

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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HONEYWELL INTERNATIONAL INC.,

Petitioner

v.

DSM IP ASSETS B.V.,

Patent Owner

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Case: IPR2024-00493

U.S. Patent No. 10,280,532

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**PETITION FOR *INTER PARTES* REVIEW  
UNDER 35 U.S.C. §311-319 AND 37 C.F.R. §42**

Mail Stop PATENT BOARD  
Patent Trial and Appeal Board  
US Patent and Trademark Office  
PO Box 1450  
Alexandria, Virginia 22313-1450

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| <b>Exhibit</b> | <b>Short Name</b> | <b>Description</b>                                                                                                                                           |
|----------------|-------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Ex. 1001       | '532 Patent       | U.S. Patent No. 10,280,532                                                                                                                                   |
| Ex. 1002       | '532 File History | File History of U.S. Patent No. 10,280,532                                                                                                                   |
| Ex. 1003       | Grubb Declaration | Declaration of Dr. David T. Grubb under 37 C.F.R. § 1.68                                                                                                     |
| Ex. 1004       | Grubb CV          | <i>Curriculum Vitae</i> of Dr. David T. Grubb                                                                                                                |
| Ex. 1005       | Simmelink         | International Publication No. WO2005066401 to Simmelink et al.                                                                                               |
| Ex. 1006       | Section 73.1015   | Chromium-cobalt-aluminum oxide, 21 C.F.R. §73.1015 (April 1, 2006)                                                                                           |
| Ex. 1007       | Nanri             | Japanese Unexamined Patent Application Publication No. H11-21721 to Nanri et al. (including translation affidavit and copy of original document in Japanese) |
| Ex. 1008       | Ohta              | Japanese Patent Publication No. 2586213 to Ohta et al. (including translation affidavit and copy of original document in Japanese)                           |
| Ex. 1009       | Kavesh            | Japanese Unexamined Patent Application Publication No. S58-5228 to Kavesh et al. (including translation affidavit and copy of original document in Japanese) |

| <b>Exhibit</b> | <b>Short Name</b> | <b>Description</b>                                                                                                                                                   |
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| Ex. 1010       | Smelt             | H. Smelt, et al. “Advances in Medical-Grade UHMWPE Fiber Development: Additives for Visualization” (7 <sup>th</sup> UHMWPE International Meeting Proceedings, 2015). |
| Ex. 1011       | Steeghs           | International Publication No. WO 01/59397 to Steeghs et al.                                                                                                          |
| Ex. 1012       | Moriguchi         | EP Patent Application No. 0472436 to Moriguchi et al.                                                                                                                |
| Ex. 1013       | van der Loo       | U.S. Patent No. 6,183,834 to van der Loo                                                                                                                             |
| Ex. 1014       | Hearle            | High-Performance Fibers, 2001, Ed. J.W. Hearle                                                                                                                       |
| Ex. 1015       | McLeod            | U.S. Patent No. 5,456,722 to McLeod et al.                                                                                                                           |
| Ex. 1016       | Foerster          | U.S. Patent Publication No. 2004/0199208 to Foerster et al.                                                                                                          |
| Ex. 1017       | Grafton II        | U.S. Patent No. 6,716,234 to Grafton et al.                                                                                                                          |
| Ex. 1018       | Grafton           | U.S. Patent Publication No. 2003/0050667 to Grafton et al.                                                                                                           |
| Ex. 1019       | Marissen          | International Publication No. WO2005065911 to Marissen et al.                                                                                                        |

| Exhibit  | Short Name    | Description                                                                                                                                                                                                                                                              |
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| Ex. 1020 | Nguyen        | U.S. Patent No. 8,709,562 to Nguyen et al.                                                                                                                                                                                                                               |
| Ex. 1021 | D4020         | ASTM D4020-00a                                                                                                                                                                                                                                                           |
| Ex. 1022 | Solomon-Ciuta | English translation of <i>J. App. Polym. Sci.</i> 24, 683-686 (1962) ‘Determination of Intrinsic Viscosity of Polymer Solutions by a Simple Viscosity Determination’ O.F. Solomon & I.Z. Ciuta (including translation affidavit and copy of original document in French) |
| Ex. 1023 | Habibe        | <i>J. Polym. Sci.: Part B Polymer Physics</i> 33,759-767 (1995) ‘Molecular Weight Distribution by Stirring-Induced Fractional Precipitation’ Maria Eunice S. Habibe and Maria Cecilia A. Esperidiao                                                                      |
| Ex. 1024 | Muratoglu     | U.S. Patent No. 6,852,772 to Muratoglu et al.                                                                                                                                                                                                                            |
| Ex. 1025 | Bellare       | U.S. Patent Publication No. 2007/0197679 to Bellare et al.                                                                                                                                                                                                               |
| Ex. 1026 | Marissen II   | International Publication No. WO2007003266 to Marissen                                                                                                                                                                                                                   |
| Ex. 1027 | Koyfman       | U.S. Patent Publication No. 20050149118 to Koyfman et al.                                                                                                                                                                                                                |
| Ex. 1028 | Iwanami       | U.S. Patent No. 5,693,708 to Iwanami et al.                                                                                                                                                                                                                              |

| <b>Exhibit</b> | <b>Short Name</b>                  | <b>Description</b>                                                                                                                                                                                                                                |
|----------------|------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Ex. 1029       | '168 Patent                        | U.S. Patent No. 9,506,168                                                                                                                                                                                                                         |
| Ex. 1030       | '168 File History                  | File History of U.S. Patent No. 9,506,168                                                                                                                                                                                                         |
| Ex. 1031       | National Judicial Caseload Profile | U.S. District Courts – National Judicial Caseload Profile (accessed via <a href="https://www.uscourts.gov/sites/default/files/cms_na_distprofile0930.2023.pdf">https://www.uscourts.gov/sites/default/files/cms_na_distprofile0930.2023.pdf</a> ) |
| Ex. 1032       | D1601                              | ASTM D1601-99 (2004)                                                                                                                                                                                                                              |
| Ex. 1033       | RESERVED                           | RESERVED                                                                                                                                                                                                                                          |
| Ex. 1034       | Amery                              | U.S. Patent Publication No. 20040267313 to Amery                                                                                                                                                                                                  |
| Ex. 1035       | Olson                              | U.S. Patent Publication No. 20100274282 to Olson                                                                                                                                                                                                  |

Honeywell International Inc. (“Petitioner” or “Honeywell”) hereby petitions for *Inter Partes* Review (“IPR”) of Claims 1-9 (“the challenged claims”) of U.S. Patent No. 10,280,532 (the “’532 Patent”). Petitioner requests cancellation of the challenged claims.

## **I. INTRODUCTION**

The purported invention of the ’532 Patent relates to a suture that was colored and extruded using a standard gel-spinning process. Ex. 1001, 2:17-42. However, as was admitted in the background of the ’532 Patent, the gel spinning process allegedly used to create the filaments of the ’532 Patent was well known in the art as of the earliest priority date of the ’532 Patent. Moreover, according to the admissions in the background of the ’532 Patent, there was a well-known need to color sutures that comprised ultra-high molecular weight polyethylene (UHMWPE)<sup>1</sup> fibers so as to allow for differentiation and identification in cases where blood or tissue was present.

Despite the well understood need, the ’532 Patent nakedly asserts that there were “issues” that dissuaded the addition of pigment to UHMWPE fibers. Not so.

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<sup>1</sup> Referred to as “UHMWPE” except when quoting from documents in which it appears differently (i.e., such as “UHMwPE” in the ’532 Patent or “UHPE” in Simmelink).

Even in the face of purported “issues,” the ’532 Patent does not explain how such purported “issues” were solved but instead teaches the POSITA to simply add known pigment to a known gel spinning process. That is, the ’532 Patent does nothing more than to confirm that known pigments, to include pigments previously exempted from certification by the Food and Drug Administration (“FDA”) for use in linear polyethylene sutures, could be successfully added to known UHMWPE in a well-known process. At bottom, the cited references demonstrate that the claimed product, a colored multi-filament yarn that was usable as a suture, would have been obvious to the POSITA.

## **II. REQUIREMENTS (37 C.F.R. §42.103 AND 104)**

Petitioners authorize Account 16-0605 to be charged for any fees (37 C.F.R. §42.103). Petitioner certifies that the ’532 Patent is available for review and that Petitioner is not barred or estopped (37 C.F.R. §42.104(a)). Petitioner requests cancellation of the claims on the following grounds:

**1**: Claims 1-9 are unpatentable under 35 U.S.C. §103 over Simmelink and Section 73.1015.

**2**: Claims 1-9 are unpatentable under 35 U.S.C. §103 over Section 73.1015, Nanri, Ohta, and Kavesh.

**3**: Claims 1-9 are unpatentable under 35 U.S.C. §103 over Section 73.1015, Nanri, and Simmelink.

(§42.104(b)(1)-(2)). Constructions are provided in Section IV. (§42.104(b)(3)). The claims are unpatentable as provided in Section V. (§42.104(b)(4)). Exhibit numbers

of the evidence relied upon to support the challenge and the relevance of the evidence to the challenge raised are included. (§42.104(b)(5)).

### **III. PROSECUTION HISTORY**

#### **A. U.S. Patent No. 10,280,532**

In the sole Office Action, the Examiner rejected Claims 1-9 on the ground of nonstatutory double patenting as being unpatentable over Claims 1-12 of U.S. Patent No. 9,506,168 (“the ’168 Patent”). A Notice of Allowance was mailed on December 21, 2018. Ex. 1002, 81-87.

#### **B. U.S. Patent No. 9,506,168**

The ’532 Patent was filed as a continuation of the ’168 Patent. The prosecution history of the ’168 Patent was much more extensive when compared to the ’532 Patent, albeit with different claims.

In the first Office Action, the Examiner rejected Claims 1-10. The Applicant argued that the cited prior art reference, Smit, did not disclose or specify any list of colorants or utilize colorants in its examples. Ex. 1030, 185. Instead, the Applicant argued that “the present applicants have discovered that using a *pigment* had major advantages over other types of colorants in that leaching was diminished” and that “no leaching or cytotoxicity was observed” in the claimed particular pigments. Ex. 1030, 185 (emphasis in original). The Applicant further argued that “the structural implication to the suture” of the claimed process “is that the suture will have *pigment*

incorporated into the filaments of the yarn,” with “[a]n unobvious difference” being a “resulting improvement in leaching behavior.” Ex. 1030, 185-186 (emphasis in original).

The Applicant and Examiner went back and forth through a number of arguments and amendments. Similar to the argument with regard to Smit, the Applicant generally distinguished dyes and/or innovations where pigment-free UHMWPE filaments were braided with polyester strands. Ex. 1030, 219, 259-260, 265-266. Applicant also asserted that the Examiner’s assertion regarding “...the more pure the material, UHMWPE, and the less of other constituent or other materials, the stronger the strength for the suture” with respect to the less than 1000 ppm of other constituents limitation actually “strongly supports the conclusion that [the claimed pigment-colored suture] is indeed a very surprising and unexpected result” as the “ordinarily skilled person (as acknowledged by the Examiner) would seek to eliminate the presence of such pigment.” Ex. 1030, 269-270.

Finally, the Applicant argued that “‘spin solvent’ is a physical constituent of the fiber” such that “the amount of ‘spin solvent’ is a quantifiable and hence physical attribute of the fiber,” and “the Examiner erroneously interpreted the amount of residual spin solvent limitation as being a ‘product-by-process’ limitation.” Ex. 1030, 258 (emphases in original).

In an Office Action some actions later, the Examiner rejected Claims 16-18 and 20-31 under pre-AIA 35 U.S.C. §103(a) as being unpatentable over Simmelink, cited herein, and Edwin.

In order to distinguish Simmelink, the Applicant argued two points but did not otherwise dispute the Examiner's mapping with respect to Simmelink. As noted in Section VIII.A, Applicant did not dispute the majority of the teaching of Simmelink, instead distinguishing Edwin. A Notice of Allowance was then mailed. Ex. 1030, 398-404.

#### **IV. CLAIM CONSTRUCTION**

The claims are construed herein "using 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. §42.100(b) (Nov. 13, 2018). Unless otherwise specified, the terms discussed herein are to have their plain meaning.

#### **V. THE CLAIMS ARE UNPATENTABLE**

##### **A. Priority Date**

The '532 Patent claims the benefit of European Application No. 07010217, filed May 23, 2007, by way of a continuation and a PCT application. For the purposes of this Petition and without waiving the opportunity to challenge priority in the co-pending district court case, Petitioner assumes that the earliest possible priority date of the '532 Patent is May 23, 2007. Ex. 1001; Ex. 1003, ¶¶91-92.

