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Paper 7
Entered: August 21, 2024

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

HONEYWELL INTERNATIONAL INC.,
Petitioner,

v.

DSM IP ASSETS B.V.,
Patent Owner.

IPR2024-00493
Patent 10,280,532 B2

Before ERICA A. FRANKLIN, JON B. TORNQUIST, and JAMES J. MAYBERRY, *Administrative Patent Judges.*

FRANKLIN, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

Honeywell International, Inc. ("Petitioner") filed a Petition requesting an *inter partes* review of claims 1–9 of U.S. Patent No. 10,280,532 B2 (Ex. 1001, "the '532 patent"). Paper 2 ("Pet."). DSM IP Assets, B.V. ("Patent Owner") filed a Preliminary Response to the Petition. Paper 6 ("Prelim. Resp.").

We have authority to determine whether to institute an *inter partes* review. 35 U.S.C. § 314. Upon considering the parties' arguments and evidence, we determine that Petitioner has not established a reasonable likelihood that it would prevail in showing the unpatentability of at least one claim challenged in the Petition. Accordingly, we do not institute an *inter partes* review of the challenged claims.

A. Real Parties-in-Interest

Petitioner identifies itself as the real party-in-interest. Pet. 67. Patent Owner identifies itself, DSM Purity, B.V., DSM Biomedical, B.V., and DSM Biomedical, Inc. as the real parties-in-interest. Paper 3, 1.

B. Related Matters

The parties explain that the '532 patent has been asserted in *DSM IP Assets, B.V. et al. v. Honeywell Int'l Inc.*, No. 23-cv-00675 (WCB) (D. Del.). Pet. 67; Paper 3, 1.

C. The '532 Patent

The '532 patent relates to a colored sutures comprising filaments produced by gel spinning a mixture of ultra-high molecular weight polyethylene (UHMwPE or UHMWPE), an inorganic chromium oxide-containing pigment, and a spin solvent. Ex. 1001, 1:17–20. Colored sutures are beneficial in surgery because the added color provides a better contrast with the blood or tissue in the operating area. *Id.* at 1:11–13. The '532 patent

explains that suture strength is another important consideration when producing a suture. *Id.* at 1:22–23. While UHMwPE produced by the gel spinning process are very strong filaments, they are difficult to color. *Id.* at 1:24–28. In particular, a colorant like a dye or a colored coating material adheres poorly to the surface of such filaments due to the a-polar character of UHMwPE. *Id.* at 1:29–33. Insufficient adhesion may cause the filament to lose part or all of the colorant during production of the suture, or once in place in a patient. *Id.* at 1:33–35.

The ’532 patent describes various attempts by others to enhance the adhesion of colorants to UHMwPE filaments by using either a plasma pre-treatment or super critical carbon dioxide as a solvent for the dye. *Id.* at 1:36–38, 43–44. These attempts were unsuccessful because they resulted in adverse effects on the mechanical properties of the filaments, such as tensile strength, or leaching out of the color, making the filaments unfavorable for use as sutures. *Id.* at 1:38–49.

Additionally, attempts to use pigments to color UHMwPE filaments was disadvised because the process requires a low viscous carrier polymer which has a negative influence on mechanical properties of the filaments and any un-dispersed or re-agglomerated clumps of pigment particles in the coloring process will have a detrimental effect on the tensile strength of the filaments. *Id.* at 1:62 –2:3. Further, the use of dispersants in preparing filaments intended for use in sutures is disadvantageous because dispersants would negatively affect biocompatibility of the sutures. *Id.* at 2:4–6.

The instant invention employs a coloring process that provides a colored suture that does not exhibit the disadvantages experienced by prior attempts to color sutures. *Id.* at 2:15–17. In particular, the process involves

gel spinning a multifilament yarn from a mixture of UHMwPE, a spinning solvent, and a pigment. *Id.* at 2:20–23. The '532 patent explains:

> Gel spinning is understood to include at least the steps of spinning filaments from a solution of ultra-high molecular weight polyethylene in a spin solvent; cooling the filament obtained to form a gel filament; removing at least partly the spin solvent from the gel filament; and drawing the filament in at least one drawing step before, during or after removing spin solvent. Suitable spin solvents include for example paraffin's, mineral oil, kerosene or decalin. Spin solvent can be removed by evaporation, by extraction, or by a combination of evaporation and extraction routes. Such filaments are commercially available as Spectra® or Dyneema® grades.

Id. at 2:31–42. Analysis of multifilament yarn prepared according to the invention demonstrated favorable results regarding mechanical properties, leaching out, and cytotoxicity. *See id.* at 1:39–6:13.

D. Illustrative Claim

Petitioner challenges claims 1–9 of the '532 patent. Claim 1, set forth below, is the only independent claim challenged and is illustrative of the claimed subject matter.

> 1. A colored multi-filament yarn comprising filaments that have been obtained by gel spinning a mixture containing ultra-high molecular weight polyethylene (UHMwPE) having an intrinsic viscosity (IV) of between about 8 and 40 dl/g, a spin solvent and a pigment, and wherein the filaments consist of UHMwPE between 0.1 and 7.0 wt.% of an inorganic chromium oxide-containing pigment, a residual amount of spin solvent of less than about 500 ppm, and less than 1000 ppm of further constituents.

Ex. 1001, 6:64–7:5. Dependent claims 2 and 3 recite amounts for the inorganic pigment. Dependent claim 4 recites that the inorganic pigment is aluminum-chromium-cobalt oxide. Dependent claims 5–8 recite residual

amounts for the spin solvent. Dependent claim 9 recites a range for the number of filaments.

E. Asserted Grounds of Unpatentability

Petitioner asserts that claims 1–9 are unpatentable on the following three grounds:

Claims Challenged	35 U.S.C. §[1]	References
1–9	103(a)	Simmelink[2], Section 73.1015[3]
1–9	103(a)	Section 73.1015, Nanri[4], Ohta,[5] Kavesh[6]
1–9	103(a)	Section 73.1015, Nanri, Simmelink

Petitioner also relies upon the Declaration of David T. Grubb, D. Phil. (Ex. 1003).

II. ANALYSIS

A. Person of Ordinary Skill in the Art

The level of skill in the art is a factual determination that provides a primary guarantee of objectivity in an obviousness analysis. *Al-Site Corp. v.*

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[1] The Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112–29, 125 Stat. 284 (2011), amended 35 U.S.C. § 103, effective March 16, 2013. Petitioner assumes, and Patent Owner does not dispute, that the '532 patent has an effective filing date prior to March 16, 2013. Pet. 5. Accordingly, we apply the pre-AIA version of §103.

[2] Joseph Simmelink et al., WO 2005/066401 A1, published July 21, 2005 (Ex. 1005, "Simmelink").

[3] Food and Drugs, Part 73–Listing of Color Additives Exempt From Certification, Subpart B–Drugs, Chromium-cobalt-aluminum oxide, 21 C.F.R. § 73.1015, revised April 1, 2006 (Ex. 1006 "Section 73.1015").

