over Meijs. Ans. 4–8.

Appellant presents separate arguments with respect to claims 1, 21, and 23–25. Appeal Br. 7–16. We select claims 1, 21, and 23–25 as representative for disposition of this appeal. 37 C.F.R. § 41.37(c)(1)(iv) (2017).

OPINION

The Examiner's Rejection

The Examiner found Meijs discloses a polysiloxane-containing polyurethane elastomeric composition, where the polysiloxane component is a lubricant component of the reaction product. Ans. 4. The Examiner found Meijs discloses a polyether diol including polytetramethylene ether glycol. *Id.* The Examiner found Meijs discloses amounts of polysiloxane of from about 1 to about 60% of the composition, which overlaps the claimed range. *Id.* at 4–5. The Examiner found Meijs discloses polyurethanes with number average molecular weights from about 37,000 to about 90,000 and having a

³ In the Answer, the Examiner withdrew the rejections of claims 12, 13, 20, 28, 29, and 30. Ans. 8.

polydispersity of from 1.87 to 2.08 such that polyurethanes having weight average molecular weights of the claims would have been envisaged or at least would have been obvious. *Id.* at 5.

Appellant's Contentions

Appellant argues a polyurethane having the weight average molecular weight (Mw) and number average molecular weight (Mn) recited in claim 1 would not have been obvious in view of Meijs, because the polyurethanes in Meijs the Examiner relied on for the molecular weights are chemically different from the recited polyurethanes. Appeal Br. 9–10. Appellant contends Meijs fails to render obvious a lubricant in an amount ranging from about 1 to about 3 weight percent, because Meijs teaches away from amounts within the recited range, which are inconsistent with providing materials that are suitable for long-term implantation. *Id.* at 11–13. Appellant argues the present application demonstrates unexpected results with respect to coefficient of friction and tensile at break properties with polyurethanes including 1 to 3 weight percent polydimethylsiloxane. *Id.* at 20–23.

Issue

The dispositive issue is:

Considering the evidence as a whole, has Appellant identified reversible error in the Examiner's determination that a polyurethane having weight average molecular weights, number average molecular weights, and a polydimethylsiloxane diol component in an amount ranging from about 1 to

about 3 weight percent of the polyurethane would have been obvious in view of Meijs?

Discussion

Molecular Weights

We are not persuaded by Appellant's arguments that the polyurethane having the diisocyanate, short chain diol, diol-containing lubricant, and poly(tetramethylene ether) glycol having a Mw in the range of 60,000 g/mol to 115,000 g/mol and a Mn in the range of from about 30,000 g/mol to 50,000 g/mol recited in claim 1 is a non-obvious difference between the claims in the prior art. Appeal Br. 9. In particular, we are not persuaded the Examiner reversibly erred in relying on polyurethanes disclosed in Meijs including polyhexamethylene oxide (PHMO) rather than polyurethanes including poly(tetramethylene ether) glycol, also known as polytetramethylene oxide (PTMO) (*see* Appeal Br. 10), as recited in claim 1.

Initially, according to Appellant, Meijs discloses polyurethanes including PTMO are non-preferred. *Id.* However, Meijs discloses polyurethanes may include PHMO or PTMO. Meijs, ¶ 68. Accordingly, we agree with the Examiner that Meijs discloses polyurethanes including PTMO are within the scope of the inventive polyurethanes disclosed therein. Ans. 8.

As to Appellant's argument that Meijs discloses examples of polyurethanes including PTMO that either fail to disclose molecular weights or discloses Mn outside of the claimed range (Appeal Br. 9), as the Examiner correctly explains, Meijs discloses useful ranges of molecular weights based on exemplary embodiments disclosed therein, including Mw

and Mn overlapping the ranges recited in claim 1. Ans. 9–10 (citing Meijs, Table 10); Final Act. 4 (citing Meijs, Exs. 3, 9, Tables 2, 6). We further agree with the Examiner that Meijs does not disclose a particular distinction between molecular weights of those polyurethanes including PHMO and those polyurethanes including PTMO. Ans. 10. Thus, we are of the view the Examiner’s findings with respect to the molecular weight ranges disclosed in Meijs are reasonable.