## **B. Prior Art**

### **1. Simmelink**

International Publication No. WO2005066401 to Simmelink et al, entitled “Process for Making High-Performance Polyethylene Multifilament Yarn”, filed by DSM IP Assets B.V., published on July 21, 2005. Ex. 1005. Simmelink is prior art to the ‘532 Patent under 35 U.S.C. §102(b). As is discussed in Section VIII, Simmelink was considered during the prosecution of a related application but was not considered in conjunction with Section 73.1015 or Nanri.

### **2. Section 73.1015**

21 C.F.R. § 73.1015, entitled “Chromium-cobalt-aluminum oxide,” published on April 1, 2006. *See* FRE 902(5); Ex. 1006, 2. Section 73.1015 is prior art to the ‘532 Patent under 35 U.S.C. §102(b). Section 73.1015 was not cited during prosecution of the ‘532 Patent.

### **3. Nanri**

Japanese Unexamined Patent Application Publication No. H11-21721 to Nanri et al, entitled “Colored High-Strength Polyethylene Fiber,” filed by Toyobo Co., Ltd., published on January 26, 1999. Ex. 1007. Nanri is prior art to the ‘532

Patent under 35 U.S.C. §102(b). Nanri was not cited during prosecution of the '532 Patent.<sup>2</sup>

#### **4. Ohta**

Japanese Patent Publication No. 2586213 to Ohta et al, entitled “High Strength Polyethylene Fiber Having Creep Resistance,” filed by Toyobo Co., Ltd., issued on February 26, 1997. Ex. 1008. Ohta is prior art to the '532 Patent under 35 U.S.C. §102(b). Ohta was not cited during prosecution of the '532 Patent.

#### **5. Kavesh**

Japanese Unexamined Patent Application Publication No. S58-5228 to Kavesh et al., entitled “Production Method of High Strength, High Modulus Crystalline Thermoplastic Article, and Fiber as New Product,” filed by Allied Corporation, published on January 12, 1983. Ex. 1009. Kavesh is prior art to the '532 Patent under 35 U.S.C. §102(b). Kavesh was not cited during prosecution of the '532 Patent.

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<sup>2</sup> Exs. 1007-1009 are accompanied by a certified translation and the original document in the same exhibit. 37 C.F.R. §42.63(b); 35 U.S.C. §312(a)(5); *Ninebot (Tianjin) Tech. Co. v. Inventist, Inc.*, No. IPR2018-00134, Paper 11 at 10-11 (PTAB Apr. 23, 2018).

## VI. LEVEL OF ORDINARY SKILL IN THE ART

A POSITA 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. Ex. 1003, ¶18. Individuals with different educational backgrounds and additional experience could still be of ordinary skill in the art if that additional experience compensates for a deficit in their education and experience stated above. *Id.* Additional education might substitute for some of the experience, and substantial experience might substitute for some educational background. *Id.*

## VII. GROUND OF INVALIDITY

The grounds presented herein confirm what was already known in the prior art and admitted in the '532 Patent – there was a well-known need to provide colored sutures made of UHMWPE and that it was well known to use pigment so as to avoid leaching. Specifically, the background of the '532 Patent admits:

- The '532 Patent admits that ***colored sutures were well known*** and that coloring sutures was an important consideration when making a suture. Ex. 1001, 1:11-21.
- The ***gel spinning process*** for preparing UHMWPE filaments was ***well known in the prior art***. Ex. 1001, 2:24-31.

- ***UHMWPE filaments***, produced according to a gel spinning process, for the ***production of sutures***, was also ***well known***. Ex. 1001, 1:22-27.
- Polyolefinic filaments are ***often colored by the incorporation of a pigment in the polymer composition*** of the filaments during extrusion of the filaments. Ex. 1001, 1:52-57.

Even in view of these admissions, the '532 Patent alleges that there are “issues” with coloring UHMwPE filaments. Ex. 1001, 1:28-29; 1:58-63. Indeed, the '532 Patent goes so far to say that it is disadvised to use pigments in UHMWPE filaments because a low viscous carrier polymer would be needed for dispersion and such filaments have a low diameter. Ex. 1001, 1:63-2:3, citing U.S. Patent No. 5,613,987. But none of these purported problems came from prior failed attempts to color UHMWPE filaments. Moreover, the '532 Patent is silent with regard to how such problems (e.g., clumps) were solved indicating that any solution was well within the abilities of the person skilled in the art. This is not an invention.

Regardless, as demonstrated below, the prior art cited herein makes clear that it was known to use pigments in a gel spinning process.

#### **A. Ground 1 Simmelink and Section 73.1015.**

##### **1. Motivation to Combine**

A POSITA at the time of the assumed priority date of the '532 Patent was well aware of the design need for colored sutures, especially colored sutures having high

strength. Ex. 1003, ¶175. Patent Owner cannot dispute this design need because the '532 Patent admits it. *See* Ex. 1001, 1:11-17, 1:22-27; Ex. 1003, ¶175. It was also well known that UHMWPE filaments were usable as sutures and that UHMWPE filaments had been colored using pigments. Ex. 1003, n.2.

A POSITA would rely on a reference, such as Simmelink, that disclosed adding colorants to produce colored sutures.<sup>3</sup> Ex. 1005, 8:28-31; Ex. 1003, ¶176. Simmelink, which was within the knowledge of a POSITA, is generally directed to “a continuous process for making high-performance polyethylene (HPPE) multifilament yarn” including “high-strength surgical sutures and cables, or other medical implants.” Ex. 1005, 1:7-8, 1:18-20, 12:3-6; Ex. 1003, ¶174. Simmelink also teaches that colorants may be used in the fiber formation process. Ex. 1005, 8:28-31; Ex. 1003, ¶176.

A POSITA would understand 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

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<sup>3</sup> As admitted in the background of the '532 Patent and as was well known in the art, there was a need to color sutures to improve visibility. *See* Ex. 1001, 1:11-17; Ex. 1003, ¶176.

(FDA). Ex. 1003, ¶177. Specific colorants for use in sutures are listed in the Code of Federal Regulations (CFR) depending on the particular suture material and whether or not the color additive is exempt from batch certification requirements. Ex. 1003, ¶177. As of the priority date of the '532 Patent, Section 73.1015 identified chromium-cobalt-aluminum oxide as a color additive that was approved for linear polyethylene surgical sutures and exempt from batch certification requirements.<sup>4</sup> Ex. 1006; Ex. 1003, ¶178. The POSITA 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. Ex. 1003, ¶178. Thus, 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. Ex. 1003, ¶¶177-179.

Patent Owner admitted that it chose chromium-cobalt-aluminum oxide and the method for incorporating chromium-cobalt-aluminum oxide to facilitate

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<sup>4</sup> The exemption from batch certification requirements for linear polyethylene sutures using chromium-cobalt-aluminum oxide according to Section 73.1015 can be traced back to at least 1977.

regulatory approval for its own suture. *See* Ex. 1010, 55-56 (“**To facilitate regulatory approval, blue fibers with Chromium-Cobalt-Aluminum Oxide were produced, as this pigment is listed on the FDA’s 21 CFR part 73 on *Color Additives Exempt from Certification* for coloring linear polyethylene surgical sutures for use in general surgery.**”) (Emphasis added); Ex. 1003, n. 3; *Yeda Rsch v. Mylan Pharms. Inc.*, 906 F.3d 1031, 1041 (Fed. Cir. 2018) (Board may rely on non-prior art “in considering the knowledge, motivations, and expectations of a POSITA regarding the prior art.”). The POSITA would have been thus 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, in its coloring procedure, the pigment is blended with the polyethylene resin to form a mixture that is then heated and extruded. Ex. 1006, 18, (c)(1); Ex. 1003, ¶180.

Consequently, a POSITA would have been motivated to combine the process of Simmelink with the exempted pigment and the pigmentation process identified in Section 73.1015 for obtaining improved colored multi-filament yarns for use in linear polyethylene surgical sutures, specifically, mixing less than 2 wt.% of the inorganic chromium-cobalt-aluminum oxide pigment of Section 73.1015 into the gel spinning mixture of Simmelink. Ex. 1003, ¶181.

Moreover, and in addition to the well-known motivation to combine the pigment of the CFR, it would have been obvious to try the chromium-cobalt-aluminum oxide pigment disclosed in Section 73.1015 when developing the HPPE multi-filament yarn 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. Ex. 1001, 1:11-17 (admitting such need for colored UHMPWE suture); Ex. 1003, ¶182. In addition, any viable colorant would need to be added so that “there is no migration of the color additive to the surrounding tissue” (Ex. 1006, 18, (c)(4)), thereby reducing the potential choices of colorants to a finite set. Ex. 1003, ¶182. The finite number of options for colorant of UHMWPE fibers in medical applications would have been further reduced by governmental requirements, such as those espoused by the FDA in Section 73.1015. *Id.* As such, it would have been obvious to try the FDA approved pigments 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. *See KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007).

The POSITA would also have a reasonable expectation of success in combining Simmelink and Section 73.1015 to achieve the predictable result of improved colored multi-filament yarns for several reasons. Ex. 1003, ¶183. First, Simmelink and Section 73.1015 expressly disclose the addition of a colorant and a

pigment, respectively, in consistent amounts. Ex. 1005, 8:28-31; Ex. 1006, 18, (a), (c)(2); Ex. 1003, ¶183. Second, Section 73.1015 and Simmelink both disclose linear polyethylene surgical sutures and Section 73.1015 discloses that the exempted pigment may be safely used for coloring linear polyethylene surgical sutures. Ex. 1005, 8:12-17; Ex. 1006, 18, (c); Ex. 1003, ¶184. Third, the processes disclosed by Section 73.1015 and Simmelink 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<sup>5</sup> and would have worked with the crystalline structure of the fiber. *See e.g.*, Ex. 1007, 2, [0005]<sup>6</sup>; Ex. 1003, ¶185. Fourth, the migration or leeching of a color additive is disfavored in medical applications and Section 73.1015 explicitly teaches that “there is no migration of the color additive to the surrounding tissue.” Ex. 1006, 18, (c)(4); Ex. 1003, ¶186. Fifth, Patent Owner later admitted that it relied on the requirements of

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<sup>5</sup> The POSITA understood that the pigment “infiltrates into the interior of the polyethylene and, as a result, the physical bonding between the polyethylene and the pigment and/or the dye becomes strong, causing substantially no color fading.” Ex. 1028, 10:35-41; Ex. 1003, n. 4.

<sup>6</sup> To be clear, this ground is obviousness in view of Simmelink and Section 73.1015. Nanri does not form part of the combination/modification.

Section 73.1015 when it added pigment to its own process, which is likely similar to what is disclosed in Simmelink, a DSM reference. *See* Ex. 1010, 55-56; Ex. 1003, n.3. A POSITA 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. Ex. 1003, ¶186.

Moreover, the lack of disclosure in the '532 Patent regarding the details of the pigment itself or the preparation thereof confirm that there was no need for a special formulation or that further steps beyond the ordinary skill of the POSITA were required and/or needed to be disclosed in order for the POSITA to add pigments to UHMWPE. Ex. 1001, 1:58-2:3, 3:43-60; Ex. 1006, 18, (c)(1); Ex. 1003, ¶¶187-189. In view of the lack of disclosure, Patent Owner cannot reasonably argue that a POSITA would not have a reasonable expectation of success in combining the pigment of Section 73.1015 with Simmelink without describing a “specially designed” pigment or a particular “specially designed” method for incorporating a pigment in the specification or the claims. *Smith & Nephew, Inc. v. Rea*, 721 F.3d 1371, 1381 (Fed. Cir. 2013) *see also Alcon Res., Ltd. v. Apotex Inc.*, 687 F.3d 1362, 1369 (Fed. Cir. 2012).

Accordingly, a POSITA would have been motivated to combine and would have had a reasonable expectation of success in combining, Simmelink and Section 73.1015. Ex. 1003, ¶190.

## 2. Claim 1

### a) [1.Pre] A colored multi-filament yarn comprising

Claim 1 of the '532 Patent is directed to a product that is developed by way of a process, such as the process described with regard to limitation [1.A]. Ex. 1003, ¶191. As such, 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.” Ex. 1030, 258 (emphases in original); Ex. 1003, ¶192. *See Kamstrup A/S v. Axioma Metering UAB*, 43 F.4th 1374, 1381 (Fed. Cir. 2022) (quoting *Greenliant Sys., Inc. v. Xicor LLC*, 692 F.3d 1261, 1268 (Fed. Cir. 2012)). Regardless, as is described in at least limitation [1.A], the '532 Patent admits that the claimed gel spinning process is well known in the art and the cited art of Ground 1 renders obvious a gel spinning process. Ex. 1003, ¶191.