[4] Shosuke Nanri et al., JP H11-21721, published Jan. 26, 1999 (Ex. 1007, "Nanri").

[5] Yasuo Ohta et al., JP 2586213, published Dec. 5, 1996 (Ex. 1008, "Ohta").

[6] Sheldon Kavesh et al., JP S58-5228, published Jan. 12, 1983 (Ex. 1009, "Kavesh").

VSI Int'l Inc., 174 F.3d 1308, 1323 (Fed. Cir. 1999) (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966)); *Ryko Mfg. Co. v. Nu-Star, Inc.*, 950 F.2d 714, 718 (Fed. Cir. 1991)).

Petitioner asserts that a person of ordinary skill in the art (POSITA, or PHOSITA) at the time of the '532 patent "would have had at least a Bachelor's degree in the field of chemistry, chemical engineering, polymer chemistry, or materials science and at least three years of relevant work experience in the field of high strength fibers." Pet. 8 (citing Ex. 1003 ¶ 18). Petitioner adds that individuals with different educational backgrounds could still be of ordinary skill in the art if they have "additional experience [that] compensates for a deficit in their education and experience stated above." *Id.*

> According to Patent Owner, a person or ordinary skill in the art,
>
> would have (i) a bachelor's degree in chemistry, polymer chemistry, materials science, chemical engineering, or biomedical engineering and (ii) three years of experience in designing and manufacturing gel-spun UHMWPE yarns. At this level of skill, a PHOSITA would have a detailed understanding of the information provided in the Technology Background, Section II, supra, including (i) the differences between linear HDPE and UHMWPE, (ii) the history underlying Section 73.1015 and the early failures of the 1960s-era blue, melt-extruded polyethylene sutures, (iii) why the molecular orientation of polyethylene molecules leads to strong yarns in the special case of gel-spun UHMWPE, and (iv) the challenges associated with coloring gel-spun UHMWPE yarns, especially for end-use medical applications.

Prelim. Resp. 33–34.

We note that the parties' proposed definitions are largely similar, except that Patent Owner additionally recognizes a Bachelor's degree in biomedical engineering and requires experience in designing and manufacturing gel-spun UHMWPE yarns. In any event, we do not need to

resolve this issue as our findings and conclusion in this Decision would be the same under either proposed definition.

B. Claim Construction

The Board applies the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. § 282(b); 37 C.F.R. § 100(b). Under that standard, claim terms "are generally given their ordinary and customary meaning" as understood by a person of ordinary skill in the art at the time of the invention. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc) (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). "In determining the meaning of the disputed claim limitation, we look principally to the intrinsic evidence of record, examining the claim language itself, the written description, and the prosecution history, if in evidence." *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 469 F.3d 1005, 1014 (Fed. Cir. 2006) (citing *Phillips*, 415 F.3d at 1312–17).

Petitioner asserts that "[u]nless otherwise specified, the terms discussed herein are to have their plain meaning." Pet. 5. Petitioner does not expand on that statement or indicate whether any terms are "otherwise specified." *See id.*

Patent Owner addresses the claim term "gel spinning," asserting that at least two arguments in the Petition implicate the scope of that term. Prelim. Resp. 34. Specifically, Patent Owner refers to Petitioner's position that: (a) the gel spinning process in Simmelink is "not inconsistent" with the pigmentation process of Section 73.1015; and (b) the "gel spinning" term should not be given patentable weight as a process in a product by process claim. *Id.* (citing Pet. 16–17, 39–41, 54–55). According to Patent Owner, "a PHOSITA would understand that a spinning process is not 'gel spinning'

according to [claim 1] if it does not use a solvent to dissolve the UHMWPE during the spinning process." *Id.* Patent Owner asserts that the use of a solvent in the gel spinning process distinguishes it from melt spinning, which does not use a solvent. *Id.* at 36–37 (citing Ex. 1014,[7] 63–65).

Additionally, Patent Owner asserts that the term "gel spinning" in claim 1 is entitled to patentable weight because the process provides "specific structure" to the product. *Id.* at 37. Petitioner's position is that "patentability is based on the product (e.g., the yarn) itself and the 'physical constituent of the fiber' that 'is a quantifiable and hence physical attribute of the fiber.'" Pet. 16 (citations omitted).

Based upon our review of the record, we agree with Patent Owner that a skilled artisan would have understood that the "gel spinning" process recited in the claims requires the use of a solvent during the spinning process. Indeed, the Specification describes this term, as follows:

> Gel spinning is understood to include at least the steps of spinning filaments from a solution of ultra-high molecular weight polyethylene in a spin solvent; cooling the filament obtained to form a gel filament removing at least partly the spin solvent from the gel filament; removing at least partly the spin solvent from the gel filament; and drawing the filament in at least one drawing step before during or after removing spin solvent.

Ex. 1001, 2:31–37. We recognize the inventor's lexicography as dispositive with respect to the meaning of the term "gel spinning." *See Phillips v. AWHCorp.*, 415 F.3d 1303, 1316 (Fed. Cir. 2005); *SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1343–44 (Fed. Cir.

[7] Hearle, J.W., "High-performance Fibres," Woodhead Publishing Ltd., Cambridge, Chapter 1, (2001).

2001). Thus, the Specification defines the term "gel spinning" and makes clear that it is a process that must use a spin solvent.

Next, we consider whether the claim term "gel spinning" is limiting. Claim 1 describes gel spinning as the manner by which the filaments comprised in the claimed colored multi-filament yarn are obtained. This, on its face, is a product-by-process claim element because it describes the filament structure being obtained in a particular way, i.e., by gel spinning. *See Kamstrup A/S v. Axioma Metering UAB*, 43 F.4th 1374, 1382 (Fed. Cir. 2022) (agreeing with the Board that "cast in one piece" is a product-by-process claim element as it describes the structure being cast "in a particular way"). For this element to be limiting, it must impart "structural and functional differences" that distinguish the claimed product from the prior art. *See Amgen Inc. v. F. Hoffman-La Roche Ltd*, 580 F.3d 1340, 1365–67 (Fed. Cir. 2009).

Patent Owner argues persuasively that gel spinning imparts structural and functional differences to the claimed product because the process "creates overlap between polyethylene molecules within the UHMWPE filaments that maximizes the intermolecular Van der Waals interactions, resulting in highly crystalline filaments with high tensile strength." Prelim. Resp. 38, 22 (citing Ex. 1014, 62–66). According to Patent Owner, "the structure of the gel spun UHMWPE is substantially different from other types of UHMWPE such as compression-molded and ram-extruded UHMWPE used to make joint replacements and other orthopedic implants." *Id.* at 38.

Indeed, as Patent Owner notes, Dr. Grubb, Petitioner's declarant, acknowledges that gel spinning provides structure to the filaments. *Id.* at 37. In particular, Dr. Grubb recognizes that the gel spinning process "makes the

molecular chains of the polymer form a lightly entangled structure. This allows the gel filaments to be drawn to high draw ratios which results in high stiffness and high tensile strength." Ex. 1003 ¶ 52.

