

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

HONEYWELL INTERNATIONAL INC.,
Petitioner,

v.

DSM IP ASSETS, B.V.,
Patent Owner

Case: IPR2024-00493
U.S. Patent No. 10,280,532

PATENT OWNER PRELIMINARY RESPONSE

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TABLE OF CONTENTS

	Page
I. INTRODUCTION	2
II. TECHNOLOGY BACKGROUND.....	8
A. UHMWPE Is a Unique Form of Polyethylene.....	8
B. The Advent of Section 73.1015 for Pigmented Linear Polyethylene	11
C. Early Blue Linear Polyethylene Sutures Failed Due to “Creep”	13
D. DSM’s Gel Spinning Process in 1979 Led to the First Commercialization of Uncolored UHMWPE Yarns	17
E. Prior Attempts to Color UHMWPE Yarns With Pigments Failed	24
III. THE ’532 PATENT CLAIMS INNOVATIVE CHROMIUM OXIDE-COLORED UHMWPE YARNS	28
A. The Claimed Colored Multi-Filament UHMWPE Yarns Are Novel Advancements Over the Prior Art	30
B. The ’532 Patent Issued After 8 Years of Prosecution of Its Family.....	32
IV. LEVEL OF ORDINARY SKILL IN THE ART	33
V. “GEL SPINNING” IS A LIMITATION THAT REQUIRES SPINNING FILAMENTS FROM A SOLUTION OF UHMWPE IN A SPIN SOLVENT.....	34
A. “Gel Spinning” Requires Spinning a Solution of UHMWPE in a Spin Solvent	35
B. The “Gel Spinning” Term Is Entitled to Patentable Weight.....	37
VI. THE PETITION FAILS TO DEMONSTRATE A REASONABLE LIKELIHOOD THAT ANY CHALLENGED CLAIM WOULD HAVE BEEN OBVIOUS	39
A. Ground 1 Fails to Meet the Institution Threshold.....	41
1. <i>There Are Significant Differences Between the Simmelink/Section 73.1015 Combination and the Challenged Claims</i>	41

TABLE OF CONTENTS

(continued)

	Page
a. Simmelink Does Not Disclose Pigmented Medical-Grade UHWMPE Yarns	41
b. Section 73.1015 Does Not Disclose Gel-Spun UHMWPE Yarns	43
2. <i>There Was No Motivation to Combine Simmelink with Section 73.1015</i>	47
a. The Incompatibility of the Pigmentation Process of Section 73.1015 With Simmelink’s Gel-Spinning Process Teaches Away From the Challenged Claims	47
b. The Prior Art as a Whole Teaches Away From the Path the Inventors Took to Arrive at the Challenged Claims	49
3. <i>Simmelink and Section 73.1015 Do Not Establish a Reasonable Expectation of Success</i>	58
4. <i>The Inventors’ Use of a Standard Pigment Does Not Render the Challenged Claims Unpatentable</i>	60
B. Grounds 2 and 3 Fail to Meet the Institution Threshold	61
VII. CONCLUSION.....	66

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>3M Innovative Props. Co. v. Avery Dennison Corp.</i> , 350 F.3d 1365 (Fed. Cir. 2003)	37
<i>Abbott Labs. v. Sandoz, Inc.</i> , 544 F.3d 1341 (Fed. Cir. 2008)	49, 50, 58
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<i>In re Kotzab</i> , 217 F.3d 1365 (Fed. Cir. 2000)	39, 40
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Statutes	
35 U.S.C. § 103 (pre-AIA)	60

35 U.S.C. § 313	1
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PATENT OWNER EXHIBIT LIST

Exhibit No.	Description
2001	<i>DSM Launches Blue Fiber for Surgery</i> , CHEMICAL & ENGINEERING NEWS, Vol. 88, No. 22 (May 31, 2010).
2002	S.M. Kurtz, <i>The UHMWPE Handbook: Ultra-High Molecular Polyethylene in Total Joint Replacement</i> , Elsevier Academic Press, San Diego, CA USA (2004).
2003	J.N. Barrows, <i>et al.</i> , <i>Color Additives: FDA's Regulatory Process and Historical Perspectives</i> , October 1, 2003, available at www.food-safety.com/articles/4207-color-additives-fdas-regulatory-process-and-historical-perspectives .
2004	21 C.F.R. § 8.501(f) (1965).
2005	21 C.F.R. § 8.6010 (1975).
2006	39 Fed. Reg. 28,421 (1974).
2007	39 Fed. Reg. 38,222 (1974).
2008	21 C.F.R. § 73.1015 (1977).
2009	J.T. Phelan, <i>Linear Polyethylene, A New Suture Material for Arterial Anastomosis</i> , SURGERY, Vol. 45, No. 4, pp. 674-680 (April 1959).
2010	A.R. Katz & H.D. Evans, <i>Linear Polyethylene Sutures, An Evaluation of Tissue Reaction</i> , AM. J. OF SURGERY, Vol. 103, pp. 208-216 (February 1962).
2011	A.R. Koontz, PROCEEDINGS OF THE ROYAL SOCIETY OF MEDICINE, Vol. 54, p. 967 (November 1961).

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2012	A.R. Koontz & R.C. Kimberly, <i>The Promise of an Ideal Suture Material—Marlex (Blue Linear Polyethylene)</i> , ARCHIVES OF SURGERY, Vol. 86, No. 1, pp. 162-163 (1963).
2013	F.C. Usher, <i>Braided Marlex Suture, A New General Purpose Suture</i> , ARCHIVES OF SURGERY, Vol. 83, No. 2, pp. 203-204 (1961).
2014	American Cyanamid Company, <i>Cr-Co-Al-oxide Color Additive Petition</i> , submitted to FDA January 31, 1964, publicly available through Freedom of Information Act since December 18, 1984.
2015	U.S. Patent No. 3,359,983 (American Cyanamid Company).
2016	J. W. Alexander, <i>et al.</i> , <i>Role of Suture Materials in the Development of Wound Infection</i> , ANNALS OF SURGERY, Vol. 165, No. 2, pp. 192-199 (1967).
2017	D.S. Starr, <i>et al.</i> , <i>Suture Material as a Factor in the Occurrence of Anastomotic False Aneurysms</i> , ARCHIVES OF SURGERY, Vol. 114, No. 4, pp. 412-415 (1979).
2018	N.A. Swanson & T.A. Tromovitch, <i>Suture Materials, 1980s: Properties, Uses, and Abuses</i> , INT’L J. OF DERMATOLOGY, Vol. 21, No. 7, pp. 373-378 (1982).
2019	T.R. Calhoun & C.M. Kitten, <i>Polypropylene suture—Is it safe?</i> , J. VASC. SURG., 4, pp. 98-100 (1986).
2020	L. Smit, <i>Dyneema Purity – A New Ultra-Strong Fibre Available for Innovative Devices</i> , BUSINESS BRIEFING: MEDICAL DEVICE MANUFACTURING & TECHNOLOGY, pp. 1-4 (2004).
2021	U.S. Patent No. 5,631,987 (Toyo Boseki Kabushiki Kaisha).
2022	DSM Dyneema Rolls Out Colored Medical Grade UHMWPE Fiber Purity Blue, May 20, 2010, available at www.nsmedicaldevices.com/news/dsm_dyneema_rolls_out_colored_medical_grade_uhmwpe_fiber_purity_blue_100521/ .

Exhibit No.	Description
2023	<i>Honeywell Introduces New Blue Spectra® Medical Grade Bio Fiber Designed to Improve Visual Contrast Within Critical Surgical Procedures</i> , April 12, 2022, available at https://www.honeywell.com/in/en/press/2022/04/honeywell-introduces-new-blue-spectra-medical-grade-bio-fiber-designed-to-improve-visual-contrast-within-critical-surgical-procedures .
2024	Honeywell's Redacted Answer and Counterclaims in Civil Action No. 23-675 (D. Del.).
2025	Honeywell, <i>Spectra® Blue MG BIO Article Safety Information Sheet</i> , February 9, 2022.
2026	E. Rudnik & Z. Dobkowski, <i>Thermal Degradation of UHMWPE</i> , J. OF THERMAL ANALYSIS, Vol. 49, pp. 471- 475 (1997).
2027	ThermoFisher Scientific, <i>Safety Data Sheet for Decahydronaphthalene</i> (October 13, 2023).
2028	Ferro Corporation, <i>Product Information for CI Pigment Blue</i> .
2029	Kremer Pigmente, <i>Specification for Pigment Blue 36, C.I. 77443</i> .
2030	Hangzhou Epsilon Chemical Co., Ltd., <i>Physical and Chemical Properties of Pigment Blue 36</i> .
2031	Henry W. Way, <i>Grinding and Dispersing Nanoparticles</i> , JCT COATINGS TECH, pp. 54-60 (January 2004).
2032	U.S. Food and Drug Administration, <i>Nanotechnology Task Force Report</i> , pp. 1-36 (July 25, 2007).

Honeywell International Inc. (“Honeywell” or “Petitioner”) filed for *inter partes* review requesting cancellation of claims 1-9 (“Challenged Claims”) of U.S. Patent No. 10,280,532 (“’532 patent”). The Petition raises three grounds of purported obviousness:

- (1) WO 2005/066401 to Simmelink *et al.* (“Simmelink”, EX1005) in combination with 21 C.F.R. § 73.1015 (2006) (“Section 73.1015”, EX1006);
- (2) Section 73.1015 in combination with JP Appl. Publ. No. H11-21721 to Nanri *et al.* (“Nanri”, EX1007), JP Pat. Publ. No. 2586213 to Ohta *et al.* (“Ohta”, EX1008), and JP Appl. Publ. No. S58-5228 to Kavesh *et al.* (“Kavesh”, EX1009); and
- (3) Section 73.1015 in combination with Nanri and Simmelink.

DSM IP Assets, B.V. and real parties-in-interest DSM Purity, B.V., DSM Biomedical, B.V., and DSM Biomedical, Inc. (collectively, “DSM” or “Patent Owner”) file this timely Preliminary Response. 35 U.S.C. § 313.

The Challenged Claims are directed to medical-grade multi-filament yarns made from gel-spun ultra-high molecular weight polyethylene (“UHMWPE”) having low levels of residual spin solvent and further constituents. The claimed yarns are colored with a chromium-oxide-containing pigment during the gel

spinning process. Because the Petition fails to demonstrate a reasonable likelihood that any Challenged Claim is unpatentable, *inter partes* review should be denied.

I. INTRODUCTION

All grounds raised in the Petition rely on Section 73.1015, a Food and Drug Administration (“FDA”) color additive regulation with origins dating back to the mid-1960s. Section 73.1015 derives from the American Cyanamid Company’s commercialization and registration of a chromium-cobalt-aluminum-oxide pigment used in linear polyethylene sutures of that era to provide a visual contrast between sutures and body tissue during surgery. Those blue polyethylene sutures failed in practice, weakening over time and breaking so frequently that surgeons quickly stopped using them. It would take more than four decades before another blue polyethylene suture was available to the public.

In 2007, the inventors of the ’532 patent demonstrated for the first time that a markedly different kind of polyethylene—gel-spun UHMWPE—could be successfully colored with a chromium-oxide-containing pigment without sacrificing the high structural integrity and strength needed for medical suture applications. This groundbreaking innovation was surprising and solved a long-felt but unmet need despite much skepticism and prior failures to color UHMWPE. When initially commercialized, medical-grade UHMWPE yarns were not available in any color. UHMWPE, a polymer made of carbon and hydrogen atoms, is

hydrophobic and had proven to be extremely difficult to color, particularly when used in yarns for medical sutures. For example, at the time of the '532 patent, dyes had been used to color UHMWPE yarns, but those dyes were known to leach out of the polymeric material over time, raising cytotoxicity concerns and making them unsuitable for medical use. Pigments had also been tried, but they created two notable problems: (1) pigments were shown to hinder the specialized manufacturing process—known as “gel-spinning”—necessary to make high-strength UHMWPE yarns; and (2) the presence of pigment in the filaments of UHMWPE yarns negatively impacted their strength, causing them to break during manufacture and rendering them unsuitable for medical sutures.

