

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

DECLARATION OF DR. DAVID T. GRUBB

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LIST OF EXHIBITS

Exhibit	Short Name	Description
Ex. 1001	'532 Patent	U.S. Patent No. 10,280,532
Ex. 1002	'532 File History	File History of U.S. Patent No. 10,280,532
Ex. 1003	Grubb Declaration	Declaration of Dr. David T. Grubb under 37 C.F.R. § 1.68
Ex. 1004	Grubb CV	<i>Curriculum Vitae</i> of Dr. David T. Grubb
Ex. 1005	Simmelink	International Publication No. WO2005066401 to Simmelink et al.
Ex. 1006	Section 73.1015	Chromium-cobalt-aluminum oxide, 21 CFR § 73.1015 (April 1, 2006)
Ex. 1007	Nanri	Japanese Unexamined Patent Application Publication No. H11-21721 to Nanri et al. (including translation affidavit and copy of original document in Japanese)
Ex. 1008	Ohta	Japanese Patent Publication No. 2586213 to Ohta et al. (including translation affidavit and copy of original document in Japanese)
Ex. 1009	Kavesh	Japanese Unexamined Patent Application Publication No. S58-5228 to Kavesh et al. (including translation affidavit and copy of original document in Japanese)
Ex. 1010	Smelt	H. Smelt, et al. "Advances in Medical-Grade UHMWPE Fiber Development: Additives for Visualization" (7 th UHMWPE International Meeting Proceedings, 2015).
Ex. 1011	Steeghs	International Publication No. WO 01/59397 to Steeghs et al.

Exhibit	Short Name	Description
Ex. 1012	Moriguchi	EP Patent Application No. 0472436 to Moriguchi et al.
Ex. 1013	van der Loo	U.S. Patent No. 6,183,834 to van der Loo
Ex. 1014	Hearle	High-Performance Fibers, 2001, Ed. J.W. Hearle
Ex. 1015	McLeod	U.S. Patent No. 5,456,722 to McLeod et al.
Ex. 1016	Foerster	U.S. Patent Publication No. 2004/0199208 to Foerster et al.
Ex. 1017	Grafton II	U.S. Patent No. 6,716,234 to Grafton et al.
Ex. 1018	Grafton	U.S. Patent Publication No. 2003/0050667 to Grafton et al.
Ex. 1019	Marissen	International Publication No. WO2005065911 to Marissen et al.
Ex. 1020	Nguyen	U.S. Patent No. 8,709,562 to Nguyen et al.
Ex. 1021	D4020	ASTM D4020-00a
Ex. 1022	Solomon-Ciuta	English translation of <i>J. App. Polym. Sci.</i> 24, 683-686 (1962) ‘Determination of Intrinsic Viscosity of Polymer Solutions by a Simple Viscosity Determination’ O.F. Solomon & I.Z. Ciuta (including translation affidavit and copy of original document in French)
Ex. 1023	Habibe	<i>J. Polym. Sci.: Part B Polymer Physics</i> 33,759-767 (1995) ‘Molecular Weight Distribution by Stirring-Induced Fractional Precipitation’ Maria Eunice S. Habibe and Maria Cecilia A. Esperidiao

Exhibit	Short Name	Description
Ex. 1024	Muratoglu	U.S. Patent No. 6,852,772 to Muratoglu et al.
Ex. 1025	Bellare	U.S. Patent Publication No. 2007/0197679 to Bellare et al.
Ex. 1026	Marissen II	International Publication No. WO2007003266 to Marissen
Ex. 1027	Koyfman	U.S. Patent Publication No. 20050149118 to Koyfman et al.
Ex. 1028	Iwanami	U.S. Patent No. 5,693,708 to Iwanami et al.
Ex. 1029	'168 Patent	U.S. Patent No. 9,506,168
Ex. 1030	'168 File History	File History of U.S. Patent No. 9,506,168
Ex. 1031	National Judicial Caseload Profile	U.S. District Courts – National Judicial Caseload Profile (accessed via https://www.uscourts.gov/sites/default/files/cms_na_distprofile0930.2023.pdf)
Ex. 1032	D1601	ASTM D1601-99 (2004)
Ex. 1033		RESERVED
Ex. 1034	Amery	U.S. Patent Publication No. 20040267313 to Amery
Ex. 1035	Olson	U.S. Patent Publication No. 20100274282 to Olson

DECLARATION OF DR. DAVID T. GRUBB

I, Dr. David T. Grubb, do hereby declare and say as follows:

1. I have personal knowledge of the facts contained in this Declaration, am of legal age, and am otherwise competent to testify about the matters set forth herein.

I. Scope of the Engagement

2. I have been retained by Alston & Bird LLP on behalf of Honeywell International Inc. (“Petitioner” or “Honeywell”) to provide analysis and opinion in connection with an *inter partes* review (“IPR”) petition to be filed before the United States Patent and Trademark Office (“PTO”) Patent Trial and Appeal Board (“Board”). I understand that my testimony will be submitted with the IPR petition to be considered by the Board.

3. I understand that the petition for IPR involves U.S. Patent No. 10,280,532 (“the ’532 Patent”) (Ex. 1001) to DSM IP Assets B.V. (“Patent Owner” or “DSM”). I have been asked to provide my opinions as to the validity of Claims 1-9 of the ’532 Patent.

4. This Declaration sets forth the opinions that I have formed related to Claims 1-9 of the ’532 Patent based on my personal knowledge, education, research, personal and professional experience, and the information I have reviewed as of the date of this Declaration. In connection with my analysis, I have

reviewed the exhibits listed in the above list of exhibits as well as each of the items referenced herein.

5. It is my understanding that for the '532 Patent, the earliest priority date, based on the face of the patent, is May 23, 2007. Accordingly, all of the opinions I express in this Declaration have been made from the standpoint of a person of ordinary skill in the art, as described below, on or around May 23, 2007.

6. My opinions directed to the invalidity of the challenged claims are based, at least in part, on the following prior art publications:

- **“Simmelink”** (Ex. 1005), which is International Publication No. WO2005066401, published on July 21, 2005;
- **“Section 73.1015”** (Ex. 1006), which is 21 CFR § 73.1015 “Chromium-cobalt-aluminum oxide”, published on April 1, 2006;
- **“Nanri”** (Ex. 1007), which is Japanese Unexamined Patent Application Publication No. H11-21721, published on January 26, 1999;
- **“Ohta”** (Ex. 1008), which is Japanese Patent Publication No. 2586213, issued on February 26, 1997; and
- **“Kavesh”** (Ex. 1009), which is Japanese Unexamined Patent Application Publication No. S58-5228, published on January 12, 1983.

