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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte SASA ANDJELIC and DENNIS D. JAMIOLKOWSKI¹

Appeal 2018-001382
Application 13/417,810
Technology Center 1600

Before RICHARD M. LEOVITZ, JEFFREY N. FREDMAN, and
ELIZABETH LAVIER, *Administrative Patent Judges*.

LEOVITZ, *Administrative Patent Judge*.

DECISION ON APPEAL

This appeal involves claims directed to a bioabsorbable comprising a bioabsorbable semicrystalline copolymer, which consists essentially of a melt polymerization reaction product. The Examiner rejected the claims as obvious under 35 U.S.C. § 103(a). Pursuant to 35 U.S.C. § 134(a), Appellants appeal the Examiner’s determination that the claims are unpatentable. We have jurisdiction under 35 U.S.C. § 6(b). The Examiner’s decision is affirmed.

¹ The Correct Appeal Brief (“Br.”; entered March 27, 2017) lists Ethicon, Inc. as the real party in interest.

STATEMENT OF THE CASE

The Examiner finally rejected claims 50–52, 54–62, 64–72, 74–82, 84–92, and 94–104 under pre-AIA 35 U.S.C. 103(a) as obvious in view of Venkatraman et al. (WO 2011/059408 A1, published May 19, 2011) (“Venkatraman”), Baimark et al. (*Synthesis and characterization of poly(L-lactide-co-ε-caprolactone) (B)-poly(L-lactide) (A) ABA block copolymers*, Polym. Adv. Technol., 16: 332–337, 2005) (“Baimark”), and Verser et al. (U.S. Pat. No. 5,633,342, issued May 27, 1997) (“Verser”). Final Act. 3.

Claims 50, 60, 70, 80, and 90 are independent claims. Appellants did not argue the claims separately. We have selected claim 60 as representative. The remaining independent and dependent claims fall with claim 60. Claim 60 reads as follows:

60. A bioabsorbable fiber, comprising:

a bioresorbable copolymer of the structure A-B-A, wherein end-segments A comprise polymerized lactide blocks and the middle segment B comprises a polymerized fully amorphous lactide-co-epsilon-caprolactone block, and wherein said middle segment B represents about 25 weight percent to about 60 weight percent of the copolymer, and said copolymer has a Young's modulus of less than about 350,000 psi, wherein said bioabsorbable semicrystalline copolymer of the structure A-B-A consists essentially of the melt polymerization reaction product of:

(c) the middle segment B formed as a fully amorphous prepolymer from melt polymerizing lactide monomer, and *epsilon*-caprolactone monomer in the presence of an initiator, wherein the mole ratio of lactide to *epsilon*-caprolactone in the middle segment B is between about 45:55 to about 30:70; and

(d) end-segments A formed from lactide monomer, wherein the mole ratio of the polymerized lactide to polymerized epsilon-caprolactone in said A-B-A copolymer is about 75:25.

DISCUSSION

All the claims are directed to bioabsorbable fibers. Because Appellants argue all the claims together, claim 60 was selected as representative. Claim 60 recites that the bioabsorbable fiber comprises a bioresorbable semi crystalline copolymer of the structure A-B-A. The end segments A comprise polymerized lactide blocks. The middle segment B comprises “a polymerized fully amorphous lactide-co-epsilon-caprolactone block.” The A-B-A copolymer is recited in the claim to be a product of melt polymerization. The middle segment B is “formed as a fully amorphous prepolymer from melt polymerizing lactide monomer, and *epsilon*-caprolactone monomer in the presence of an initiator.”

The Examiner found that Venkatraman describes the same structure of the claimed bioabsorbable semicrystalline copolymer. Final Act. 3–5. However, the Examiner found that Venkatraman does not describe making the copolymer by “melt polymerization” as required by the claims. *Id.* at 5. The Examiner also found that Venkatraman does not describe a “monofilament suture” as recited in certain dependent claims. *Id.*

To meet this deficiency, the Examiner cited the disclosure in Verser of melt polymerization. Final Act. 5–6. The Examiner found that Verser describes making a copolymer of lactide and epsilon-caprolactone by melt polymerization, the same monomers as claimed. *Id.* at 6. The Examiner found it would have been obvious to have utilize melt polymerization to make Venkatraman’s polymer because,

the material costs for melt polymerization are reduced relative to those for solution polymerization and when using melt polymerization techniques the amount of by-products and wastes produced are typically minimized. Verser et al. continue

that when using melt polymerization, less equipment is needed because there is no solvent to be removed from the synthesized block copolymers and treated or otherwise handled and as a result, melt polymerization generates less volatile organics than solution polymerization, making melt polymerization a technically less complicated and more environmentally sound process than solution polymerization.