Given these problems, the conventional wisdom at the time of the '532 patent was that UHMWPE yarns could not be colored effectively without adversely impacting the functional properties necessary to withstand the gel-spinning process. Bucking this conventional wisdom, the inventors discovered that a chromium-oxide-containing pigment could be used effectively to produce a blue gel-spun UHMWPE yarn. Surprisingly, the strength of those blue UHMWPE yarns was not diminished, and the pigment did not leach out of the filaments. DSM filed for patent protection and has been the exclusive provider of blue medical-grade UHMWPE yarn to medical device manufacturers in the United

States since the launch of its blue DYNEEMA PURITY® products in 2010. (EX2001, 33). That is, until recently.

Although its own UHMWPE yarn products had been used to make medical sutures since at least 1993, Honeywell did not offer its own blue, medical-grade UHMWPE yarn for much of the past three decades. The absence of a blue UHMWPE yarn in Honeywell's product offerings over that span is telling because, as Honeywell admits, "there was a well-known need to color [UHMWPE] sutures" long before the time of the '532 patent. (Pet., 1). In fact, as numerous others repeatedly tried—*and failed*—to color UHMWPE yarns, this need went unmet until the invention claimed in the '532 patent. Honeywell now challenges the '532 patent. Because the evidence presented in the Petition fails to demonstrate a reasonable likelihood that any Challenged Claim would have been obvious, respectfully, *inter partes* review should be denied.

First, Petitioner's contention that it would have been obvious to combine the pigmentation process disclosed in Section 73.1015 with the gel-spinning process disclosed in the prior art is misguided. The pigmentation process of Section 73.1015 requires temperatures that are above both (1) the point at which UHMWPE begins to undergo thermal decomposition and (2) the boiling points of many of the common spin solvents used in the gel-spinning process. The Petition evidence explains that in the absence of a spin solvent, it is "almost impossible" to

spin UHMWPE into yarn. Thus, Section 73.1015's pigmentation process would render the prior art gel-spinning process inoperable. Honeywell's only attempt to rebut the inoperability of combining the heat extrusion method of Section 73.1015 with gel spinning UHMWPE is its double-negative statement that the "coloring procedure" described in Section 73.1015 "is ***not inconsistent*** with the gel spinning process disclosed in Simmelink." (EX1003, ¶ 185) (emphasis added)). However, the two processes are undeniably incompatible, so much so that Section 73.1015's pigmentation process required by the FDA would begin to destroy the UHMWPE and evaporate off the spin solvent. Accordingly, a PHOSITA would not have been motivated to combine them.

Second, Petitioner's contention that it would have been obvious to try the Section 73.1015 pigment in the prior art gel-spinning process is also misguided. In the 28-year span between the 1979 invention of gel-spun UHMWPE and DSM's 2007 filing of the present invention, the prior art was replete with instances of UHMWPE's mechanical properties being adversely affected by the addition of pigments and dyes during gel-spinning. Unsurprisingly, the Petition's own evidence explains that coloring UHMWPE yarns "is extremely difficult." (EX1014, 82). The prior art, including references cited in the Petition, confirm that critical functional properties of UHMWPE yarns are weakened when dyes, pigments and other compounds are contained in the filaments.

Ohta teaches that the amount of solvent and other additives in the UHMWPE filaments should be 1000 ppm or less based on weight fraction. At higher concentrations, the residual solvent and other additives act as defects within the crystalline regions of the gel-spun UHMWPE, leading to a phenomenon referred to as creep. This property is problematic in medical applications because creep can lead to failed sutures with harmful consequences. Nanri explains that when pigments have an average aggregate particle size of greater than 100 nm, they act as defects within the crystalline structure of the UHMWPE filaments. Thus, Ohta and Nanri would have taught away from incorporating a pigment having a particle size greater than 100 nm in the claimed concentrations.

Accordingly, a PHOSITA having knowledge of the entire 45+-year history prior to DSM's patent filing (*i.e.*, 1960-2007) would not have been motivated to combine Section 73.1015 with any of the Petition's references and would not have had a reasonable expectation of success in achieving the claimed invention. This is consistent with Petitioner's own commercial activities. Despite the well-known "design need" for blue sutures, Petitioner did not offer its own blue-pigmented UHMWPE product until 2022—almost **30 years** after its own UHMWPE yarn products were being used to make sutures and **43 years** after DSM's invention of gel-spun UHMWPE yarns.

Third, effectively acknowledging that Nanri teaches away from pigment sizes larger than 100 nm, Grounds 2 and 3 limit the Section 73.1015 pigment to be “sized according to Nanri.” Nanri does not disclose the Section 73.1015 pigment. Aside from a conclusory statement from Dr. Grubb the pigments can be pretreated by grinding, milling, or pulverizing, there is no evidence presented in the Petition demonstrating that at the time of the ’532 patent, the Section 73.1015 pigment, sized to have an average aggregate particle size between 10-100 nm, was within the general knowledge or skill of a PHOSITA. In fact, this Preliminary Response presents evidence that the particle size of a pigment obtained from mechanical milling depends on its material properties and dimensions lower than 100 nm may not be achieved for hard pigments. Having failed to consider the differences between the carbon-based pigment disclosed in Nanri and the non-carbon-based pigment disclosed in Section 73.1015, the Petition fails to demonstrate obviousness.

In arriving at the Challenged Claims, the Petition ignores the complexity of the claimed technology and the conventional wisdom in the art at the time. The Petition also misconstrues the portions of the prior art references on which it relies, ignores the portions that teach away from the invention, and rejects in conclusory fashion the repeated failure of others identified in the specification and its own art that unequivocally demonstrate the invention’s nonobviousness. The Petition’s

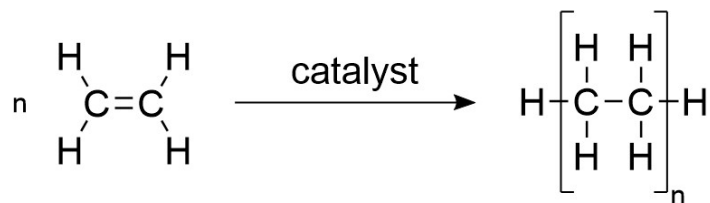
litigation-driven reconstruction of the Challenged Claims is based on hindsight bias derived solely from the '532 patent itself. Respectfully, the Petition should be denied.

II. TECHNOLOGY BACKGROUND

The '532 patent relates to certain gel-spun UHMWPE yarns colored with a chromium-oxide-containing pigment used to make medical sutures. (*See, e.g.*, EX1001, 2:14-3:60). UHMWPE yarns are high-performance materials whose unique properties and structure result from the specialized process used to manufacture them. Aside from the prior art references in Grounds 1-3, the Petition is devoid of any substantive discussion of the general state of the art prior to the '532 patent. However, a basic understanding of the technology and the state of the art permits one to immediately appreciate that the grounds raised in the Petition are fatally deficient. DSM summarizes that background information here.

A. UHMWPE Is a Unique Form of Polyethylene

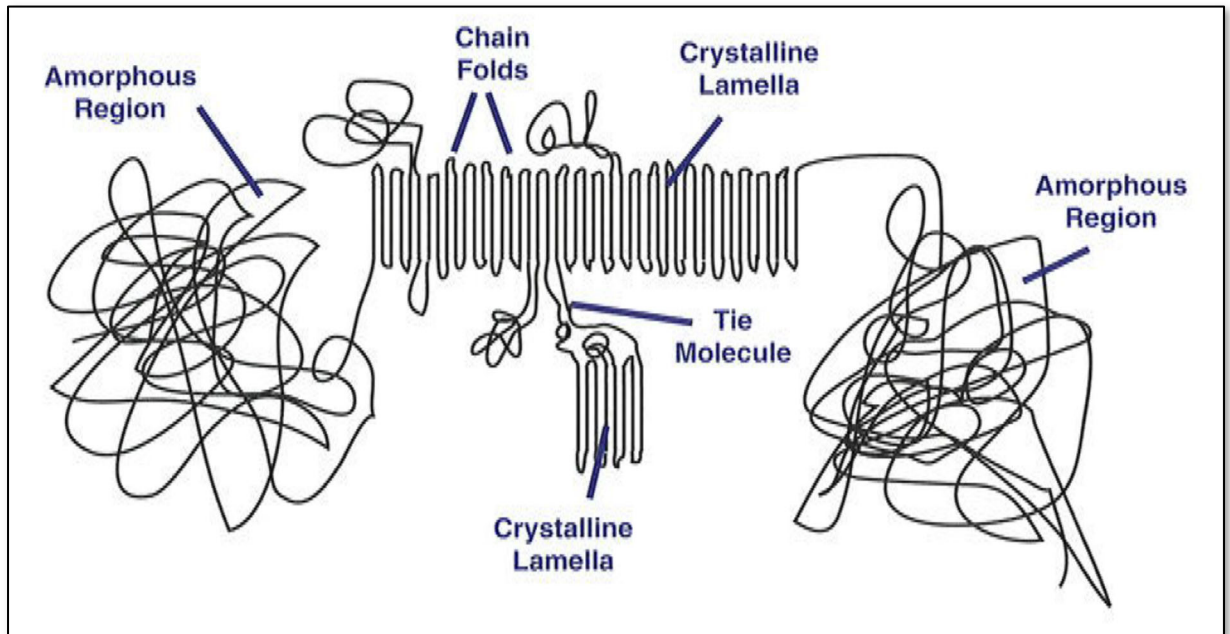
Polyethylene is a polymeric material made from the polymerization of ethylene monomer gas:



(EX 2002, 4, FIG. 1.4). There are several types of polyethylene, which differ by their (i) molecular weights and (ii) side-chain architectures (*i.e.*, the extent of alkyl group branching off the C-C polymeric backbone): (a) low-density polyethylene, (b) linear low-density polyethylene, (c) high-density polyethylene, and (d) UHMWPE. (*Id.*, 3-4). Low-density polyethylene (“LDPE”) has a branched side-chain architecture and a molecular weight typically below 50,000 g/mol. (*Id.*). Linear low-density polyethylene (“LLDPE”) has a similar molecular weight but very little side-chain branching. (*Id.*). High-density polyethylene (“HDPE”) is a linear polymer with a typical molecular weight of up to 200,000 g/mol and very little side-chain branching. (*Id.*). UHMWPE is also a linear polymer but has a substantially higher molecular weight up to 6 million g/mol—so high that it is typically measured indirectly from its intrinsic viscosity. (*Id.*; *see also* EX1022; EX1032).

UHMWPE is a unique polymer exhibiting favorable physical and mechanical properties, including inertness, lubricity, impact resistance, and abrasion resistance. (EX2002, 1). Although UHMWPE has a “deceptively simple chemical composition, consisting of only hydrogen and carbon[,]” it contains a “complex hierarchy of organizational structures at the molecular and supermolecular length scales.” (*Id.*). For example, the molecular backbone of polyethylene has a tendency to rotate about the C-C bonds and create chain folds,

which enables the molecules to form locally ordered, sheet-like regions known as crystalline lamellae. (*Id.*, 6). The crystalline lamellar regions are embedded with non-crystalline, amorphous regions and may be tied to other crystalline, lamellar regions through “tie molecules,” as illustrated below:



(*Id.*, 6-7, FIG. 1.6).

Most bulk UHMWPE is about 50-55% crystalline and is therefore deemed semicrystalline in such form. (*Id.*, 8). Bulk HDPE also exhibits a relatively high degree of crystallinity in bulk form. (*Id.*, 5 (noting HDPE exhibits 60-80% crystallinity)). As the temperature of a semicrystalline polymer is raised above the melting point, it may undergo a phase transition and become a flowing liquid. (*Id.*, 8). Polyethylene grades with a molecular weight less than 500,000 g/mol (such as LDPE and HDPE) undergo such a transition and can be extruded through an orifice

when heated to a temperature above their melting point. (*Id.*). When the molecular weight is above 500,000 g/mol, however, entanglement of the polymeric chains prevents the polymer from flowing in its melted state. (*Id.*, 8-9). Consequently, unlike LDPE and HDPE, UHMWPE does not flow above its melting temperature.¹ (*Id.*). Because spinning UHMWPE yarns from the melted polymer “is almost impossible due to the extremely high melt viscosity” (EX1014, 63), UHMWPE yarns cannot be manufactured by melt spinning and requires a specialized process called gel spinning first invented in 1979, as will be described in Section II.D, *infra*.