Further, and to the extent the preamble is limiting, the combination of Section 73.1015 and Simmelink disclose a colored multi-filament yarn. Ex. 1003, ¶¶192-197; *see also* limitations [1.A]-[1.E]. Simmelink specifies a variety of parameters and process steps for making high-performance polyethylene multifilament yarn from a gel spinning process, including teaching that the UHMWPE “may further contain small amounts, **generally less than 5 mass%, preferably less than 3 mass% of customary additives**, such as...**colorants**.” Ex. 1005, 8:28-31 (emphasis added); Ex. 1003, ¶¶194-195. With respect to pigment, Section 73.1015 expressly

discloses blending chromium-cobalt-aluminum oxide with polyethylene resin, heating and extruding the mixture “through a fixed orifice” and cooling, drawing, and annealing “[t]he filaments” to produce linear polyethylene sutures. Ex. 1006; Ex. 1003, ¶193.

- b) [1.A] 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**

Regardless of whether limitation [1.A] should be given patentable weight as a process in a product by process claim, the combination of Simmelink and Section 73.1015 renders obvious limitation [1.A].<sup>7</sup> Ex. 1003, ¶198.

Simmelink specifies a variety of parameters and process steps for making high-performance polyethylene multifilament yarn from a gel spinning process, including specifying the IV range of the UHMWPE and identifying “relatively volatile solvents,” including decalin, as “solvents suitable for gel spinning of

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<sup>7</sup> As is admitted in the ’532 Patent, the gel spinning process for preparing UHMWPE filaments was not only well known in the prior art, but by the earliest priority date of the ’532 Patent, the gel spinning process for preparing UHMWPE filaments was conventional. Ex. 1001, 2:24-31 (citing numerous gel-spinning references extending back to the 1980s).

[UHMPWE].” Ex. 1005, 8:34-9:5; Ex. 1003, ¶¶199-202. The process steps generally include, *inter alia*, “making a 3-25 mass% **solution of [UHMWPE] having an [IV] as measured on solutions in decalin at 135°C of between about 8 and 40 dl/g, in a solvent,**” “**spinning of the solution through a spinplate...to form fluid filaments,**” and “cooling the fluid filaments **to form solvent-containing gel filaments.**” Ex. 1005, 1:7-17 (emphasis added); Ex. 1003, ¶200. Simmelink discloses the number of filaments in the multi-filament yarn is preferably “at least 10, 50, 100, 150, 200, 300, 375 or even at least 450.” Ex. 1005, 5:21-24; Ex. 1003, ¶200. A POSITA would understand Simmelink discloses at least “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 [and] a spin solvent.” Ex. 1003, ¶200.

Simmelink further discloses that a small amount of customary additives, such as “colorants,” may be added to the gel spinning process. Ex. 1005, 8:28-31; Ex. 1003, ¶203. As is outlined above with regard to the motivation to combine, the POSITA would have added the pigment of Section 73.1015 in the gel spinning process. Ex. 1003, ¶205. Section 73.1015 specifically discloses the use of a chromium-cobalt-aluminum oxide pigment in polyethylene, including blending such pigment with the polyethylene, heating the mixture, and extruding the mixture. Ex. 1006, 18; Ex. 1003, ¶204. As such, the POSITA would have been motivated to blend

the pigment with the gel spinning mixture of Simmelink such that the filaments of the colored multifilament yarn would be obtained from such gel spinning mixture containing UHMWPE having an intrinsic viscosity of between about 8 and 40 dl/g, a spin solvent (e.g., decalin), and the exempted pigment. Ex. 1003, ¶205. Thus, the combination of Simmelink and Section 73.1015 renders obvious limitation [1.A]. Ex. 1003, ¶206. Indeed, Patent Owner itself confirmed that Section 73.1015 provided an obvious pigment choice for gel spun UHMWPE. Ex. 1010, 55-56.

**c) [1.B] wherein the filaments consist of UHMwPE,**

As discussed with respect to limitation [1.A], Simmelink specifies a variety of parameters and process steps for making multiple filaments of high-performance polyethylene multifilament yarn. Ex. 1005, 1:7-17 (describing making a solution of UHMwPE in a solvent, “spinning of the solution through a spinplate containing at least 5 spinholes into an air-gap to form fluid filaments), 5:21-24, 7:32-8:2; Ex. 1003, ¶207; limitation [1.A]. A POSITA would understand the filaments resulting from the process of Simmelink described in [1.A] to contain “UHMwPE.” Ex. 1003, ¶207. Indeed, Simmelink teaches keeping the amount of other components or foreign materials low, elaborating such teachings with respect to UHMWPE multifilament yarns containing low levels of solvent for medical implants containing such yarn. Ex. 1005, 12:8-12; Ex. 1003, ¶208. Thus, the combination of Simmelink and Section 73.1015 renders obvious limitation [1.B]. Ex. 1003, ¶209.

**d) [1.C] between 0.1 and 7.0 wt. % of an inorganic chromium oxide-containing pigment,**

Section 73.1015 and Simmelink disclose filaments consisting of “between 0.1 and 7.0 wt. % of an inorganic chromium oxide-containing pigment.” Ex. 1003, ¶214. Simmelink, for its part, discloses that the polyethylene may further contain “small amounts, generally less than 5 mass%, preferably less than 3 mass% of customary additives,” including “colorants.” Ex. 1005, 8:28-31; Ex. 1003, ¶210. As discussed in the motivation to combine section above, a POSITA would have been motivated to combine the exempted pigment and pigmentation process teachings of Section 73.1015 with the process for producing high performance multifilament polyethylene yarns disclosed in Simmelink to produce a colored multifilament yarn for a colored suture. Section 73.1015 discloses the color additive “chromium-cobalt-aluminum oxide,” which “may be safely used for coloring linear polyethylene surgical sutures.” Ex. 1006, 18; Ex. 1003, ¶211. Section 73.1015 further recites that the “[t]he quantity of the color additive does not exceed 2 percent by weight of the suture material.” Ex. 1006, 18, (c)(2); Ex. 1003, ¶212. The POSITA would understand that a suture formed from polyethylene filaments having some pigment but less than 2 percent by weight of the exempted pigment would not have to go through an additional FDA certification process. Ex. 1003, ¶212; Ex. 1010, 55-56. Regardless, Section 73.1015’s disclosure that the pigment not exceed 2 percent by weight overlaps the claimed range. Ex. 1003, ¶212. A range that overlaps a range

claimed is sufficient to establish a *prima facie* case of obviousness. *In re Peterson*, 315 F.3d 1325, 1330 (Fed. Cir. 2003); *In re Harris*, 409 F.3d 1339 (Fed. Cir. 2005); *E.I. du Pont Nemours & Co. v. Synvina C.V.*, 904 F.3d 996, 1006 (Fed. Cir. 2018); Ex. 1003, ¶213.

**e) [1.D] a residual amount of spin solvent of less than about 500 ppm, and**

Simmelink discloses filaments consisting of “a residual amount of spin solvent of less than about 500 ppm.” Ex. 1005, 1:15, 9:31-33, 12:6-12, 17:17-20:30; Ex. 1003, ¶¶215-221. Simmelink confirms that “[f]or medical applications[,] the amount of other components or foreign materials in the yarn is very important, in addition to its mechanical properties.” Ex. 1005, 12:6-7; Ex. 1003, ¶215. Indeed, in the case of decalin as the spin solvent, the POSITA would have been motivated to obtain as low of a level of residual spin solvent in the UHMWPE filaments as possible in order to prevent irritation when used as a suture in the body.<sup>8</sup>

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<sup>8</sup> Patent Owner admitted during prosecution of the '168 Patent, the parent application of the '532 Patent, that the amount of decalin should be low, preferably below 100 ppm, for biocompatibility reasons. Ex. 1030, 266. (“Amery confirms that the level of residual spin solvent, especially decalin, in gel-spun UHMwPE should be low, and preferably below 100 ppm for biocompatibility reasons.”); Ex. 1003, ¶220.

Simmelink specifically discloses multi-filament yarn “containing less than 150 ppm of residual solvent, specifically of solvent having a boiling point at atmospheric conditions of less than 275°C, preferably containing less than 100, 75, or even less than 50 ppm of solvent, and to medical implants containing such yarn.” Ex. 1005, 12:8-12; Ex. 1003, ¶215. Simmelink further discloses that “[s]olvent removal can be performed by known methods,” such as “by evaporating a relatively volatile solvent, by using an extraction liquid, or by a combination of both methods.” Ex. 1005, 1:15, 9:31-33; Ex. 1003, ¶216. Indeed, Simmelink discloses the preparation of multiple multi-filament yarn examples, including Examples 19, 29, and 30, and Comparative Experiment E, which contain residual decalin solvent contents of 135 ppm, 16 ppm, 18 ppm, and 400 ppm, respectively. Ex. 1005, 17:17-30, 18:8-13, 19:15-22, 20:13-30; Ex. 1003, ¶¶217-218. As such, Simmelink’s range of less than 150 ppm of residual solvent demonstrates an overlapping range which establishes *prima facie* obviousness and the examples anticipate the claimed range. *Peterson*, 315 F.3d at 1330; *Harris*, 409 F.3d 1339; *Synvina*, 904 F.3d at 1006; *Ineos USA LLC v. Berry Plastics Corp.*, 783 F.3d 865, 869 (Fed. Cir. 2015) (if the prior art discloses a point within a claimed range, the prior art anticipates the claimed range), citing *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 782 (Fed. Cir. 1985); MPEP 2131; Ex. 1003, ¶219.

**f) [1.E] less than 1000 ppm of further constituents.**

The '532 Patent is silent as to what the further constituents entail, why further constituents should be limited, or how they are limited. *See* Ex. 1001, 3:61-67; Ex. 1003, ¶¶222-223. The claims are likewise silent. Ex. 1003, ¶223. As a result, a POSITA would understand that “further constituents” could include anything other than the UHMWPE and the pigment (e.g., spin solvent as well as other additives). Ex. 1003, ¶223; *see also*, Ex. 1001, 3:61-63 (“The UHMwPE filaments in the suture according to the invention consist preferably of UHMwPE, the pigment and less than 1000 ppm of further constituents”). As is demonstrated in limitation [1.D], Simmelink renders obvious minimizing spin solvent. Ex. 1003, ¶223; limitation [1.D]. Regardless, the references cited render obvious limitation [1.E], whether or not “further constituents” is construed to include spin solvent or not. Ex. 1003, ¶223.

With respect to “further constituents,” the POSITA would understand that Simmelink discloses that any additives, including colorants (as Simmelink specifically contemplates colorants as a customary additive), are preferably less than 3 mass% or 30,000 ppm. Ex. 1005, 8:28-31; Ex. 1003, ¶224. A POSITA would understand that, as colorant is added to Simmelink (as is disclosed by the combination of Simmelink and Section 73.1015), such amount of colorant will necessarily lower the amount (i.e., lower the upper bound of 3 mass% or 30,000 ppm) of any other customary additives that Simmelink discloses may be added. Ex.

1003, ¶225. In other words, as Section 73.1015 discloses the addition of the pigment in an amount that “does not exceed 2 percent by weight of the suture material” (Ex. 1006), the amount, in mass% or ppm, of additives could go down to as low as 1 mass% or 10,000 ppm in view of the upper bound of the pigment. Ex. 1003, ¶225.

Simmelink further teaches that “[f]or medical applications[,] the amount of other components or foreign materials in the yarn is very important, in addition to its mechanical properties,” and the POSITA would have understood that any additives or components other than the pigment should be minimized to comply and, thus, be as close to non-existent as possible for use in medical applications (e.g., for biocompatibility reasons). Ex. 1005, 12:6-12; Ex. 1030, 266; Ex. 1003, ¶226. Given that sutures are medical applications, the POSITA would have minimized the amount of “further constituents,” if present. Indeed, the examples of Simmelink confirm the lack of further constituents. Ex. 1005, 16:17-20:30; Ex. 1003, ¶¶227-229. As such, a POSITA would have understood that Simmelink disclosed an overlapping range and suggested that within the overlapping range, further constituents should be limited. *Peterson*, 315 F.3d at 1330; *Harris*, 409 F.3d 1339; *Synvina*, 904 F.3d at 1006; Ex. 1003, ¶¶225-226.

Further, a POSITA would have understood that “further constituents” is a result effective variable because increasing further constituents is known to reduce the strength of the fiber and may introduce dangerous foreign substances in the body.