7. I am being compensated at a rate of \$350 per hour for my time spent on the present matter. My compensation in this matter is not in any way contingent on my performance, the outcome of this proceeding, or any of the issues involved therein. I am also being reimbursed for expenses incurred as a result of activities performed as an expert.

II. Professional Background and Qualifications

8. I earned my Bachelor of Arts degree in Physics in 1966 from Brasenose College of the University of Oxford. I earned a Master of Arts degree in Physics and a Doctor of Philosophy in Metallurgy and Materials Science degree from the same institution in 1969 and 1970, respectively.

9. After post-doctoral employment at the Physics Department of Bristol University and at the Macromolecular Research Center in Strasbourg, France, I joined the faculty of the Department of Materials Science and Engineering at Cornell University in 1978. I served on the faculty for thirty-five years, including nearly twenty years as an Associate Professor, until my retirement in 2013. After my retirement, I continued to teach a course in materials chemistry each summer semester from 2013-2019.

10. During my tenure, I taught many courses at the undergraduate and graduate level covering mechanical properties of materials, polymeric materials,

materials structure, introduction to biomaterials, advanced biomaterials, thermodynamics and kinetics, electrical properties of materials, and laboratories.

11. I also taught a class on the FDA Blue Book. As part of this class, I covered the process for obtaining approval for a medical device, which included instructions on biocompatibility. The materials we covered included polymeric materials, such as ultra-high molecular weight polyethylene in prosthetics, such as joint replacements.

12. I have also performed research projects pertaining to polymer structure and its relation to mechanical properties. I have extensive experience with electron microscopy, micro-Raman spectroscopy, and X-ray scattering at both wide and small angles (including use of synchrotron radiation sources), as tools for structural investigation of polymer structures, including use in fibers. I have authored or co-authored about 100 papers and technical presentations based on such research.

13. I have served on many professional committees and supported professional organizations. For example, from 1977 to 1992, I was a member of the Editorial Board of the Journal of Microscopy. I was also a Member of the Field of Textiles. I am a Member of the American Physical Society, a Member of the American Chemical Society, a Member of the Microscopy Society of America, and a Fellow of the Royal Microscopical Society. I was also awarded a NATO

European Fellowship in 1972. I have also received numerous teaching awards from Cornell University during my tenure.

14. My qualifications and publications are set forth more fully in my curriculum vitae. *See* Ex. 1004.

15. On the basis of my education and the personal and professional experiences described above and set forth in my curriculum vitae, I believe I am qualified to give the opinions set forth herein.

III. Person of Ordinary Skill in the Art

16. I understand that validity of a patent must be analyzed from the perspective of a hypothetical person of ordinary skill in the art in the same field as the patent. I have been informed that such hypothetical person of ordinary skill is presumed to be aware of all of the relevant art at the time of the invention, i.e., the effective filing date of the application for the asserted patent. I have been informed that a person of ordinary skill would think along the lines of conventional wisdom in that art. The person of ordinary skill is not an automation and may be able to fit together the teachings of multiple patents employing ordinary creativity and the common sense that familiar items may have obvious uses in another context or beyond their primary purposes.

17. I have been informed that several factors to consider in determining the level of ordinary skill in the art include (i) the educational level of workers in

the field, (ii) the types of problems encountered in the art, (iii) prior-art solutions to such problems, (iv) rapidity with which innovations are made, and (v) the complexity of the technology.

18. All of the opinions I express in this Declaration have been made from the standpoint of a person of ordinary skill. Based on my knowledge and experience, and taking into account each of the above-identified factors, it is my opinion that the person of ordinary skill in the field of the '532 Patent at the time of the presumed effective filing date (i.e., May 23, 2007) would be expected to have at least a Bachelor's degree in the field of chemistry, chemical engineering, polymer chemistry, or materials science and at least three years of relevant work experience in the field of high strength fibers. Individuals with different educational backgrounds and additional experience could still be of ordinary skill in the art if that additional experience compensates for a deficit in their education and experience stated above. Additional education might substitute for some of the experience, and substantial experience might substitute for some educational background. I had those capabilities myself as of the earliest priority date as I was working directly in the field in question and consider myself a person of ordinary skill in the art as of at least May 23, 2007.

19. Through my work with undergraduates and graduates, including my instruction of undergraduate and graduate courses as well as training, supervising,

and advising numerous researchers in the field of polymer materials, I was able to judge their competency in appreciating polymer chemistry and materials technology and the capabilities of a person of ordinary skill in the art.

20. Accordingly, my opinions expressed in this Declaration are based on this level of ordinary skill in the art at the time of the invention.

IV. Legal Principles

21. I use the legal principles below, of which I have been informed by counsel, as a guide in formulating my opinions.

A. Claim Interpretation

22. I have been informed that assessing the validity of a patent claim requires a two-step analysis. The first step involves the proper interpretation or construction of the claim language in order to determine its scope and meaning. The second step requires comparing the claim, as properly construed, to the alleged prior art to determine whether the limitations of the claim are met by the prior art.

23. I have been informed that claim terms are typically given their plain and ordinary meanings, as would have been understood by a person of ordinary skill in the art at the time of the earliest alleged priority date. I have further been informed that when considering the meaning of any terms of the claims, one must consider the language of the claims, the specification, and the prosecution history of record. I understand that one must be careful not to read a specific embodiment

appearing in the written description into the claim if the claim language is broader than the embodiment. I further understand that any special definition for a claim term must be set forth with reasonable clarity, deliberateness, and precision.

B. Prior Art

24. It has been explained to me by counsel for Petitioner that information which satisfies one of the categories of prior art set forth in pre-America Invents Act (“pre-AIA”) 35 U.S.C. § 102 may be used in an invalidity analysis under §§ 102 or 103. If information is not properly classified as prior art under one of the subsections of § 102 of the Patent Code, then it may not form the basis of an anticipation or obviousness determination.

25. It is also my understanding that, for *inter partes* review, applicable prior art is limited to patents and printed publications.

26. It is my further understanding that in an IPR proceeding, a patent claim may be deemed invalid if it is shown by a preponderance of the evidence (i.e., that the patent claim is more likely than not invalid) that the claim was anticipated by a prior art patent or publication and/or rendered obvious by one or more prior art patents or publications.

C. Anticipation

27. It has been explained to me by counsel for the Petitioner that a patent claim is invalid due to anticipation under 35 U.S.C. § 102 if each and every

element of the patent claim is disclosed in a single asserted prior art reference. I am informed that such disclosure may be either explicit or inherent. I also understand that a disclosure of an asserted prior art reference can be “inherent” if the missing element is necessarily present or is the inevitable outcome of the process and/or thing that is explicitly described in the asserted prior art reference. I further understand that a specific example or disclosure in the prior art which is within a claimed range, anticipates the claimed range.

