



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/221,245	08/30/2011	Dejan Djuric	BSE44US(0000070723US03)	3198
48394	7590	10/26/2016	EXAMINER	
SERVILLA WHITNEY LLC 33 WOOD AVE SOUTH SUITE 830 ISELIN, NJ 08830			BUTCHER, ROBERT T	
			ART UNIT	PAPER NUMBER
			1768	
			NOTIFICATION DATE	DELIVERY MODE
			10/26/2016	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

doCKET@dsiplaw.com
jescobar@dsiplaw.com
lmurphy@dsiplaw.com

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte DEJAN DJURIC, MONIKA HABERECHT,
KARL KOLTER, and BERND BRUCHMANN

Appeal 2015-005841
Application 13/221,245
Technology Center 1700

Before LINDA M. GAUDETTE, ELIZABETH M. ROESEL, and
AVELYN M. ROSS, *Administrative Patent Judges*.

ROSS, *Administrative Patent Judge*.

DECISION ON APPEAL¹

Appellants² appeal under 35 U.S.C. § 134(a) from the Examiner's final rejection of claims 17–22 and 24–33. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

¹ In our Decision below we refer to the Specification filed August 30, 2011 (Spec.), the Final Office Action mailed May 14, 2014 (Final Act.), the Appeal Brief filed January 2, 2015 (Appeal Br.), the Examiner's Answer mailed April 15, 2015 (Ans.), and the Reply Brief filed May 5, 2015 (Reply Br.).

² Appellants identify the real party in interest as BASF SE. Appeal Br. 3.

STATEMENT OF CASE

The claims are directed to methods for improving solubility of low solubility substances by mixing low solubility substances with branched polyesters prepared by polycondensation of citric acid and polyalcohol. Claims Appendix at Appeal Br. 17. According to Appellants, “the present invention produces **rapid-release** pharmaceutical formulations, which are highly soluble in the gastrointestinal tract of patients.” Appeal Br. 11; Spec. ¶28. Claim 17, reproduced below, is illustrative of the claimed subject matter:

17. A method of improving the solubility for substances of low solubility in water comprising:

mixing a branched noncrosslinked polyester with substances of low solubility in water, wherein the branched polyester is obtained by polycondensation of citric acid with at least one polyalcohol having at least two hydroxyl groups at a molar ratio of citric acid to polyalcohol of 2.4:1 to 1:3, and the polyester has an acid number in the range from 132 to 400 mg KOH/g polymer and having a degree of crosslinking of less than 15% by weight.

Claims Appendix at Appeal Br. 17.

REJECTIONS

The Examiner maintains the following rejections³:

³ The Examiner also rejects claim 33 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Final Act. 3. The Examiner later withdraws that rejection. Ans. 9.

- A. Claims 17–22, 24–25, and 28 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Pramanick⁴ as evidenced by the datasheet for methyl dopa. Final Act. 3.
- B. Claims 17–22, 24–26, and 30–33 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Bruggeman⁵ as evidenced by the datasheet for paclitaxel. *Id.* at 6.
- C. Claim 27–29 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Bruggeman as evidenced by the data sheet for paclitaxel and further in view of Stumbe.⁶ *Id.* at 10.

Appellants appeal the rejections of claims 17–22 and 24–33.

Appellants argue independent claim 17 but do not separately argue claims 18–22 and 24–33. Appeal Br. 3–9. We therefore focus our discussion below on claim 17 (Rejections A and B) to resolve the issues on appeal.

OPINION

Rejection A – Obviousness

The Examiner rejects claim 17 (among others) as unpatentable over Pramanick as evidenced the datasheet for methyl dopa. Final Act. 3. The Examiner finds that Pramanick teaches “a method of controlled drug release of methyl dopa (equivalent to a method of improving the solubility).” *Id.*

⁴ D. Pramanick & T. T. Ray, *Synthesis and biodegradation of copolyesters from citric acid and glycerol*, 19 POLYMER BULLETIN 365–370 (Spring 1988) (hereinafter “Pramanick”).

⁵ Bruggeman et al., WO 2008/144514 A2, published November 27, 2008 (hereinafter “Bruggeman”).

⁶ Stumbe et al., US 2009/0099319 A1, published April 16, 2009 (hereinafter “Stumbe”).

The Examiner acknowledges that Pramanick “does not elucidate the acid number of the polyester” and “does not mention the degree of crosslinking.” *Id.* at 4. But, the Examiner finds that because Pramanick teaches preparing a polyester that is “substantially identical to the process described in Example B of the instant invention, there is a sound basis for determining the polyester of Pramanick has an acid number within the scope of claim 1.” *Id.* The Examiner also finds that Pramanick “teaches crosslinking sensitivity is linearly proportional to the Tg, which is ultimately dependent upon the molar ratio of citric acid to glycerol (see page p. 368 and Table 1 of Pramanick).” *Id.* The Examiner explains that because the molar ratios of Pramanick are the same as recited by claim 17, “there is a sound basis for determining the products of Pramanick have a degree of crosslinking within the scope of claim 1.” *Id.* at 5.

Appellants urge that the resulting polyester of the instant invention is not the same as the polymer in Pramanick. Specifically, Appellants contend that “the polyesters of the instant invention are **soluble in water**” and “[t]he polymers of Pramanick . . . are **amorphous solids which are insoluble in water** and other common organic solvents.” Appeal Br. 11. In addition, Appellants argue that the copolyesters of Pramanick, *characterized as crosslinked*, are useful for preparation of a controlled release formulation of drugs, in contrast to the non-crosslinked polyesters of the instant invention—i.e., having a crosslinkage of less than 15% by weight—which result in a rapid release formulation. *Id.* at 11–12; Reply Br. 4.