When a variable is “result-effective” and “the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” *In re Applied Materials, Inc.*, 692 F.3d 1289, 1295-96 (Fed. Cir. 2012); Ex. 1003, ¶226. The combination discloses the conditions of the claim, reduce additives, especially in medical applications. *See infra*. Any further reductions in the amount of further constituents, to include further minimizing the ranges disclosed by the combination, is not inventive and could have been discovered by routine experimentation. *Id.* Indeed, a POSITA would have been motivated to reduce further constituents as low as reasonably possible for biocompatibility reasons and so as to maintain the highest strength of fiber. Ex. 1003, ¶¶225-226. No weight should be given to the range recited in limitation [1.E].

Accordingly, Simmelink discloses filaments consisting of “less than 1000 ppm of further constituents.” Ex. 1005; Ex. 1003, ¶¶222-230.

**3. Claim 2: The multi-filament yarn according to claim 1, wherein the amount of the inorganic pigment present in the filaments is between 0.3 and 5.0 wt. %.**

As discussed with respect to limitation [1.C], Section 73.1015 and Simmelink disclose “wherein the amount of the inorganic pigment present in the filaments is between 0.3 and 5.0 wt. %.” Ex. 1003, ¶234. Simmelink discloses that the polyethylene may further contain “small amounts, generally less than 5 mass%, preferably less than 3 mass% preferably less than 3 mass% of customary additives,

such as...colorants.” Ex. 1005, 8:28-31; Ex. 1003, ¶231. Section 73.1015 discloses “[t]he quantity of the [inorganic chromium-cobalt-aluminum oxide pigment] does not exceed 2 percent by weight of the suture material.” Ex. 1006, 18; Ex. 1003, ¶232. As such and similar to [1.C] above, the disclosed range overlaps a range claimed in the ’532 Patent establishing a *prima facie* case of obviousness. *Peterson*, 315 F.3d at 1330; *Harris*, 409 F.3d 1339; *Synvina*, 904 F.3d at 1006; Ex. 1003, ¶233.

**4. Claim 3: The multi-filament yarn according to claim 1, wherein the amount of the inorganic pigment present in the filaments is lower than 2.0 wt. %.**

For the same reasons as [1.C], Section 73.1015 and Simmelink disclose “wherein the amount of the inorganic pigment present in the filaments is lower than 2.0 wt. %.” Ex. 1003, ¶237. Simmelink discloses that the polyethylene may further contain “preferably less than 3 mass% of customary additives,” including “colorants.” Ex. 1005, 8:28-31; Ex. 1003, ¶235. Section 73.1015 discloses “[t]he quantity of the [inorganic chromium-cobalt-aluminum oxide pigment] does not exceed 2 percent by weight of the suture material.” Ex. 1006, 18; Ex. 1003, ¶236.

**5. Claim 4: The multi-filament yarn according to claim 1, wherein the inorganic pigment is aluminum-chromium-cobalt oxide.**

Section 73.1015 discloses this limitation for the reasons discussed above with respect to [1.C]. That is, Section 73.1015 discloses the color additive “chromium-cobalt-aluminum oxide,” which is an inorganic “blue-green pigment” *See generally*,

Ex. 1006, 18; Ex. 1003, ¶238. A POSITA would have understood that “chromium-cobalt-aluminum oxide” as disclosed by Section 73.1015 is “aluminum-chromium-cobalt oxide.” Ex. 1003. ¶239. Even if it were to be argued that chromium-cobalt-aluminum oxide is not the same, which would be incorrect, aluminum-chromium-cobalt oxide would nonetheless be obvious. *Id.*

**6. Claim 5: The multi-filament yarn according to claim 1, wherein the residual amount of spin solvent is less than 250 ppm.**

For the same reasons as [1.D], Simmelink discloses “wherein the residual amount of spin solvent is less than 250 ppm.” Ex. 1005, 12:6-12, 19:15-22, 20:13-30; Ex. 1003, ¶¶241-244; *see also, Ineos*, 783 F.3d at 869; MPEP 2131.

**7. Claim 6: The multi-filament yarn according to claim 1, wherein the residual amount of spin solvent is less than 100 ppm.**

For the same reasons as [1.D], Simmelink discloses “wherein the residual amount of spin solvent is less than 100 ppm.” Ex. 1005, 12:6-12, 20:13-30; Ex. 1003, ¶¶245-248; *Ineos*, 783 F.3d at 869; MPEP 2131.

**8. Claim 7: The multi-filament yarn according to claim 1, wherein the residual amount of spin solvent is less than 60 ppm.**

For the same reasons as [1.D], Simmelink discloses “wherein the residual amount of spin solvent is less than 60 ppm.” Ex. 1005, 12:6-12, 20:13-30; Ex. 1003, ¶¶249-252; *Ineos*, 783 F.3d at 869; MPEP 2131.

**9. Claim 8: The multi-filament yarn according to claim 1, wherein the filaments contain less than 500 ppm of further constituents.**

For the same reasons as [1.E], Simmelink discloses that “[f]or medical applications[,] the amount of other components or foreign materials in the yarn is very important, in addition to its mechanical properties,” and the POSITA would have understood that as preparation of a colored multi-filament yarn for a colored suture would necessarily require the addition of a pigment and a spin solvent, any other additives or other components should be minimized and, thus, be as close to non-existent as possible for use in medical applications (e.g., for biocompatibility reasons). Ex. 1005, 12:6-12; Ex. 1030, 236-237, 266; Ex. 1003, ¶¶253-255. Indeed, the examples of Simmelink further confirm the lack of further constituents. Ex. 1005, 16:17-20:30; Ex. 1003, ¶¶256-258. “Further constituents” is a result effective variable and should not be given weight. *See* [1.E]. Accordingly, Simmelink discloses “wherein the filaments contain less than 500 ppm of further constituents.” Ex. 1005, 8:28-31; Ex. 1003, ¶¶253-259.

**10. Claim 9: The multi-filament yarn according to claim 1, wherein the number of filaments is between 10 and 1000.**

Simmelink discloses the number of filaments in the multi-filament yarn is preferably “at least 10, 50, 100, 150, 200, 300, 375 or even at least 450.” Ex. 1005, 5:21-24; Ex. 1003, ¶260. Simmelink further specifies that “[y]arn of relatively low titer, containing for example from 5 to 300 filaments, but of extremely high strength

is a.o. very suited for making high-strength surgical sutures and cables, or other medical implants.” Ex. 1005, 12:3-6; Ex. 1003, ¶260.

A range that overlaps a range claimed in the ’532 Patent is sufficient to establish a *prima facie* case of obviousness. *Peterson*, 315 F.3d at 1330; *Harris*, 409 F.3d 1339; *Synvina*, 904 F.3d at 1006; Ex. 1003, ¶¶261-262.

## **B. Ground 2: Section 73.1015, Nanri, Ohta, and Kavesh**

### **1. Motivation to Combine**

A POSITA at the time of the assumed priority date of the ’532 Patent was well aware of the design need for colored sutures. Ex. 1001, 1:11-27; Ex. 1003, ¶303. It was also well known that UHMWPE filaments were usable as sutures and that UHMWPE filaments had been colored using pigments. Ex. 1003, n.10.

A POSITA would understand 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). Ex. 1003, ¶304. Specific colorants for use in sutures are listed in the CFR. *Id.* As of the priority date of the ’532 Patent, Section 73.1015, which was within the knowledge of the POSITA, specifically identified chromium-cobalt-aluminum oxide as a color additive that was approved for linear polyethylene surgical sutures and exempt from batch certification requirements. Ex. 1006, 18; Ex. 1003, ¶¶303, 305. The POSITA would have understood 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. Ex. 1003, ¶305. Thus, to facilitate regulatory approval and in view of the admitted design need, a POSITA would have started with 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.<sup>9</sup> Ex. 1003, ¶¶304-306.

In view of the disclosure of colored linear polyethylene surgical sutures in Section 73.1015 and a POSITA's understanding of the well-known importance of "suture strength" in "selecting filaments for producing a suture,"<sup>10</sup> the POSITA would have understood the need for selecting high strength polyethylene filaments for use in the colored linear polyethylene surgical suture. *See* Ex. 1001, 1:22-27; Ex. 1006, 18; Ex. 1003, ¶307. Thus, the POSITA would have turned to Nanri, a reference that explicitly discloses incorporating pigments in a gel-spinning process, one of the

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<sup>9</sup> Patent Owner admitted that it chose chromium-cobalt-aluminum oxide to facilitate regulatory approval for its own suture. *See* Ex. 1010, 55-56.

<sup>10</sup> As admitted by the '532 Patent, the POSITA was well aware of the design need for colored sutures having high strength. Ex. 1001, 1:22-27.

few processes used to make UHMWPE fibers, to implement a colored linear polyethylene surgical suture that had high strength, high modulus, and that was colored so as make the suture better contrast with the blood or tissue in the operating area.<sup>11</sup> Ex. 1003, ¶307.

Nanri, which was within the knowledge of a POSITA, is generally directed to a colored high-strength polyethylene fiber prepared from gel spinning UHMWPE. Ex. 1007, 1; Ex. 1003, ¶¶302, 308. Specifically, Nanri teaches incorporating pigments, including inorganic pigments, in a gel spinning process so as to “not act as defects in the crystal formation process and the like for expressing high strength,” the pigment particles being stably held by incorporating pigment particles into the polyethylene crystal such that “migration to [the] outside of the fiber is suppressed.” Ex. 1007, 2, [0005]-[0008]; Ex. 1003, ¶308. In particular, a POSITA would understand Nanri as disclosing adding a finely pulverized pigment to the gel spinning mixture. Ex. 1007, 2, [0006], 3, [0015]-[0017]; Ex. 1003, ¶¶309-310.

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

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<sup>11</sup> As admitted by the '532 Patent, the POSITA was well aware of the design need for colored sutures. Ex. 1001, 1:11-17.

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). Ex. 1003, ¶311. The POSITA would have been similarly motivated to use the gel spinning mixture of Nanri such that “migration to outside the fiber is suppressed” and “there is no migration of the color additive to the surrounding tissue” and related process when making sutures having the chromium-cobalt-aluminum oxide pigment of Section 73.1015. Ex. 1006, 18, (c)(4); Ex. 1007, 2, [0005]; Ex. 1003, ¶312.

Indeed, 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<sup>12</sup> as well as the above properties and benefits of the fiber

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<sup>12</sup> Patent Owner admitted that it chose chromium-cobalt-aluminum oxide and the method for incorporating chromium-cobalt-aluminum oxide to facilitate regulatory approval for its own suture. *See* Ex. 1010, 55-56; Ex. 1003, n.14.

resulting from the Nanri gel-spinning process, would have been successful in doing so,<sup>13</sup> 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. Ex. 1006; Ex. 1007, 2, [0005]; Ex. 1003, ¶¶311-314. This is confirmed by the lack of disclosure in the '532 Patent regarding the details of the pigment itself or the preparation thereof. *See* Ground 1, Motivation to Combine.

In addition to suture strength, the POSITA would also understand creep resistance to be a necessary consideration for the production of sutures as UHMWPE fibers in medical applications often experience or encounter static tensions, which may cause the fibers to elongate and, in some instances, fail, with time. Ex. 1003, ¶315. A POSITA would have understood that elongated or failed sutures would be unacceptable in medical applications. Ex. 1003, ¶65. For example, creep reduces the load that a fiber can support over time (e.g., the load that the fiber would support if it was used to suture two bones together) and as creep occurs, the load will drop, resulting in the separation of bones or other sutured items. *Id.*

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<sup>13</sup> The POSITA understood that the pigment “infiltrates into the interior of the polyethylene and, as a result, the physical bonding between the polyethylene and the pigment and/or the dye becomes strong, causing substantially no color fading.” Ex. 1028, 10:35-41; Ex. 1003, n.15.

Ohta, which was within the knowledge of a POSITA, is generally directed to “a high strength polyethylene fiber having extremely superior creep resistance.” Ex. 1008, 1; Ex. 1003, ¶¶302, 316. Specifically, Ohta teaches that a high strength polyethylene fiber having excellent creep resistance can be obtained by keeping the residual components, particularly the solvent and additives, in fibers made from a polymer mainly composed of UHMWPE, at 1000 ppm or less. Ex. 1008, 1, 3, 4, 5; Ex. 1003, ¶¶316-318.