28. I further understand that, in order to be an anticipatory prior art reference, the prior art reference also must be enabling such that it teaches one of ordinary skill in the art how to make or carry out the claimed invention without undue experimentation.

D. Obviousness

29. I further have been informed that a patent claim is invalid under pre-AIA 35 U.S.C. § 103(a) if it would have been obvious to a person of ordinary skill in the art in view of the prior art at the time the application was filed. In other words, even though the claimed invention may not be identically disclosed or described in a single prior art reference, a patent claim is invalid for obviousness if the differences between the claimed invention and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was

made to a person having ordinary skill in the art to which the subject matter pertains.

30. I have been informed that the following factors are used in making an obviousness determination: (i) the scope and content of the prior art are to be determined; (ii) the differences between the prior art and the claims at issue are to be ascertained; and (iii) the level of ordinary skill in the pertinent art resolved.

31. I understand that whether there are any relevant differences between the prior art and the claimed invention is to be analyzed from the view of a person of ordinary skill in the art at the time of the invention. I have been informed, for purposes of this IPR proceeding, to assume that the alleged date of invention for the challenged claims is May 23, 2007.

32. In analyzing the relevance of the differences between the claimed invention and the prior art, I understand that I must consider the impact, if any, of such differences on the obviousness or non-obviousness of the invention as a whole, not merely some portion of it.

33. The person of ordinary skill faced with a problem is able to apply his or her experience and ability to solve the problem and also look to any available prior art to help solve the problem.

34. I understand that a reference may be modified and/or combined with one or more other references and/or with the knowledge of one of ordinary skill in

the art if such person of ordinary skill in the art would have found the modification and/or combination obvious. In other words, I understand that I do not need to look for precise teaching in the prior art directed to the subject matter of the claimed invention. I understand that I may take into account the inferences and creative steps that a person of ordinary skill in the art would have employed in reviewing the prior art at the time of the invention.

35. In determining whether a piece of prior art could have been combined with other prior art or with other information within the knowledge of a person having ordinary skill in the art, it is my understanding that the following are examples of approaches and rationales that may be considered to support a conclusion of obviousness:

- Combining prior art elements according to known methods to yield predictable results;
- Simple substitution of one known element for another to obtain predictable results;
- Use of a known technique to improve similar devices, methods, or products in the same way;
- Applying a known technique to a known device, method, or product ready for improvement to yield predictable results;
- Applying a technique or approach that would have been “obvious to try” (choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success);

- Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations would have been predictable to a person having ordinary skill in the art; or
- Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

36. I understand that if the claimed invention combined elements known in the prior art and the combination yielded results that were predictable to a person of ordinary skill in the art at the time of the invention, then this evidence would make it more likely that the claim was obvious.

37. I understand that an invention would have been obvious if a person of ordinary skill in the art, facing the wide range of needs created by developments in the field, would have seen an obvious benefit in the solutions tried by the applicant. When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, it would be obvious to a person of ordinary skill to try the known options. If a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique would have been obvious.

38. I understand that a key inquiry is whether any improvement allegedly achieved by a claimed invention is more than the predictable use of prior art elements according to their established functions.

39. I understand that a claimed invention may be obvious if some teaching, suggestion, or motivation exists that would have led a person of ordinary skill in the art to combine the invalidating references. I also understand that this suggestion or motivation may come from sources such as explicit statements in the prior art, or from the knowledge of a person having ordinary skill in the art. Alternatively, any need or problem known in the field at the time and addressed by the patent may provide a reason for combining elements of the prior art.

40. I also understand that when there is a design need or market pressure, and there are a finite number of predictable solutions, a person of ordinary skill may be motivated to apply both his skill and common sense in trying to combine the known options in order to solve the problem.

41. I understand that a reason to modify or combine prior art may support an obviousness determination, provided there is a reasonable expectation of success. I further understand that whether a proposed modification or combination of the prior art has a reasonable expectation of success is determined at the time the invention was made.

42. On the other hand, if the combination of known elements yielded unexpected or unpredictable results, or if the prior art teaches away from combining the known elements, then this evidence would make it more likely that the claim that successfully combined those elements was not obvious. I understand that hindsight must not be used when comparing the prior art to the invention for obviousness.

43. I am also aware that before concluding a claim is obvious, secondary considerations of nonobviousness, to the extent they exist, must be considered, such as: long-felt need, failure of others, copying by others, praise by others in the industry, licensing of the claimed invention, departure from accepted principles, widespread recognition by those in the art of the invention's significance, and commercial success. I understand that there must be a demonstrated nexus between the claimed invention and these secondary considerations for them to be considered.

V. Technical Background/State of the Art

A. Background

44. Ultra-high molecular weight polyethylene (UHMWPE or UHMwPE)¹ is a linear polyethylene having a weight-average molecular weight of at least 500,000 g/mol. *See e.g.*, International Publication No. WO 01/59397 to Steeghs et al. (Ex. 1011), Page 4, lines 13-15. “Ultra-high molecular weight polyethylene” has also been abbreviated to UHPE. *See e.g.*, EP Patent Application No. 0472436 to Moriguchi et al. (Ex. 1012), Page 1, lines 4-5; *see also*, Ex. 1005, Page 2, lines 1-2.

45. UHMWPE has been used in a variety of technologies, not just to form fibers. For example, UHMWPE has been used in truck liner beds and hip replacements, as UHMWPE is wear-resistant and low-friction. *See e.g.*, International Publication No. WO2005065911 to Marissen et al. (Ex. 1019), Page 1, lines 9-17 (“Polyethylene and in particular ultra-high molecular weight polyethylene (UHMWPE) is a known and frequently applied material in the manufacture of prosthetic or replacement joints. The biological inertia and the high

¹ I will refer to ultra-high molecular weight polyethylene as “UHMWPE” except when quoting from documents in which it appears differently (i.e., such as “UHMwPE” in the ’532 Patent or “UHPE” in Simmelink).

wear resistance make the material very suitable for internal application in mammals, esp. humans. The application in prosthetic joints, in particular in the loaded parts thereof, is known. In particular the inside of joint sockets, which when loaded come into contact with the joint balls moving therein and usually made of metal, are an example hereof, as are components of artificial knee, hip, elbow, shoulder, wrist, ankle, toe and finger joints.”).

46. Two well-known commercially available, multi-filament, gel-spun UHMWPE fibers are Spectra® by Honeywell and Dyneema® by DSM. *See e.g.*, U.S. Patent No. 6,183,834 to van der Loo (Ex. 1013), Col. 7, ll. 5-20; Col. 8, line 65-Col. 9, line 13; *see also, e.g.*, High-Performance Fibers, Ed. J.W. Hearle (2001) (Ex. 1014), Page 69, Table 3.1. The term ‘UHMWPE fiber’ or ‘drawn UHMWPE’ is often used interchangeably with high performance polyethylene (HPPE) fibers, high modulus polyethylene (HMPE) fibers, or extended chain polyethylene (ECPE) fibers. *See e.g.*, Ex. 1014, Page 62; *see also*, Ex. 1011, Page 4, lines 11-15 (referring to “drawn ultra-high molecular weight polyethylene” as “HPPE”).