Unlike the other types of polyethylenes, this gel-spinning process allows UHMWPE to be spun into yarns that are 10-15 times stronger than quality steel. Thus, UHMWPE is not interchangeable with other types of linear polyethylenes.

B. The Advent of Section 73.1015 for Pigmented Linear Polyethylene

All three grounds of alleged unpatentability raised in the Petition rely on Section 73.1015. (Pet., 2). In a footnote, the Petition suggests that this regulation “can be traced back to at least 1977.” (*Id.*, 11, n. 4). This regulation arose in response to the Color Additive Amendments of 1960 (the “1960 amendments”) to the Food,

¹ For context, UHMWPE with an intrinsic viscosity of 8 dl/g—the lower end of the range of the Challenged Claims—has a molecular weight of about 930,000 g/mol. (EX1001, 2:56-60).

Drug, and Cosmetics Act (the “FDCA”). Under the 1960 amendments, a color additive can be used in food, drugs, cosmetics, and medical devices only if it is deemed “suitable and safe” for an approved use subject to certain restrictions (called “use restrictions”). (EX2003, 3).

Color additives required to be listed by the FDA are either subject to or exempt from a batch certification process. (*Id.*, 4). Batch certification requires that each newly manufactured batch of color additive must comply with their listing regulations. (*Id.*). Color additives exempt from such certification process do not need to be certified on a batch-by-batch basis. (*Id.*). Moreover, color additives that were in commercial use at the time of the 1960 amendments could be provisionally listed and used on an interim basis until they were permanently listed. (*Id.*, 3). Permanently listing a color additive for a specific use is permitted only after scientific data establishes its safety for that use. (*Id.*). Thus, absent justification that any deviation from the approved use restrictions does not impact product safety, the use of a listed color additive that does not conform to the FDA’s use restrictions may be subject to an enforcement action taken against products containing such additive. (*Id.*).

Chromium-cobalt-aluminum-oxide pigment was “provisionally listed” in 1965 at 21 C.F.R. § 8.501(f) for “[p]olyethylene surgical suture use only” “on the basis of prior commercial sale.” (EX2004, 97). It was permanently listed and

exempted from batch certification ten years later at 21 C.F.R. § 8.6010 (1975) subject to the same use restrictions that are applicable today. (EX2005, 146; *see also* EX2006; EX2007). Two years after that, the Code of Federal Regulations was renumbered, and what was 21 C.F.R. § 8.6010 (1975) became 21 C.F.R. § 73.1015 (1977), which remains in effect today. (*Compare* EX2008, 187 *with* EX1006, 357).

Accordingly, the regulatory approval set forth in Section 73.1015 is based on a blue linear polyethylene suture that was commercially available prior to the 1960 amendments. The Petition fails to identify or provide any details about this commercial suture. Although the chromium-cobalt-aluminum oxide pigment additive was ultimately deemed safe for use in linear polyethylene sutures subject to the specific use restrictions of what eventually became Section 73.1015, those linear polyethylene sutures failed so frequently in practice that surgeons had stopped using them within only a few years of their introduction into the market in the 1960s.

C. Early Blue Linear Polyethylene Sutures Failed Due to “Creep”

Surgeons began experimenting with blue polyethylene sutures in the early 1960s. (*See generally* EX2009; EX2010; EX2011; EX2012; EX2013). The blue polyethylene used to make these sutures was commercially available from the American Cyanamid Company and sold under the tradename Marlex. (EX2011,

967; EX2012). Shortly thereafter, the American Cyanamid Company filed a petition with the FDA in 1964 requesting the listing of the chromium-cobalt-aluminum oxide pigment “for use in or on surgical sutures made of linear polyethylene.”² (EX2014, 2). The pigment was manufactured by the Ferro Corporation. (*Id.*, 3). According to the FDA petition, the pigment is blended with the linear polyethylene resin, heated to 500-550° F, and then the mixture is hot-melt extruded through a fixed orifice. (*Id.*, 5). The filaments are cooled in air or water, oriented by cold drawing and set by annealing in a hot water bath—the result of which is a “strong, dimensionally stable filament whose colorant is firmly embedded in an inert, nontoxic matrix.” (*Id.*). The pigment may be present in an amount of up to 2% by weight. (*Id.*, 9). The FDA petition provided results from animal studies demonstrating that the blue-pigmented linear polyethylene sutures showed no toxigenic or tumorigenic properties after 2 years in rats. (*Id.*, 19-21).

Two important points necessarily follow. First, the use restrictions now reflected in Section 73.1015 derive from the American Cyanamid Company’s color additive petition from 1964. Second, a PHOSITA would have understood that *the “linear polyethylene” described in the color additive petition—and therefore Section 73.1015—is not UHMWPE* because (i) UHMWPE does not flow when melted and

² The American Cyanamid Company’s FDA color additive petition was publicly available as of December 1984. (EX2014, 1).

cannot be hot-melt extruded (*see* Section II.A, *supra*) and (ii) UHMWPE yarns were not commercially available until DSM invented the gel-spinning process 15 years later in 1979 (*see* Section II.D, *infra*).

The American Cyanamid Company patented its colored linear polyethylene sutures in Great Britain in 1961 and the United States in 1967. (EX1030, 101-105; EX2015). GB879,069 appears on the face of the '532 patent and was expressly considered by the examiner. (EX1001; EX1002, 53). According to this patent, “linear polyethylene . . . as either a monofilament suture or as a braided or woven suture constructed from a plurality of smaller filaments . . . give a suture which is unexpectedly and uniquely useful to the surgeon.” (Ex. 1030, 102). It further discloses that “[i]t is desirable that the suture be one that can be colored so that it contrasts with tissues and can be easily located in the operating field even though it is of small diameter.” (*Id.*). The U.S. patent—No. 3,359,983—goes further and identifies the linear polyethylene as HDPE: “high-strength, heat-resistant, **high density polyethylene** . . . as either a monofilament suture or as a braided or woven suture constructed from a plurality of smaller filaments . . . gives a suture which is unexpectedly and uniquely useful to the surgeon.” (EX2015, 2:28-35 (emphasis added)). The identification of the suture material being HDPE—and not UHWMPE—is consistent with the hot melt extrusion process described in Section 73.1015 and the American Cyanamid Company’s FDA petition.

Blue linear polyethylene sutures were commercialized and discussed in the medical literature in the mid- to late-1960s. (See, e.g., EX2016 at 194-99 (comparing blue linear polyethylene suture performance to braided waxed silk, iodized catgut, and twisted steel)). But their actual use was short-lived. It quickly became clear that the “linear polyethylene” sutures of the 1960s failed in human clinical practice and resulted in aneurysms significantly more frequently than other materials:

Polyethylene suture material was used for a two-year period (1965 to 1967) and was soon abandoned because of early suture failures.

(EX2017, 413). By 1980, surgeons no longer used these linear polyethylene sutures. (See, e.g., EX2018 (failing to identify polyethylene as a suture material used in the 1980s)).

These early failures of polyethylene sutures were due to a phenomenon now known to weaken polyethylene over time that remains an important consideration for polyethylene sutures even today: **creep**. (See EX2019, 98 (“Because . . . polyethylene sutures lose tensile strength with time, their use in synthetic anastomoses has been abandoned by most surgeons.”)). As Petitioner’s declarant explains, “[c]reep is the long term, longitudinal deformation of a material over time when subjected to a continuing load.” (EX1003, ¶ 65). In a polymeric

material, “[c]reep over a long period of time was generally known to result in breakage or compromised integrity over time[.]” (*Id.*). Because “polyethylene . . . does not have a hydrogen bond between molecular chains[.]” it “readily creeps.” (EX1008, 2). “[I]n medical applications . . . creep over a long term could potentially cause harm” such as “separation of bones or other sutured items.” (EX1003, ¶ 65). “[E]longated or failed sutures would be unacceptable in medical applications[.]” and “creep resistance” is a “necessary consideration for the production of sutures” made of polyethylene for that reason. (Pet., 33).

Accordingly, surgeons long ago abandoned blue polyethylene sutures—that is, until the 2007 filing of the ’532 patent, which was more than 40 years after the FDA’s provisional listing of chromium-cobalt-aluminum-oxide pigment for linear polyethylene.

D. DSM’s Gel Spinning Process in 1979 Led to the First Commercialization of Uncolored UHMWPE Yarns

As explained in Section II.A, *supra*, certain grades of polyethylene (*i.e.*, LDPE and HDPE) exhibit flow when heated above their melting temperature and can therefore be extruded. This process, which does not use a solvent to dissolve the polyethylene, is known as hot melt extrusion or melt spinning. (*See* EX1003 at ¶ 185 (explaining that Section 73.1015 “may be interpreted as being consistent with a melt process”)). In such a process, the polymer is melted, and then the molten polymer (called the “melt”) is forced under high pressure through an

orifice. (See, e.g., EX2014, 5; see also EX1003, ¶ 53 (explaining that melt spinning forms fibers by “melting a polymer substance and then extruding it through a spinneret”)). For LDPE and HDPE, melt spinning is easy to accomplish because “the molecules are . . . easily torn apart.” (EX1014, 63).

That is not the case for UHMWPE. As the Petition evidence explains:

The problem is that spinning [UHMWPE] fibres from the melt is *almost impossible* due to the extremely high melt viscosity. Furthermore, the drawing of a melt-processed UHMW-PE is *only possible to a very limited extent* owing to the high degree of entanglement of the molecular chains.

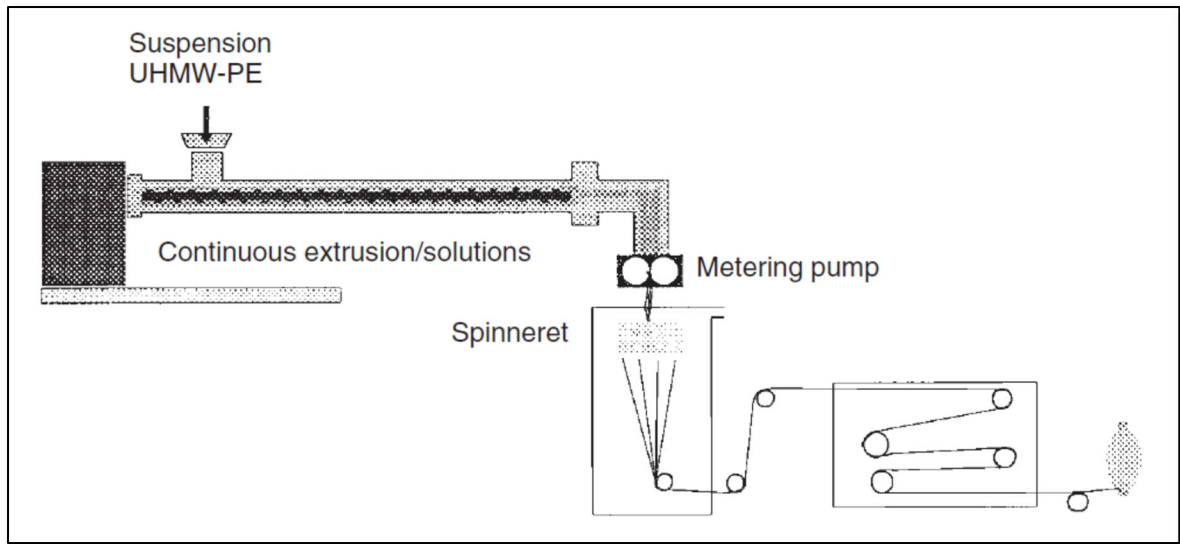
(*Id.* (emphases added); see also EX1030, 218 (distinguishing prior art melt-spinning process because UHMWPE “resins could not be melt-spun”)). Thus, in melt spinning, UHMWPE creates problems at both the spinning and drawing stages. In 1979, DSM was the first to overcome these problems and patented its gel spinning process—technology that Honeywell originally licensed. (EX1014, 63-64). Gel spinning enabled the first manufacture of high-strength UHMWPE yarns. (*Id.*; see also EX2020, 1 (“[T]he very high viscosity of molten UHMWPE . . . has, for a long time, prevented the material being formed into fibres, until the discovery of the so-called gel spinning process by DSM in the Netherlands.”)).