Final Act. 6.

The Examiner further found that Baimark describes copolymers of lactide and epsilon-caprolactone and that such copolymers are used as absorbable monofilament sutures. Final Act. 6.

Appellants argue that the copolymers of Venkatraman are made by a solution polymerization process and that it “would not be possible to manufacture Applicants’ novel copolymers using the solution polymerization process disclosed and required by Venkatraman.” Br. 21. As evidence of this, Appellants provided a first declaration under 37 C.F.R. § 1.132 by Sasa Andjelic, Ph.D., a co-inventor of the claimed invention which was submitted on July 29, 2014 (“1st Andjelic Decl.”).

Dr. Andjelic stated in his declaration that bioabsorbable copolymers, having a composition similar to the polymers disclosed in his patent application, which are made by a solution polymerization process as disclosed in Venkatraman, would have a semi-crystalline “B” segment of the lactide-epsilon-caprolactone copolymer because “the transesterification reactions that would normally occur in high temperature melt polymerization would be very much reduced (minimized) in the low temperature solvent polymerization” of Venkatraman. 1st Andjelic Decl. ¶ 5. Dr. Andjelic explained that the “transesterification reactions scramble the sequence distribution making it difficult to retain the chain symmetry to allow

crystallization.” *Id.* Dr. Andjelic provided evidence to support his opinion, citing the Grijpma publication as showing that a lactide and epsilon-caprolactone copolymer formed a semi-crystalline structure when prepared by solution polymerization as in the Venkatraman process. *Id.* Dr. Andjelic cited a second publication by den Dunnen to further support his opinion. *Id.*

Dr. Andjelic also stated that the molecular weight distribution of the claimed polymers distinguishes them from Venkatraman. 1st Andjelic Decl. ¶ 5 (p. 3). Dr. Andjelic stated the polymers made by the “patent application”, although not reported in the application, had a molecular weight distributions which “were generally about half, or a little less” than those of Venkatraman. *Id.* at ¶ 5 (pp. 4–5). The referenced data were not shown in his declaration.

Dr. Andjelic also provided a second corrected declaration executed July 19, 2016 in which he described experiments “to determine whether the solvent polymerization process of Venkatraman et al. would yield block copolymers having a fully amorphous center block.” 2nd Corrected Andjelic Decl. ¶ 6. Based on the test results of the experiments described in that declaration, Dr. Andjelic reported that

copolymers having the chemical composition of the copolymers of the present invention that were made using the solvent process of Venkatraman et al. had a semicrystalline middle block (prepolymer) structure in contrast to the copolymers of the present invention which have a fully amorphous middle block and which are made using fully amorphous prepolymer.
Id.

Dr. Andjelic also stated that it is his opinion that Baimark does not disclose an amorphous prepolymer as claimed, and that such copolymers would be crystalline. 2nd Corrected Andjelic Decl. ¶ 7. Dr. Andjelic

explained technically why Baimark's process utilizing solid state polymerization would result in crystallization in contrast to the melt polymerization in the claims. *Id.* While Baimark concluded their polymers were amorphous, Dr. Andjelic stated, "their own data suggest that all of their prepolymers are, in fact, semicrystalline." *Id.* (para. 7).

We have considered the 1st and 2nd Andjelic declarations, but are not persuaded that they demonstrate an error in the rejection. Primarily, while Dr. Andjelic's declarations explain why the process described in Venkatraman and Baimark would not result in the claimed amorphous polymer, the Examiner specifically cited Verser for teaching the melt polymerization process to produce the claimed copolymer with the amorphous component. Thus, while certain process conditions in Venkatraman and Baimark might produce crystalline polymers, the rejection was based on Verser's process, not on those of Venkatraman and Baimark.

