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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
95/002,219	09/13/2012	8067215	10007-115RX1	3938

96039 7590 01/22/2020

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EXAMINER
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ART UNIT	PAPER NUMBER
3991	

MAIL DATE	DELIVERY MODE
01/22/2020	PAPER

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SNF HOLDING COMPANY
Requester and Respondent

v.

CIBA SPECIALTY CHEMICALS
WATER TREATMENT LIMITED
Patent Owner and Appellant

Appeal 2020-00001
Reexamination Control 95/002,219
Patent 8,067,215 B2
Technology Center 3900

BEFORE RICHARD M. LEBOVITZ, RAE LYNN P. GUEST, and WESLEY B. DERRICK, *Administrative Patent Judges*.

LEBOVITZ, *Administrative Patent Judge*.

DECISION UNDER § 41.77(f)

This is a final decision under 37 C.F.R. § 41.77(f) in the above-identified *inter partes* reexamination of U.S. 8,067,215 B2 ("the '215 patent"). The Board's jurisdiction for this appeal is under 35 U.S.C. §§ 6(b), 134, and 315. Claims 1–46 are pending. We affirm the Examiner's determination under 37 C.F.R. § 41.77(d) that claims 1–46 remain unpatentable under 35 U.S.C. § 103.

A Decision under 37 C.F.R. § 41.77(f) was entered April 30, 2018, setting forth a new ground of rejection ("41.77(f) Dec."). The new ground of rejection is as follows:

Claims 1–8, 10, 15, 17–25, 27, 30, 35, and 37–46 under pre-AIA 35 U.S.C. § 103(a) as obvious in view of JP '714. 41.77(f) Dec. 22. Claims 47–49 are newly added by amendment and included in the new ground of rejection.

The rejection of claims 1–46 as obvious in view of WO '680, JP '714, Munk, Kulicke, and Watanabe '855 was affirmed in the 41.77(f) Decision. 41.77(f) Dec. 22.

In response to the rejection, Patent Owner filed a Request to Reopen Prosecution under 37 C.F.R. § 41.77(b) ("Request" or "Req.") (dated May 30, 2018) and an accompanying amendment. Requester provided comments on the Patent Owner's Request under 37 C.F.R. § 41.77(c) ("Comments") (dated Jun. 29, 2018). In the Comments, Requester proposed new rejections based on the claim amendments.

The claim amendment was entered by the Examiner. The Examiner entered a Determination under 37 C.F.R. § 41.77(b) ("Determination") (dated Apr. 17, 2019) in which the § 103 rejection based on JP '714 was maintained. The Examiner also set forth additional rejections of the amended claims based on Requester's Comments. The new rejections are as follows:

Claims 7, 18, and 47 under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement. Determination 7–8.

Claims 1 and 18 under 35 U.S.C. § 112, second paragraph as indefinite. Determination 8.

Claims 7, 18, and 46 under 35 U.S.C. § 314(a) as enlarging the scope of the claims of the patent. Determination 8–9.

Patent Owner responded to the Determination, *inter alia*, by amending the claims. Patent Owner's Response under 37 C.F.R. § 41.77(e) (dated May 17, 2019). The Examiner did not enter this response because it included an amendment and evidence (Ödman Declaration dated May 15, 2019) which are not permitted under 37 C.F.R. § 41.77(e). Miscellaneous Action (entered Sept. 27, 2019). Accordingly, the amendment and response have not been considered in this Decision. Requester's Comments under 37 C.F.R. § 41.77(e) were therefore also not considered.

Claim 1 as amended reads as follows (indentations were added for clarity, and the markup of the claim is as indicated by the Examiner and relative to the original claims):

> 1. A process for preparing a [polymer] homopolymer or copolymer of an ethylenically unsaturated monomer, in which the monomer includes a (meth)acrylamide monomer [is] obtained from a nitrile substrate that can be converted into the ethylenically unsaturated monomer in a biocatalysed reaction using a biocatalyst, which substrate is (meth)acrylonitrile,
>
> wherein the biocatalyst comprises a nitrile hydratase enzyme and whole cells, fractured cells, or a combination thereof, [or a fermentation process], and
>
> wherein the monomer contains [cellular material and/or components of] the biocatalyst and a fermentation broth[,] from a fermentation process used to produce the biocatalyst, and
>
> forming the polymer by polymerising the ethylenically unsaturated monomer or a monomer mixture comprising the ethylenically unsaturated monomer and [cellular material and/or

components of a] the fermentation broth in the presence of a redox and/or thermal initiator and

the formed polymer exhibits an intrinsic viscosity of at least 3 dl/g measured using a suspended level viscometer in I M sodium chloride at 25°C.