We observe also that the ranges of Mw and Mn recited in claim 1 appear to be derived from Table 1 of the Specification, and include molecular weights from polymers prepared from the same diisocyanate, short chain diol, long chain polyether diol, and the same polydimethylsiloxane diol (PDMS) containing lubricant in amounts of 1%, 2%, and 3%. Spec. ¶ 21, Table 1. Claim 1 is not limited to such particular components and the molecular weight ranges recited in claim 1 are from different polymer examples and include endpoints outside those disclosed in Table 1. For instance, the Mw range recited in claim 1 “about 60,000 g/mol to about 115,000 g/mol” appears to be derived from the Mw of a polymer containing 1% PDMS of 67,837 g/mol and the Mw of a polymer containing 3% PDMS of 110,300 g/mol. Further, the Mn range recited in claim 1 of “about 30,000 g/mol to 50,000 g/mol” appears to be derived from the Mn of a polymer containing 2% PDMS of 31,020 g/mol and the Mn of a polymer containing 3% PDMS of 48,640 g/mol.

Accordingly, we are of the view that the Examiner’s findings with respect to the molecular weights of the polyurethanes in Meijs mirror Appellant’s own disclosure with respect to the Mw and Mn values in claim 1, and as such, are reasonable.

Thus, we are not persuaded by Appellant's argument that one of ordinary skill in the art would have understood that the molecular weights of polyurethanes in Meijs would be limited by the identity of the polyether macrodiols used in forming the polymer.

Claim 21

Regarding claim 21, which recites the polyurethane comprises a polydispersity (Mw/Mn) in the range of from about 1.8 to 2.3, similar to the above argument, Appellant contends the Examiner's reliance on Examples 3 and 6 of Meijs in determining the polydispersity recited in claim 21 would have been obvious is not informative of the claimed polyurethanes because the polyurethanes of claim 21 are chemically different than those in Examples 3 and 6 of Meijs. Appeal Br. 14; Final Act. 4, 6.

We are not persuaded for similar reasons as discussed above with respect to the weight average and number average molecular weights.

Amount of polydimethylsiloxane

We are not persuaded by Appellant's arguments that Meijs teaches away from amounts of PDMS recited in claim 1 or that the claimed PDMS amounts would render Meijs's composition unsatisfactory for its intended purpose. Appeal Br. 10–13. In this regard, Meijs discloses expressly "the weight ratio of polysiloxane to polyether and/or polycarbonate may be in the range of from 1:99 to 99:1," which the Examiner found to correspond to an amount of about 1 to about 60% of the composition. Meijs ¶ 67; Final Act. 4. Although Appellant references a number of other disclosures in Meijs to argue that when considered in context, Meijs would not lead one of ordinary

skill in the art to the lower amounts of the disclosed range (Appeal Br. 10–13, citing Meijs, Abstract, ¶¶ 8, 9, 28, 67, 68, 82, 84, 85, 89, 96, 99, 103, 105, 109; claims 8, 9), this does not change the express disclosure in Meijs that all ratios of polysiloxane to polyether/and or poly carbonate in the range of 1:99 to 99:1 form part of the invention, even if less preferred. *See* Ans. 11–12.

The prior art must be considered as a whole, including non-preferred embodiments disclosed therein. *See Merck & Co., Inc. v. Biocraft Labs., Inc.*, 874 F.2d 804, 807 (Fed. Cir.), *cert. denied*, 493 U.S. 975 (1989) (quoting *In re Lamberti*, 545 F.2d 747, 750 (CCPA 1976)). Indeed, as the Examiner points out, Meijs discloses a wide range of applications, such that usefulness of PDMS diol at lower amounts is not precluded. Ans. 12 (citing Meijs, ¶ 27.)

To the extent Appellant’s argument is based on the position that the ratios of polysiloxane to polyether/and or poly carbonate disclosed in paragraph 67 of Meijs are in error, we observe that given the express disclosure of Meijs of the ratios and the wide range of applications we discern no apparent error in Meijs. *See In re Garfinkel*, 437 F.2d 1005, 1008 (CCPA 1971) (“Finally, appellant alleges that the analysis of 5.12% AL(2)O(3) by Kistler [(the cited prior art publication)] is erroneous. An affidavit was submitted to show that the glass Kistler used actually contained only about 2% AL(2)O(3) We agree with the board that Kistler’s disclosure would teach one of ordinary skill in the art to use up to 5.12% AL(2)O(3) since the error, if it exists, is not apparent or obvious from reading the publication. *See, In re Yale*, . . . 434 F.2d 666 (CCPA 1970)”). In addition, Appellant has not provided sufficient evidence, such as

declaration testimony to support the position that one of ordinary skill in the art would have understood Meijs to be limited in the way Appellant argues.