The gel spinning process solves both of the problems associated with melt-spinning UHMWPE by dissolving the UHMWPE in a solvent and spinning that solution (*i.e.*, the UHMWPE dissolved in the solvent) through a spinneret. (EX1014, 63-64). “In the solution the molecules become disentangled and remain in that state after the solution is spun and cooled to give filaments.” (*Id.*). These filaments can then be drawn to a high extent to provide UHMWPE filaments having a “very high level of macromolecular orientation[,]” which provides “a very high tenacity and modulus.” (*Id.*). Thus, the presence of a solvent—called a “spin solvent”—during spinning is a necessary feature of the gel spinning process. This is confirmed by the specification of the ’532 patent:

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

(EX1001, 2:31-37 (emphases added); *see also id.* at claim 1 (claiming filaments obtained by gel spinning UHMWPE, spin solvent, and pigment)).

The gel spinning process is generally illustrated below:



(EX1014, 65, FIG. 3.2; *see also* EX1003, ¶¶ 51-52 (citing EX1014, 63-67)).

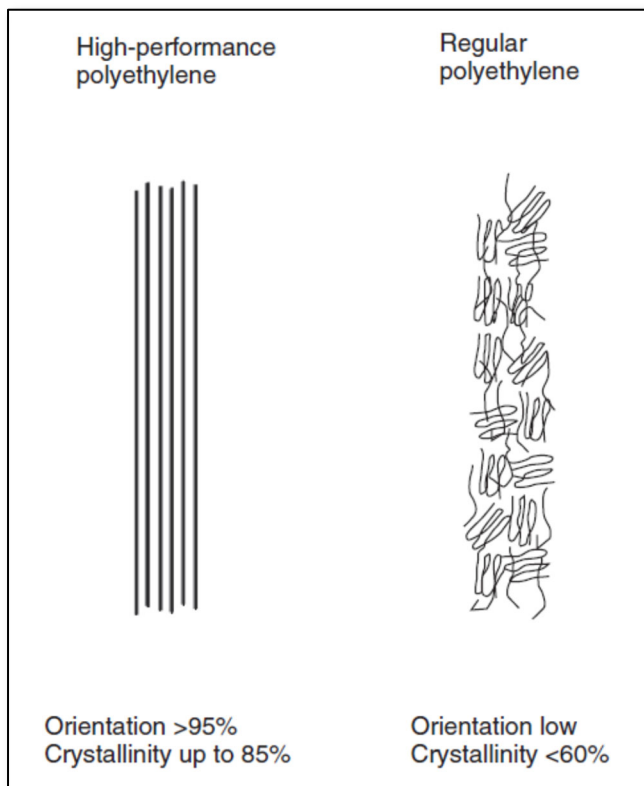
UHMWPE is a flexible polymer that can be manufactured into very strong yarns due to intermolecular interactions called Van der Waals forces between individual polyethylene molecules that make up the filaments. (EX1014, 65). On an atom-by-atom basis, Van der Waals forces are extremely weak. (*Id.*). However, due to its size, UHMWPE has a sufficient number of atoms that all the Van der Waals forces taken together can provide substantial strength to the yarn—so long as there is high overlap lengths between the polyethylene molecules within the filaments. (*Id.*).

Molten UHMWPE can be processed by compression molding or ram extrusion, which is used to manufacture joint and other orthopedic implants. (EX2020, 1; *see also* EX2002, 22-32 (describing compression molding and ram extrusion for manufacturing orthopedic implants); EX1003, ¶ 45 (noting use of

UHMWPE as prosthetic joint replacements)). However, melt-processed UHMWPE can only be drawn up to 5 times its original length because the “interaction between the molecular chains is too high [due to] molecular entanglements.” (EX1014, 66). When dissolved in a spin solvent, “the molecules disentangle” and “assume a roughly spherical shape[.]” (*Id.*). “As soon as strain is applied when the solution is pressed through the spinneret, the molecules are forced into a more elongated form[.]” which is the first step in molecular orientation during the gel spinning process. (*Id.*).

The spin solvent used is one in which the polyethylene dissolves at higher temperatures and from which it easily crystallizes at lower temperatures. (*Id.*). Thus, in the gel spinning process, the polyethylene is dissolved in a hot spin solvent and spun through the spinneret. (*Id.*). The solution is then cooled and solvent removed to form gel filaments and eventually a solid multi-filament yarn. (*Id.*). After removal of the solvent, the filaments contain crystalline and non-crystalline regions and are therefore drawn to convert lamellar crystals with folded chains and non-crystalline regions into long, thread-like crystals with extended chains. (*Id.*, 67). This drawing process allows substantial overlap and maximum Van der Waals interactions between the polyethylene molecules in the highly crystalline filaments.

The result is polyethylene filaments with increased crystallinity and high orientation, as illustrated below (left):



(EX1014, 64, 67, FIG. 3.1). UHMWPE yarns made from these filaments exhibit high strength and high modulus. (*Id.*, 69). The tenacity is 10-15 times that of quality steel. (*Id.*). This strength is due to the very high draw ratio (50-100 times the original length of the yarn) obtained through the gel-spinning process, which increases the number of overall Van der Waals interactions between polyethylene molecules in the highly orientated, highly crystalline filaments. (*Id.*, 62-66). Effectively, this high molecular orientation increases the amount of energy it takes

to separate the polymeric chains within each filament, giving multi-filament UHMWPE yarns their superior strength.

The importance of the Van der Waals interactions created by the gel spinning process cannot be overstated, especially as it relates to creep. Ohta explains that “polyethylene has a drawback in that it does not have a hydrogen bond between molecular chains and readily creeps. These drawbacks significantly limit the scope of application of polyethylene fiber in applications where long-term loads are applied.” (EX1008, 2). “As a result of diligent research,” Ohta “discovered that there is little disorder in the crystal structure in polyethylene fiber and that creep resistance is more favorable the more scarce impurities other than polyethylene are[.]” (*Id.*). In other words, “the greater the amount of impurities such as residual solvent and additives, the worse the creep resistance” of the resulting UHMWPE fiber. (*Id.*). Ohta explains “it is presumed that disorder in the crystal[line UHMWPE] causes weaker intermolecular force[s], promoting slip between molecular chains[.]” (*Id.*). Ohta teaches that it “is important . . . to reduce defects and impurities in the fiber crystals as much as possible [to] improve creep resistance.” (*Id.*, 3). Ohta further teaches “that it is important that the amount of residual components other than . . . polyethylene that are contained in the polyethylene fiber, specifically, the amount of solvent and additives, be 1000 ppm

or less in terms of weight fraction.” (*Id.*). “When the residual components exceed 1000 ppm, the creep resistance deteriorates significantly.” (*Id.*).

Thus, Ohta expressly teaches that for UHMWPE yarns in which creep resistance is an important consideration, less than 1000 ppm of residual spin solvent and other additives should be contained within the UHMWPE filaments. The Examiner even acknowledged this point during prosecution of U.S. Patent No. 9,506,168 (the “’168 patent”), which is the parent of the ’532 patent: “the more pure the material, UHMWPE, and the less of other constituent[s] or other material, the stronger the strength for the suture.” (EX1030, 279).

The Petition concedes that creep is an important consideration when designing a polyethylene yarn for medical sutures. (Pet., 33; *see also* EX1003, ¶ 65 (noting creep in UHMWPE yarn “result[s] in the separation of bones or other sutured items”)). Accordingly, as of the priority date of the ’532 patent, a PHOSITA would have appreciated the importance of minimizing the amount of spin solvent and other additives (such as pigments) in the UHMWPE filaments to provide superior tensile strength and creep properties needed for medical sutures.

E. Prior Attempts to Color UHMWPE Yarns With Pigments Failed

The ’532 patent claims certain UHMWPE yarns colored with a chromium oxide-based pigment contained within the polyethylene filaments. (EX1001, claim 1). UHMWPE had been used in medical suture applications for more than a

decade prior to the '532 patent. (EX1003, ¶ 47 (citing Ex. 1015)). Yet despite the “design need for [blue-]colored sutures . . . having high strength,” (Pet., 9-10 (citing EX1003, ¶ 175)), the Petition does not identify any example in which a chromium-oxide containing pigment was used to color the filaments in a medical-grade UHMWPE yarn until the inventors successfully did so in the '532 patent. This is not surprising because the prior art demonstrates that others had repeatedly tried to color UHMWPE yarns prior to the '532 patent without impacting its strength and/or processability but failed.

“Owing to their chemical inertness and high crystallinity,” the conventional wisdom in the art at the time of the '532 patent was that coloring UHMWPE yarns “is *extremely difficult*.” (EX1014, 82 (emphasis added)). These difficulties are explained in detail in the specification of the '532 patent. (EX1001, 1:28-2:13). The '532 patent states that “it is disadvised in U.S. Pat. No. 5,613,987 [(“'987 patent)]to use pigments in UHMWPE filaments.” (*Id.*, 2:2-3). The Petition dismisses this statement because allegedly “none of [the] purported problems [described in the specification] came from prior failed attempts to color UHMWPE filaments.” (Pet., 9). But the Petition ignores the teachings of the prior art '987 patent.

The '987 patent discloses coloring UHMWPE yarns using a dye that is soluble in the spin solvent:

The process for producing a colored high-tenacity fiber of ultra-high molecular weight polyethylene according to the present invention is characterized in that a dye for coloration which is substantially soluble in a solvent used for preparing a solution of ultra-high molecular weight polyethylene at the melting temperature of solvent-containing filaments which are obtained by spinning a solution of ultra-high molecular weight polyethylene is added to the solution of ultra-high molecular weight polyethylene at an amount below the solubility thereof in the solvent at the melting temperature of solvent-containing filaments.

(EX2021, 3:7-17). This is exemplified in Example 1 of the '987 patent, in which a UHMWPE yarn was colored by a gel spinning process where Solvent Green 28 (an organic dye) was dissolved with the UHMWPE in the spin solvent. (*Id.*, 5:5-32). This process, which results in a solution containing the UHMWPE and dye dissolved in the spin solvent, produced colored UHMWPE yarns. (*Id.*). However, as the '532 patent explains, this type of dye tends to leach out of the filaments and is therefore unsuitable for medical suture applications. (EX1001, 1:43-51).

As noted during prosecution of the DSM parent '168 patent, the art typically

distinguishes between a (i) dye, which readily dissolves in the spin solvent and forms a solution, and (ii) pigment, which does not dissolve in the spin solvent and therefore forms a suspension. (EX1030, 265-66). In contrast to dyes, when pigments were used during the gel spinning process of the '987 patent, suitable yarns were not obtained. In Comparative Example 1, carbon black was used as the pigment, but the resulting “fibers were not satisfactory from an operational point of view because of an increase in the back pressure of the nozzle filter and a frequent occurrence of fiber breaking” such that a satisfactory yarn could not be produced. (EX2021, 5:35-45). This was attributed to the insolubility of carbon black in the spin solvent. (*Id.*). A similar failure was observed in Comparative Example 4, which employed insoluble Pigment Blue 15. (*Id.*, 6:1-12). The malachite green oxalate pigment employed in Comparative Example 2 also resulted in a significant and undesired reduction in the tensile strength of the yarn due to the insolubility of the pigment in the spin solvent. (*Id.*, 5:46-58).

The teachings in the prior art '987 patent are consistent with the disclosures of both the Ohta and Nanri references on which the Petition relies, as explained in more detail in Section VI, *infra*. Ohta teaches that the introduction of defects into crystalline UHMWPE due to small levels of impurities increases creep significantly and weakens the UHMWPE filaments. (Ex. 1008, 2-3). Nanri discloses a process to color UHMWPE using carbon black. (Ex. 1007). Nanri

explains that “when the average particle diameter exceeds 100 nm, it acts as a defect during crystallization, and the colored high-strength polyethylene fiber obtained as a result thereof has low strength.” (*Id.*, 2). Nanri also discloses that particle migration occurs when the particle size is less than 10 nm, which is not desirable. (*Id.*). Nanri thus teaches away from using pigments to color UHMWPE yarns except in the special case of when the particle size falls within the narrow nanoscale range of 10-100 nm. (*Id.*).

Accordingly, the conventional wisdom at the time was that adding standard pigments during the gel spinning process to color UHMWPE yarns would negatively impact the gel-spinning process and the tensile strength and creep properties of the resulting UHMWPE filaments. (EX1008, 2-3).