47. UHMWPE fibers were prevalent in many applications by the time of the priority date of the ’532 Patent. Indeed, UHMWPE fibers were known to be used in suture applications. For example, U.S. Patent No. 5,456,722 to McLeod (“McLeod”) describes a suture made from ultra-high molecular weight polyethylene (e.g., Spectra 1000™) that is used to assist in the repair of torn

ligaments and tendons. *See e.g.*, Ex. 1015, Col. 1, line 65-Col. 2, line 2; Col. 3, line 67-Col. 4, line 16. As described by McLeod, UHMWPE fibers were ideal for sutures because they had a better fatigue life than the metal cables formed of cobalt-chrome, or titanium. Ex. 1015, Col. 6, lines 2-6. In addition, sutures formed from UHMWPE were preferred over metal cables due to having similar strength but being formed with a much smaller diameter, allowing for smaller openings or holes in performing the underlying repair. *See e.g.*, Ex. 1015, Col. 2, lines 10-15; *see also, e.g.*, U.S. Patent Publication No. 20050149118 to Koyfman et al. (Ex. 1027), Para. [0004] (“Sutures made from ultra high molecular polyethylene have the advantage of having high tensile strength while having a smaller suture size.”).

48. As the person of ordinary skill in the art would have understood, the UHMWPE fibers produced at the time of the priority date of the '532 Patent under trade names such as Dyneema® or Spectra® generally were produced in one color, “making multiple suture distinction difficult, especially arthroscopically.” *See* U.S. Patent Publication No. 2004/0199208 to Foerster (Ex. 1016), Para. [0003]. As a result, and in view of the need for high tensile strength, the person of ordinary skill in the art understood that there was a desire for UHMWPE fibers and a need to add color to UHMWPE fibers. For example, U.S. Patent No. 6,716,234 to Grafton disclosed that suture strength was an important consideration in any surgical suture material. *See e.g.*, Ex. 1017, Col. 1, lines 13-14. U.S. Patent Publication No.

2003/0050667 to Grafton (“Grafton”) further disclosed that, in addition to the use of UHMWPE fibers in sutures, it was well known to include color to enhance visibility of UHMWPE fibers, albeit by adding strands of polyester or nylon. *See e.g.*, Ex. 1018, Para. [0007]. Grafton described that adding color allows a surgeon to “distinguish different ends of lengths of suture[] and determine the direction of travel of a moving length of suture.” Ex. 1018, Para. [0013]. Such techniques were common among third party providers of sutures.

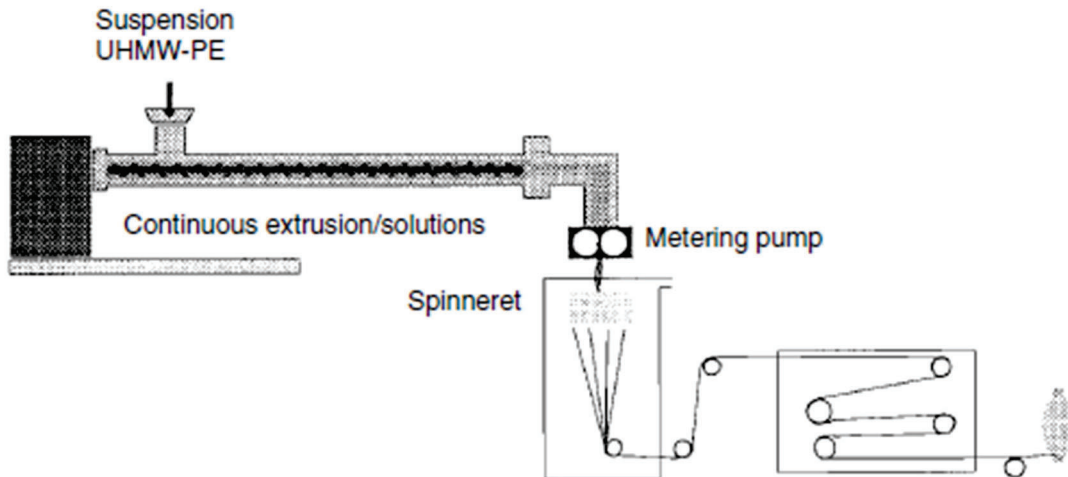
49. In addition to these sutures that were developed by third parties based on single colored UHMWPE fibers, it was also well known to color polyolefin material of high strength and high modulus. Specifically, U.S. Patent No. 5,693,708 to Iwanami et al. (“Iwanami”) discloses the use of organic pigments and inorganic pigments, including chromium pigments such as chromium oxide. *See* Ex. 1028, 7:37-64. The pigment is mixed with the ultra-high-molecular-weight polyethylene powder prior to forming the stretched material, such as a fiber. *See* Ex. 1028, 8:60-67; 10:26-29; 11:4-32 (Example 1). The mixing is carried out by any of dry powder mixing, wet mixing in slurry form, mixing in the presence of a solvent, etc. Ex. 1028, 8:23-26. Based on the mixing disclosed in Iwanami, and “unlike the case wherein a stretched material is colored by simply immersing it in a solution containing a pigment or a dye, the pigment or the dye infiltrates into the interior of the polyethylene and, as a result, the physical bonding between the

polyethylene and the pigment and/or the dye becomes strong, causing substantially no color fading.” Ex. 1028, 10:35-41.

50. At the time of the priority date of the ’532 Patent, it was also well known to color UHMWPE fibers during a gel spinning process. For example, Simmelink discloses that the UHPE (UHMWPE) used to make the high-performance polyethylene multifilament yarn 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.” Ex. 1005, Page 8, lines 28-31 (emphasis added). Nanri also disclosed a colored UHMWPE fiber using pigments. *See generally*, Ex. 1007. Specifically, Nanri discloses “a strong polyethylene fiber described above wherein the particle aggregate is composed of 10 or fewer particles and the strong polyethylene fiber described above wherein a pigment content is 0.01 to 2.50 wt%.” Ex. 1007, 2, Para. [0004]. According to Nanri, “it is essential that the colorant contained in the fiber is composed of a pigment such as an organic pigment, inorganic pigment, and carbon black” to obtain high-strength polyethylene fibers that are colored while maintaining a sufficiently high strength. Ex. 1007, 2, Para. [0005].