Nonetheless, Venkatraman describes making its B segment amorphous. Venkatraman ¶¶ 23, 42. Verser, as found by the Examiner, "further teach that the pre-copolymer has 'reduced crystallinity' and is exemplified as having no melting peak, which would indicate an amorphous pre-copolymer (e.g. column 4, lines 55-63; Example 50)." Final Act 6. Thus, as found by the Examiner, the skilled worker reading Venkatraman's disclosure of making the B segment amorphous would had reason to use Verser's melt polymerization process to make a polymer with reduced crystallinity and amorphous. Final Act. 6.

Appellants also argue that Verse teaches that its polymers "are environmentally degradable for use in plastic bags and packaging films having accelerated degradation after disposal" and "distinguish their

polymers from biodegradable plastics that are implanted in the body and teach away from bioabsorbable implantable polymers (See col. 3, lines 20-30).” Br. 22.

While we agree that Verser distinguishes its polymers from ones utilized in the body, Verser specifically states this is a preferred embodiment. (“Preferably, the environmentally degradable block copolymers of the present invention can be distinguishable from biodegradable plastics which are used in the body . . .”). Verser col. 3, ll. 20–22. Thus, Verser is not limited to such embodiments.

Moreover, the Examiner did *not* rely on Verser for disclosing the claimed copolymer structure, rather the Examiner cited Venkatraman for described the claimed bioabsorbable copolymers. *See* Venkatraman ¶¶ 2–4, 6, and 44 (describing the polymers as “biodegradable”). Baimark also describes a copolymer of lactide and epsilon-caprolactone as biodegradable and biocompatible materials. Baimark §332. Thus, even if Verser teaches that its polymers are preferably distinguished from biodegradable plastics, both Venkatraman and Baimark teach biodegradable polymeric materials made from the same monomers which are recited in the claims. Appellants did not establish that one of ordinary skill in the art would have been dissuaded from utilizing melt polymerization, as taught by Verser, for making bioabsorbable polymers as required by all the rejected claims.

Mole ratio

Appellants contend that the mole ratio of lactide to epsilon-caprolactone described in the claims is not disclosed in either Venkatraman or Baimark. Br. 23. This argument is not persuasive.

Claims 60 recites “the mole ratio of lactide to *epsilon*-caprolactone in the middle segment B is between about 45:55 to about 30:70.” The Examiner found that the claimed mole ratio of the two components overlaps with the ratio described in Venkatraman. Final Act. 4. It is well established that, when there is a range disclosed in the prior art, and the claimed invention overlaps or falls within that range, as there is here, there is a presumption of obviousness. *In re Peterson*, 315 F.3d 1325, 1329 (Fed. Cir. 2003); *Iron Grip Barbell Co. v. USA Sports, Inc.*, 392 F.3d 1317, 1322 (Fed. Cir. 2004).

[The] law is replete with cases in which the difference between the claimed invention and the prior art is some range or other variable within the claims...in such a situation, the applicant must show that the particular range is critical, generally by showing that the claimed range achieves unexpected results relative to the prior art range.

In re Woodruff, 919 F.2d 1575, 1578 (Fed. Cir. 1990).

Appellants have not provided evidence that the claimed ratio of lactide to epsilon-caprolactone is critical, achieves unexpected results, or has different properties that the broader ranges disclosed in Venkatraman.

Reasonable expectation of success

Appellants contend “that a person skilled in this art would have no reasonable expectation of success in obtaining Applicants’ novel fibers and polymers by combining the references cited by the Examiner.” Br. 23. Appellants also contend that the “novel polymers and fibers surprisingly and unexpectedly provide” certain advantages that “derive from the morphology of Applicants’ novel block copolymers having a fully amorphous center block formed from a fully amorphous prepolymer.” *Id.* at 21.

First, Appellants have not provided persuasive evidence or explanation as to why it would not have been expected that Verser's process could be used to produce a polymer of Venkatraman. Appellants have simply made conclusory statements, without identifying a specific reason as to why melt polymerization as described in Verser would not have been reasonably expected to successfully produce Venkatraman's polymer. As explained above, the declarations by Dr. Andjelic address the process described in Verser and Baimark, but not the melt polymerization process of Verser, which formed the basis of the obviousness rejection of the claims.

Second, Appellants have not provide adequate evidence of unexpected results. A showing of "unexpected results" can be used to demonstrate the non-obviousness of the claimed invention. *In re Soni*, 54 F.3d 746, 750 (Fed. Cir. 1995).