III. THE '532 PATENT CLAIMS INNOVATIVE CHROMIUM OXIDE-COLORED UHMWPE YARNS

Bucking this conventional wisdom, Patent Owner developed the world’s first blue, UHMWPE yarn using a chromium oxide-containing pigment. This was “a significant industry milestone” due to its “potential to enable surgeons to work more confidently and effectively by eliminating multiple suture strand confusion and ultimately minimize error and improve patient outcomes.” (EX2022).

In recently launching its own competing products 15 years after the 2007 priority date of the '532 patent, Petitioner extolled the innovative nature of blue UHMWPE yarns:

[A] blue-hued fiber . . . provides a strong visual aid to better differentiate between multiple suture sets in more complex surgeries. *By creating a clear color contrast, the new fiber enables healthcare professionals to operate more accurately and efficiently, promoting greater safety and comfort for patients.*

“We are providing major manufacturers the opportunity to modernize orthopedic devices and improve surgical methods with *our colored Spectra MG Bio fiber*, and to deliver *that innovation* in a collaborative, supportive manner,” said Abey Paul, business leader for Spectra MG Bio Fiber at Honeywell. “*This technology is extremely important for orthopedic applications around the world,* fostering successful procedures that protect both patients and professionals[.]”

. . . . For the orthopedic market, *colored Spectra MG Bio fiber provides new advantages* for both existing devices and emerging trends used in corrective surgeries, such as robotics that reduce procedure durations and smart implants that flag dangerous bacterial presence. *This*

advancement will help to support the growing worldwide market for orthopedic devices[.]

(EX2023 (emphases added)). Notably, Petitioner’s products employ the same blue pigment—a chromium-cobalt-aluminum oxide referred to as C.I. Pigment Blue 36—disclosed and claimed in the ’532 patent and used in Patent Owner’s commercial products. (EX2024, 20, ¶ 39 (pleading that “Honeywell’s Spectra® BIO Blue products use the same *FDA-approved* pigmentation in DSM’s PURITY® Products.”); EX2025 (identifying Petitioner’s blue UHMWPE yarn products as containing C.I. Pigment Blue 36)).

A. The Claimed Colored Multi-Filament UHMWPE Yarns Are Novel Advancements Over the Prior Art

The inventors discovered that a chromium-oxide containing pigment could be introduced during the gel spinning process to provide a colored multi-filament yarn. (EX1001, 5:37-6:61). Slurries containing decalin (a spin solvent), 6 mass % of UHMWPE powder having an intrinsic viscosity of 14 dl/g, and 0.5, 1, 1.5, and 2 wt.% of an aluminum-chromium-cobalt oxide pigment (32.5% Co, 32% Al, and 35.5% Cr) were prepared. (*Id.*, 5:39-43). The colored slurries were fed into a screw extruder with a gear pump at a temperature of 180° C to dissolve the UHMWPE in the decalin. (*Id.*, 5:44-46). The mixtures were extruded through a spin plate having 24 spin holes into a nitrogen atmosphere at a rate of 1.0 g/min per hole. (*Id.*, 5:46-50). The gel filaments obtained were cooled in a water bath at 35°

C and drawn at a ratio of 15 in a 15 mm air gap. (*Id.*, 5:50-55). The filaments entered an oven at 130° C and were further drawn, and residual decalin solvent was removed. (*Id.*, 5:55-60). Surprisingly, the resulting yarns had favorable mechanical (*i.e.*, tenacity, modulus, and elongation at break), leaching, and cytotoxicity properties compared to yarns that had been colored using other methods. (*Id.*, 5:61-67, TBL. 1).

The '532 patent contains one independent claim:

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

(EX1001, 6:64-7:5). Claims 2-9 depend from claim 1 and further recite narrower ranges of pigment, spin solvent, and further constituents. (*Id.*, 7:6-25).

B. The '532 Patent Issued After 8 Years of Prosecution of Its Family

Although the '532 patent was granted after overcoming a nonstatutory double patenting rejection in the first Office Action (*see generally* EX1002), the path to its allowance was not unimpeded, despite the Petition's insinuation to the contrary. (Pet., 3). The '532 patent is a continuation of the '168 patent. (Pet., 3; EX1001; EX1029). The Petition concedes that the prosecution of the '168 patent "was much more extensive[.]" (Pet., 3). In fact, the '168 patent endured more than eight years of a robust back-and-forth with the Patent Office before being granted. (*See generally* EX1030).

During that time, the Examiner was fully engaged in prosecution. In assessing the patentability of the '168 patent, the examiner conducted a multitude of prior art searches and considered numerous prior art references. (EX1030, 175-179, 199-204, 240-253, 283-290, 316, 354-364, 372-382, 405-415). The Examiner issued numerous Office Actions containing substantive rejections to the pending claims. (*Id.*, 170-174, 193-198, 228-239, 276-282, 310-315, 365-370). And the claims were amended multiple times all along the way. (*Id.*, 181-187, 211-220, 254-270, 291-302, 383-392). Thus, the summary of the prosecution of the '168 patent by Petitioner's declarant understandably spans more than 40 paragraphs over the course of 20 pages. (EX1003, ¶¶ 98-144).

The Petition dismisses this prosecution history because the '168 patent allegedly has “different claims.” (Pet., 3). But there is substantial overlap between the claim limitations of the '532 and '168 patents, and the '532 patent was terminally disclaimed over the '168 patent. (*Compare* EX1001, claim 1 with EX1029, claim 1; EX1002, 44-48, 69-70). Accordingly, the prosecution history of the parent '168 patent is relevant to the Challenged Claims.

The '532 patent therefore is not an example of a patent that was improvidently granted early in the prosecution stage without due consideration. It is the result of the Patent Office’s years-long consideration of the claim limitations that were ultimately granted. As demonstrated below, the art raised in the Petition fares no better than the voluminous art already raised and considered during prosecution, and *inter partes* review should be denied.

IV. LEVEL OF ORDINARY SKILL IN THE ART

Based on the disclosure of the '532 patent as well as the references cited in the Petition, a PHOSITA would have (i) a bachelor’s degree in chemistry, polymer chemistry, materials science, chemical engineering, or biomedical engineering and (ii) three years of experience in designing and manufacturing gel-spun UHMWPE yarns. At this level of skill, a PHOSITA would have a detailed understanding of the information provided in the Technology Background, Section II, *supra*, including (i) the differences between linear HDPE and UHMWPE, (ii) the history

underlying Section 73.1015 and the early failures of the 1960s-era blue, melt-extruded polyethylene sutures, (iii) why the molecular orientation of polyethylene molecules leads to strong yarns in the special case of gel-spun UHMWPE, and (iv) the challenges associated with coloring gel-spun UHMWPE yarns, especially for end-use medical applications.

V. “GEL SPINNING” IS A LIMITATION THAT REQUIRES SPINNING FILAMENTS FROM A SOLUTION OF UHMWPE IN A SPIN SOLVENT

Although it must specify “[h]ow the challenged claim is to be construed[.]” 37 C.F.R. § 42.104(b)(3), the Petition here fails to provide constructions for any terms and instead contends that “the terms discussed herein are to have their plain meaning.” (Pet., 5). However, the Petition makes at least two arguments that implicate the scope of the “gel spinning” term. *First*, the Petition suggests that the gel spinning process disclosed in Simmelink is “not inconsistent” with the pigmentation process of Section 73.1015. (Pet., 14 (citing EX1003, ¶ 185)). *Second*, the Petition suggests that the gel spinning term [1.A] should not be given patentable weight “as a process in a product by process claim[.]” (Pet., 16-17, 39-41, 54-55). Because the Petition is wrong on both counts, Patent Owner addresses certain aspects of the scope of the claimed gel spinning term [1.A] here. *See Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1361 (Fed. Cir. 2011) (noting claim construction is necessary when needed to resolve dispute).

A. “Gel Spinning” Requires Spinning a Solution of UHMWPE in a Spin Solvent

According to Dr. Grubb, the “coloring procedure” described in Section 73.1015 “is not inconsistent with the gel spinning process disclosed in Simmelink.” (EX1003, ¶ 185). But in the very next sentence, he suggests that Section 73.1015 “may be interpreted as being consistent with a melt process[.]” (*Id.*). Accordingly, it is appropriate to consider the scope of the gel spinning limitation [1.A] to determine whether the “pigmentation process” described in Section 73.1015 is a gel-spinning or melt-spinning process.

Forming UHMWPE filaments by spinning a solution of UHMWPE *in a spin solvent* is a necessary feature of the claimed gel spinning term. (EX1014, 64-67). This is confirmed by the specification of the ’532 patent:

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

(EX1001, 2:31-37 (emphases added)). The claim language also confirms that a solvent is used in gel spinning. (*Id.* at claim 1 (claiming filaments obtained by gel spinning UHMWPE, spin solvent, and pigment)).

In contrast, solvents are not used in melt spinning. (*See* EX1014, 63-65 (distinguishing between melt spinning and gel spinning); EX1030, 218 (noting melt spinning does not employ solvent and instead uses a “dry blend of resin”)). As Dr. Grubb explains:

The person of ordinary skill in the art would have understood that in the melt spinning process, fibers are formed by melting a polymer substance and then extruding it through a spinneret. The substance is then solidified by cooling. Unlike UHMWPE, which has a high melt viscosity, nylons and polyesters have lower melt viscosities and, thus, *solvents are generally not used.*

(EX1003, ¶ 53 (emphases added); *see also id.*, ¶ 185 (noting that gel spinning differs from melt spinning due to “the addition of an inert solvent”)).

Accordingly, a PHOSITA would understand that a spinning process is not “gel spinning” according to limitation [1.A] if it does not use a solvent to dissolve the UHMWPE during the spinning process. (*See* EX1014, 63-65 (distinguishing

melt spinning and gel spinning)). This distinction between melt spinning, which does not use a solvent, and gel spinning has important implications when considering the prior art combinations raised in Grounds 1-3, as will become clear in Section VI, *infra*.

B. The “Gel Spinning” Term Is Entitled to Patentable Weight

Next, Dr. Grubb contends that “no patentable weight should be given to” the gel spinning term [1.A]. (EX1003, ¶¶ 198, 343, 451). His conclusory opinion is not supported by law or fact.

“Words of limitation that can connote with equal force a structural characteristic of the product or a process of manufacture are commonly and by default interpreted in their structural sense[.]” *3M Innovative Props. Co. v. Avery Dennison Corp.*, 350 F.3d 1365, 1371-72 (Fed. Cir. 2003). Thus, although “the patentability of product claims that contain process limitations . . . is generally based on the product itself,” where the process provides “specific structure” to the product, the process limitations must be “afforded weight when assessing patentability.” *In re Nordt Dev. Co.*, 881 F.3d 1371, 1374-75 (Fed. Cir. 2018). Such is the case here.

Dr. Grubb admits that the gel spinning process provides structure to the claimed filaments:

Such a process makes the molecular chains of the polymer form a lightly entangled *structure*. This allows the gel filaments to be drawn to high draw ratios *which results in high stiffness and high tensile strength*.

(EX1003, ¶ 52 (emphases added)). Indeed, the gel spinning process (through spinning, gel filament formation, solvent removal, and drawing at a high draw ratio) creates overlap between polyethylene molecules within the UHMWPE filaments that maximizes the intermolecular Van der Waals interactions, resulting in highly crystalline filaments with high tensile strength. Section II.D, *supra*. Thus, the structure of gel spun UHMWPE is substantially different from other types of UHMWPE such as compression-molded and ram-extruded UHMWPE used to make joint replacements and other orthopedic implants. *Id*.

Because it imparts structure onto the claimed yarns, the gel spinning term [1.A] must be considered in assessing the patentability of the Challenged Claims. *See In re Nordt*, 881 F.3d at 1376 (reversing Board and finding that “injection molded” was entitled to patentable weight). This determination is relevant because the Petition relies on a prior art reference disclosing compression-molded UHMWPE to establish a purported reasonable expectation of success. (Pet., 14, n.5 (citing EX1028, 10:35-41)).