CLAIM 1

Claim 1 is directed to a process for preparing a homopolymer or copolymer of an ethylenically unsaturated monomer. The monomer includes a (meth)acrylamide monomer. The (meth)acrylamide monomer is obtained from a nitrile substrate. The nitrile substrate is (meth)acrylonitrile. The claim recites that the "nitrile substrate . . . can be converted into the . . . monomer" using a biocatalyst.

The biocatalyst comprises "a nitrile hydratase enzyme and whole cells, fractured cells, or a combination thereof." As explained in the Specification, "Nitrile[]hydratase enzymes are known to catalyse the hydration of nitrites directly to the corresponding amides." '215 patent, col. 1, ll. 15–16. The Specification discloses a list of microorganisms from which the enzyme can be obtained. *Id.* at col. 1, ll. 16–24. The Specification further discloses that it was known to use "nitrile hydratase to catalyse the conversion of acrylonitrile to acrylamide." *Id.* at col. 1, ll. 30–34.

The monomer is formed into a polymer by a polymerization reaction. The claim requires that the monomer used in the polymerization reaction contains (1) the biocatalyst; and (2) "a fermentation broth from a fermentation process used to produce the biocatalyst." Thus, ***fermentation***

broth must be present in the monomer which is subsequently used in the polymerization reaction to produce the polymer.

Claim 1 does not recite a specific amount of the fermentation broth. In contrast, claim 18, for example, discloses that the fermentation broth is present in the monomer mixture in an amount of at least 5% by weight. However, no such weight restriction is present in claim 1. There is no recitation of the function of the fermentation broth, but rather it is present only as a consequence of the monomer having been polymerized with the enzymatic activity of a biocatalyst, which itself was made by a fermentation process. For these reasons, we conclude that the monomer of claim 1 used to produce the polymer can include as little as trace amounts of the fermentation broth.

The phrase "substrate that can be converted" using the biocatalyst was added by the amendment entered May 30, 2018. Because of the recitation of the term "can," we interpret the phrase to indicate that the nitrile substrate is not *required* by the claim to be converted to the (meth)acrylamide monomer by a biocatalyst, i.e., the substrate has the *capability* of being converted into the monomer by the biocatalyst. However, the claim also requires the presence of fermentation broth in the monomer, indicating that at least some of monomer was produced by the biocatalyst.

WRITTEN DESCRIPTION REJECTION

The Examiner rejected claim 7 based on the amendment adding "optionally" and "mixtures" to claim. Determination 7. We reverse this

rejection of claim 7 because the terms are adequately described in the '216 patent at column 6, lines 44–61.

Claims 18 and 47 are rejected by the Examiner because of the recitation of "wherein the fermentation broth is present in the monomer mixture in an amount of at least 5% by weight," which has no upper range limit. Determination 8. The Examiner found that the only support in the '215 patent is for a range up to 20% by weight. Accordingly, there is no written descriptive support for an amount greater than 20% by weight, which is encompassed by the language of the claims. We agree with the Examiner's determination and affirm the rejection of claims 18 and 47.

INDEFINITENESS REJECTION

The Examiner rejected claims 1 and 18 for lack of antecedent basis of "the polymer" and "the monomer," respectively. We reverse this rejection because the disputed terms would be understood by one of ordinary skill in the art to refer to the polymer ("a homopolymer or copolymer") and the monomer ("an ethylenically unsaturated monomer") recited in the claims.

§ 314(a) REJECTION

The Examiner rejected claim 1 as enlarging the scope of the claim in contravention of § 314(a) because of the recitation of "can be converted." Determination 9. The Examiner also rejected claim 7 because it changed the scope of the recited Markush group by amending the claim from "consisting of" to "comprising." *Id.* We affirm the rejections for the reasons set forth by the Examiner.

§ 103 REJECTION

The rejection of claims 1–8, 10, 15, 17–25, 27, 30, 35, and 37–49 as obvious in view of JP '714 is based on the determination that "it would have been obvious to one of ordinary skill in the art to have performed polymerization of the monomer in the presence of the fermentation broth, when 'culture medium' of the bacteria is utilized as the biocatalyst as described in JP '714 (¶14), because there is no direction to remove it, no disclosure that broth would be deleterious, and no evidence of the criticality or need of removing it." 41.77(f) Dec. 14.