Appellants do not convince us of reversible error. “Where, as here, the claimed and prior art products . . . are produced by identical or substantially identical processes, the PTO can require an applicant to prove

that the prior art products do not necessarily or inherently possess the characteristics of his claimed product.” *In re Best*, 562 F.2d 1252, 1255 (CCPA 1977); *see also In re Spada*, 911 F.2d 705, 708 (Fed. Cir. 1990). And, whether the rejection is under 35 U.S.C. § 102 or under 35 U.S.C. § 103, the burden of proof is the same, and its fairness is evidenced by the PTO’s inability to manufacture products or to obtain and compare prior art products. *Id.* Here, the Examiner has provided evidence and analysis sufficient to shift the burden to Appellants to show that polyester of Pramanick would not necessarily possess the claimed acid number and degree of crosslinking as claimed. Appellants contend that the polyester of Pramanick and the instant invention are different because the polymer of the present invention is soluble where the polymer of Pramanick is insoluble. Appeal Br. 11. Appellants’ contention is not persuasive because solubility is not recited in the body of claim 17. Appellants do not adequately explain the relationship, if any, between solubility and the claimed features (acid number and degree of crosslinking). Appellants do not show sufficiently that Pramanick’s statements regarding insolubility demonstrate that the recited acid number and degree of cross-linking features are not necessarily present in the disclosed polyester. The Examiner, on the other hand, compares Pramanick to Appellants’ Specification and finds that both are directed to polyesters that are insoluble to a degree. More specifically, the Examiner finds (Ans. 10) that Pramanick teaches that its polymers are indeed soluble, i.e., within 8 to 10 days. Pramanick at 367. Moreover, the instant Specification observes that the degree of crosslinking is determined by the “**insoluble fraction** of the polymer.” Ans. 10 (citing Spec. ¶34). Therefore, both Pramanick and the instant application are soluble to a

degree. Appellants fail to provide evidence sufficient to distinguish the degree of solubility for the polyester of the instant invention from that of Pramanick and, as a result, Appellants have not met their burden.

Rejection B – Obviousness

The Examiner rejects claim 17 (among others) as unpatentable under 35 U.S.C. § 103(a) over Bruggeman as evidenced by the datasheet for paclitaxel. Final Act. 6. The Examiner finds that “Bruggeman discloses a method of combining a branched polyester comprising a biological active agent” having low solubility in water. *Id.* The Examiner acknowledges that Bruggeman “doesn’t mention the acid number of the resulting branched polymer.” *Id.* But, the Examiner finds that because “the branched polyester was made by polycondensation at 100 °C for 3 hours under vacuum in a molar ration of 1:1 . . . which is substantially identical to the process described in the instant specification” the polyesters are essentially the same as claimed. *Id.* at 7.

Appellants argue that the polymers of Bruggeman are not the same as the polymers of the instant invention. Appeal Br. 13. In particular, Appellants contend that the polymer of Bruggeman is made in such a way that “the M_w of Bruggeman’s polymer is 6 times larger than the claimed polyester, and the M_n of Bruggeman’s polymer is about 4.5 times larger than the claimed polyester.” *Id.* at 14. Therefore, according to Appellants, the polyesters cannot be the same as they do not possess the same characteristics. *Id.*

Appellants’ arguments are not persuasive of reversible error as Appellants have not carried their burden of showing that the polyester of

Bruggeman does not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d 1252, 1256 (CCPA 1977). The Examiner finds that Bruggeman teaches a method of combining a branched polyester with an insoluble active biological agent and that the polyester is prepared by a substantially identical process to that claimed. Final Act. 6–7.

Appellants’ argument that the molecular weight of the Bruggeman polyester is much greater than the claimed polyester is not convincing because molecular weight is not required by the claims. In addition, Appellants fail to identify a connection between molecular weight of the polyester and the claimed features. Moreover, the Examiner finds that the polyester of Bruggeman has a molecular weight of 4 kDa, which is well within the range of the molecular weights taught by Appellants’ disclosure. Ans. 12; *compare* Bruggeman ¶¶289, 291, *with* Spec. ¶20. Appellants’ argument that the polyester identified by the Examiner (i.e., Bruggeman ¶289) is merely a “pre-polymer which is then further modified” and that “Bruggeman does not teach or suggest that the prepolymer itself is useful as a solubilizer” (Reply Br. 5) is not supported by the evidence on this record. Bruggeman’s teachings are not as limited as Appellants suggest. In particular, Bruggeman broadly instructs that a polymer—resulting from a reaction of a polyol with a polycarboxylic acid (e.g., citric acid)—can be combined with a biologically active agent without modification to the polymer. Bruggeman Abstract, ¶¶275–277 and 285 (Table 3, no. 2). Accordingly, we sustain the Examiner’s rejection.

CONCLUSION

Appellants have not identified reversible error in the Examiner's rejection of claims 17–22, 24–25, and 28, under 35 U.S.C. § 103(a), as being unpatentable over Pramanick as evidenced by the datasheet for methyl dopa.

Appellants have not identified reversible error in the Examiner's rejection of claims 17–22, 24–26, and 30–33, under 35 U.S.C. § 103(a), as being unpatentable over Bruggeman as evidenced by the datasheet for paclitaxel.

Appellants have not identified reversible error in the Examiner's rejection of claims 27–29, under 35 U.S.C. § 103(a), as being unpatentable over Bruggeman as evidenced by the data sheet for paclitaxel and further in view of Stumbe.

DECISION

For the above reasons, the Examiner's rejections of claims 17–22 and 24–33 is 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).

AFFIRMED