VI. THE PETITION FAILS TO DEMONSTRATE A REASONABLE LIKELIHOOD THAT ANY CHALLENGED CLAIM WOULD HAVE BEEN OBVIOUS

All grounds raised in the Petition rely on Section 73.1015, an FDA color additive regulation. The Petition makes much ado over the inventors' selection of the chromium-cobalt-aluminum oxide pigment disclosed in Section 73.1015 "[t]o facilitate regulatory approval" of Patent Owner's commercial products. (Pet., 11-12 (citing EX1010, 55-56)). But "[t]he inventor's own path itself never leads to a conclusion of obviousness; that is hindsight." *Otsuka Pharm. Co. v. Sandoz, Inc.*, 678 F.3d 1280, 1296 (Fed. Cir. 2012). "What matters is the path that the person of ordinary skill in the art would have followed, as evidenced by the pertinent prior art." *Id.* The prior art of record, when considered in its entirety, would have taught away from the path the inventors ultimately took in inventing the world's first blue-pigmented, medical-grade UHMWPE yarn. In reaching the opposite conclusion, the Petition falls "victim to the insidious effect" of litigation-driven hindsight and reconstructs the Challenged Claims based solely on the invention itself. *In re Kotzab*, 217 F.3d 1365, 1369 (Fed. Cir. 2000).

Petitioner's own evidence decisively explains that coloring UHMWPE yarns "is *extremely difficult*." (EX1014, 82 (emphasis added)). Pigment particles act as defects when incorporated into the crystalline structure of UHMWPE filaments, which would have been expected to weaken the resulting yarn making it prone to

breaking during the gel-spinning process and after implantation. *See* Section II.E, *supra*. The prior art, including art raised in the Petition, is replete with instances where others had tried to color UHMWPE yarns with pigments but repeatedly failed. (*See id.*). Section 73.1015—an FDA regulation dating from the 1960s originally covering non-UHMWPE sutures that failed so frequently surgeons abandoned their use more than 40 years ago (*see* Section II.B-C, *supra*)—discloses nothing that would have given a PHOSITA any motivation or expectation that its particular pigment could be successfully incorporated into gel-spun UHMWPE filaments while maintaining their strength. *See Endo Pharms., Inc. v. Actavis LLC*, 922 F.3d 1365, 1376-77 (Fed. Cir. 2019) (finding nonobviousness where FDA communications “would not have been enough to overcome the disclosures of [the prior art]”). “It is only with the benefit of hindsight that a person of skill in the art would have had a reasonable expectation of success in view of the asserted references.” *OSI Pharms., LLC v. Apotex Inc.*, 939 F.3d 1375, 1385 (Fed. Cir. 2019). “[W]here the prior art evidences only failures to achieve that at which the inventors succeeded, no reasonable fact finder could find an expectation of success based on the teachings of that same prior art.” *See Univ. of Strathclyde v. Clear-Vu Lighting LLC*, 17 F.4th 155, 165 (Fed. Cir. 2021).

Respectfully, *inter partes* review should be denied.

A. Ground 1 Fails to Meet the Institution Threshold

Ground 1 challenges the patentability of claims 1-9 based on alleged obviousness over the combination of Simmelink and Section 73.1015. (Pet., 9-29). But the Petition misreads the disclosures of both Simmelink and Section 73.1015 and inexplicably ignores the prior art as a whole, including the disclosures of Nanri, Ohta, and the '987 patent, all of which teach away from the path the inventors took in developing colored medical-grade UHMWPE yarns. For at least the reasons explained herein, the Petition fails to demonstrate a reasonable likelihood that the Challenged Claims would have been obvious in view of the Simmelink/Section 73.1015 combination.

1. There Are Significant Differences Between the Simmelink/Section 73.1015 Combination and the Challenged Claims

a. Simmelink Does Not Disclose Pigmented Medical-Grade UHMWPE Yarns

Simmelink discloses high-performance, multi-filament UHMWPE yarns manufactured using a gel-spinning process employing certain cone-shaped orifices and drawing procedures. (EX1005). Simmelink explains that for a commercially viable process, “it is important that such process can be run continuously without interruptions and with high throughput rate, with a high number of filaments in the as-spun yarn.” (*Id.*, 2:30-34). Simmelink discloses preferred spin solvents having boiling points less than 275° C. and “more preferably less than 250 or 225°C[.]”

(*Id.*, 8:35-9:5). The spin solvent used in all of Simmelink's working examples is decalin. (*Id.*, Examples 1-20).

Simmelink suggests its yarns are “an interesting material for use in various semi-finished and end-use products, like ropes and cords, mooring lines, fishing nets, sports equipment, medical applications, and ballistic-resistant composites.” (*Id.*, 2:4-7). Tensile properties and creep behavior are important considerations in determining the performance of UHMWPE yarns in many of these applications. (*Id.*, 2:35-3:2, 12:24-30). This is consistent with the Petition, which admits that for medical sutures made of polyethylene, creep resistance is an important property consideration. (Pet., 33; *see also* EX1003, ¶ 65). Not surprisingly, 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[.]” (EX1005, 12:6-7 (emphasis added)).

Simmelink discloses that “[t]he [ultra-high molar mass polyethylene] *applied in the process* according to the invention may further contain small amounts, generally less than 5 mass%, preferably less than 3 mass% of customary additives, such as anti-oxidants, thermal stabilizers, colorants, flow promoters, etc.” (*Id.*, 8:28-31 (emphasis added)). The Petition construes this statement to mean that the filaments in Simmelink's yarns may contain up to 5 mass% of customary additives. (Pet., 20 (citing EX1003, ¶ 210)). Importantly, that

interpretation is incorrect. Simmelink makes clear that this statement refers to the UHMWPE starting material, not the final UHMWPE in the filaments after gel-spinning and removal of the spin solvent. (EX1005,7:32-9:12). Simmelink does not disclose any UHMWPE yarn that contains such high amounts of additives in the UHMWPE filaments formed by its gel-spinning process.

Moreover, Simmelink does not disclose any UHMWPE yarn that was actually colored by any process, much less with a chromium-oxide containing pigment during the gel-spinning process. In fact, Simmelink does not disclose any particular colorant or coloring procedure at all and does not tie its purported “colorants” to any medical or suture application.

b. Section 73.1015 Does Not Disclose Gel-Spun UHMWPE Yarns

Although the Petition relies on the 2006 version of Section 73.1015, the regulation arose from a color additive petition filed by the American Cyanamid Company in 1964 with the FDA to use a specific chromium-cobalt-aluminum oxide in linear polyethylene surgical sutures. *See generally*, Sections II.B-C, *supra*. The early blue linear polyethylene sutures covered by this regulation performed poorly in clinical practice, and polyethylene was no longer used as a suture material by the 1980s. *See* Section II.C, *supra*.

Section 73.1015 discloses that “[t]he color additive chromium-cobalt-aluminum oxide may be safely used for coloring linear polyethylene surgical

sutures” subject to certain use restrictions. (EX1006, 357). Three of those use restrictions are relevant to this proceeding:

(1) For coloring procedure, the color additive is blended with the polyethylene resin. The mixture is heated to a temperature of 500°-550° F. and extruded through a fixed orifice. The filaments are cooled, oriented by drawing, and set by annealing.

(2) The quantity of the color additive does not exceed 2 percent by weight of the suture material.

...

(4) When the sutures are used for the purpose specified in their labeling, there is no migration of the color additive to the surrounding tissue.

(*Id.*). Three important points follow from these use restrictions.

First, because use restriction (1) does not disclose dissolving the “polyethylene resin” in a solvent during spinning, a PHOSITA would understand that Section 73.1015 discloses a melt-spinning process, not a gel-spinning process as claimed. (See EX1003, ¶ 53 (“[I]n the melt spinning process, fibers are formed by melting a polymer substance and then extruding it through a spinneret.”); see also Section V.A, *supra* (distinguishing melt spinning and gel spinning)). This is

consistent with the underlying color additive petition from which Section 73.1015 derives. (See EX2014, 5 (describing coloring process as “blend[ing the pigment] with the polyethylene resin prior to a hot melt extrusion”); *see generally* Section II.B, *supra*).

Second, because use restriction (1) of Section 73.1015 discloses a melt spinning process, a PHOSITA would understand that the “linear polyethylene” disclosed in Section 73.1015 is not UHMWPE. Petitioner’s own evidence demonstrates that “spinning [UHMWPE] fibres is almost *impossible* due to the extremely high melt viscosity” of UHMWPE. (EX1014, 63 (emphasis added); *see also* EX1030, 218 (noting UHMWPE resins cannot be melt spun); EX1003, ¶ 53 (noting solvent must be used when spinning UHMWPE due to its “high melt viscosity”)). That Section 73.1015 does not disclose UHMWPE is further confirmed by the fact that the regulation arose prior to the development of the gel-spinning process in 1979—a process that enabled the first commercially viable UHMWPE yarns. *See* Section II.C-D, *supra*.

Third, the Petition repeatedly asserts “Section 73.1015 teaches that ‘there is no migration of the color additive to the surrounding tissue.’” (Pet., 14 (citing EX1003, ¶ 186), 39 (citing EX1003, ¶ 333), 53 (citing EX1003, ¶ 442)). But this misconstrues Section 73.1015 and ignores important context from other language in the regulation. Based on the plain language of Section 73.1015 in full, a

PHOSITA would understand that the “chromium-cobalt-aluminum oxide may be safely used for coloring linear polyethylene surgical sutures” *but only if* “there is not migration of the color additive to the surrounding tissue” “when the sutures are used for the purpose specified in their labeling[.]” (EX1006, 357). One who seeks the batch certification benefit of Section 73.1015 must still demonstrate that the exempted pigment does not migrate out of the polyethylene in a given suture application.³ Accordingly, a PHOSITA would not understand use restriction (4) of Section 73.1015 to be generally applicable to all linear polyethylene sutures, especially those made of gel-spun UHMWPE yarns given that the linear polyethylene disclosed in Section 73.1015 is not gel-spun UHMWPE. Moreover, a PHOSITA would not understand use restriction (4) to mean that all sutures colored with the Section 73.1015 pigment are safe and effective, particularly given the known clinical failures associated with the early linear polyethylene sutures to which Section 73.1015 originally applied.

Section 73.1015 does not disclose pigmenting any gel-spun UHMWPE yarn and does not disclose the particle size of its chromium-cobalt-aluminum oxide pigment.

³ The '532 patent provides such data confirming that its pigment does not leach out from the filaments. (EX1001, Examples I-IV).

2. *There Was No Motivation to Combine Simmelink with Section 73.1015*

a. **The Incompatibility of the Pigmentation Process of Section 73.1015 With Simmelink's Gel-Spinning Process Teaches Away From the Challenged Claims**

The Petition contends that “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[.]” (Pet., 12 (emphasis added)). This contention is misguided.

The pigmentation process of Section 73.1015 requires first blending the pigment with the polyethylene resin and then heating the mixture to 500-550° F prior to extrusion. This temperature range is not compatible with Simmelink's gel spinning process. *First*, this range is above the temperature at which UHMWPE begins to undergo thermal decomposition, which occurs above 240° C (~464° F). (EX2026, TBL. 3). Accordingly, all of the UHMWPE gel spinning processes disclosed in Simmelink are performed at 180° C (356° F)—far below the temperature range disclosed in Section 73.1015. (EX1005, Examples 1-2). A PHOSITA thus would have been dissuaded from incorporating the pigmentation process disclosed in Section 73.1015 into Simmelink's gel spinning process.

Second, the temperature range used in Section 73.1015's pigmentation process exceeds the boiling point of many of the common spin solvents used in the

gel spinning process for making UHMWPE yarns. For example, the boiling point of decalin—the preferred spin solvent used in each and every working example of Simmelink (*see, e.g.*, EX1005, 8:34-9:6, Examples 1-20)—has a boiling point of 369° F and an autoignition temperature of 482° F. (EX2027, 5). Thus, heating the UHMWPE and pigment to 500° F as required by Section 73.1015 would evaporate decalin, resulting in a melt containing the polymer and pigment. Indeed, spinning UHMWPE from a melt is “almost impossible” due to its high melt viscosity (EX1014, 63). Thus, applying the Section 73.1015 pigmentation process would render the gel spinning process disclosed in all of Simmelink’s working examples inoperable. If references taken in combination would produce an inoperative process, those references teach away from the combination and cannot serve as predicates for an obviousness case. *McGinley v. Franklin Sports, Inc.*, 262 F.3d 1339, 1354 (Fed. Cir. 2001); *see also In re Gordon*, 733 F.2d 900, 902 (Fed. Cir. 1984) (inoperable modification teaches away).