Patent Owner argues that "it was generally accepted at the time the application corresponding to the '215 patent was filed that the presence of impurities, such as those found in fermentation broth, would negatively impact polymerization." Req. 15. Patent Owner cites to the Specification which discloses that "[i]t is generally accepted that even small quantities of impurities can affect the polymerisation of monomers or prevent polymerization taking place at all." '215 patent, col. 2, ll. 51–52. The Specification further discloses:

> By their very nature impurities tend to be variable and give rise to unexpected and usually undesired effects on the polymer. Even small amounts of such impurities may adversely affect the molecular structure of the polymer and in such circumstances would render the polymer product unsuitable for the intended application.

'215 patent, col. 3, ll. 39–44.

The Specification also discloses:

> It would be generally expected that the presence of either the biocatalyst or the fermentation broth would have a detrimental effect on the polymerisation and the final polymer product that is formed. However, contrary to these expectations polymerising the monomer in the presence of the biocatalyst or the fermentation broth results in the desired polymers without any impairment.

'215 patent, col. 5, ll. 7–13.

However, while the Specification states that it was accepted that impurities present in fermentation broth would negatively impact polymerization, the Specification does not disclose a publication in which such fact is described. The Specification also does not disclose a modification or technological improvement to the known processes for making monomer enzymatically, and then polymerizing it to make the polymer, which made it possible to accomplish polymerization without removing the included "impurities" in the fermentation broth. Rather, it appears that Appellant just discovered that the presence of some (up to 20% by weight) fermentation broth did not adversely affect the polymerization. As explained in the Specification:

> We have found that it is possible to manufacture polymers having specifically designed features and properties without the need for removing either the biocatalyst or the fermentation broth.

'215 patent, col. 4, ll. 54–57.

New evidence

Appellant provides new evidence (summarized in Exhibit A) in the Request that Appellant contends establishes "it was generally accepted at the

time the '215 patent was filed that (a) even small quantities of impurities can negatively impact the polymerization of monomers; and (b) as a consequence, monomers should be purified prior to polymerization to remove any impurities in order to prepare high molecular weight polymers." Request 17. We address these publications below.

US '558[1] describes making acrylamide by direct hydration of acrylonitrile substrate using microorganisms capable of hydrating nitriles. US '558, col. 1, ll. 41–43. US '558 discloses that "if the acrylamide concentration is increased, pigments and traces of impurities tend to be extracted from the microorganism to enter into the aqueous solution." US '558, col. 1, ll. 49–53. For this reason, US '558 teaches that "it is desirable to purify the aqueous solution obtained by this process by treating with activated carbon similarly as in the case of the aforesaid catalytic hydration process." US '558, col. 1, ll. 53–56. With respect to the referenced catalytic hydration process, US '558 teaches the desirability of purification "to remove the color or turbidity before it is commercially presented in the form of an aqueous solution or crystals." US '558, col. 1, ll. 25–28. In other words, US '588 suggests purifying might be desirable for some certain commercial presentations. US '558 does not teach that the pigments and trace impurities were known in the art to adversely affect polymerization as asserted by Appellant.

EP '555[2] also employs microbial enzyme catalysis to make the acrylamide monomer prior to polymerization. EP '555, pp. 19–20. EP '555

[1] US 4,701,558, issued Oct. 20, 1987.
[2] EP 0 204 555 A2, published Jun. 4, 1986.

teaches that when monomer is made using microorganisms which do not have high activity "to convert a nitrile to the corresponding amide," a "drawback" is "the amount of organic acids formed as by-products is not on a level that is allowable from the viewpoint of industrial production." EP '555, p. 3, ll. 5–11. EP '555 also teaches purification of the resulting amide:

> From the resulting reaction mixture, the amide produced may be isolated by means of customary techniques such as centrifugation, membrane separation, vacuum concentration, crystalization, [sic] etc., thereby to obtain a purified amide. According to need, coloring substances, impurities and the like may be removed, before the vacuum concentration, crystalization [sic] or the like, by the treatment using an activated charcoal, an ion exchange resin or the like.

EP '555, p. 22, ll. 2–10.