Therefore, we determine that the record supports finding that the gel spinning process recited in claim 1 imparts to the claimed multifilament yarn product a feature, i.e., high tensile strength, that may distinguish the claimed invention from the prior art. *See Amgen Inc.*, 580 F.3d at 1365–67. Accordingly, we consider the claim phrase "obtained by gel spinning" to limit claim 1.

C. Obviousness over Simmelink and Section 73.1015

Petitioner asserts that claims 1–9 would have been obvious over the combined teachings of Simmelink and Section 73.1015. Pet. 9–29. Patent Owner disagrees. Prelim. Resp. 41–61.

A patent claim is unpatentable under 35 U.S.C. § 103(a) if the differences between the claimed subject matter and the prior art are such that the subject matter, as a whole, would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). "An obviousness determination requires finding both 'that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so.'" *CRFD Research, Inc. v. Matal*, 876 F.3d 1330, 1340 (Fed. Cir. 2017) (quoting *Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1367–68 (Fed. Cir. 2016)). Obviousness grounds must be supported with "articulated reasoning with some rational underpinning" and not by "mere conclusory statements." *See KSR Int'l Co.*, 550 U.S at 418.

1. Simmelink

Simmelink is directed to a process for making high-performance polyethylene (HPPE) multifilament yarn. Ex. 1005, 1:7–8. The process comprises the following steps:

> a) making a 3-25 mass% solution of ultra-high molar mass polyethylene having an intrinsic viscosity as measured on solutions in decalin at 135°C of between about 8 and 40 dl/g, in a solvent;
> b) spinning of the solution through a spinplate containing at least 5 spinholes into an air-gap to form fluid filaments, while applying a draw ratio DR_{fluid};
> c) cooling the fluid filaments to form solvent-containing gel filaments;
> d) removing at least partly the solvent from the filaments; and
> e) drawing the filaments in at least one step before, during and/or after said solvent removing, while applying a draw ratio DR_{solid} of at least 4.

Id. at 1:9–17. Simmelink explains that its reference to "high-performance polyethylene multifilament yarn" means "a yarn containing at least 5 filaments made from ultra-high molar mass, or ultra-high molecular weight, polyethylene having an intrinsic viscosity . . . of at least 4 dl/g (UHPE), the yarn having a tensile strength of at least 3.0 GPa and a tensile modulus of at least 100 GPa." *Id.* at 1:37–2:3. The HPPE yarns may be used in "various semi-finished and end-use products, like ropes and cords, mooring lines, fishing nets, sports equipment, medical applications, and ballistic-resistant composites." *Id.* at 2:4–7.

The high-strength yarn is very suited for making high-strength surgical sutures and other medical implants. *Id.* at 12:1–6. For such medical applications, "the amount of other components or foreign material in the yarn is very important, in addition to its mechanical properties." *Id.* at 12:6–7. In this regard, Simmelink discloses "HPPE multifilament yarn according

to the invention containing less than 150 ppm of residual solvent . . . preferably containing less than 100, 75, or even less than 50 ppm of solvent, and to medical implants containing such yarn." *Id.* at 12:7–12.

Simmelink teaches that "[t]he UHPE that is applied in the process according to the invention may further contain small amounts, generally less than 5 mass%, preferably less than 3 mass% of customary additives, such as anti-oxidants, thermal stabilizers, colorants, flow promoters, etc." *Id.* at 8:28–31.

2. Section 73.1015

Section 73.1015 describes chromium-cobalt-aluminum oxide as a blue-green pigment that may be used as a color additive. Ex. 1006, 357. Section 73.1015 states that "[c]ertification of this color additive is not necessary for the protection of the public heath, and batches thereof are exempt from certification requirements of section 721(c) of the act." *Id.* Additionally, Section 73.1015 sets forth "[u]ses and restrictions" for the color additive, as follows:

> The color additive chromium-cobalt-aluminum oxide may be safely used for color linear polyethylene surgical sutures, United States Pharmacopeia (U.S.P.), for use in general surgery, subject to the following restrictions:
>
> (1) For coloring procedure, the color additive is blended with the polyethylene resin. The mixture is heated to a temperature of 500°–550 °F. and extruded through a fixed orifice. The filaments are cooled, oriented by drawing, and set by annealing.
>
> (2) The quantity of the color additive does not exceed 2 percent by weight of the suture material.
>
> (3) The dyed suture shall conform in all respects to the requirements of the U.S.P. XX (1980).
>
> (4) When the sutures are used for the purpose specified in their labeling, there is no migration of the color additive to the surrounding tissue.

> (5) If the suture is a new drug, an approved new drug application, pursuant to section 505 of the Federal Food, Drug, and Cosmetic Act, is in effect for it.

Id.

3. Discussion

Petitioner asserts that, at the time of the invention, there was a design need for colored sutures having high strength, as recognized in the '532 patent. Pet. 9–10 (citing Ex. 1001, 1:11–17, 1:22–27; Ex. 1003 ¶ 175). Petitioner asserts that it was also known in the art that UHMWPE filaments could be used as sutures and had been colored using pigments. *Id.* at 10 (citing Ex. 1003 n.2). Petitioner contends that a skilled artisan would rely on Simmelink for its disclosure of adding colorants to colored sutures. *Id.* (citing Ex. 1005, 1:7–8, 1:18–20, 12:3–6; Ex. 1003 ¶ 174.).

When designing colored sutures, Petitioner asserts that a skilled artisan would have understood that "sutures are implantable devices and thus are subject to specific regulatory requirements, including containing only colorants approved for use in sutures by the United States Food and Drug Administration. (FDA)." *Id*. at 10–11 (citing Ex. 1003 ¶ 177).

Petitioner asserts that because chromium-cobalt-aluminum oxide is "identified [ ] as a color additive that was approved for linear polyethylene surgical sutures and exempt from batch certification requirements," a skilled artisan designing colored sutures "would understand that using an exempted color additive would save not only time, but significant expense, as compared to petitioning for use of a new, not already authorized, color additive or otherwise requiring certification of each new batch of sutures." *Id.* at 11 (citing Ex. 1003 ¶ 178). In other words, Petitioner asserts, "to facilitate regulatory approval, a POSITA would have turned to Section 73.1015 and its disclosure of the exempted color additive chromium-cobalt-

aluminum oxide as a pigment in an amount that does not exceed 2 percent by weight of the suture material in coloring linear polyethylene surgical sutures." *Id.* (citing Ex. 1003 ¶¶ 177–179).

According to Petitioner, the skilled artisan would have been "motivated to add the chromium-cobalt-aluminum oxide pigment to the gel spinning mixture of Simmelink, in accordance with the pigmentation process of Section 73.1015, which discloses that . . . the pigment is blended with the polyethylene resin to form a mixture that is then heated and extruded." *Id.* at 12 (citing Ex. 1006 ¶ 18(c)(1); Ex. 1003 ¶ 180).