In light of these disclosures in Ohta and understanding the importance of creep resistance in sutures, a POSITA would have been motivated to improve the properties and benefits of the colored linear polyethylene surgical sutures of Section 73.1015 and Nanri by including Ohta’s teachings of the high strength polyethylene fiber with excellent creep resistance and process for making same to improve the creep resistance of the resultant colored linear polyethylene surgical sutures. Ex. 1003, ¶319. That is, the POSITA would have been motivated to apply the teachings of Ohta – 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 – to thereby obtain a colored fiber having extremely superior creep resistance. Ex. 1008; Ex. 1003, ¶320.

In doing so, 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" nor would the POSITA interpret Ohta's teaching to keep residual components below 1000 ppm<sup>14</sup> as being inclusive of the pigment added to the fiber formation process as taught by Section 73.1015 and Nanri. Ex. 1008, 3; Ex. 1003, ¶¶321-322. That is, 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 (i.e., to improve visibility).<sup>15</sup> Ex. 1007, 2, [0008]; Ex. 1003, ¶¶321-322. Indeed, the POSITA would understand that removal of pigment would be undesirable. *Id.* Regardless, the POSITA would 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. Ex. 1003, ¶322. The POSITA would also understand that the pigment and pigmentation process taught by Nanri would not "act as a defect during

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<sup>14</sup> Ohta does not consider the use of pigments or colorants generally in its disclosed process.

<sup>15</sup> As admitted in the background of the '532 Patent and as was well known in the art, there was a need to color sutures to improve visibility. Ex. 1001, 1:11-17.

orientated crystallization that occurs during the fiber formation process of the polyethylene” or leach or migrate from the fiber, such that the addition of the pigment would not affect the g value or be present as a residual material, as taught by Ohta. Ex. 1007, 2, [0005]-[0006], 3, [0015]-[0017]; Ex. 1008, 4; Ex. 1003, ¶¶323-324. As such, it would have been within the skill of the POSITA to combine Section 73.1015 with Nanri and Ohta. Ex. 1003, ¶325.

A POSITA would also have understood that the colored high strength polyethylene fibers prepared in accordance with Section 73.1015, Nanri, and Ohta, could be manufactured in the form of monofilaments or multifilaments. Ex. 1003, ¶54. A POSITA would also know that multi-filament yarns are common and are indeed preferred for UHMWPE sutures (e.g., multi-filament yarn bundles of small denier filaments that are braided together to form a suture) due to the high modulus of elasticity of the UHMWPE. Ex. 1003, ¶¶55-58, 326; Ex. 1005, 4:25-27; Ex. 1009, 8, 27, 28; Ex. 1014, 68; Ex. 1026, 1:31-33; Ex. 1034, [0004], [0031]-[0032].<sup>16</sup> Confirming that the number of filaments was well-known, Ohta explicitly cites to

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<sup>16</sup> To be clear, this ground is obviousness in view of Section 73.1015, Nanri, Ohta, and Kavesh. The identified Exs. 1005, 1014, 1026, and 1034 do not form part of the combination/modification.

Kavesh, which was within the knowledge of a POSITA and which discloses that it is common knowledge to have spinnerets or spinning dies with various numbers of spinholes. Ex. 1008, 3; Ex. 1003, ¶¶302, 326. Given the explicit teaching in Ohta to look to Kavesh, the POSITA would have combined Kavesh when producing fibers, especially fibers for use as sutures, so as to have fibers having multiple filaments. Ex. 1003, ¶326.<sup>17</sup> A POSITA would also know that the number of holes in the spinneret or spinning die forms a corresponding number of filaments, that using a spinneret with multiple spinholes or orifices would result in a yarn of multiple individual filaments, i.e., a multi-filament yarn, and that multi-filament yarns can also be prepared by combining the products of multiple spinnerets depending on the filament count (i.e., number of fibers) that is desired for the multi-filament yarn. Ex. 1009, 8, 27, 28, 31; Ex. 1003, ¶¶327-328.

The POSITA would have a reasonable expectation of success in combining Section 73.1015 with Nanri, Ohta, and Kavesh to achieve the predictable result of

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<sup>17</sup> See also, Olson, Ex. 1035, [0003] (“Thus, polyester and UHMWPE sutures are used in multifilament braids, while polypropylene is used as a monofilament suture.”); *Yeda Research v. Mylan Pharms. Inc.*, 906 F.3d 1031, 1041 (Fed. Cir. 2018). To be clear, this ground is obviousness in view of Section 73.1015, Nanri, Ohta, and Kavesh. Olson does not form part of the combination/modification.

improved colored multi-filament yarns. Ex. 1003, ¶329. Section 73.1015 and Nanri expressly disclose the addition of a pigment in consistent amounts. Ex. 1006, 18; Ex. 1007, 2, Claim 3; Ex. 1003, ¶329. Each of the cited references disclose use of linear polyethylene and at least Nanri, Ohta, and Kavesh are all directed to retaining or improving mechanical properties of the resulting UHMWPE fibers and disclose the same or similar gel-spinning processes, UHMWPE, intrinsic viscosity values, and same or similar spin solvents, to prepare their respective UHMWPE fibers. Ex. 1003, ¶329. Additionally, at least Nanri and Ohta teach the same or similar screw extruder temperatures for mixing the gel spinning slurry mixture. Ex. 1007, 3, [0015]; Ex. 1008, 4; Ex. 1003, ¶329. The POSITA would have had a reasonable expectation of success in combining the teachings of Kavesh, because the POSITA would have understood that any configuration of apertures was common and was usable and while multiple filaments would be needed, the number of filaments would simply be a matter of a design choice by the user based on the thickness and required strength of the resultant yarn. Ex. 1009, 8; Ex. 1003, ¶330. The POSITA also would have had 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<sup>18</sup> so that

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<sup>18</sup> The '532 Patent is silent with regard to any requirements as to the sizing of pigment particles.

the pigment would be incorporated into the UHMWPE fibers and would not cause defects during crystallization. Ex. 1007, 2, [0005]-[0006]; Ex. 1003, ¶331. In addition, Nanri explicitly teaches that “the pigment particles in the fiber are incorporated into the polyethylene crystal, and therefore migration to outside the fiber is suppressed” and Section 73.1015 teaches that “there is no migration of the color additive to the surrounding tissue.” Ex. 1006, 18, (c)(4); Ex. 1007, 2, [0005]; Ex. 1003, ¶333. The POSITA 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. Ex. 1003, ¶332.

Accordingly, a POSITA would have been motivated to combine and would have had a reasonable expectation of success in combining Section 73.1015, Nanri, Ohta, and Kavesh. Ex. 1003, ¶334.

## **2. Claim 1**

### **a) [1.Pre]**

For the same reasons as Ground 1, Claim 1 of the '532 Patent is directed to a product that is developed by way of a process. Regardless, as is described in at least limitation [1.A], the '532 Patent admits that the claimed gel spinning process is well

known and the cited art of Ground 2 renders obvious a gel spinning process. Ex. 1003, ¶335.

Further, and to the extent the preamble is limiting, the combination of Section 73.1015, Nanri, Ohta, and Kavesh discloses a colored multi-filament yarn. Ex. 1003, ¶¶336, 342; *see also* limitations [1.A]-[1.E].

Section 73.1015, which is an FDA regulatory provision identifying chromium-cobalt-aluminum oxide and a maximum weight percent for its use as a color additive exempt from certification for coloring linear polyethylene sutures, expressly discloses blending chromium-cobalt-aluminum oxide with polyethylene resin, heating and extruding the mixture “through a fixed orifice” and cooling, drawings, and annealing “[t]he filaments” to be used as linear polyethylene sutures. Ex. 1006, 18; Ex. 1003, ¶¶ 264-269, 337.

Nanri discloses the preparation of colored high strength polyethylene fibers “obtained by solution spinning an [UHMWPE] solution” (i.e., via a gel spinning method), including the addition of a pigment, while maintaining favorable strength and initial modulus of elasticity. Ex. 1007, 2; Ex. 1003, ¶¶273-277. Nanri further details extruding the UHMWPE/pigment/solvent mixture “from an orifice of a 0.5 mm diameter.” Ex. 1007, 3, [0013], [0015]; Ex. 1003, ¶338.

Ohta relates to a high strength polyethylene fiber having extremely superior creep resistance and details the preparation of such UHMWPE yarn. Ex. 1008, 1, 2,

3, 4; Ex. 1003, ¶¶283, 286-289, 339. Kavesh generally relates to producing high strength, high modulus fibers or films and discloses spinnerets having a plurality of apertures and the preparation of multi-filament yarns using such spinnerets. Ex. 1009, 3, 8, 27, 31; Ex. 1003, ¶¶297, 340-341.

**a) [1.A]**

Regardless of whether limitation [1.A] should be given patentable weight as a process in a product by process claim, the combination of Section 73.1015, Nanri, Ohta, and Kavesh renders obvious limitation [1.A].<sup>19</sup> Ex. 1003, ¶¶343, 369.

Section 73.1015 specifically discloses blending a chromium-cobalt-aluminum oxide pigment in polyethylene and heating and extruding the mixture. Ex. 1006, 18. Ex. 1003, ¶368. As described above in the motivation to combine section, the POSITA would use the Section 73.1015 pigment in the Nanri gel spinning process.

Nanri specifically discloses manufacturing a colored high-strength polyethylene fiber including “solution spinning an [UHMWPE].” Ex. 1007, 3, [0013]; Ex. 1003, ¶344. The examples of Nanri disclose gel spinning a mixture of “[UHMWPE] having a viscosity average molecular weight of 3,200,000” (19.79

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<sup>19</sup> As is admitted in the '532 Patent, the gel spinning process for preparing UHMWPE filaments was not only well known in the prior art, but was conventional. Ex. 1001, 2:24-31.

dl/g) and decahydronaphthalene,” including adding carbon black pigment subjected to “fine pulverization processing...to the mixture of polyethylene and decahydronaphthalene.” Ex. 1007, 3, [0015]-[0017]; Ex. 1003, ¶¶345-347. The POSITA would understand that Nanri discloses the addition of the finely pulverized pigment to the gel spinning mixture. Ex. 1007, 2, [0006], 3, [0015]; Ex. 1003, ¶350. The disclosed decahydronaphthalene is decalin and Nanri teaches that “it is essential that the colorant contained in the fiber is composed of a pigment such as an organic pigment, inorganic pigment, and carbon black.” Ex. 1003, 2, [0005], 3, [0015]-[0017]; Ex. 1003, ¶¶348-349. Nanri expressly discloses using UHMWPE having an intrinsic viscosity of, 19.79 dl/g, which falls inside the ranges claimed in limitation [1.A]. *Ineos*, 783 F.3d at 869; MPEP 2131; Ex. 1003, ¶347.

While the limitation is rendered obvious by Nanri alone, Ohto and Kavesh likewise disclose the claimed range. Specifically, Ohta likewise discloses the preparation of yarn via a gel spinning method using decalin and UHMWPE having a viscosity average molecular weight corresponding to an IV value of 13.53 dl/g. Ex. 1008, 2, 3, 4; Ex. 1003, ¶¶352-358.

Kavesh likewise discloses the preparation of multiple multi-filament yarn examples via a gel spinning process, wherein the yarns are prepared from a solution of paraffin oil and UHMWPE having IV values of 17.5 or 22.6. Ex. 1009, 12, 24-32; Ex. 1003, ¶¶360-366.

Accordingly, the combination of Section 73.1015, Nanri, Ohta, and Kavesh renders obvious limitation [1.A]. Ex. 1003, ¶¶351, 359, 367, 369.

**b) [1.B]**

As discussed with respect to limitation [1.A], Nanri discloses “a method for stretching gel filaments obtained by solution spinning an [UHMWPE] solution” in order to manufacture a colored high-strength polyethylene fiber, such that the colored high strength polyethylene fiber of Nanri contains UHMwPE. Ex. 1007, 3, [0013]; Ex. 1003, ¶370.

To the extent [1.B] is interpreted as requiring multiple filaments, the combination discloses it. Ex. 1003, ¶375. As is outlined above with regard to the motivation to combine, the POSITA would have understood that the colored high strength polyethylene fibers could be manufactured in the form of monofilaments or multifilaments and the POSITA would know that multi-filament yarns are common and are indeed preferred for UHMWPE sutures due to the high modulus of elasticity of the UHMWPE. Ex. 1003, ¶¶54-58, 326; Ex. 1005, 4:25-27; Ex. 1009, 8, 27, 28;

Ex. 1014, 68; Ex. 1026, 1:31-33; Ex. 1034, [0004], [0031]-[0032].<sup>20</sup> Indeed, Ohta explicitly cites to Kavesh, which discloses that it is common knowledge to have spinnerets or spinning dies with various numbers of spinholes. Ex. 1008, 3; Ex. 1003, ¶326. That is, Kavesh discloses the preparation of multi-filament yarns by extruding a polymer solution including UHMWPE through a spinneret containing many apertures. Ex. 1009, 5, 8; Ex. 1003, ¶375.