One way for a patent applicant to rebut a *prima facie* case of obviousness is to make a showing of 'unexpected results,' *i.e.*, to show that the claimed invention exhibits some superior property or advantage that a person of ordinary skill in the relevant art would have found surprising or unexpected.

Id.

Appellants state in the Appeal Brief that the claimed polymers have surprisingly and unexpected advantages, but provided no extrinsic, objective evidence that such properties are possessed by the claimed polymers and not by other polymers, namely, no "showing" under *Soni* was made.

In addition to this, to establish unexpected results, the claimed subject matter must be compared with the closest prior art. *Soni*, 54 F.3d at 750; *Iron Grip Barbell*, 392 F.3d at 1322 (A showing of "new and unexpected results" must be "relative to the prior art."); *In re Baxter Travenol Labs.*, 952 F.2d 388, 392 (Fed. Cir. 1991) ("[W]hen unexpected results are used as

evidence of nonobviousness, the results must be shown to be unexpected compared with the closest prior art”). Appellants did not provide a comparison with the closest prior art to establish that the properties asserted to be surprising and unexpected were actually not possessed by the cited prior art polymers.

Unexpected results must be “commensurate in scope with the degree of protection sought by the claimed subject matter.” *In re Harris*, 409 F.3d 1339, 1344 (Fed. Cir. 2005). Appellants have not explained or provided evidence that the surprising and unexpected results are for the full scope of each rejected independent and dependent claim.

Consisting essentially

The claims recite that the absorbable semi crystalline segmented copolymer “consists essentially” of the product of the melt polymerization reaction. The phrase “consisting essentially of” in a patent claim “has long been understood to permit inclusion of components not listed in [a] claim, provided that they do not ‘materially affect the basic and novel properties of the invention.’” *AK Steel Corp. v. Sollac*, 344 F.3d 1234, 1239 (Fed. Cir. 2003) (citations omitted). The Examiner states that if “applicant” contends that “additional steps or materials in the prior art are excluded by the recitation of ‘consists essentially of,’ applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant’s invention.” Final Act. 8. *Cf. PPG Indus. v. Guardian Indus. Corp.*, 156 F.3d 1351, 1354 (Fed. Cir. 1998).

Appellants argue that the addition of additives and monomers would “reduce the crystallinity and such additives or monomers would materially

affect the basic and novel characteristics of their polymer.” Br. 25.

Appellants state that the use of “consisting essentially” in the claims is “to exclude . . . additives and monomers that materially affect their polymers is proper and is in contradistinction to Venkatraman et al. who may include additives which may materially alter (‘influence’) the properties of their polymers as disclosed in their Paragraph [0029].” *Id.*

This argument does not persuade us that the Examiner erred.

The “bioabsorbable fiber” of the claim preamble is “comprising” the “bioabsorbable semicrystalline copolymer.” The phrase “consists essentially of” applies to the “bioabsorbable semicrystalline copolymer of the structure A-B-A” which “consists essentially of the melt polymerization reaction product.” The bioabsorbable fiber is thus open to the addition of components not recited in the claim. *See, e.g., In re Crish*, 393 F.3d 1253, 1257 (Fed. Cir. 2004). Appellants have not provided evidence that the addition of the components in paragraph 29 of Venkatraman to the claimed “bioabsorbable fiber”, which is permitted by the claims, would affect the properties of the bioabsorbable semicrystalline copolymer, particularly the amorphous middle segment B.

While certain additives described in paragraph 29 of Venkatraman are said to affect the crystallinity of the polymer A,² which is the end polymer of the A-B-A structure, Venkatraman does not teach the components affect the amorphous polymer B segment. Appellants have not established that the

² “[0029] In addition to the above, in one embodiment of the present invention an additive may be added to the polymer A. An additive according to the present invention may be any compound that may influence the properties of polymer A.”

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crystallinity of the A segment is basic and novel property of the claimed bioabsorbable fiber. In addition, as pointed out by the Examiner, Appellants' own Specification on pages 15–16 describes that additional monomers may be added to achieve desired characteristics.

For the foregoing reasons the obviousness rejection of claim 60 is affirmed. Claims 50–52, 54–59, 61, 62, 64–72, 74–82, 84–92, and 94–104 were not argued separately and fall with claim 60. *See* 37 C.F.R. § 41.37(c)(1)(iv).

TIME PERIOD

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