Petitioner additionally asserts that it "would have been obvious to try the chromium-cobalt-aluminum oxide pigment disclosed in Section 73.1015 when developing the HPPE multi-filament yard disclosed by Simmelink, based on at least the well-known need for a colored suture made from UHMWPE fiber and the limited number of solutions to color an UHMWPE fiber." *Id.* at 13. Petitioner contends that the potential options for colorant would have been reduced due to the need for "no migration of the color additive to the surrounding tissue," and by "governmental requirements, such as those espoused by the FDA in Section 73.1015." *Id.*

Petitioner asserts that a skilled artisan would have had a reasonable expectation of success in combining Simmelink and Section73.1015 to achieve the predictable result of improved colored multi-filament yarns because, allegedly: (1) Simmelink discloses the addition of a colorant and Section 73.1015 discloses the addition of a pigment, in consistent amounts; (2) both references disclose linear polyethylene surgical sutures and Section 73.1015 discloses the exempted pigment may be safely used for coloring such sutures; (3) the processes disclosed in each reference "are not inconsistent with each other such that the POSITA would have understood

the addition of an inert pigment with polyethylene in a gel spinning process would have likewise been successful and would have worked with the crystalline structure of the fiber;" (4) "Section 73.1015 explicitly teaches that 'there is no migration of the color additive to the surrounding tissue;"' and (5) Patent Owner "relied on the requirements of Section 73.1015 when it added pigment to its own process, which is likely similar to what is disclosed in Simmelink, a DSM reference." *Id.* at 13–15. According to Petitioner, a skilled artisan "would have expected the addition of the chromium-cobalt-aluminum oxide pigment to the gel spinning mixture of Simmelink to form a colored multi-filament yarn to be effective." *Id.* at 15 (citing Ex. 1003 ¶ 186).

Patent Owner asserts that the Petitioner "misreads the disclosures of both Simmelink and Section 73.1015 and inexplicably ignores the prior art as a whole, including the disclosures . . . [that] teach away from the path the inventors took in developing colored medical-grade UHMWPE yarns." Prelim. Resp. 41. In particular, Patent Owner contends that a skilled artisan would understand that Section 73.1015 discloses a melt-spinning process and not a gel-spinning process because its process does not dissolve the polyethylene resin in a solvent during spinning. *Id.* at 44. Patent Owner asserts that the skilled artisan would, therefore, understand that the linear polyethylene disclosed in Section 73.1015 is not UHMWPE, which cannot be melt spun due to its high melt viscosity. *Id.* at 45 (citing Ex. 1014, 63; Ex. 1030,[8] 218, Ex. 1003 ¶ 53). In this regard, Patent Owner notes also that the regulation in Section 73.1015 "arose prior to the development of the gel-

[8] File History of U.S. Patent No. 9,506,168.

spinning process in 1979—a process that enabled the first commercially viable UHMWPE yarns." *Id.*

Patent Owner contends that Petitioner also misconstrues the statement in Section 73.1015 that "there is no migration of the color additive to the surrounding tissue." *Id.* (quoting Ex. 1006, 357; citing Pet. 14; Ex. 1003 ¶ 186). According to Patent Owner, a skilled artisan would understand that statement is part of the restriction in Section 73.1015 that the color additive "'may be safely used for coloring linear polyethylene surgical sutures' but only if 'there is not migration of the color additive to the surrounding tissue.'" *Id.* at 46 (quoting Ex. 1006, 357). Patent Owner asserts that the skilled artisan would not understand that Section 73.1015 teaches that no migration of the color occurs when used with all linear polyethylene sutures, or that all sutures colored with the Section 73.1015 pigment are safe and effective. *Id.*

Patent Owner contends also that a skilled artisan would not have combined Simmelink with the pigment and process of Section 73.1015 because the temperature range required by the heating step in Section 73.1015, i.e., 500–550 ºF, is not compatible with Simmelink's gel spinning process. *Id.* at 47. Specifically, Patent Owner asserts that UHMWPE begins to undergo thermal decomposition above 240 ºC (about 464 ºF), therefore Simmelink's gel spinning process is performed at 180 ºC (356 ºF). *Id.* Additionally, Patent Owner asserts that the temperature range used in the Section 73.1015 process exceeds the boiling point of many common spin solvents used in the gel spinning process for making UHMWPE yarns, including decalin, the preferred solvent used in Simmelink. *Id.* at 47–48. Therefore, according to Patent Owner, a skilled artisan "would not have been motivated to incorporate the pigmentation process of Section 73.1015,

which requires heating the polymer resin to 500-550 ºF, into Simmelink's gel-spinning process." *Id.* at 48.

Patent Owner contends also that Petitioner's reliance on an obvious-to-try theory is misguided. *Id.* at 49. Patent Owner asserts that "[t]he fundamental problem the Petition has is that its own prior art teaches away from using pigments with particle sizes greater than 100 nm—like the commercially available C.I. Pigment Blue 36 product." *Id.* at 55. For example, Patent Owner asserts that "Ohta teaches that excess residual components within UHMWPE filaments negatively impacts their resistance against creep." *Id.* In support of that assertion, Patent Owner refers to the following passage in Ohta:

> in order to obtain the polyethylene fiber having superior creep resistance according to the present invention, it was found that it is important that the amount of residual components other than the polymer mainly composed of polyethylene that are contained in the polyethylene fiber, specifically, the amount of solvent and additives, be 1000 ppm or less in terms of weight fraction.

Id. at 55–56 (quoting Ex. 1008, 3). Based on this passage, and because 1000 ppm is 0.1% by weight, Patent Owner asserts that "Ohta teaches away from incorporating more than 0.1% by weight of a pigment into UHMWPE filaments for medical sutures." *Id.* at 56 (citing Ex. 1003 ¶ 65) (explaining that "in medical applications, creep over a long term could potentially cause harm.").

Patent Owner asserts that the position of Petitioner and Dr. Grubb that a skilled artisan would not consider the pigment as one of the "residual components" referenced by Ohta is conclusory and "contradicted by the record evidence, all of which unambiguously refers to pigments as 'additives' in the context of gel-spun UHMWPE filaments." *Id.* (citing

Ex. 1005, 8:38–31 (colorants as "additives"); Ex. 1006, 336 (referring to colorants as "additives").

Additionally, Patent Owner contends that "Nanri expressly teaches away from incorporating pigments with average aggregate particle sizes less than 10 nm and greater than 100 nm." *Id.* at 57; Ex. 1007 ¶¶ 2–4. Patent Owner here refers to Nanri's disclosure, based on "diligent research," of "a high-strength polyethylene fiber containing a pigment composes of a particle aggregate having an average particle diameter of 10 to 100 nm." *Id.* at 57; Ex. 1007 ¶ 4. Patent Owner notes that Nanri teaches that at this diameter, the pigment "does not act as a defect during orientated crystallization that occurs during the fiber formation process," and there is no migration of the pigment particles out of the polymer. *Id.* at 52–53 (quoting Ex. 1007 ¶¶ 5–6). According to Patent Owner, "the Petition does not present any evidence demonstrating that the chromium-cobalt-oxide disclosed in Section 73.1015 falls within the narrow particle size range Nanri discloses." *Id.* at 57. Patent Owner asserts that the Section 73.1015 pigment, C.I. Pigment Blue 36, has an average particle size of 0.70 microns or 700 nm. *Id.* at 54 (citing Ex. 2028)[9].