Thus, the combination of Section 73.1015, Nanri, Ohta, and Kavesh renders obvious limitation [1.B]. Ex. 1003, ¶376.

**c) [1.C]**

Section 73.1015 discloses limitation [1.C] for the same reasons discussed above with respect to Ground 1. Ex. 1006; Ex. 1003, ¶¶377-378.

Nanri similarly teaches that a pigment, including an inorganic pigment (similar to the pigment of Section 73.1015), is essential for coloring “because the pigment particles in the fiber are incorporated into the polyethylene crystal, and therefore migration to outside the fiber is suppressed,” such “that the pigment

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<sup>20</sup> To be clear, this ground is obviousness in view of Section 73.1015, Nanri, Ohta, and Kavesh. The identified Exs. 1005, 1014, 1026, and 1034 do not form part of the combination/modification.

particles will be held stably.” Ex. 1007, 2, [0005]; Ex. 1003, ¶379. Nanri further describes a “strong polyethylene fiber...wherein a pigment content is 0.01 to 2.50 wt%” “preferably 0.10 to 2.00 wt%” for sufficient “coloring effect” and without reducing “strength and initial modulus of elasticity.” Ex. 1007, 2, [0004], [0008], Claim 3; Ex. 1003, ¶380. The POSITA would have understood that the ranges disclosed by Nanri are consistent with those disclosed by Section 73.1015 and such a range overlaps the claimed range. *Peterson*, 315 F.3d at 1330; *Harris*, 409 F.3d 1339; *Synvina*, 904 F.3d at 1006; Ex. 1003, ¶¶381-382.

**d) [1.D]**

Ohta discloses filaments consisting of “a residual amount of spin solvent of less than about 500 ppm.” Ex. 1008, 2, 3; Ex. 1003, ¶383. Ohta discloses that the solvent used in the gel-spinning method “is the main residual component” and teaches heating the “gel-like undrawn yarn” to “remove the solvent.” Ex. 1008, 3; Ex. 1003, ¶384.

Ohta further describes the preparation of Examples 1-4 and Comparative Examples 1-5, each of which have remaining residual components other than polyethylene of 60 ppm or less, including solvent residual fraction, as demonstrated in Table 2 of Ohta:

Table 2

| Experiment No.        | g Value | Creep Rate ( $\text{sec}^{-1}$ ) | Residual Fraction (ppm) | Symbol |
|-----------------------|---------|----------------------------------|-------------------------|--------|
| Example 1             | 0.022   | $8.0 \times 10^{-7}$             | 55                      | ○      |
| Comparative Example 1 | 0.052   | $6.1 \times 10^{-6}$             | 55                      | ×      |
| Comparative Example 2 | 0.044   | $5.3 \times 10^{-6}$             | 60                      | ×      |
| Comparative Example 3 | 0.030   | $1.2 \times 10^{-6}$             | 35                      | ○      |
| Example 2             | 0.033   | $8.0 \times 10^{-7}$             | 45                      | ○      |
| Example 3             | 0.025   | $7.1 \times 10^{-7}$             | 37                      | ○      |
| Example 4             | 0.031   | $9.5 \times 10^{-7}$             | 55                      | ○      |
| Comparative Example 4 | 0.043   | $5.2 \times 10^{-6}$             | 45                      | ×      |
| Comparative Example 5 | 0.032   | $8.2 \times 10^{-6}$             | 55                      | ×      |
| Comparative Example 6 | 0.025   | $5.4 \times 10^{-6}$             | 1030                    | ×      |
| Comparative Example 7 | 0.031   | $3.2 \times 10^{-5}$             | 2210                    | ×      |
| Comparative Example 8 | 0.031   | $5.3 \times 10^{-6}$             | 1050                    | ×      |

Ex. 1008, 4-5, Table 2; *Ineos*, 783 F.3d at 869; MPEP 2131; Ex. 1003, ¶385.<sup>21</sup>

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<sup>21</sup> Patent Owner admitted during prosecution of the '168 Patent, the parent application of the '532 Patent, that the amount of decalin should be low, preferably below 100 ppm, for biocompatibility reasons. Ex. 1030, 266.

e) [1.E]

Ohta discloses filaments consisting of “less than 1000 ppm of further constituents.” Ex. 1003, ¶387. Ohta teaches that “[w]hen the residual components exceed 1000 ppm, the creep resistance deteriorates significantly” and “[w]hen additives other than solvents are also used, the residual components must be 1000 ppm or less, including these.” Ex. 1008, 2, 3; Ex. 1003, ¶¶387-388.

Ohta further describes the preparation of Examples 1-4 and Comparative Examples 1-5, each of which have remaining residual components other than polyethylene of 60 ppm or less, including solvent residual fraction, as demonstrated in Table 2 of Ohta:

Table 2

| Experiment No.        | g Value | Creep Rate ( $\text{sec}^{-1}$ ) | Residual Fraction (ppm) | Symbol |
|-----------------------|---------|----------------------------------|-------------------------|--------|
| Example 1             | 0.022   | $8.0 \times 10^{-7}$             | 55                      | ○      |
| Comparative Example 1 | 0.052   | $6.1 \times 10^{-6}$             | 55                      | ×      |
| Comparative Example 2 | 0.044   | $5.3 \times 10^{-6}$             | 60                      | ×      |
| Comparative Example 3 | 0.030   | $1.2 \times 10^{-6}$             | 35                      | ○      |
| Example 2             | 0.033   | $8.0 \times 10^{-7}$             | 45                      | ○      |
| Example 3             | 0.025   | $7.1 \times 10^{-7}$             | 37                      | ○      |
| Example 4             | 0.031   | $9.5 \times 10^{-7}$             | 55                      | ○      |
| Comparative Example 4 | 0.043   | $5.2 \times 10^{-6}$             | 45                      | ×      |
| Comparative Example 5 | 0.032   | $8.2 \times 10^{-6}$             | 55                      | ×      |
| Comparative Example 6 | 0.025   | $5.4 \times 10^{-6}$             | 1030                    | ×      |
| Comparative Example 7 | 0.031   | $3.2 \times 10^{-5}$             | 2210                    | ×      |
| Comparative Example 8 | 0.031   | $5.3 \times 10^{-6}$             | 1050                    | ×      |

Ex. 1008, 4-5, Table 2; *Ineos*, 783 F.3d at 869; MPEP 2131; Ex. 1003, ¶389. The examples of Nanri similarly confirm the lack of further constituents. Ex. 1007, 3, [0015]-[0017]; Ex. 1003, ¶390. Regardless, “further constituents” is a result effective variable and should not be given weight. *See* Ground 1, [1.E]. Accordingly, the combination of Section 73.1015, Nanri, Ohta, and Kavesh discloses filaments consisting of “less than 1000 ppm of further constituents.” Ex. 1003, ¶391.

### **3. Claim 2**

Section 73.1015 discloses “[t]he quantity of the [inorganic chromium-cobalt-aluminum oxide pigment] does not exceed 2 percent by weight of the suture material.” Ex. 1006, 18; Ex. 1003, ¶¶392-393. Nanri similarly describes a “strong polyethylene fiber...wherein a pigment content is 0.01 to 2.50 wt%” “preferably 0.10 to 2.00 wt%” for sufficient “coloring effect” and without reducing “strength and initial modulus of elasticity.” Ex. 1007, 2, [0004], [0005], [0008], Claim 3; Ex. 1003, ¶¶394-395. A range that overlaps a range claimed in the ’532 Patent is sufficient to establish a *prima facie* case of obviousness. *Peterson*, 315 F.3d at 1330; *Harris*, 409 F.3d 1339; *Synvina*, 904 F.3d at 1006; Ex. 1003, ¶¶396-397.

### **4. Claim 3**

Section 73.1015 and Nanri disclose Claim 3 for the same reasons discussed above with respect to Claim 2. Ex. 1006, 18; Ex. 1007, 2, [0004], [0005], [0008], Claim 3; Ex. 1003, ¶¶398-403; *see also*, *Ineos*, 783 F.3d at 869; MPEP 2131.

## **5. Claim 4**

Section 73.1015 discloses the color additive “chromium-cobalt-aluminum oxide,” which is an inorganic “blue-green pigment.” Ex. 1006, 18; Ex. 1003, ¶404. A POSITA would have understood that “chromium-cobalt-aluminum oxide” as disclosed by Section 73.1015 is “aluminum-chromium-cobalt oxide.” Ex. 1003, ¶¶405, 407; *see also* Ground 1, Claim 4 (asserting the pigment would be obvious).

## **6. Claim 5**

For the same reasons as [1.D] and the disclosure of at least Example 3, which discloses a residual fraction of 37 ppm, including solvent residual fraction, Ohta discloses “wherein the residual amount of spin solvent is less than 250 ppm.” Ex. 1008, 4-5, Table 2; Ex. 1003, ¶¶408-409; *see also, Ineos*, 783 F.3d at 869; MPEP 2131.

## **7. Claim 6**

For the same reasons as [1.D], and the disclosure of at least Example 3, which discloses a residual fraction of 37 ppm, including solvent residual fraction, Ohta discloses “wherein the residual amount of spin solvent is less than 100 ppm.” Ex. 1008, 4-5, Table 2; Ex. 1003, ¶¶410-411; *Ineos*, 783 F.3d at 869; MPEP 2131.

## **8. Claim 7**

For the same reasons as [1.D], and the disclosure of at least Example 3, which discloses a residual fraction of 37 ppm, including solvent residual fraction, Ohta

discloses “wherein the residual amount of spin solvent is less than 60 ppm.” Ex. 1008, 4-5, Table 2; Ex. 1003, ¶¶412-413; *Ineos*, 783 F.3d at 869; MPEP 2131.

## **9. Claim 8**

For the same reasons as [1.E], and the disclosure of at least Example 3, which discloses a residual fraction of 37 ppm, Ohta discloses the filaments containing “less than 500 ppm of further constituents.” Ex. 1008, 2-5, Table 2; Ex. 1003, ¶¶414, 416; *Ineos*, 783 F.3d at 869; MPEP 2131. The examples of Nanri similarly confirm the lack of further constituents. Ex. 1007, 3, [0015]-[0017]; Ex. 1003, ¶415.

## **10. Claim 9**

Kavesh discloses multi-filament yarns “wherein the number of filaments is between 10 and 1000.” Ex. 1003, ¶421. That is, Kavesh discloses spinnerets having a plurality of apertures, such as 16, 120, or 240, and the preparation of multi-filament yarns using such spinnerets. Ex. 1009, 8, 27, 28 (combining 3 rolls of 16-filament gel yarns “to prepare a 48 filament stretched gel yarn.”), 31; Ex. 1003, ¶¶419-420.

### **C. Ground 3: Section 73.1015, Nanri, and Simmelink**

#### **1. Motivation to Combine**

A POSITA would have combined Section 73.1015 with Nanri for the reasons outlined in Ground 2. Ex. 1001, 1:11-27; Ex. 1006, 18; Ex. 1007, 1, 2, [0005]-[0008], [0015]-[0017]; Ex. 1010, 55-56; Ex. 1003, ¶¶303-314, 424-435. To the extent that it is argued that the POSITA would not have combined Ohta and/or Kavesh with

Section 73.1015 and Nanri, which would be incorrect, the POSITA would also have been motivated to combine Simmelink with Section 73.1015 and Nanri.

Simmelink, which was within the knowledge of a POSITA, specifies a variety of parameters and process steps for making HPPE. *See* Ground 1, Motivation to Combine (providing an overview of Simmelink); Ex. 1005, 1:7-20, 9:31-33; 10:34-11:30, 12:1-12; Ex. 1003, ¶¶157, 423, 436-437.

A POSITA would have been motivated to improve the fiber production process of the colored linear polyethylene surgical sutures of Section 73.1015 and Nanri by including the teachings of Simmelink of minimizing the amount of other components or foreign materials in the yarn<sup>22</sup> to improve the resultant colored linear polyethylene surgical sutures for use in the human body. Ex. 1003, ¶438. Next, the POSITA would have been further motivated to include the filament count and relatively low titer (i.e., a yarn with multiple fine filaments) teachings for multi-filament surgical sutures. *Id.* That is, the POSITA would have been motivated to

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<sup>22</sup> Patent Owner admitted during prosecution of the parent to the '532 Patent that it was well known in the art “that the level of residual spin solvent, especially decalin, in gel-spun UHMwPE should be low, and preferably below 100 ppm for biocompatibility reasons.” Ex. 1030, 266.