B. UHMWPE Fiber Creation

51. When UHMWPE fibers are created using the extrusion process, generally a gel spinning process is used. See, for example, Ex. 1014, Figure 3.2, reproduced below:



3.2 Gel-spinning process.

52. The person of ordinary skill in the art would have understood that in the gel spinning process, a polymer is mixed with a spin solvent and heated to form a solution that can be extruded. After extrusion through a spinneret, the solution is cooled, some solvent may be removed, and the polymer crystallizes, forming one or more gel 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. Prior to or

concurrent with drawing the gel filaments, more of the spin solvent would be removed. *See generally*, Ex. 1014, Pages 63-67.

53. Other types of fibers, such as nylons or polyesters, use a closely related process for extrusion which is referred to as a melt spinning process. 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. Otherwise, a person of ordinary skill in the art would have understood that gel spinning and melt spinning processes are very similar.

54. UHMWPE fibers can be manufactured in the form of monofilaments or multifilaments. *See e.g.*, International Publication No. WO2007003266 to Marissen (EX 1026), Page 1, lines 31-33 (“A multi-filament yarn is a bundle of a plurality of continuous filaments, which may have been given a certain twist level to provide the yarn with some coherency.”). A person of ordinary skill in the art would understand that the number of spinholes or orifices defined in a spinplate, which is also referred to as a “spinneret”, determines the number of filaments in an as-spun fiber. *See e.g.*, Ex. 1005, Page 4, lines 25-27 (“A spinplate is also called spinneret in the art, and contains multiple spinholes, also called orifices, dies,

apertures, capillaries or channels. **The number of spin holes determines the maximum number of filaments in as-spun yarn.**"); *see also, e.g.*, Ex. 1009, page 8 ("A motor 24 is provided to drive gear pump 23 and extrude the polymer solution, still hot, through a spinneret 25. The spinneret 25 contains apertures, which may be circular, X-shaped, or, oval-shaped, or in any of a variety of shapes having a relatively small major axis in the plane of the spinneret when it is desired to form fibers....**The number of apertures, and thus the number of fibers formed**, is not critical, but convenient numbers of apertures are 16, 120, or 240.") (Emphases added). That is, when the solution is passed through the spinneret, it can be extruded into any suitable number of filaments depending on the number of spinholes or orifices defined in the spinneret. Indeed, the person of ordinary skill in the art would have understood that the size and quantity of apertures were selected based on the desired properties of the fiber.

55. For example, a person of ordinary skill in the art would understand that a single aperture producing a single-drawn UHMWPE filament may be used for testing purposes, as it is easier to spot issues/damage with one filament than compared to multiple filaments. However, a person of ordinary skill in the art would also understand that the drawing steps of a gel spinning process create a longer, finer filament and that such a single UHMWPE filament is difficult to work with. The person of ordinary skill would further understand that using a spinplate

with a plurality of apertures, such as 20 apertures, results in 20 times the amount of filaments for almost the same amount of work. Switching out the spinplate would not otherwise affect other parts of the process or product. A person of ordinary skill in the art would also know that multi-filament yarns are common and are indeed preferred for UHMWPE sutures (e.g., multi-filament yarn bundles of small denier filaments that are combined together to form a suture) due to the high modulus of elasticity of the UHMWPE, which leads to stiffness in bending, such that a monofilament UHMWPE suture would be difficult to work with and have poor knot tying ability. *See, e.g.*, U.S. Patent Publication No. 20040267313 to Amery (Ex. 1034), Paras. [0004] (“Braided multifilament sutures are commonly used in surgery because of their excellent combination of properties. These property requirements include biocompatibility, sterilizability, tensile strength, diameter, slidability, and knot-tying retention properties.”), [0031]-[0032] (“some of the preferred embodiments include: A surgical braid comprising a cover and core, the cover manufactured from multifilament fibers of biocompatible UHMWPE and/or biocompatible UHMWPE composite fibers. The number of filaments in braid 12 can vary between 4 and 24.”).

56. In addition, the person of ordinary skill in the art would understand that a single UHMWPE filament would have a smaller load bearing capacity than a multi-filament UHMWPE yarn such that a person of ordinary skill in the art would

further understand an UHMWPE suture to require multiple filaments as spun for load bearing capacity.

57. As such, a person of ordinary skill in the art would understand that using a spinneret with multiple spinholes or orifices would result in a yarn of multiple individual filaments, i.e., a multi-filament yarn. Alternatively, such multi-filament yarns can also be prepared by combining the products of multiple spinnerets depending on the filament count (i.e., number of fibers) that is desired for the multifilament yarn. *See e.g.*, Ex. 1005, page 11, lines 31-35 (recognizing that a yarn may also be “made by assembling separately produced yarns containing less filaments” and “the as-produced yarn according to the invention can further be assembled into yarns, or ropes etc, of higher titer or linear density”); Ex. 1009, page 28 (“In the first stage, three of the rolls of 16 filament gel yarns described in Example 502 above were combined and stretched together to prepare a 48 filament stretched gel yarn.”), page 31 (setting forth yarn properties of various multi-filament yarns in a table, including several yarns prepared by combining “[s]everal 16 filament yarn ends” resulting in 48-filament and 64- filament multi-filament yarns).

58. Practical UHMWPE fibers like Spectra® or Dyneema® are produced as yarns or multifilament bundles of individual filaments. Ex. 1014, Page 68.

59. The extruded UHMWPE fiber is drawn to increase the stiffness and strength of its constituent filaments. *See, e.g.,* Ex. 1014, Page 67. Once drawn, UHMWPE fibers are sometimes referred to as extended chain polyethylene fibers (ECPE) because many polymer chains of the polyethylene are extended during drawing.

C. UHMWPE Properties

60. Concerning the intrinsic viscosity of polyethylene, the viscosity of a polymer solution η is greater than the viscosity of the solvent without any solute, η_0 . The viscosity increases with concentration, c , of solute, but at the same concentration a polymer of higher molecular weight (molar mass) will have a larger effect on solution viscosity. Thus, measurement of viscosity can be used to determine an average molecular weight of a polymer (and vice versa). The standard measure used is called the intrinsic viscosity $[\eta]$, sometimes written as IV. It is defined as:

$$[\eta] = \lim_{c \rightarrow 0} \left(\frac{\eta - \eta_0}{\eta_0 c} \right)$$

61. To determine intrinsic viscosity, the viscosity may be measured at a range of concentrations using standard procedures such as ASTM D1601. *See* ASTM D1601 (Ex. 1032). When the concentration c is given as a ratio, for example, mass of solute: mass of solvent, then the intrinsic viscosity is a

dimensionless number. However, the concentration is often determined as mass of solute / volume of solution. Then intrinsic viscosity has the dimensions of volume/mass and the standard unit used is dl/g.