Having considered the arguments and the evidence on the record, we agree with Patent Owner that Petitioner has not shown sufficiently for institution that the claimed invention would have been obvious over the proposed combination of Simmelink and Section 73.1015.

Petitioner proposes "add[ing] the chromium-cobalt-aluminum oxide pigment [disclosed in Section 73.1015] to the gel spinning mixture of

[9] Ferro Corporation, *Product Information for CI Pigment Blue*, V-9248 Ocean Blue.

Simmelink, in accordance with the pigmentation process of Section 73.1015, which discloses that, in its coloring procedure, the pigment is blended with the polyethylene resin to form a mixture that is then heated and extruded." Pet. 12. According to Petitioner, a skilled artisan would have been motivated to use the color additive and pigmentation process in Section 73.1015 to facilitate regulatory approval, as that color additive is exempt from FDA batch certification requirements and using it would save time and significant expense. *Id.* at 11.

Additionally, Petitioner asserts that "it would have been obvious to try the FDA approved pigments, [including the Section 73.1015 color additive,] as they make up a finite number of predictable solutions to the need to color a UHMWPE fiber that could be used in the body as a suture." *Id.* at 13.

Even if the alleged motivation existed for Petitioner's proposed combination, Petitioner's contention that a skilled artisan would have had "a reasonable expectation of success in combining Simmelink and Section 73.1015 to achieve the predictable result of improved colored multi-filament yarns" is deficient, as well as Petitioner's obvious to try rationale, as both positions rely on an erroneous reading of Section 73.1015 and unsupported testimony of Dr. Grubb. *See* Pet. 13–15.

According to Petitioner and Dr. Grubb, "Section 73.1015 discloses that the exempted pigment may be safely used for coloring linear polyethylene surgical sutures." Pet. 14; Ex. 1003 ¶ 184. We disagree. As Patent Owner correctly observes, Section 73.1015 plainly states that "[t]he color additive chromium-cobalt-aluminum oxide may be safely used for coloring linear polyethylene surgical sutures, United States Pharmacopeia (U.S.P.), for use in general surgery, *subject to the following restrictions*," wherein such restrictions are directed to, among other things the coloring

procedure, the quantity of color additive used, and the lack of migration of the color additive when used according to its drug label. Ex. 1006, 357. Thus, to the extent that Petitioner relies on Section 73.1015 as teaching that the disclosed color additive is considered safe to use for coloring linear polyethylene sutures, apart from meeting the listed restrictions in Section 73.1015, such reliance is unsupported by the reference and not a basis for alleging a reasonable expectation of success.

Petitioner also mistakenly relies on Section 73.1015 as "explicitly teach[ing] that 'there is no migration of the color additive to the surrounding tissue.'" Pet. 14 (quoting Ex. 1006, 357). This statement in Section 73.1015 is not, however, set forth as a general teaching about the disclosed color additive. Rather, the statement is made as one of the restrictions, i.e., conditions, for safe use of the color additive. Ex. 1006, 357. Further, we read Section 73.1015 as indicating that when used in accordance with the list of "[u]ses and restrictions," "[c]ertification of this color additive is not necessary for the protection of the public health, and batches thereof are exempt from certification s requirements." *Id.* In other words, as Patent Owner argues persuasively, for the color additive to be considered safe and exempt from certification, it must demonstrate no migration of the color additive to the surrounding tissue when in use. Therefore, the existence of this use restriction in Section 73.1015 does not serve as a persuasive basis for alleging a reasonable expectation of success.

We are also unpersuaded by Petitioner's assertion that a skilled artisan would have had a reasonable expectation of success with Petitioner's proposed combination based upon Dr. Grubb's testimony that the coloring procedure in Section 73.1015 "is not inconsistent with the gel spinning process disclosed in Simmelink." Ex. 1003 ¶ 185; Pet. 14. Dr. Grubb

recognizes that the coloring process in Section 73.1015 "may be interpreted as being consistent with a melt process." Ex. 1003 ¶ 185. He also acknowledges that Simmelink's process uses a spinning solvent and that the Simmelink and Section 73.1015 processes use different temperatures. *Id.*

In this regard, Petitioner has not shown that its proposed combination provides a multifilament yarn "obtained by gel-spinning," as required by claim 1. At most, Petitioner and Dr. Grubb allege that the pigmentation process in Section 73.1015 is "similar" to, or "not inconsistent with," gel-spinning. Ex. 1003 ¶ 185; Pet. 14. Even if true, a similarity between the two different processes disclosed in Simmelink and Section 73.1015 would be insufficient to meet the claim limitation at issue. In any event Petitioner has not shown that those processes are similar, consistent with each other, or otherwise compatible.

Also critically, Petitioner and Dr. Grubb have not persuasively supported their position that a skilled artisan would have had a reasonable expectation of successfully combining the gel spinning mixture of Simmelink with the color additive in Section 73.1015, according to the coloring process described in the latter for a certification exemption. Rather, Dr. Grubb merely states that the differences between these two processes would not affect or impact the added pigment. *Id.* Without more, we find this rationale insufficient as it is not supported by evidence and does not address whether other aspects of the mixture or product would be impacted by the proposed combination.

On the other hand, Patent Owner has argued persuasively that a skilled artisan would not have considered the gel-spinning process in Simmelink and the melt-spinning process in Section 73.1015 to be similar or compatible. Prelim. Resp. 41–45. In particular, Patent Owner provides

persuasive evidence that the linear polyethylene disclosed in Section 73.1015 is not UHMWPE, as that fiber cannot be melt spun due to its high melt viscosity. *Id.* at 45 (citing Ex. 1014, 63; Ex. 1030, 218; Ex. 1003 ¶ 53). Indeed, as Patent Owner has shown, the regulation in Section 73.1015 "arose prior to the development of the gel-spinning process in 1979—a process that enabled the first commercially viable UHMWPE yarns." *Id.*

Further, Patent Owner persuasively explains that a skilled artisan would have found the temperature range required for the heating step in Section 73.1015, i.e., 500–550 ºF, is not compatible with Simmelink's gel spinning process, as UHMWPE begins to undergo thermal decomposition above 240 ºC (about 464 ºF). *Id.* at 47. Simmelink's gel spinning process accounts for this characteristic by performing at 180 ºC (356 ºF). *Id.*

Additionally, Patent Owner demonstrates persuasively that the temperature range used in the Section 73.1015 process exceeds the boiling point of many common spin solvents used in the gel spinning process for making UHMWPE yarns, including decalin, the preferred solvent used in Simmelink. *Id.* at 47–48 (citing Ex. 1005, 8:34–9:6, Examples 1–20; Ex. 2027, 5).