Appellant states that EP '555 "reflects an understanding in the art that fermentation broth (even with little to no by-products) should be purified prior to polymerization to prepare high molecular weight polymers." Req. 19. However, Appellant did not direct us to disclosure in EP '555 which addressed the effect of impurities on the polymer's molecular weight. The disclosure does not even require that the enzymatically-produced monomer is purified, but rather states it "may" be isolated and "[a]ccording to need . . . impurities and the like may be removed," indicating it is within the skilled worker's discretion to do so. EP '555, p. 22, ll. 1–10 (reproduced above). EP '555 therefore does not establish that it was known in the art that the impurities interfere with monomer polymerization.

Appellant also cites the general disclosure in Dechow[3] describing fermentation broth as "combination of insoluble, gelatinous biomass, the nutrient fluid, and the soluble metabolites resulting from the fermentation operation," and that consequently, "[d]ownstream processing, therefore, has to deal with a viscous, highly non-Newtonian slurry as its feedstock." Dechow 1; *see* Req. 17, Ex. A. However, Dechow does not describe the conversion of acrylonitrile into acrylamide, and does not discuss polymerization of a monomer produced by a biocatalyst. Further, Appellant has not identified the relevance of the fermentation broth of Dechow to directly produce a monomer using a biocatalyst and then subsequently polymerize that monomer. More specifically, Appellant also has not provide evidence that such viscosity and metabolites of Dechow's fermentation broth would interfere with the polymerization processes described in JP '714. Dechow therefore does not establish that it was known in the art that the impurities interfere with monomer polymerization.

Appellant further cites WO '716[4] which Appellant states "emphasizes that the level of impurities such as monosaccharides need to be controlled in order to produce a polymer having satisfactory quality, higher molecular weight and higher solubility. ¶ *bridging pages 10 and 11*." Request 18. Appellant states that the content of monosaccharide in the microbial process is reduced in WO '716 and therefore "reflects an understanding in the art that fermentation broth includes impurities (specifically sugars) that would

[3] Dechow, F.J., 1989, *Separation and Purification Techniques in Biotechnology*, 1–33.
[4] WO 03/033716 A1, published Apr. 24, 2003.

be expected to negatively impact polymerization, and suggests that the monomer should be purified prior to polymerization to prepare high molecular weight polymers." Request 18. We do not agree with Appellant's analysis.

> WO '716 contains the following pertinent teachings:
>
> The object of the present invention is to provide a process for producing acrylamide and so forth using a microbial catalyst that produces nitrile hydratase enzyme that is capable of producing acrylamide-based polymers *having a high molecular weight* and a high degree of solubility.

WO '716, p. 5 (*emphasis added*).

> (2) A process for producing an acrylamide/methacrylamide-based polymer comprising: treating acrylonitrile and/or methacrylonitrile using a nitrile hydratase producing microbial catalyst *in which the content of monosaccharide is 5% by mass or less* to obtain a corresponding amide compound, followed by polymerizing a monomer containing said amide compound.

WO '716, p. 6 (*emphasis added*).

> Although there are no particular restrictions on the method for making the content of the monosaccharide in the microbial catalyst used 5% by mass or less, examples of such methods include washing a culture liquid containing the aforementioned microorganism following completion of culturing of the microorganism with physiological saline or phosphate buffer and so forth followed by centrifugal separation, and a method in which a culture liquid containing said microorganism is filtered using a filtration membrane such as a hollow fiber.

WO '716, p. 9.

> A high molecular weight and/or highly soluble acrylamide/methacrylamide-based polymer can be produced by using as monomer acrylamide and/or methacrylamide in which the *monosaccharide content is 500 ppm or less* obtained in the manner described above.

WO '716, p. 10 (emphasis added).

WO '716 thus teaches that a "nitrile hydratase producing microbial catalyst in which the content of monosaccharide is 5% by mass or less" (WO '716, p. 6) is used to produce the monomer and the resulting monomer having 500 ppm saccharide or less is used to make "high molecular weight" polymer (WO '716, p. 10). The monosaccharide may be from the culture liquid used to make the microbial catalyst (WO '716, p. 7: "nitrile hydratase producing microbial catalyst is used for which the content of monosaccharide derived from the microbial culture liquid is 5% by mass or less, and preferab1y 3% by mass or less"). The "microbial liquid culture" is fermentation broth. Therefore, WO '716 teaches that a fermentation broth ("microbial culture liquid") can be present during polymerization to produce a *high molecular weight* as long as long the content of monosaccharide in it is below a specific amount, and sets forth different limits, including 500 ppm or 5% by mass.