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.* Indeed, such a modification specifically improves the combination of Section 73.1015 and Nanri as it relates to sutures because of the increased biocompatibility that results from the minimization of solvent, as is taught by Simmelink. *Id.*

The POSITA would have had a reasonable expectation of success in combining Section 73.1015 with Nanri. *See* Ground 2, Motivation to Combine. Moreover, the POSITA would have a reasonable expectation of success in combining Section 73.1015 with Nanri and Simmelink to achieve the predictable result of improved colored multi-filament yarns. Ex. 1003, ¶439. Each of the cited references disclose use of linear polyethylene and a colorant, and at least Nanri and Simmelink are directed to retaining or improving mechanical properties of the resulting UHMWPE fibers and disclose the same or similar gel-spinning processes, UHMWPE, intrinsic viscosity values, and same or similar spin solvents, to prepare their respective UHMWPE fibers. Ex. 1005, 8:12-17; Ex. 1006, 18, (c); Ex. 1007, 3, [0013], [0015]-[0017]. Ex. 1003, ¶439. Section 73.1015 and Nanri each expressly discloses the addition of a pigment, and Simmelink expressly discloses a colorant, in consistent

amounts. Ex. 1005, 8:28-31; Ex. 1006, 18, (a), (c)(2); Ex. 1007, 2 [0008], Claim 3; Ex. 1003, ¶¶439-440.

The POSITA also would have understood to select particles of the exempted pigment disclosed in Section 73.1015 and sized according to the disclosure of Nanri<sup>23</sup> so that the Section 73.1015 pigment would be incorporated into the UHMWPE fibers and would not cause defects during crystallization. Ex. 1007, 2, [0005], [0006]; Ex. 1003, ¶440. In addition, Nanri explicitly teaches that “the pigment particles in the fiber are incorporated into the polyethylene crystal, and therefore migration to outside the fiber is suppressed” and Section 73.1015 teaches that “there is no migration of the color additive to the surrounding tissue.” Ex. 1006, 18, (c)(4); Ex. 1007, 2, [0005]; Ex. 1003, ¶442. This is confirmed by the lack of disclosure in the ’532 Patent regarding the details of the pigment itself or the preparation thereof. *See* Ground 1, Motivation to Combine.

Moreover, the POSITA would have had a reasonable expectation of success in the incorporation of Simmelink. Simmelink discloses a similar gel-spinning process to the one of Nanri. *See e.g.*, Claim 1, limitation [1.A] *supra*; Ex. 1003, ¶439. In addition, Simmelink reduces the amount of solvent and other additives, which

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<sup>23</sup> The ’532 Patent is silent with regard to any requirements as to the sizing of pigment particles.

Simmelink itself confirms is well within the skill of the POSITA. Ex. 1005; Ex. 1003, ¶439.

In light of these teachings, the POSITA 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 medical application considerations for the fiber production process of Simmelink to be effective. Ex. 1003, ¶441.

## **2. Claim 1**

### **a) [1.Pre]**

For the same reason as Ground 1, Claim 1 of the '532 Patent is directed to a product that is developed by way of a process. Regardless, as is described in at least limitation [1.A], the '532 Patent admits that the claimed gel spinning process is well known. Ex. 1003, ¶444.

Further, and to the extent the preamble is limiting, the combination of Section 73.1015, Nanri, and Simmelink discloses a colored multi-filament yarn. Ex. 1003, ¶¶445, 450; *see also* limitations [1.A]-[1.E]. For the same reasons as limitation [1.Pre] in Ground 2, the combination of Section 73.1015 and Nanri disclose “a colored multi-filament yarn. *See also*, Ex. 1006, 18; Ex. 1007, 3, [0013], [0015]; Ex. 1003, ¶¶446-447.

Simmelink similarly specifies a variety of parameters and process steps for making high-performance polyethylene multifilament yarn from a gel spinning process, including teaching that the UHMWPE may contain colorants. Ex. 1005, 8:28-31; Ex. 1003, ¶¶448-449.

**b) [1.A]**

Regardless of whether limitation [1.A] should be given patentable weight as a process in a product by process claim, the combination of Section 73.1015, Nanri, and Simmelink renders obvious limitation [1.A].<sup>24</sup> Ex. 1003, ¶¶451, 466. For the same reasons as limitation [1.A] in Ground 2, the combination of Section 73.1015 and Nanri disclose limitation [1.A]. Ex. 1006, 18; Ex. 1007, 2: [0005],[0006], 3, [0013], [0015]-[0017]; Ex. 1003, ¶¶452-459, 465.

Further underscoring the combination and the reasonable expectation of success thereof, Simmelink discloses a similar process to that of Nanri. Simmelink similarly specifies a variety of parameters and process steps for making high-performance polyethylene multifilament yarn from a gel spinning process, including specifying the IV range of the UHMWPE, identifying “relatively volatile solvents,”

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<sup>24</sup> As is admitted in the '532 Patent, the gel spinning process for preparing UHMWPE filaments was not only well known in the prior art, but was conventional. Ex. 1001, 2:24-31.

including decalin, as “solvents suitable for gel spinning of [UHMPWE],” and teaching that the UHMWPE “may further contain small amounts, preferably less than 3 mass% of customary additives, such as...colorants.” Ex. 1005, 1:7-17, 7:32-8:2, 8:28-9:5, 10:34-11:30, 12:24-30; Ex. 1003, ¶¶460-464. Simmelink discloses the number of filaments in the multi-filament yarn is preferably “at least 10, 50, 100, 150, 200, 300, 375 or even at least 450.” Ex. 1005, 5:21-24; Ex. 1003, ¶461.

**c) [1.B]**

For the same reasons as limitation [1.B] in Ground 2, the combination of Section 73.1015 and Nanri disclose limitation [1.B]. Ex. 1006, 18; Ex. 1007, 3, [0013]; Ex. 1003, ¶467.

Simmelink likewise discloses this limitation for the reasons discussed above with respect to limitation [1.B.] in Ground 1. *See* Ex. 1005, 1:7-21 (describing making a solution of UHMwPE in a solvent, “spinning of the solution through a spinplate containing at least 5 spinholes into an air-gap to form fluid filaments); 7:32-8:2; Ex. 1003, ¶468. Additionally, to the extent [1.B] is interpreted as requiring multiple filaments, Simmelink discloses it, and a POSITA would understand the resulting filaments of Simmelink to contain “UHMwPE.” Ex. 1003, ¶¶468-469; *see also* Ex. 1005, 5:21-24. Thus, the combination of Section 73.1015, Nanri, and Simmelink renders obvious limitation [1.B]. Ex. 1003, ¶470.

**d) [1.C]**

For the same reasons as limitation [1.C] in Ground 2, the combination of Section 73.1015 and Nanri disclose limitation [1.C]. Ex. 1006, 18; Ex. 1007, 2, [0004], [0005], [0008], Claim 3; Ex. 1003, ¶¶471-474.

Simmelink likewise discloses that the polyethylene may further contain “small amounts, ...preferably less than 3 mass% of customary additives,” including “colorants.” Ex. 1005, 8:28-31; Ex. 1003, ¶475.

The POSITA would have understood that the ranges disclosed by Nanri and Simmelink are consistent with those disclosed by Section 73.1015 and overlaps the claims. *Peterson*, 315 F.3d at 1330; *Harris*, 409 F.3d 1339; *Synvina*, 904 F.3d at 1006; Ex. 1003, ¶476.

**e) [1.D]**

As demonstrated in Ground 1, limitation [1.D], Simmelink discloses “a residual amount of spin solvent of less than about 500 ppm.” Ex. 1005, 1:15, 9:31-33, 12:6-12, 17:17-30, 18:8-13, 19:15-22, 20:13-30 (disclosing, for example, Example 29 having a decalin content of 16 ppm); Ex. 1003, ¶¶478-483. That is, Simmelink’s range of less than 150 ppm of residual solvent demonstrates an overlapping range which establishes *prima facie* obviousness and the examples anticipate, and thus render unpatentable, the claimed range. *Peterson*, 315 F.3d at 1330; *Harris*, 409 F.3d 1339; *Synvina*, 904 F.3d at 1006; *Ineos*, 783 F.3d at 869;

MPEP 2131; Ex. 1003, ¶¶482. Indeed, in the case of decalin as the spin solvent, the POSITA would have been motivated to obtain as low of a level of residual spin solvent in the UHMWPE filaments as possible in order to prevent irritation when used as a suture in the body.<sup>25</sup>

**f) [1.E]**

As demonstrated in Ground 1, limitation [1.E], Simmelink discloses “less than 1000 ppm of further constituents. Ex. 1001, 3:61-67, Ex. 1005, 8:28-31, 12:6-12; 16:17-20:30; Ex. 1030, 266; Ex. 1003, ¶¶485-492; *Peterson*, 315 F.3d at 1330; *Harris*, 409 F.3d 1339; *Synvina*, 904 F.3d at 1006; *Applied Materials*, 692 F.3d at 1295-96.

The examples of Nanri similarly confirm the lack of further constituents. Ex. 1007, 3, [0015]-[0017]; Ex. 1003, ¶493. Moreover, “further constituents” is a result effective variable and should not be given weight. *See* Ground 1, [1.E].

**3. Claim 2**

For the same reasons as Claim 2 in Ground 2, the combination of Section 73.1015 and Nanri disclose “the amount of the inorganic pigment present in the

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<sup>25</sup> Patent Owner admitted during prosecution of the '168 Patent, the parent application of the '532 Patent, that the amount of decalin should be low, preferably below 100 ppm, for biocompatibility reasons. Ex. 1030, 266; Ex. 1003, ¶483.

filaments is between 0.3 and 5.0 wt. %.” Ex., 1006, 18; Ex. 1007, 2, [0004], [0005], [0008], Claim 3; Ex. 1003, ¶¶495-498.

Simmelink similarly discloses this limitation for the reasons discussed above with respect to limitation [1.C] in Ground 3, as well as with respect to Claim 2 in Ground 1. Ex. 1005, 8:28-31 (the polyethylene may further contain “small amounts, ...preferably less than 3 mass% of customary additives,” including “colorants.”); Ex. 1003, ¶499.

The POSITA would have understood that the ranges disclosed by Nanri and Simmelink are consistent with those disclosed by Section 73.1015 and overlaps the claimed range. *Peterson*, 315 F.3d at 1330; *Harris*, 409 F.3d 1339; *Synvina*, 904 F.3d at 1006; Ex. 1003, ¶500.

#### **4. Claim 3**

For the same reasons as Claim 3 in Ground 2, the combination of Section 73.1015 and Nanri disclose “the amount of the inorganic pigment present in the filaments is lower than 2.0 wt. %.” Ex., 1006, 18; Ex. 1007, 2, [0004], [0005], [0008], Claim 3; Ex. 1003, ¶¶502-505; *see also*, *Ineos*, 783 F.3d at 869; MPEP 2131. A range that overlaps a range claimed in the ’532 Patent is sufficient to establish a *prima facie* case of obviousness. *Peterson*, 315 F.3d at 1330; Ex. 1003, ¶¶507-508.

Simmelink similarly discloses this limitation for the same reasons discussed above with respect to Claim 2 in Ground 3, as well as with respect to Claim 3 in Ground 1. Ex. 1005, 8:28-31; Ex. 1003, ¶506.

#### **5. Claim 4**

For the same reasons as Claim 4 in Ground 2, the combination of Section 73.1015 and Nanri disclose “the inorganic pigment is aluminum-chromium-cobalt oxide.” Ex. 1006, 18; Ex. 1007, 2, [0005]; Ex. 1003, ¶¶509-512.

#### **6. Claim 5**

For the same reasons as Claim 5 in Ground 1 and in limitation [1.D] above, Simmelink discloses “wherein the residual amount of spin solvent is less than 250 ppm.” Ex. 1005, 12:6-12, 19:15-22, 20:13-30 (disclosing, for example, Example 29 having a decalin content of 16 ppm); Ex. 1003, ¶¶513-516; *see also, Ineos*, 783 F.3d at 869; MPEP 2131.

#### **7. Claim 6**

For the same reasons as Claim 6 in Ground 1 and in limitation [1.D] above, Simmelink discloses “wherein the residual amount of spin solvent is less than 100 ppm.” Ex. 1005, 12:6-12, 20:13-30 (disclosing, for example, Example 29 having a decalin content of 16 ppm); Ex. 1003, ¶¶517-520; *Ineos*, 783 F.3d at 869; MPEP 2131.