Thus, while Petitioner and Dr. Grubb recognize differences in the processes of Simmelink and Section 73.1015, they fail to address adequately the impact of at least the temperature differences between those processes with respect to the proposed combination. Based on the record, and in view of Patent Owner's persuasive arguments and evidence, we find that Petitioner's contention that a skilled artisan would have had a reasonable expectation of success in combining the teachings of Simmelink and Section

73.1015 or that such combination would have led to a predictable result is insufficiently supported for institution.[10]

Accordingly, we determine that Petitioner has not shown a reasonable likelihood of prevailing in its obviousness challenge of independent claim 1 or dependent claims 2–9 over the combination of Simmelink and Section 73.1015.

D. Obviousness over Section 73.1015, Nanri, Ohta, and Kavesh

Petitioner asserts that claims 1–9 would have been obvious over the combined teachings of Section 73.1015, Nanri, Ohta, and Kavesh. Pet. 29–50. Patent Owner disagrees. Prelim. Resp. 61–65. We incorporate our description and discussion of Section 73.1015 in Section II.C. here.

1. Nanri

Nanri is directed to a colored high-strength polyethylene fiber which contains a pigment composed of a particle aggregate having an average particle diameter of 10 to 100 nm, a strength of 2.0 GPa (gigapascal) or more and an initial modulus of elasticity of 70 GPa or more. Ex. 1007 ¶ 4. The fiber is suitable as a material for highly strong ropes, nets, fishing lines, protective good, and clothing-approximating goods. *Id.* ¶ 1. Nanri explains,

> to color a high-strength polyethylene fiber, there is a so-called "spin-dyeing method" of producing by mixing various dyes, pigments, or inorganic compounds such as carbon black and titanium oxide with a raw material polymer, or a method for obtaining a colored fiber by various dyeing techniques generally performed after forming the fiber. In the spin-dyeing method,

[10] We additionally find merit in Patent Owner's argument that Ohta and Nanri teach away from the proposed combination of Simmelink and Section 73.1015. Prelim. Resp. 49–58. While Ohta and Nanri do not form the basis of the challenge in this ground, they are part of the relevant prior art for the claimed invention, as Petitioner alleges in Grounds 2 and 3. In any event, we address these references in those later grounds rather than here.

> because an inorganic compound or the like is added in ethe manufacturing process, the additive acts as a defect in the crystal formation process and the like for expressing high strength, and is a factor in strength reduction, and therefore becomes difficult to add at a high concentration.

Id. ¶ 2. Nanri explains that its invention "is the result of diligent research into the particle diameter, agglomeration state, and content of pigments that do not act as defects in the crystal formation process and the like for expressing high strength." *Id.* ¶ 3. Nanri teaches using a pigment as the colorant in the fiber because "the pigment particles in the fiber are incorporated into the polyethylene crystal, and therefore migration to outside the fiber is suppressed, therefore it is thought that the pigment particles will be held stably." *Id.* ¶ 5. Nanri teaches that the average particle diameter of the pigment is preferably in the range of 10 nm to 100 nm because these pigments "are of a diameter that does not act as a defect during orientated crystallization that occurs during the fiber formation process of the polyethylene and is thus incorporated into the crystal." *Id.* ¶ 6. Nanri explains that if the "average particle diameter exceeds 100 nm, it acts as a defect during crystallization, and the colored high-strength polyethylene fiber obtained as a result thereof has low strength." *Id.* Nanri explains also that if the average particle diameter is less than 10 nm, migration occurs. *Id.*

Nanri discloses that the pigment in its high-strength polyethylene fiber is 0.01 to 2.50 wt%, and preferably 0.10 to 2.00 wt%, because a coloring effect cannot be seen at less than 0.01 wt%, while strength and initial modulus of elasticity are reduced when the content of the pigment exceeds 2.50 wt%. *Id.* ¶ 7.

2. Ohta

Ohta is directed to a high strength polyethylene fiber having creep resistance. Ex. 1008, 1. Ohta explains that a drawback of polyethylene is that it does not have a hydrogen bond between molecular chains and readily creeps. *Id.*at 2. Ohta explains that "the present inventors discovered that the greater the amount of disorder in the crystals or the greater the amount of impurities such as residual solvent and additives, the worse the creep resistance." *Id.* Ohta teaches "to obtain the polyethylene fiber having superior creep resistance according to the present invention, it was found that it is important that the amount of residual components other than the polymer mainly composed of polyethylene that are in the polyethylene fiber, specifically, the amount of solvent and additives, be 1000 ppm or less in terms of weight fraction. *Id.* at 3.

3. Kavesh

Kavesh is directed to a method of producing high strength, high modulus crystalline thermoplastic article, such as a fiber or film. Ex. 1009, 3, 8.

4. Discussion

For this obviousness ground, Petitioner asserts that a skilled artisan seeking to produce colored sutures would have begun with the color additive in Section 73.1015 "to facilitate regulatory approval and in view of the admitted design need," as Section 73.1015 "disclos[es] the exempted color additive chromium-cobalt-aluminum oxide as a pigment in an amount that does not exceed 2 percent by weight of the suture material in coloring linear polyethylene surgical sutures." Pet. 30.

Petitioner asserts that "the POSITA would have understood the need for selecting high strength polyethylene filaments for use in the colored

linear polyethylene surgical suture" disclosed in Section 73.1015. *Id.* Petitioner asserts that the skilled artisan would have, therefore, turned to Nanri as it "explicitly discloses incorporating pigments in a gel-spinning process . . . to implement a colored linear polyethylene surgical suture that had high strength, high modulus, and that was colored so as [to] make the suture better contrast with the blood or tissue in the operating area." *Id.* at 30–31 (footnote omitted) (citing Ex. 1003 ¶ 307). Petitioner contends that a skilled artisan would understand Nanri as disclosing adding a finely pulverized pigment to the gel spinning mixture. *Id.* at 31.

According to Petitioner,

> A POSITA would have been motivated to improve the properties and benefits of the colored linear polyethylene surgical sutures of Section 73.1015, which were already exempted from batch certification by the FDA, by including the teachings of the colored high strength polyethylene fiber and pigmentation process, as disclosed by Nanri, to increase the strength of the resultant colored linear polyethylene surgical sutures while continuing to suppress migration of the colorant to the outside of the fiber and otherwise facilitate regulatory approval (i.e., maintain exemption of the resultant colored linear polyethylene surgical sutures from certification.

Pet. 31–32. Petitioner asserts that the skilled artisan would have been similarly motivated to use Nanri's gel spinning mixture so that migration outside the fiber is suppressed and to use Nanri's process when making sutures having the color additive disclosed in Section 73.1015. *Id.* at 32. Petitioner contends,

> the POSITA would have understood that the chromium-cobalt-aluminum oxide of Section 73.1015 would have been readily used in the process of Nanri to achieve both the exemption from certification benefits of the chromium-cobalt-aluminum oxide as well as the above properties and benefits of the fiber resulting from the Nanri gel-spinning process, would have been successful

> in doing so, and such combination would require nothing more than the knowledge or common sense of a skilled artisan using known methods to yield predictable results in this field of technology.