Appellant provided WO '716 as evidence that "impurities (specifically sugars) that would be expected to negatively impact polymerization, and suggests that the monomer should be purified prior to polymerization to prepare high molecular weight polymers," but failed to address the express disclosure in WO '716 that certain amounts of sugar, and

therefore fermentation broth, can be present during polymerization and still produce high molecular weight polymer (WO '716, p. 10).

Claim 18 recites "wherein the fermentation broth is present in the monomer mixture in an amount of at least 5% by weight." Dependent claims 47–49 recite that "the fermentation broth present in the monomer or the monomer mixture" is in an amount of at least 5% by weight and 5% to 20% by weight." Appellant did not distinguish these amounts of monosaccharide, and the accompanying fermentation broth in which the monosaccharide resides, from the amounts of fermentation broth recited in the claims.

> 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).

Appellant also cited WO '680[5] to support the argument that purification of monomer was necessary after microbial production of monomer and prior to polymerization. We do not agree with Appellant that WO '680 supports this contention. WO '680 teaches that the "use of a biocatalyst that has nitrile hydratase activity enabled the production of acrylamide by a very simple process," which produces acrylamide "without the use of reduced copper as a catalyst . . . while generating substantially no by-product." WO '680, p. 7, ll. 25–28. Thus, WO '680 teaches the

[5] WO 03/080680 A1, published Oct. 2, 2003.

advantages of using a microbial catalyst. Furthermore, WO '680, like WO '760, teaches that saccharide can be present with no deleterious effect on the polymer. WO '680, p. 1, ll. 24–28. In fact, WO '680 teaches that "an aqueous solution of acrylamide containing saccharides can provide an aqueous solution of polyacrylamide with a higher viscosity than that of polyacrylamide obtained from an aqueous solution with an equivalent acrylamide content that contains no saccharide." WO '680, p. 3, ll. 24–27. Thus, WO '680 provides a reason to use the saccharide from a fermentation broth in the monomer mixture used for polymerization.

Appellant cited the following disclosure from WO '680 to support their argument:

> However, the quality of acrylamide is presumed to significantly affect the quality of the acrylamide polymer. This can be deduced based on the fact that, for example, a variety of processes for producing acrylamide from which impurities such as acrolein or oxazole have been removed have been proposed.

WO '680, p. 2, ll. 20–24.

This statement in WO '680 is a reference to the catalytic process which does not employ microbial enzymes to make the monomer used in subsequent polymerization steps. Thus, this teaching in WO '680 is not necessarily relevant to monomer made using a biocatalyst as claimed. Indeed, WO '680 further disclosed:

> Acrylamide produced with the use of a microbial enzyme generates only small amounts of impurities. Thus, high-quality polyacrylamide that has a very high molecular weight and is free from insoluble impurities can be produced therefrom.

WO '680, p. 3, ll. 5–7. Thus, WO '680 teaches that the monomer produced with a biocatalyst has only small amounts of impurities as compared to non-biocatalytic processes.

US '883[6] discloses the production of acrylamide monomer using a copper-base catalyst. US '883, col. 1, l. 6–14. Appellant cites the following statement in US '833 (Appeal Br., Exhibit A):

> To produce an acrylamide polymer having such high molecular weight and sufficient water solubility as described above, it is considered important to pay attention not only to a process for the production of the polymer but also to the quality of acrylamide. Further, the quality of acrylonitrile as the raw material is also considered to significantly affect the production of such an acrylamide polymer.

US '883, col. 1, l. 65–col. 2, l. 4.

This statement cited by Appellant does not provide evidence that the acrylamide produced by a biocatalyst, as described in JP '714, has a quality that would adversely affect the production of the acrylamide polymer. As discussed above, WO '680 teaches that the monomer produced with a biocatalyst has only small amounts of impurities as compared to non-biocatalytic processes. WO '680, p. 3, ll. 5–7.

US '900[7] also describes the production of acrylamide monomer using microorganisms. Appellant cites to the following disclosure from US '900 as evidence that impurities interfere with polymerization of the acrylamide monomer:

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[6] US 5,476,883, issued Dec. 19, 1995.
[7] US 4,343,900, issued Aug. 10, 1982.

> However, the use as an aqueous medium of the above-described physiological saline solution, phosphate buffer solution, etc., is not preferred, *in that the acrylamide aqueous solution formed contains large amounts of sodium chloride, phosphoric acid salts, etc., leading to the formation of low quality acrylamide*. In particular, when acrylamide of a solution containing phosphoric acid salts is polymerized to produce acrylamide based polymers having high degrees of polymerization, the acrylamide based polymers formed are *undesirably liable to become insoluble in water*. Therefore, post-treatments such as an ion exchange treatment, etc., become essential for the removal of the phosphoric acid salts prior to polymerization.