## **8. Claim 7**

For the same reasons as Claim 7 in Ground 1 and in limitation [1.D] above, Simmelink discloses “wherein the residual amount of spin solvent is less than 60 ppm.” Ex. 1005, 12:6-12, 20:13-30 (disclosing, for example, Example 29 having a decalin content of 16 ppm); Ex. 1003, ¶¶521-524; *Ineos*, 783 F.3d at 869; MPEP 2131.

## **9. Claim 8**

For the same reasons as Ground 1, Claim 8, Simmelink discloses “wherein the filaments contain less than 500 ppm of further constituents.” Ex. 1005, 8:28-31, 12:6-12; 16:17-20:30; Ex. 1030, 236-237, 266; Ex. 1003, ¶¶525-530, 532; *Peterson*, 315 F.3d at 1330.

The examples of Nanri similarly confirm the lack of further constituents. Ex. 1007, 3, [0015]-[0017]; Ex. 1003, ¶531.

## **10. Claim 9**

For the same reasons as Ground 1, Claim 9, Simmelink discloses “wherein the number of filaments is between 10 and 1000.” Ex. 1005, 5:21-24, 12:3-6; Ex. 1003, ¶¶533, 535.

## **VIII. DISCRETIONARY ISSUES**

### **A. The Petition Does Not Present the Same References**

Under *Advanced Bionics*, the Board should not deny institution under §325(d). *Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH*, No. IPR2019-01469, Paper 6 (P.T.A.B. Feb. 13, 2020), at 7 (precedential).

The Board has held that the first prong of *Advanced Bionics* is not met where “neither [the combination references] nor similar prior art was before the examiner and ... the prosecution history does not include any overlapping arguments directed to this prior art.” *Godbersen-Smith Constr. Co. v. Guntert & Zimmerman Const. Div., Inc.* No. IPR2021-00050, Paper 24 (P.T.A.B. May 7, 2021), at 19–21. And in such a case, the Board “need not address part two of the analysis.” *Id.* at 21.

At least one prior art reference in each ground was not cited during prosecution and is not cumulative of the art considered. *See* §V.B, *supra*. For example, in Ground 1, Section 73.1015 (Ex. 1006) was not cited. *See generally* Exs. 1002, 1030. Moreover, none of the references cited in Ground 2 were cited. *See id.* Finally, with regard to Ground 3, neither Nanri nor Section 73.1015 were cited. *See id.*

During prosecution, Simmelink was cited in the parent of the ’532 Patent as disclosing the majority of the elements of the claim. Ex. 1030, 312-313, 367-368. In response, the Applicant did not dispute the Examiner’s findings regarding

Simmelink, instead distinguishing Simmelink because it did not disclose a pigment. Ex. 1030, 389. But the Examiner did not cite Simmelink for the purposes of disclosing pigments.

Applicant also distinguished a secondary reference, Edwin, which the Examiner had cited as teaching pigments, by asserting that “Edwin does not indicate or suggest to color the ePTFE graft material itself.” Ex. 1030, 390-391. Unlike Edwin, and as is noted herein, Section 73.1015 specifically discloses details regarding how to make a polyethylene suture that incorporates chromium-cobalt-aluminum oxide. In fact, Section 73.1015 is particularly important for surgical sutures because reliance on the CFR (e.g., by using chromium-cobalt-aluminum oxide using the disclosed process and the disclosed amount) allows a manufacturer to be exempt from certification. Indeed, Patent Owner itself relies on the CFR to avoid costly batch certification. Ex. 1010, 55-56.

Finally, the cited references (e.g., Section 73.1015) are not cumulative of the prosecution because there was no reference relied upon that related to sutures having an inorganic chromium oxide-containing pigment. Instead, Applicant overcame any reference related to a pigment by arguing, for example, that the pigment reference failed to teach or suggest “pigments would or could be employed in gel spun UHMwPE filaments.” Ex. 1030, 390-391.

Because the first prong is not met, the Board need not move to the second. *See Oticon Med. AB v. Cochlear Ltd.*, No. IPR2019-00975, Paper 15 (P.T.A.B. Oct. 16, 2019), at 20.

Even if considering the second prong, Petitioner has demonstrated a material error by the Examiner by pointing out and explaining how the combinations teach the limitations of the claims. *See Celco v. Huawei*, No. IPR2020-01117, Paper 10 (P.T.A.B. Feb. 3, 2021). Indeed, in all grounds, Petitioner demonstrates that pigments would be mixed with UHMWPE in a gel-spinning process. Moreover, the Examiner was not aware of Section 73.1015 and, thus, could not have presented it as part of a rejection. *Oticon*, No. IPR2019-00975, Paper 15 at 19-20. The same is true with regard to Grounds 2 and 3. As such, in addition to not having the grounds presented during examination, the Examiner erred by not considering the extensive file history in the parent case and the prior art cited herein when evaluating the patentability of the claims of the '532 Patent.

**B. The Board Should Not Deny Institution Under *Fintiv***

The Board balances six factors in considering denial. *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 (PTAB Mar. 20, 2020) (precedential). Here, the factors (“*Fintiv* factors”) favor institution.

*Fintiv Factor 1* (potential for stay) is at least neutral given that no stay motion has yet been filed. *See Sand Revolution II, LLC v. Cont’l Intermodal*

*Grp. - Trucking LLC*, IPR2019-01393, Paper 24 at 7 (PTAB June 16, 2020) (informative).

*Fintiv Factor 2* (timing of trial) favors institution. As of the time of filing, trial has been set for August 4, 2025. Assuming eighteen months from the filing date of the original filing date, a final written decision will issue on or about the time of trial. However, and in view of the likelihood that trial dates will shift, the PTAB relies on median trial date for Factor 2. *See* Memorandum, Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings with Parallel District Court Litigation (USPTO June 21, 2022), 8. The median-time-to-trial for civil cases in Delaware is currently 37.8 months (Ex. 1031 (National Judicial Caseload Profile), 14), which suggests a likely actual trial date no earlier than April 2026, 9 months after the final written decision.

*Fintiv Factor 3* (litigation investment) favors institution. The district court case is at the very outset, and although the parties have served preliminary discovery, discovery has not yet begun in earnest. Initial infringement contentions will not be served until March 1, 2024, and initial invalidity contentions are not due until April 5, 2024, with final invalidity contentions not due until November 13, 2024.

The parties have not yet begun claim construction briefing. Only after filing of a status report by August 16, 2024, will the court set a hearing on claim construction.

*Fintiv Factor 4* (overlap of issues) favors institution. DSM asserts Claims 1-7 and 9 in the district court, while Petitioner addresses all claims in this Petition. Moreover, Petitioners stipulate that if this IPR proceeding is instituted, they will withdraw any identical grounds from the district court litigation, which weighs in favor of institution. *See Sand Revolution II, LLC v. Continental Intermodal Grp - Trucking LLC*, IPR2019-01393, Paper 24 at 12 n.5 (PTAB June 16, 2020).

*Fintiv Factor 5* (overlap in parties) weighs against institution because Petitioners are parties in this Petition as well as in the parallel district court litigation.

*Fintiv Factor 6* (other circumstances) favors institution because this Petition presents a compelling case and “plainly lead[s] to a conclusion that one or more claims are unpatentable” because it is “highly likely...[to] prevail with respect to at least one challenged claim.” *CommScope Technologies LLC v. Dali Wireless, Inc.*, IPR2022-01242, Paper 23 at 4 (PTAB Feb. 27, 2023) (precedential).

## **IX. MANDATORY NOTICES UNDER 37 C.F.R. §42.8**

### **A. Real Party in Interest (37 C.F.R. §42.8(b)(1))**

The real party in interest is Honeywell International Inc.

### **B. Related Matters (37 C.F.R. §42.8(b)(2))**

Pursuant to 37 C.F.R. §42.8(b)(2), Petitioner is aware of the following pending lawsuits or related matters involving the '532 Patent:

- *DSM IP Assets, B.V. et al. v. Honeywell International Inc.*, C.A. No. 23-CV-00675 (WCB) (D. Del., Jun. 22, 2023)

### **C. Designation of Counsel (37 C.F.R. §42.8(b)(3))**

Lead counsel is S. Benjamin Pleune (Reg. No. 52,421), of Alston & Bird LLP, Vantage South End, 1120 South Tryon Street, Suite 300, Charlotte, NC 28203-6818, Tel: 704.444.1000, Fax: 704.444.1111. Backup counsel is Christopher T.L. Douglas (Reg. No. 56,950) of Alston & Bird LLP, Vantage South End, 1120 South Tryon Street, Suite 300, Charlotte, NC 28203-6818, Tel: 704.444.1000, Fax: 704.444.1111; Miranda Sooter (Reg. No. 57,126) of Alston & Bird LLP, Vantage South End, 1120 South Tryon Street, Suite 300, Charlotte, NC 28203-6818, Tel: 704.444.1000, Fax: 704.444.1111; Lauren Griffin (Reg. No. 77,865) of Alston & Bird LLP, Vantage South End, 1120 South Tryon Street, Suite 300, Charlotte, NC 28203-6818, Tel: 704.444.1000, Fax: 704.444.1111; and Erin Beaton (Reg. No. 79,218) of Alston & Bird LLP, Vantage South End, 1120 South Tryon Street, Suite

300, Charlotte, NC 28203-6818, Tel: 704.444.1000, Fax: 704.444.1111. Pursuant to 37 C.F.R. §42.10(b), Powers of Attorney are being submitted with this Petition.

**D. Service Information (37 C.F.R. §42.8(b)(4))**

Petitioners consent to electronic service directed to ben.pleune@alston.com, christopher.douglas@alston.com, miranda.sooter@alston.com, lauren.griffin@alston.com, and erin.beaton@alston.com.

Date: February 12, 2024

By: / S. Benjamin Pleune /  
S. Benjamin Pleune  
Reg. No. 52,421

## **CLAIMS APPENDIX**

| Claim  | Recitation                                                                                                                                                                                                                    |
|--------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1[Pre] | A colored multi-filament yarn comprising                                                                                                                                                                                      |
| 1[A]   | 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 |
| 1[B]   | wherein the filaments consist of UHMwPE,                                                                                                                                                                                      |
| 1[C]   | between 0.1 and 7.0 wt. % of an inorganic chromium oxide-containing pigment,                                                                                                                                                  |
| 1[D]   | a residual amount of spin solvent of less than about 500 ppm, and                                                                                                                                                             |
| 1[E]   | less than 1000 ppm of further constituents.                                                                                                                                                                                   |
| 2      | The multi-filament yarn according to claim 1, wherein the amount of the inorganic pigment present in the filaments is between 0.3 and 5.0 wt. %.                                                                              |
| 3      | The multi-filament yarn according to claim 1, wherein the amount of the inorganic pigment present in the filaments is lower than 2.0 wt. %.                                                                                   |
| 4      | The multi-filament yarn according to claim 1, wherein the inorganic pigment is aluminum-chromium-cobalt oxide.                                                                                                                |

| Claim | Recitation                                                                                                             |
|-------|------------------------------------------------------------------------------------------------------------------------|
| 5     | The multi-filament yarn according to claim 1, wherein the residual amount of spin solvent is less than 250 ppm.        |
| 6     | The multi-filament yarn according to claim 1, wherein the residual amount of spin solvent is less than 100 ppm.        |
| 7     | The multi-filament yarn according to claim 1, wherein the residual amount of spin solvent is less than 60 ppm.         |
| 8     | The multi-filament yarn according to claim 1, wherein the filaments contain less than 500 ppm of further constituents. |
| 9     | The multi-filament yarn according to claim 1, wherein the number of filaments is between 10 and 1000.                  |

**CERTIFICATION UNDER 37 C.F.R. §42.24**

Under the provisions of 37 CFR §42.24, the undersigned hereby certifies that the word count for the foregoing Petition for *inter partes* review totals 13,993 words (Sections I-VIII), which is less than the 14,000 allowed under 37 CFR §42.24(a)(i).

Date: February 12, 2024

By: / S. Benjamin Pleune /  
S. Benjamin Pleune  
Reg. No. 52,421

### **CERTIFICATE OF SERVICE**

Pursuant to 37 C.F.R. §§42.6(e), 42.105, the undersigned hereby certifies service on the Patent Owner of a copy of this Petition and its respective exhibits to Patent Owner via UPS Next Day Air on the correspondence address of record for U.S. Patent No. 10,280,532 as follows:

Nixon & Vanderhye, PC  
901 North Glebe Road, 11th Floor  
Arlington, VA 22203

Petitioner also certifies that a courtesy copy of this Petition was sent via email to Patent Owner's litigation counsel:

Erick J. Palmer (ejpalmer@mayerbrown.com)  
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Christopher Kelly (cjkelly@mayerbrown.com)

Date: February 12, 2024

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