Pet. 32–33.

Petitioner asserts that a skilled artisan would have also understood that creep resistance is a necessary consideration when producing sutures because UHMWPE fibers used in medical applications often experience or encounter static tensions, which may cause the fibers to elongate or fail over time. *Id.* at 33. For this concern, Petitioner asserts that the skilled artisan would have been motivated to improve the properties and benefits of colored sutures of Section 73.1015 and Nanri by applying Ohta's teachings. *Id.* at 34. Specifically, Petitioner asserts that the skilled artisan would have applied Ohta's teaching to obtain a colored fiber having extremely superior creep resistance by "reducing the disorder of the crystal structure by obtaining a 'g value' below 0.35, keeping the residual components to 1000 ppm or less, and sufficiently dissolving and mixing the mixture by optimizing the number of screw revolutions and the melting temperature (screw temperature) of the melting to form a uniform mixture." *Id.*

According to Petitioner, "the POSITA would not be deterred by Ohta's preference for 'a mixture composed of only the ultra high molecular weight polymer component and solvent . . . as the spinning solution.'" *Id.* at 35 (citing Ex. 1003 ¶¶ 321–322). Petitioner asserts also that the POSITA would not "interpret Ohta's teaching to keep residual components below 1000 ppm as being inclusive of the pigment added to the fiber formation process as taught by Section 73.1015 and Nanri." *Id.* (footnote omitted) (citing Ex. 1008, 3; Ex. 1003 ¶¶ 321–322). According to Petitioner and Dr. Grubb, the POSITA would, however, "look to minimize the amount of

pigment, which is described in both Section 73.1015 and Nanri, as well as residual components, but would not eliminate pigments altogether." *Id.* (citing Ex. 1003 ¶ 322).

Next, Petitioner turns to Kavesh for its disclosure of using spinnerets or spinning dies with various numbers of spinholes to provide fibers having multiple filaments, i.e., a multi-filament yarn. Pet. 36 (citing Ex. 1009, 8).

Petitioner asserts that "[t]he POSITA would have a reasonable expectation of success in combining Section 73.1015 with Nanri, Ohta, and Kavesh to achieve the predictable result of improved colored multi-filament yarns" because: (a) Section 73.1015 and Nanri expressly disclose the addition of a pigment in consistent amounts; (b) each cited reference discloses the use of linear polyethylene; (c) Nanri, Ohta, and Kavesh are directed to retaining or improving mechanical properties of UHMWPE fibers and disclose the same or similar gel-spinning process, spin solvents, and intrinsic viscosity values; Nanri and Ohta teach the same or similar screw extruder temperatures for mixing the gel spinning slurry mixture; and Kavesh merely provides a means of achieving a design choice for a multi-filament yarn. *Id.* at 37–38.

Additionally, Petitioner asserts that there would have been a "reasonable expectation of success in selecting particles of the exempted pigment disclosed in Section 73.1015 and sized according to the disclosure of Nanri so that the pigment would be incorporated into the UHMWPE fibers and would not cause defects during crystallization." Pet. 38–39 (footnote omitted) (citing Ex. 1007, ¶¶ 5, 6; Ex. 1003, ¶ 331). According to Petitioner, the skilled artisan "would have expected the addition of the pigment particles of the color additive disclosed in Section 73.1015 and sized according to the gel-spinning disclosure of Nanri with the creep

resistance modifications for the fiber production process of Ohta using the multi-aperture spinplate of Kavesh to be effective." *Id.* at 39 (citing Ex. 1003 ¶ 332).

Patent Owner argues that Ohta and Nanri teach away from Petitioner's use of the pigment in Section 73.1015 with UHMWPE, as discussed above in ground 1. Prelim. Resp. 49–57, 61. Additionally, Patent Owner asserts that Petitioner's proposed combination requires the Section 73.1015 pigment to be "sized according to Nanri," however "the Petition is devoid of any competent evidence demonstrating that the Section 73.1015 pigment, sized according to Nanri (i.e., having an average aggregate particle size of 10-100 nm), was within the general knowledge of the art or skill of a PHOSITA at the relevant time." *Id.* at 62. Moreover, Patent Owner asserts that Patent Owner's commercial UHMWPE yarns covered by the challenged patent do not have an average aggregate particle size of less than 100 nm and that size is shorter than the wavelength of light it typically reflects. *Id.* at 65. Additionally, Patent Owner refers to an FDA Nanotech Task Force Report asserting that it explains that a nanoscale version of an approved color additive may raise safety concerns. According to Patent Owner, this was not an issue in Nanri as it was focused on an investigation of the use of nanoscale carbon black as a UV absorber to provide weather resistance for ropes, net, fishing lines, protective good and clothing. *Id.* (citing Ex. 2032,[11] 4, 27; Ex. 1007, Summary, 1).

Having considered the arguments and evidence on the record, we agree with Patent Owner that Petitioner has not sufficiently shown for

[11] U.S. Food and Drug Administration, Nanotechnology Task Force Report, pp. 1–36 (July 25, 2007).

institution that the claimed multi-filament yarn would have been obvious over the proposed combination of Section 73.1015, Nanri, Ohta, and Kavesh. In particular, we focus on the deficiencies in the Petition with respect to combining the chromium-cobalt-aluminum oxide color additive disclosed in Section 73.1015 with the combined processes of Nanri and Ohta. To begin, Petitioner here again refers to chromium-cobalt-aluminum oxide color additive of Section 73.1015 as "already exempted from batch certification by the FDA." Pet. 32. However, as we have discussed, we read Section 73.1015 as setting forth restrictions for the safe use in coloring linear polyethylene surgical sutures, including a specific coloring procedure. Ex. 1006, 357. In other words, we do not read Section 73.1015 as simply listing a color additive that will be exempt from certification when used in any manner or according to any coloring process. Thus, if the motivation for selecting the Section 73.1015 color is to facilitate regulatory approval, the uses and restrictions in that provision must be satisfied.

Petitioner's position is that a skilled artisan "would have been motivated to improve the properties and benefits of the colored linear polyethylene surgical sutures of Section 73.1015 . . . by including the teachings of the colored high strength polyethylene fiber and *pigmentation process*, as disclosed by Nanri," as well as the gel spinning mixture of Nanri. Pet. 31–32 (emphasis added). Thus, insofar as Petitioner asserts that the motivation to use the chromium-cobalt-aluminum oxide color additive was to benefit from the exemption from batch certification disclosed in Section 73.1015, we find that argument unsupported as Nanri's processes differ from the coloring procedure in Section 73.1015 and Petitioner has not persuasively argued that a skilled artisan would have expected the Section

73.1015 exemption to apply when the disclosed color additive is used according to Nanri's processes.