Claims 23–25

Appellant contends Meijs does not disclose a polyurethane having the tensile at the break properties recited in claims 23 and 24, or the coefficient of friction property recited in claim 25, because Meijs does not disclose the claimed polyurethanes. Appeal Br. 15–16. We are not persuaded because, as discussed above, we do not agree that Meijs does not render obvious the claimed polyurethanes. As pointed out by the Examiner, Appellant has not provided any meaningful discussion beyond the identity of the polyurethanes being different to rebut the Examiner’s position. Ans. 13.

Unexpected Results

We are not persuaded by Appellant’s arguments that the results presented in the Specification are sufficient to demonstrate unexpected results. Specifically, we are in complete agreement with the Examiner that the inventive examples are not commensurate in scope with the claims. Appeal Br. 14–15. As discussed above, the examples are limited to polyurethanes prepared only with MDI as the isocyanate, 1,4-butane diol as the short chain diol, a specific polytetramethylene ether glycol, and a specific polydimethylsiloxane diol. Spec. ¶ 21. Thus, the polyurethanes encompassed by the scope of the claims are considerably broader than the polyurethanes tested in the examples. The scope of the “objective evidence of non-obviousness must be commensurate in scope with the claims which the evidence is offered to support.” *In re Tiffin*, 448 F.2d 791, 792 (CCPA 1971); *see also In re Peterson*, 315 F.3d 1325, 1329–31 (Fed. Cir. 2003).

Moreover, we are not persuaded by Appellant's arguments that the Examiner's position with respect to the Coefficient of Friction data results being close and random are conclusory, unclear, and have no technical basis. Reply Br. 3. That is, the coefficient of friction data in Table 3 demonstrates that polyurethanes having amounts of PDMS within the range recited in claim 1 have Coefficients of Friction that are both below and above polyurethanes having amounts of PDMS outside the range recited in claim 1. Compare Coefficients of Friction of polyurethanes with 1% PDMS (0.215), 2% PDMS (0.174), 3% PDMS (0.197) with polyurethanes with 4% PDMS (0.202), 5% PDMS (0.190), 6% PDMS (0.204), 7% PDMS (0.286), and 10% PDMS (0.190). Thus, the Examiner's reasoning is supported by the Specification itself. In addition, we agree with the Examiner that the results appear to relate to the intrinsic lubricating properties of polydimethylsiloxane diol (Ans. 15), and thus it is not clear that the Coefficient of Friction results would have been unexpected.

Regarding the tensile at the break properties, we emphasize that the examples are not commensurate in scope with the claims. Appellant's argument that the values of tensile at the break of polyurethanes with amounts of PDMS of 3% or less are significantly improved compared to 4% or higher demonstrating criticality (Reply Br. 3-4) is also not persuasive as Meijs discloses the addition of PDMS has poor mechanical properties including tensile strength and elongation at break (Meijs, ¶ 6). Therefore, it stands to reason that a decrease of the values of tensile at the break as the amount of PDMS is increased does not appear to be unexpected, but rather depends of the desired tensile at the break of the resulting polyurethane. Indeed, the Specification allows for the presence of lubricant in amounts

ranging from about 1 to 10 weight percent of the polyurethane composition. Spec. ¶ 6, *see also* claim 24 (reciting a tensile at the break of about 3936 to about 8210 psi, which encompasses values outside the ranges of polyurethanes having amounts of PDMS of 1–3% in Table 2).

Thus, considering the evidence as a whole we are not persuaded the Examiner erred in rejecting the claims as obvious over Meijs.

CONCLUSION

The Examiner’s rejection of claims 1, 10, 11, 15–18, 21, and 23–27 under 35 U.S.C. § 103(a) is affirmed.

DECISION SUMMARY

In summary:

Claims Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
1, 10, 11, 15–18, 21, 23–27	103	Meijs	1, 10, 11, 15–18, 21, 23–27	

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