Accordingly, a PHOSITA would not have been motivated to incorporate the pigmentation process of Section 73.1015, which requires heating the polymer resin to 500-550° F, into Simmelink’s gel-spinning process. *See Rembrandt Wireless Techs., LP v. Samsung Elecs. Co.*, 853 F.3d 1370, 1379 (Fed. Cir. 2017) (“[A] showing that a prior art reference teaches away from a given combination is evidence that one of skill in the art would not have been motivated to make that

combination to arrive at the claimed invention.”). Because the ’532 patent does not employ the temperature range disclosed in Section 73.1015, the Petition’s reliance on *Smith & Nephew, Inc. v. Rea*, 721 F.3d 1371 (Fed. Cir. 2013) and *Alcon Res., Ltd. v. Apotex Inc.*, 687 F.3d 1362 (Fed. Cir. 2012) is inapposite. (See Pet., 15).

b. The Prior Art as a Whole Teaches Away From the Path the Inventors Took to Arrive at the Challenged Claims

The Petition next contends that “it would have been obvious to try the chromium-cobalt-aluminum oxide pigment disclosed in Section 73.1015” in combination with the gel-spun UHMWPE yarns of Simmelink “based on at least the well-known need for a colored suture made of UHMWPE fiber and the limited number of solutions to color an UHMWPE fiber.” (Pet., 13 (citing *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007))). The Petition’s reliance on an obvious-to-try theory under *KSR* is misguided.

“*KSR* did not create a presumption that all experimentation in fields where there is already a background of useful knowledge is ‘obvious to try,’ without considering the nature of the science or technology.” *Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1352 (Fed. Cir. 2008). “Each case must be decided in its particular context, including the characteristics of the science or technology, its state of advance, the nature of the known choices, the specificity or generality of the prior

art, and the predictability of results in the area of interest.” *Id.* The *KSR* Court recognized that “[w]hen there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007). But this framework “presupposes that the record up to the time of invention would give some reasons, available within the knowledge of one of skill in the art, to make particular modifications to achieve the claimed [invention].” *Eisai Co. Ltd. v. Dr. Reddy’s Labs., Ltd.*, 533 F.3d 1353, 1359 (Fed. Cir. 2008). When the “invention would not have presented itself as an option at all[,]” as here, it would not have been obvious to try. *Rolls-Royce, PLC v. United Techs. Corp.*, 603 F.3d 1325, 1339 (Fed. Cir. 2010).

The Ground 1 combination largely ignores the teachings of the Ohta and Nanri references, which are raised separately in the combinations of Grounds 2-3 and Ground 2, respectively. This is legal error. “When the PTAB examines the scope and content of prior art, . . . it must consider the prior art in its entirety, *i.e.*, as a whole.” *In re Warsaw Orthopedic, Inc.*, 832 F.3d 1327, 1332 (Fed. Cir. 2016) (internal citations and quotations omitted). Because the disclosures of Ohta and Nanri directly bear on the contentions alleged in Ground 1—***and in fact teach***

away from the purported combination—Patent Owner summarizes those disclosures here.

Ohta explains that “polyethylene has a drawback in that it does not have a hydrogen bond between molecular chains and readily creeps. These drawbacks significantly limit the scope of application of polyethylene fiber in applications where long-term loads are applied.” (EX1008, 2). “As a result of diligent research,” Ohta “discovered that there is little disorder in the crystal structure in polyethylene fiber and that creep resistance is more favorable the more scarce impurities other than polyethylene are[.]” (*Id.*). In other words, “the greater the amount of impurities such as residual solvent and additives, the worse the creep resistance” of the resulting UHMWPE fiber. (*Id.*). Ohta explains “it is presumed that disorder in the crystal[line UHMWPE] causes weaker intermolecular force[s], promoting slip between molecular chains[.]” (*Id.*). Thus, Ohta teaches that it “is important . . . to reduce defects and impurities in the fiber crystals as much as possible [to] improve creep resistance.” (*Id.*, 3). Ohta further teaches “that it is important that the amount of residual components other than . . . polyethylene that are contained in the polyethylene fiber, specifically, the amount of solvent and additives, be 1000 ppm or less in terms of weight fraction.” (*Id.*). “When the residual components exceed 1000 ppm, the creep resistance deteriorates significantly.” (*Id.*).

Thus, Ohta expressly teaches that for UHMWPE yarns in which creep resistance is an important consideration, less than 1000 ppm of residual spin solvent and other additives should be contained within the UHMWPE filaments. Confirming the relevance of Ohta, the Petition concedes that creep is an important consideration when designing a polyethylene yarn for a suture application. (Pet., 33; *see also* EX1003, ¶ 65 (noting creep in UHMWPE yarn “result[s] in the separation of bones or other sutured items”)).

Noting the difficulty in obtaining “colored high-strength polyethylene fiber,” Nanri discloses that upon “diligent research,” its “invention is a high-strength polyethylene fiber containing a pigment composed of a particle aggregate having an average particle diameter of 10 to 100 nm[.]” (EX1007, [0002]-[0004]). Nanri further discloses that “a strong polyethylene fiber” is obtained “wherein the particle aggregate is composed of 10 or fewer particles” and the “pigment content is between 0.01 and 2.50 wt%.” (*Id.*, [0004]). Based on studies using carbon black, at this particle size, aggregation state, and weight percentage, Nanri discloses that its specially sized pigments “do not act as defects in the crystal formation process” necessary to manufacture high-strength UHMWPE yarns. (*Id.*, [0003]). Nanri further explains that at this size, the pigment “does not act as a defect during orientated crystallization that occurs during the fiber formation process” and is “incorporated into the crystal” without migration of the pigment

particles out of the polymer. (*Id.*, [0005]-[0006]). Nanri generally discloses that pigments can be “organic” or “inorganic pigments” but does not disclose any particular pigments other than carbon black used in all its working examples. (*Id.*, [0005], [0015]-[0017]).

Nanri does not disclose any chromium-oxide containing pigment such as the one disclosed in Section 73.1015, much less any working examples employing the same. In fact, Nanri does not provide any data for any gel-spun UHMWPE yarn that contains any pigment other than carbon black. Moreover, Nanri does not disclose medical sutures and, unlike Ohta, does not disclose the impact of incorporating nanoscale carbon black pigment during the gel spinning process on the creep resistance of the resulting UHMWPE filaments.

The Petition asserts that the '532 patent does not “describ[e] a ‘specially designed’ pigment” for incorporation into the claimed UHMWPE yarns. (Pet., 15). According to Petitioner’s declarant:

The [PHOSITA] would have understood that to incorporate the pigment of Section 73.1015 into the gel spinning mixture of Simmelink, the particle size of the pigment as related to the diameter of the final filament would need to be taken into consideration. Accordingly, the [PHOSITA] would consider either [1] selecting a

pigment with a particle size much less than such diameter and/or [2] pre-treat the pigment particles (e.g., pulverize, grind, or mill) such that the pigment particles and any re-agglomerated pigment particles would ultimately have a particle size much less than the diameter of the final filaments, so as not to weaken the final filaments.

(EX1003, ¶ 187). As explained below, commercially available C.I. Pigment Blue 36—the chromium-cobalt-aluminum oxide pigment disclosed in Section 73.1015—meets the first criterion, and therefore there was not necessarily a need to “pre-treat” the Section 73.1015 pigment.

The '532 patent discloses Honeywell's SPECTRA® brand gel-spun UHMWPE yarns. (EX1001, 2:41-42). The Petition evidence demonstrates that the filaments in these particular yarns, which have been used to manufacture medical sutures since at least the mid-1990s, had an average diameter of about 27 microns. (EX1015, 3:32-42). C.I. Pigment Blue 36 commercially available from Ferro Corporation (*i.e.*, the original manufacturer of the Section 73.1015 pigment) has an average particle size of 0.70 microns or 700 nm. (EX2028). As the Ferro product specification indicates, the Section 73.1015 pigment, C.I. Pigment Blue 36, produces its blue color due to a strong reflectance of visible light in the blue/blue-green region between about 450-520 nm. (*Id.*). With an average particle

size of 700 nm, the commercial C.I. Pigment Blue 36 from Ferro is able to reflect the corresponding visible light. It is also much smaller than the diameter of a typical UHMWPE filament and can fit within its confines.

Consequently, the '532 patent did not need to disclose any special preparation for the claimed chromium-oxide pigment because the commercially available pigment was already properly sized to be much smaller than the diameter of an individual gel-spun UHMWPE filament. *See Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1367 (Fed. Cir. 2011) (“[A]n inventor need not explain every detail because a patent is read by those of skill in the art.”).

The fundamental problem the Petition has is that its own prior art teaches away from using pigments with particle sizes greater than 100 nm—like the commercially available C.I. Pigment Blue 36 product. *See Arctic Cat Inc. v. Bombardier Rec. Prods.*, 876 F.3d 1350, 1360 (Fed. Cir. 2017) (“Prior art teaches away when a person of ordinary skill, upon reading the reference, . . . would be led in a direction divergent from the path that was taken by the applicant.”). **First**, Ohta teaches that excess residual components within UHMWPE filaments negatively impacts their resistance against creep:

in order to obtain the polyethylene fiber having superior creep resistance according to the present invention, it was found that it is important that the amount of residual

components other than the polymer mainly composed of polyethylene that are contained in the polyethylene fiber, specifically, the amount of solvent and additives, be 1000 ppm or less in terms of weight fraction.

(EX1008, 3). In other words, because 1000 ppm is 0.1% by weight, Ohta teaches away from incorporating more than 0.1% by weight of a pigment into UHMWPE filaments for medical sutures. (*See* limitation [1.C] (claiming inorganic chromium oxide-containing pigment between 0.1-7.0 wt. %); *see also* EX1003, ¶ 65 (noting importance of creep resistance for medical sutures)).

The Petition dismisses this teaching in Ohta. According to the Petition, a PHOSITA “would not be deterred by Ohta’s preference for ‘a mixture composed of only the [UHMWPE] and solvent as the spinning solution’ nor . . . interpret Ohta’s teaching to keep residual components below 1000 ppm as being inclusive of the pigment[.]” (Pet., 35 (citing EX1003, ¶¶ 321-322)). The Petition is wrong on both counts. Dr. Grubb’s opinion that a PHOSITA would not consider “the pigment” “as being inclusive of the” less than 1000 ppm of “residual components” is conclusory and not entitled to any weight. (EX1003, ¶ 322). It is also contradicted by the record evidence, all of which unambiguously refers to pigments as “additives” in the context of gel-spun UHMWPE filaments. (*See, e.g.*, EX1005, 8:38-31 (colorants as “additives”); EX1006, 336 (“Part 73—Listing of

Color Additives Exempt from Certification”)). Moreover, a generic “design need for colored sutures”, (EX1003, ¶ 321), does not overcome the fact Ohta expressly discloses that the presence of 1000 ppm or more of additives in the UHMWPE filaments “deteriorates [creep resistance] significantly.” (EX1008, 3). As the Petition concedes, “creep resistance [is] a necessary consideration for the production of sutures as UHMWPE fibers in medical applications” because creep can lead to elongated or failed sutures. (Pet., 33 (citing EX1003, ¶¶ 65, 315)).

Second, Nanri expressly teaches away from incorporating pigments with average aggregate particle sizes less than 10 nm and greater than 100 nm. Yet, the Petition does not present any evidence demonstrating that the chromium-cobalt-aluminum oxide disclosed in Section 73.1015 falls within the narrow particle size range Nanri discloses. In fact, the Petition expressly disclaims Nanri from the Ground 1 combination. (Pet., 14, n.6 (“To be clear, this ground is obviousness in view of Simmelink and Section 73.1015. Nanri does not form part of the combination/modification.”)).⁴ Ohta and Nanri are consistent with other prior art of record described in the specification of the ’532 patent that would have

⁴ To the extent that Ground 1 can reasonably be interpreted to suggest that pretreating the Section 73.1015 will necessarily or reasonably be expected to result in the pigment size disclosed in Nanri, it still fails for the same reasons as Grounds 2 and 3. See Section VI.B, *infra*.

dissuaded a PHOSITA from attempting to incorporate a pigment into the filaments of a medical-grade UHMWPE yarn used for sutures. *See* Section II.E, *supra*.