62. Short cuts exist by which one may estimate intrinsic viscosity from a single measurement of viscosity. The ASTM D4020 industry standard describes such a method using the formula of Solomon-Ciuta. *See* ASTM D4020-00a (Ex. 1021); *see also*, *J. App. Polym. Sci.* 24, 683-686 (1962) ‘Determination of Intrinsic Viscosity of Polymer Solutions by a Simple Viscosity Determination’ O.F. Solomon & I.Z. Ciuta (Solomon-Ciuta) (Ex 1022) at 683-686.

63. The relation between IV and average molecular weight M is normally given by the Mark-Houwink equation:

$$\eta = KM^a$$

where K and a are constants that depend on the polymer, the solvent, and the temperature of the solution.

64. For polyethylene, the standard method is to use decalin at 135°C, and over time, a range of values for K and a have been obtained for UHMWPE. *See* Figure 4 of *J. Polym. Sci.: Part B Polymer Physics* 33, 759-767 (1995) ‘Molecular Weight Distribution by Stirring-Induced Fractional Precipitation’ Maria Eunice S. Habibe and Maria Cecilia A. Esperidiao (Ex. 1023); *see also*, Ex. 1021 at Fig X3.1. A standard set of values for K and a is implied in ASTM D4020-00a which

states: “Nominal Viscosity Molecular Weight = $5.37 \times 10^4 [\eta]^{1.37}$ ”. Inverting this gives $K = 3.53 \times 10^{-4}$; $a = 0.73$. ASTM D4020-00a specifies test solution concentration as 0.02 g/dl (section A1.1.1) but the instructions are designed to give a 0.02 mass% solution (0.022 g/dl) and while the figure (X3.1) shows IV in dl/g, the material specification section (section 3.2.1) uses concentration in %. This shows that a dimensionless IV obtained from % concentration is not distinguished from the IV in dl/g as they have close numerical values.

65. Creep resistance is another well studied property of UHMWPE fibers. Creep is the long term, longitudinal deformation of a material over time when subjected to a continuing load. *See e.g.*, U.S. Patent No. 8,709,562 to Nguyen et al. (Ex. 1020), 3:54-56. “The creep tendency of a fiber, yarn or fabric may be determined, for example, by the Stepped Isothermal testing method (SIM) of ASTM D6992. According to ASTM D6992, the SIM is a method of exposure that uses temperature steps and dwell times to accelerate the creep response of a single specimen being tested under load.” *Id.*, 3:56-61. Creep over a long period of time was generally known to result in breakage or compromised integrity over time. Moreover, creep also reduces the load that a fiber can support over time (e.g., the load that the fiber would support if it was used to suture two bones together). As such, as creep occurs, load will drop, resulting in the separation of bones or other sutured items. It was thus well known that in certain areas, such as in medical

applications, that creep over a long term could potentially cause harm. *See e.g.*, U.S. Patent No. 6,852,772 to Muratoglu et al. (Ex. 1024), 1:53-57 (“Yet for high stress applications, such as unicompartmental knee designs, thin polyethylene tibial knee inserts, low conformity articulations, etc., high modulus is desired to minimize creep.”); U.S. Patent Publication No. 2007/0197679 to Bellare et al. (Ex. 1025), Para. [0002] (“Desirable characteristics for the polymeric materials used in medical endoprotheses include biocompatibility, a low coefficient of friction, a relatively high surface hardness, and resistance to wear and creep.”)

VI. The '532 Patent

A. Background of the '532 Patent

66. Consistent with what the person of ordinary skill in the art would have known, the '532 Patent admits that colored sutures were well known and that coloring sutures was an important consideration when making a suture. In fact, the coloring of a suture was necessary to be able to see the suture amongst blood and to be able to readily track the travel direction of the suture during surgery. Ex. 1001, 1:11-21 (“The coloring of sutures is for example used to make the suture better contrast with the blood or tissue in the operating area. In complicated surgical operations, for example in arthroscopic surgery, when different suture ends are used in a small area, sutures of different color are used to assist surgeons in differing between the suture ends. It is also possible for this reason to combine

filaments of different colors in a suture in a certain pattern, to aid surgeons in identifying the travel direction of the suture during surgery, particularly during arthroscopic operations.”).

67. The '532 Patent further recognizes that “suture strength is an important consideration in selecting filaments for producing a suture” and admits that the use of UHMWPE filaments, produced according to a gel spinning process, for the production of sutures, was also well known. Ex. 1001, 1:22-27 (“Very strong filaments, at present available for the production of sutures, are filaments of ultra-high molecular weight polyethylene (UHMwPE), produced according to the gel spinning process.”). The background of the '532 Patent is clear that both coloring sutures and suture strength are important considerations when producing a suture. Ex. 1001, 1:22-23.

68. The '532 Patent further indicates that the gel spinning process for preparing UHMWPE filaments was well known in the prior art. Ex. 1001, 2:24-31 (“The preparation of filaments of ultra high molecular weight polyethylene (UHMWPE) filaments, prepared by a gel spinning process, is for example described in EP 0205960 A, EP 0213208 A1, U.S. Pat. No. 4,413,110, GB 2042414 A, EP 0200547 B1, EP 0472114 B1, WO 01/73173 A1, and Advanced Fiber Spinning Technology, Ed. T. Nakajima, Woodhead Publ. Ltd (1994), ISBN 1-855-73182-7, and references cited therein.”). Indeed, the '532 Patent described

gel spinning as “understood to include at least the steps of spinning filaments from a solution of ultra-high molecular weight polyethylene in a spin solvent; cooling the filament obtained to form a gel filament; removing at least partly the spin solvent from the gel filament; and drawing the filament in at least one drawing step before, during or after removing spin solvent. Suitable spin solvents include for example paraffin's [sic], mineral oil, kerosene or decalin. Spin solvent can be removed by evaporation, by extraction, or by a combination of evaporation and extraction routes.” Ex. 1001, 2:24-31. The '532 Patent also states that such gel-spun UHMWPE filaments provided under the Spectra® and Dyneema® brands were commercially available prior to the presumed priority date of the '532 Patent. Ex. 1001, 2:41-42.

69. The '532 Patent indicates, however, that there are issues with coloring UHMwPE filaments. Ex. 1001, 1:28-29. For example, the '532 Patent describes “the a-polar character of the UHMwPE [as causing] a colorant like a dye or a colored coating material [to adhere] poorly to the surface of the filament”, which may cause the filaments to lose part or all of the colorant due to “handling during production of the sutures” or when “in place in the human or animal body, which is undesired because of negative effects on the health.” Ex. 1001, 1:31-36.