US '900, col. 1, ll. 43–56 (emphasis added).

Prior to this discussion in US '900, the patent describes "production of acrylamide from acrylonitrile by use of such microorganisms . . . carried out by bringing the microorganism, either as is or after being fixed on a polymeric gel, into contact with acrylonitrile in an aqueous medium (e.g., water, a physiological saline solution, a phosphate buffer solution, etc.)." US '900, col. 1, ll. 23–28. Thus, the reason that "*large amounts of sodium chloride, phosphoric acid salts*" are present is that saline or phosphate buffered solutions were used in the process to make the monomer from the acrylonitrile substrate. Appellant did not provide evidence that the fermentation broth would contain the amount of salts described the US '900 which makes the polymer "undesirably liable to become insoluble in water." US '900, col. 1, ll. 43–56 (reproduced above).

US '855 (Watanabe '855) describes using immobilized microorganisms to produce acrylamide. '855, col. 1, ll. 5–10. The patent has similar disclosure as US '900 about the undesirability of salts and

eliminating the salts and impurities. US '855, col. 1, l. 64–col. 2, l. 6; col. 4, l. 28–67. However, US '855 does not use a fermentation broth and its disclosure about eliminating salts and impurities are not addressed to the components of a fermentation broth.

Indicia of non-obviousness

We have considered the evidence non-obviousness discussed in the Request, but do not find it persuasive because one of ordinary skill in the art, particularly based on JP '714, WO '716, and WO '680 would have had a reasonable expectation that fermentation broth could be included during polymerization without adverse effects. As to the advantages and long-felt need cited by Patent Owner (Req. 20), Appellant did not provide objective evidence, as compared to the cited prior art, to establish non-obviousness. *In re Harris*, 409 F.3d 1339, 1344 (Fed. Cir. 2005); *In re Greenfield*, 571 F.2d 1185, 1189 (CCPA 1978); *In re Baxter Travenol Labs.*, 952 F.2d 388, 392 (Fed. Cir. 1991). For example, it was found in the previous Decision that high molecular weight polymer in the scope of the claims is described in JP '714. Decision on Appeal 11, 13, 23–24, 32 (decision entered Aug. 1, 2016).

Summary

We have considered all the evidence, including the publications listed in Exhibit A, as well as the evidence previously made of record. Based on a preponderance of the evidence, impurities in the monomer mixture were known, prior to the filing date of the claims, to affect polymer quality and

molecular weight. For this reason, the prior art (*see* Req., Exhibit A) described various ways to purify the monomer mixture prior to polymerization and/or avoid impurities (e.g., US '558, EP '555, US '883, US '855). However, the issue in this rejection is whether one of ordinary skill in the art would have considered the presence of fermentation broth in the monomer mixture deleterious when used to make the polymer. On this narrower issue, we find a lack of evidence that one of ordinary skill in the art would have been dissuaded from using a monomer mixture comprising fermentation media and biocatalyst to make the polymer. As discussed above, WO '716 specifically discloses that certain amounts of monosaccharide derived from the fermentation broth can be present and still produce high molecular weight polymer. WO '680 described advantages of having a saccharide present in the monomer mixture used in the polymerization process, providing a reason to have included broth with monosaccharides. Therefore, while certain impurities were known to affect polymerization of the monomer, Appellant did not establish that these impurities are present in fermentation broth and/or in amounts that would adversely affect polymerization. *See* also Requester Comments 19. Accordingly, for the foregoing reasons, the obviousness rejection based on JP '714 is affirmed.

CONCLUSION

In summary (as to the claims involved in the new ground of rejection in the 41.77 Decision and newly added claims 47–49):

Claim(s) Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
1–8, 10, 15, 17–25, 27, 30, 35, and 37–49	103	JP ’714	1–8, 10, 15, 17–25, 27, 30, 35, and 37–49	
7, 18, 47	112, first paragraph	Written description	18, 47	7
1, 18	112, second paragraph	Indefiniteness		1, 18
1	314(a)	Enlarging claim scope		
1–46	103	WO ’680, JP ’714, Munk, Kulicke, and Watanabe ’855	1–46	
Overall Outcome			1–49	

AFFIRMED

tc

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