Thus, in view of Ohta and Nanri, adding more than 0.1% by weight of the Section 73.1015 pigment to a gel-spun UHMWPE filament “would not have presented itself as an option at all” for fulfilling the design need of providing colored sutures. *Rolls-Royce*, 603 F.3d at 1339. By relying on a “design need” with no obvious solution, the Petition fails to establish that the Challenged Claims would have been obvious. *See Innogenetics, N.V. v. Abbott Labs.*, 512 F.3d 1363, 1373 (Fed. Cir. 2008) (“[K]nowledge of a problem and motivation to solve it are entirely different from motivation to combine particular references.”); *Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1352 (Fed. Cir. 2008) (“[K]nowledge of the goal does not render its achievement obvious.”).

3. Simmelink and Section 73.1015 Do Not Establish a Reasonable Expectation of Success

The Petition contends that a PHOSITA would have had a reasonable expectation of success in combining Simmelink and Section 73.1015. (Pet., 13-15). But the Petition misreads both Simmelink and Section 73.1015.

As noted above, Simmelink discloses that its UHMWPE starting material “may further contain small amounts, generally less than 5 mass%, preferably less than 3 mass% of customary additives, such as . . . colorants”—not that those amounts of additives are in the gel-spun filaments of the claimed yarns. (EX1005,

8:28-30). Moreover, there is nothing in Simmelink that ties its disclosure of up to 5 mass% of additives such as colorants to medical-grade UHMWPE yarns. In fact, Simmelink explains that “[f]or medical applications the amount of other components or foreign materials in the yarn is very important[.]” (EX1005, 12:6-7). And although Simmelink discloses “colorants,” it does not disclose pigments. As the ’532 patent admits, UHMWPE yarns had previously been colored using soluble dyes—as opposed to pigments—during the gel spinning process (although those dyes leached out of the yarn over time). (EX1001, 1:43-51). Accordingly, a PHOSITA would not interpret Simmelink’s disclosure of “colorants” as disclosing adding pigments to medical-grade UHMWPE yarns in the amounts claimed.

The other prior art references on which the Petition relies for coloring UHMWPE do not fare any better. The pigmentation process disclosed in Section 73.1015 is a melt spinning process, not a gel spinning process, and the colored sutures originally covered by Section 73.1015 readily failed. *See* Section II.C, *supra*. Similarly, the process disclosed in the Iwanami patent is a compression molding process, not a gel spinning process. (Pet., 14, n.5 (citing EX1028); EX1028, 8:60-9:26; *see also* Section II.D, *supra* (describing structural differences between compression molded and gel-spun UHMWPE)). Moreover, Iwanami discloses using a dispersant for the pigment (EX1028, 8:56-59), which the ’532 patent explains is not desirable in gel-spun UHMWPE (EX1001, 2:3-6). The

Petition does not disclose any prior art reference in which a chromium oxide-containing pigment was used to color an UHMWPE yarn during the gel spinning process—and therefore does not overcome the clear disclosures in Ohta, Nanri, and other prior art advising against it.

Accordingly, the Petition fails to demonstrate a reasonable expectation of success in achieving the Challenged Claims based on the prior art.

4. *The Inventors’ Use of a Standard Pigment Does Not Render the Challenged Claims Unpatentable*

The Petition contends that because the inventors took a path that did not employ a “special” pigment or take “further steps beyond the ordinary skill of the [PHOSITA,]” the Challenged Claims are somehow unpatentable. (Pet., 15 (citing EX1003, ¶¶ 187-189)). But this contention misunderstands the obviousness inquiry. “Patentability shall not be negated by the manner in which the invention was made.” 35 U.S.C. § 103 (pre-AIA). This statutory mandate “was enacted to ensure that routine experimentation does not necessarily preclude patentability.” *Honeywell Int’l Inc. v. Mexichem Amanco Holding S.A. De C.V.*, 865 F.3d 1348, 1356 (Fed. Cir. 2017). Accordingly, the inventors’ use of a commercially available pigment does not negate the patentability of the Challenged Claims. *See McGinley*, 262 F. 3d at 1351 (“The genius of invention is often a combination of known elements[.]”).

Moreover, because the prior art of record taught away from adding pigments to UHMWPE filaments used for medical sutures, the path the inventors took diverged significantly from that which a PHOSITA would have followed. Thus, that a PHOSITA could have taken the steps the inventors took in discovering the world's first blue UHMWPE yarn for medical suture applications is inapposite to the question of obviousness. *See TQ Delta, LLC v. Cisco Sys., Inc.*, 942 F.3d 1352,1359-60 (Fed. Cir. 2019) (explaining that whether specific references *could be combined* is different from whether PHOSITA *would have been motivated to combine* them).

B. Grounds 2 and 3 Fail to Meet the Institution Threshold

Because Ohta and Nanri teach away from the Challenged Claims, Grounds 2 and 3 fail for the very same reasons as Ground 1. *See* Section VI.A, *supra*. They also fail for an additional reason. Implicitly acknowledging that Nanri teaches away from using pigments having average aggregate particle sizes greater than 100 nm, the contentions raised in Grounds 2 and 3 (both of which rely on Nanri) are limited in scope and require a specialized nanoscale pigment—despite the admission in Ground 1 that the Challenged Claims do not require a specialized pigment. (Pet., 38-39, 53-54). As Dr. Grubb puts it:

Nanri explains that it is desirable to have particularly sized particles, specifically “a particle aggregate

dispersed in the cross-section of the fiber, is preferably in the range of 10 nm to 100 nm. As such, [a PHOSITA] would have understood to select particles of the exempted pigment disclosed in Section 73.1015 and *sized according to the disclosure of Nanri* so as to not cause defects during crystallization.

(EX1003, ¶¶ 331, 440). Accordingly, Grounds 2 and 3 are based on the Section 73.1015 pigment “*sized according to Nanri*. (Pet., 38-39, 53-54).

“Obviousness cannot be predicated on what is unknown.” *In re Rijckaert*, 9 F.3d 1531, 1534 (Fed. Cir. 1993). Yet, the Petition is devoid of any competent evidence demonstrating that the Section 73.1015 pigment, sized according to Nanri (*i.e.*, having an average aggregate particle size of 10-100 nm), was within the general knowledge of the art or skill of a PHOSITA at the relevant time. This evidentiary deficiency is fatal to Grounds 2 and 3. *See Intelligent Bio-Sys., Inc. v. Illumina Cambridge, Ltd.*, 821 F.3d 1359, 1369 (Fed. Cir. 2016) (“It is of the utmost importance that petitioners in the IPR proceedings adhere to the requirement that the initial petition identify with particularity the evidence that supports the grounds for the challenge to each claim.”).

The Petition does not identify any prior art reference that actually discloses the Section 73.1015 pigment having an average aggregate particle size between 10-

100 nm—a size that is substantially shorter than the wavelength of visible light the Section 73.1015 pigment typically reflects in providing its blue color. Section 73.1015 itself does not disclose any particle size of its chromium-cobalt-aluminum oxide pigment. Although Nanri discloses pulverizing carbon black pigment into particles with average aggregate particle sizes between 10-100 nm, it does not disclose the chromium-cobalt-aluminum oxide pigment of Section 73.1015. And a particle size between 10-100 nm is not an inherent property of the Section 73.1015 pigment. Indeed, the average particle size of commercially available C.I. Pigment Blue 36 from various companies is much greater than 100 nm. (*See, e.g.*, EX2028; EX2029; EX2030). And there is no dispute that Pigment Blue 36 meets the specifications of Section 73.1015. (EX2024, 20, ¶ 39 (noting Petitioner’s pigment is FDA-approved)).

Dr. Grubb assumes that at the time of the ’532 patent, the Section 73.1015 pigment could be reduced to the particle size disclosed in Nanri. (*See, e.g.*, EX1003, ¶¶ 331-332, 440-441). But he does not provide any actual evidence to support his conclusory assumption. At best, Dr. Grubb suggests that a PHOSITA can “pretreat the pigment particles (e.g., pulverize, grind, or mill) such that the pigment particles and any re-agglomerated pigment particles would ultimately have a particle size” that does “not . . . weaken the final filaments.” (*Id.*, ¶ 187). Dr. Grubb further states that such “pre-treatment methods would be common and

within the skill of the person of ordinary skill.” (*Id.*). To the extent these statements suggest that the Section 73.1015 pigment could have been milled to have an average aggregate particle size of 10-100 nm, Dr. Grubb once again does not support his conclusory opinion with any evidence. (*See id.*, ¶¶ 187-189).

Dr. Grubb’s failure to do so is a fundamental deficiency. *See Randall Mfg. v. Rea*, 733 F.3d 1355, 1362 (Fed. Cir. 2013) (noting “importance of a factual foundation to support a party’s claim about what [a PHOSITA] would have known”). At the time of the ’532 patent, it was known that the extent to which the particle size of a pigment can be reduced to nanoscale by physical means (*e.g.*, milling) “is a function of the material properties.” (EX2031, 60). “If the material is soft and easily friable”—like carbon black—“then particle size reduction to sub 100-nanometer size is possible.” (*Id.*). But for harder materials, “further particle size reduction may not occur” with milling. (*Id.*). “***Each application becomes very product specific. Laboratory testing is required*** to determine whether the material can be processed.” (*Id.* (emphasis added)). Accordingly, there is no evidence of record demonstrating that when the Section 73.1015 pigment is pre-treated with milling, grinding, or pulverizing, an average aggregate particle size between 10-100 nm necessarily results or that a PHOSITA would reasonably expect such a result. There is nothing in the record evidence, including Kavesh

(EX1009), demonstrating otherwise. This evidentiary failure is fatal to all three grounds raised in the Petition.

To be sure, the Section 73.1015 pigment used in Patent Owner’s commercial UHMWPE yarns covered by the ’532 patent do not have an average aggregate particle size of < 100 nm. Because that size is shorter than the wavelength of light it typically reflects, a <100 nm version of the Section 73.1015 pigment may have different optical properties than its larger counterparts and therefore may be subject to additional FDA regulations when incorporated into medical devices due to safety concerns. (See EX2032 at 4, 27 (noting nanoscale version of approved color additive may raise “safety concerns”)). These safety concerns were not a consideration in Nanri, which investigated the use of nanoscale carbon black as a UV absorber to provide “*weather resistance*” for “ropes, nets, fishing lines, protective goods, and clothing[.]” (EX1007, [Summary], [0001] (emphasis added)).

Having failed to provide evidence sufficient to support its obviousness contentions based on a specialized nanoscale version of the Section 73.1015 pigment, the Petition should be denied. See *TQ Delta*, 942 F.3d at 1359 (“[C]onclusory expert testimony is inadequate to support an obviousness determination[.]”).

VII. CONCLUSION

There has been a “design need” for colored sutures dating back to at least the 1960s. Petitioner’s SPECTRA® UHMWPE yarns have been used to make sutures since at least 1993. Yet despite the well-known “design need,” Petitioner did not offer its own colored UHMWPE yarn product until almost 30 years later in 2022. And for good reason. Prior to the ’532 patent, the conventional wisdom in the field was that pigments acted as defects within the crystalline UHMWPE filaments, thereby weakening them and making the yarns prone to breaking and unsuitable for medical sutures. The Petition’s prior art confirms this. Thus, a PHOSITA would have been dissuaded from incorporating a chromium oxide-containing pigment into UHMWPE filaments at the claimed concentrations, and the Petition presents no competent evidence to the contrary. The Petition instead reconstructs the Challenged Claims from disparate teachings of the prior art based on the teachings of the ’532 patent itself. *Inter partes* review should be denied.

Dated: May 28, 2024

Respectfully submitted,

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CERTIFICATION UNDER 37 C.F.R. § 42.24(d)

I hereby certify that this **PATENT OWNER PRELIMINARY RESPONSE** contains 13,990 words as counted using Microsoft Word in accordance with 37-C.F.R. § 42.24(c) and inclusive of footnotes. This wordcount is less than the allotted 14,000 words permitted under 37 C.F.R. § 42.24(b)(1).

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CERTIFICATE OF SERVICE

I hereby certify that on this 28th day of May, 2024, a copy of the attached **PATENT OWNER PRELIMINARY RESPONSE** and supporting exhibits were served by electronic mail to the attorneys of record, at the following addresses:

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