70. To solve these issues, the '532 discusses attempts to “enhance the adhesion of colorants to the [UHMwPE] filaments by giving the filaments a pre-

treatment”, using “a dye to color the UHMwPE filaments”, or dyeing the UHMwPE filaments “using super critical carbon dioxide as a solvent for the dye.” Ex. 1001, 1:36-51. The ’532 Patent, however, identifies issues with these previous attempts. For example, the ’532 Patent describes the adverse effects of pre-treatments on mechanical properties of the filaments and tendencies of dyes to leach out, “which is unfavorable for application of the filaments in sutures.” Ex. 1001, 1:36-51.

71. In order to address these well-known problems, the ’532 Patent admits that polyolefinic filaments are often colored by the incorporation of a pigment in the polymer composition of the filaments during extrusion of the filaments. Ex. 1001, 1:51-57 (“Polyolefinic filaments, of which polypropylene filaments are the best example, are often colored by the incorporation of a pigment in the polymer composition of the filaments during extrusion of the filaments. In Prog. Polym. Sci. 27 (2002) 853-913 the process for pigmentation of polypropylene filaments is described.”). The ’532 Patent, however, identifies issues with such processes when applied to UHMwPE filaments. For example, according to the ’532 Patent, “[i]n order to obtain a sufficient dispersion of the pigment [in a concentrated pre-mixture,] the wetting of the pigment particles must be enhanced by the use of a low viscous carrier polymer and dispersants.” Ex. 1001, 1:58-63. The ’532 Patent further asserts that it is disadvised to use pigments in UHMwPE filaments because

such a “low viscous carrier polymer has a negative influence on mechanical properties of the UHMwPE filaments” and UHMwPE “filaments have a very low diameter compared to the diameter of polypropylene filaments [such] that undispersed or re-agglomerated clumps of pigment particles will have a detrimental effect on the tensile strength of filaments.” Ex. 1001, 1:63-2:3, citing U.S. Patent No. 5,613,987.

72. As would be readily understood when developing sutures, the ’532 Patent further indicates that filaments that are used in sutures must be biocompatible, and the use of dispersants has a negative effect on such biocompatibility. Ex. 1001, 2:3-6.

73. The ’532 Patent further describes past attempts “to combine the [UHMwPE] filaments in a suture with filaments of a different polymer, preferably nylon”, however, the ’532 Patent indicates that “[s]uch sutures [] have a complicated structure and the nylon filaments only contribute to the strength of the suture at a lower level compared to the filaments of UHMwPE.” Ex. 1001, 2:7-14, citing U.S. Patent No. 7,029,490.

74. Accordingly, the ’532 Patent indicates it is an “[o]bject of the invention [] to provide a colored suture, which suture does not show the problems described above.” Ex. 1001, 2:15-16.

B. Disclosure of the '532 Patent

75. Claims 1-9 of the '532 Patent are directed to 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.

76. The '532 Patent indicates that the UHMwPE is preferably “a linear polyethylene with less than one branch per 100 carbon atoms” and “can be a single polymer grade, but also a mixture of two or more different grades.” Ex. 1001, 2:61-3:20.

77. The '532 Patent indicates that “[i]n a preferred embodiment, the UHMWPE contains a small amount of relatively small groups as side chains, preferably a C1-C4 alkyl group. It is found that a filament from UHMWPE with a certain amount of such groups show reduced creep behaviour.” Ex. 1001, 3:1-5.

78. The '532 Patent indicates that “[i]ntrinsic viscosity is a measure for molar mass (also called molecular weight) that can more easily be determined than actual molar mass parameters like M_n and M_w ”, that “[t]here are several empirical relations between IV and M_w , but such relation is highly dependent on molar mass

distribution”, and that “[b]ased on the equation $M_w = 5.37 \times 10^4 [\text{IV}]^{1.37}$ [] an IV of 8 dl/g would be equivalent to M_w of about 930 kg/mol.” Ex. 1001, 2:53-60. The ’532 Patent further indicates that “[g]ood results are obtained if the UHMWPE has an intrinsic viscosity” of “above 5 dl/g”, particularly “between about 8 and 40 dl/g, more preferably between 10 and 30, even more preferably between 12 and 28, most preferably between 15 and 25 dl/g.” Ex. 1001, 2:43-52. According to the ’532 Patent, such “ranges represent an optimum in polymer processability and filament properties.” Ex. 1001, 2:52-53. The ’532 Patent further indicates that intrinsic viscosity is “determined according to method PTC-179 (Hercules Inc. Rev. Apr. 29, 1982) at 135° C. in decalin, with dissolution time of 16 hours, with anti-oxidant DBPC in an amount of 2 g/l solution, and the viscosity at different concentrations extrapolated to zero concentration.” Ex. 1001, 2:44-48, 4:51-57.

79. With respect to spin solvent, the ’532 Patent indicates that suitable spin solvents include paraffins, mineral oil, kerosene, or decalin and that such spin solvent can be removed by evaporation, by extraction, or by a combination of evaporation and extraction routes. Ex. 1001, 2:38-41. The ’532 Patent further indicates that the UHMwPE filaments preferably contain less than 800 ppm of residual amounts of spin solvent, more preferably less than 500, even more preferably less than 250, most preferably less than 100 ppm, such as less than 80 ppm, or less than 60 ppm. Ex. 1001, 3:36-42.

80. The '532 Patent indicates that “[e]xamples of inorganic pigments include pigments containing...chromium oxide” and “[g]ood results are obtained with aluminum-chromium-cobalt oxide, since a suture with good mechanical properties and a low degree of leaching out is obtained.” Ex. 1001, 3:46-51.

81. With respect to the amount of pigment, the '532 Patent indicates the pigment may be between 0.1-7 wt. % of the final filament, preferably at least 0.3 wt. %, more preferably at least 0.5 wt. %, and even more preferably at least 0.7 wt. % of pigment. Ex. 1001, 3:52-56. The '532 Patent further indicates that the final filament preferably contains at most 5.0 wt. % of pigment, more preferably at most 3 wt. % of pigment, even more preferably at least 2.5 wt. %, and most preferably at most 2 wt. %. Ex. 1001, 3:56-59.

82. According to the '532 Patent, “[t]he mixture containing the UHMwPE, the spinning solvent and the pigment may be provided at different stages in the gel spinning process.” Ex. 1001, 3:25-27. For example, the '532 Patent describes preparing a dry mixture of UHMwPE powder and the pigment and producing a slurry of that mixture in a spinning solvent as well as producing a solution of UHMwPE in the spinning solvent first and thereafter adding the pigment to that solution. Ex. 1001, 3:27-35.

83. With respect to further constituents, the '532 Patent indicates that UHMwPE filaments consist preferably of UHMwPE, the pigment, and less than

1000 ppm of further constituents, preferably less than 500 ppm of further constituents, more preferably less than 200 ppm of further constituents, most preferably less than 100 ppm of further constituents, such as less than 80 ppm, or less than 60 ppm. Ex. 1001, 3:61-67.