Next, we consider Petitioner's assertion that a skilled artisan "would have understood that chromium-cobalt-aluminum oxide of Section 73.1015 would have been *readily used in the process of Nanri*" and that "such combination would require nothing more than the knowledge or common sense of a skilled artisan using known methods to yield predictable results in this field of technology." *Id.* at 32–33 (emphasis added). According to Petitioner, "[t]his is confirmed by the lack of disclosure in the '532 Patent regarding the details of the pigment itself or the preparation thereof." *Id.* at 33. That rationale is insufficient as the '532 patent does not subject the color additive of Section 73.1015 to Nanri's process, which requires "adding a finely pulverized pigment to the gel spinning mixture," *id.* at 31, 42, wherein the average particle size of the pigment is between 10–100 nm, so that it does not act as a defect during crystallization, *see* Ex. 1007 ¶ 5. Indeed, as Patent Owner notes, the UHMWPE yarns covered by the challenged patent do not have an average aggregate particle size of less than 100 nm. *See* Prelim. Resp. 65.

Further, in this regard, Patent Owner has provided persuasive evidence that an average aggregate particle size of less than 100 nm is shorter than the wavelength of light that C.I. Pigment Blue 36, i.e., chromium-cobalt-aluminum oxide pigment, typically reflects in providing its blue color (between about 450-520 nm). *Id.* at 54, 65; Ex. 2028. Additionally, Patent Owner identified the FDA Nanotech Task Force Report that explains "because of some of their special properties, nanoscale materials may pose different safety issues than their larger or smaller (i.e., molecular) counterparts." Ex. 2032, 4. Petitioner has neither identified these

potential issues nor addressed how any characteristics of the Section 73.1015 color additive may impact its ability to be successfully sized according to Nanri for use in Nanri's process. Thus, the Petition does not provide us with a basis for determining that a skilled artisan would have had a reasonable expectation of success in combining the teachings Section 73.1015 and Nanri as Petitioner proposes.

Similarly, we find missing in the Petition a persuasive basis for determining that a skilled artisan would have a reasonable expectation of successfully combining Section 73.1015 and Nanri with Ohta. Ohta teaches, that "it is preferable to use a mixture composed of *only* the ultra high molecular weight polymer component and solvent described above as the spinning solution." Ex. 1008, 3 (emphasis added). Ohta explains,

> in order to obtain the polyethylene fiber having superior creep resistance according to the present invention, it was found that it is important that the amount of *residual components other than the polymer* mainly composed of polyethylene that are contained in the polyethylene fiber, specifically, the *amount of solvent and additives, be 1000 ppm or less* in terms of weight fraction.

Id. (emphasis added). In view of this teaching, Petitioner asserts that a skilled artisan would have been motivated to improve the creep resistance of the colored sutures produced by the combination of Section 73.1015 and Nanri by keeping residual components to 1000 ppm or less. Pet. 34. However, Petitioner and Dr. Grubb assert, without any persuasive evidence or explanation, that a skilled artisan "would not be deterred" by Ohta's preference for a mixture composed only of UHMWPE and solvent. *Id.* at 35; Ex. 1003 ¶¶ 321–322.

Further, Petitioner and Dr. Grubb curiously take the position that the skilled artisan would not have "interpret[ed] Ohta's teaching to keep residual

components below 1000 ppm as being inclusive of the pigment added to the fiber formation process as taught by Section 73.1015 and Nanri." *Id.* (footnote omitted) (citing Ex. 1008, 3; Ex. 1003 ¶¶ 321–322). Petitioner and Dr. Grubb support this position only by reasoning that "the POSITA developing a colored suture would be well aware of the design need for such colored sutures, especially colored sutures having high strength, and would know that a sufficient amount of pigment would be required in order to provide the benefit of the color to the fiber." *Id.* According to Petitioner and Dr. Grubb, the POSITA would, however, "look to minimize the amount of pigment, which is described in both Section 73.1015 and Nanri, as well as residual components, but would not eliminate pigments altogether." *Id.* (citing Ex. 1003 ¶ 322).

Based on our consideration of the record, we again agree with Patent Owner who contends that the position of Petitioner and Dr. Grubb is conclusory and contradicted by the evidence. In particular, Ohta expressly refers to "residual components other than the polymer mainly composed of polyethylene that are contained in the polyethylene fiber, specifically, the amount of solvent and additives, be 1000 ppm or less." Ex. 1008, 3. We find nothing in Ohta, nor does Petitioner refer us to any disclosure in Ohta or elsewhere that would lead a skilled artisan to interpret Ohta's use of "additives" to exclude a color additive. Indeed, Section 73.1015 refers to the disclosed chromium-cobalt-aluminum oxide pigment as a "color additive." Thus, the Petition has not adequately reconciled how its combination of the color additive in Section 73.1015 with Nanri's spin mixture restricts the amount of solvent and additives to 1000 ppm or less, as required by Ohta for superior creep resistance. Without that showing, Petitioner fails to

demonstrate that a skilled artisan would have had a reasonable expectation of successfully combining Section 73.1015 and Nanri with Ohta.

Accordingly, we determine that Petitioner has not shown a reasonable likelihood of prevailing in its obviousness challenge of claims 1–9 over the combination of Section 73.1015, Nanri, Ohta, and Kavesh.

E. Obviousness over Section 73.1015, Nanri, and Simmelink

Petitioner asserts that claims 1–9 would have been obvious over the combined teachings of Section 73.1015, Nanri, and Simmelink. Pet. 50–61. Patent Owner disagrees. Prelim. Resp. 61–65. We incorporate our description and discussion of Section 73.1015, Nanri, and Simmelink in Sections II.C. and II.D. here.

1. Discussion

For this obviousness ground, Petitioner contends that "[a] POSITA would have combined Section 73.1015 with Nanri for the reasons outlined in Ground 2." Pet. 50. Petitioner adds Simmelink to the combination asserting,

> the POSITA would have been motivated to combine the fiber production process considerations with respect to medical applications as disclosed in Simmelink with the colored high strength polyethylene fiber and pigmentation process of Nanri and the chromium-cobalt-aluminum oxide pigment and pigmentation process of Section 73.1015, thereby, obtaining improved colored multi-filament yarns for use in linear polyethylene surgical sutures.

Id. at 51–52.

Because Petitioner relies on the same combination of Section 73.1015 and Nanri as set forth for Ground 2, we find that it is deficient for the same reasons discussed in Ground 2. Petitioner does not recognize those deficiencies and the addition of Simmelink does not cure them.

Accordingly, we determine that Petitioner has not shown a reasonable likelihood of prevailing in its obviousness challenge of claims 1–9 over the combination of Section 73.1015, Nanri, and Simmelink.

III. CONCLUSION

For the foregoing reasons, we conclude that Petitioner has not established a reasonable likelihood of prevailing in its assertion that at least one challenged claim of the ’532 patent is unpatentable. Accordingly, we deny the Petition and decline to institute the requested *inter partes* review.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that the Petition is *denied*, and no trial is instituted.

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