84. The '532 Patent further indicates that the number of filaments in the multi-filament yarn be between 10 and 1000, preferably more than 20, and more preferably more than 30. Ex. 1001, 3:21-24.

85. The '532 Patent describes four example colored multi-filament yarns. Ex. 1001, 5:37-6:13. However, each of these examples appear to require additional requirements that are not found in Claims 1-9, such as tenacity, tensile modulus (modulus), and elongation at break (eab). These examples fail to disclose certain of the values recited in Claims 1-9, such as the amounts of residual solvent and further constituents.

86. Examples 1-4 of the '532 Patent describe the preparation of example colored multi-filament yarns. Ex. 1001, 5:37-6:13. Specifically, “[s]lurries containing decalin, 6 mass % of power of UHMwPE having an IV of 14 and 0.5, 1, 1.5 [and] 2 wt. %[, respectively,] of aluminum-chromium-cobalt oxide pigment (of the cations 32.5% Co, 32% Al and 35.5 Cr) were prepared in a mixer. The slurries were fed to a twin screw extruder having a diameter of 25 mm, being equipped with a gear-pump at a temperature setting of 180° C. In the extruder the UHMwPE

was dissolved in the decalin and the so obtained mixture of the UHMwPE dissolved in the decalin and the pigment was extruded through a spin plate having 24 spin holes into a nitrogen atmosphere with a rate of 1.0 g/min per hole. The so obtained solution filaments were cooled in a water bath kept at about 35 °C. and with a water flow rate of about 5 cm/s perpendicular to the filaments entering the bath, and taken-up at such rate that a draw ratio of 15 was applied to the as-spun filaments in the air-gap of 15 mm. The filaments subsequently entered an oven at 130° C. The filaments were further stretched, during which process the decalin evaporated from the filaments. After the stretching process the filaments were kept taut in an oxygen free environment for 24 hours at 100° C.” Ex. 1001, 5:39-60. The ’532 Patent indicated that the multi-filament yarns of Examples 1-4 “show[ed] a homogenous and bright colour.” Ex. 1001, 6:12-13.

87. The ’532 Patent further describes subjecting the multi-filament yarns obtained in Examples 1-4 to tests for determining mechanical properties, leaching out, and cytotoxicity. Ex. 1001, 5:61-62. According to the ’532 Patent, the mechanical properties of tenacity, tensile modulus (modulus), and elongation at break (eab) were determined “with a procedure in accordance with ASTM D885M” and the results were reported in Table 1. Ex. 1001, 4:58-5:3, 5:63-64, and Table 1.

88. With respect to leaching out, the '532 Patent indicates that a leaching test was performed “[a]ccording to the requirements of ISO 10993-12:2002(E), [wherein] an extraction was performed with samples of multi-filament yarn in both polar (distilled water) and non-polar (cotton-seed oil) solvents. The extraction conditions were 37°C for 24 and 72 hours. After dilution with acetonitrile, the different phases were analyzed on the presence of pigment using Liquid Chromatography-Mass Spectrometry (LC-MS) and Gas Chromatography-Mass Spectrometry (GC-MS). In case no leaching [] was observed means that leaching was lower than 10 ppb.” Ex. 1001, 5:4-15. The '532 Patent further provides that “[n]o compounds related to pigment, or other unknown compounds, [were] found. The pigment <10 µg/kg (<10 ppb).” Ex. 1001, 5:65-67.

89. The '532 Patent further described two comparative tests, Comparative Test A and Comparative Test B, which were colored multi-filament yarns prepared using a dye in a solution of super-critical carbon dioxide and dip-coating a prepared multi-filament yarn in a polyurethane coating containing a dye, respectively. Ex. 1001, 6:15-48. The '532 Patent asserted that both comparative tests resulted in sutures that were not suitable for use in surgery due to considerable leaching out and insufficient cytotoxicity. *Id.*; *see also*, Table 1:

TABLE 1

Example/ Xomp. exp.	Tenacity [cN/ dTex]	Modulus [cN/ dTex]	Eab [%]	leach- ing [-]	cytotox. [-]	colouring [-]
I	37	1439	2.8	No	0	homogeneous
II	37	1377	2.9	No	0	Homogeneous
III	40	1501	3.0	No	0	Homogeneous
IV	37	1414	2.9	No	0	Homogeneous
A	21	—	—	Yes	—	In- homogeneous
B	37	1381	2.8	Yes	—	In- homogeneous

Ex. 1001, Table 1. Like examples 1-4, neither the description of Comparative Tests A and B, nor the data provided in Table 1, disclose the amounts of residual solvent or further constituents.

C. Challenged Claims of the '532 Patent

90. The challenged claims of the '532 Patent are Claims 1-9. I have reproduced the challenged claims below.

Claim	Recitation
1[Pre]	A colored multi-filament yarn comprising
1[A]	filaments that have been obtained by gel spinning a mixture containing ultra-high molecular weight polyethylene (UHMwPE) having an intrinsic viscosity (IV) of between about 8 and 40 dl/g, a spin solvent and a pigment, and
1[B]	wherein the filaments consist of UHMwPE,

Claim	Recitation
1[C]	between 0.1 and 7.0 wt. % of an inorganic chromium oxide-containing pigment,
1[D]	a residual amount of spin solvent of less than about 500 ppm, and
1[E]	less than 1000 ppm of further constituents.
2	The multi-filament yarn according to claim 1, wherein the amount of the inorganic pigment present in the filaments is between 0.3 and 5.0 wt. %.
3	The multi-filament yarn according to claim 1, wherein the amount of the inorganic pigment present in the filaments is lower than 2.0 wt. %.
4	The multi-filament yarn according to claim 1, wherein the inorganic pigment is aluminum-chromium-cobalt oxide.
5	The multi-filament yarn according to claim 1, wherein the residual amount of spin solvent is less than 250 ppm.
6	The multi-filament yarn according to claim 1, wherein the residual amount of spin solvent is less than 100 ppm.
7	The multi-filament yarn according to claim 1, wherein the residual amount of spin solvent is less than 60 ppm.

Claim	Recitation
8	The multi-filament yarn according to claim 1, wherein the filaments contain less than 500 ppm of further constituents.
9	The multi-filament yarn according to claim 1, wherein the number of filaments is between 10 and 1000.

D. Priority Date of the '532 Patent

91. I am informed and understand that the earliest possible priority date of the claims of the '532 Patent is May 23, 2007. In particular, the '532 Patent is a continuation of U.S. Patent No. 9,506,168 ("the '168 Patent") (Ex. 1029), which was the U.S. national phase filing of International Application No. PCT/EP2008/004135 ("the '135 Application"), which claimed priority to European Application No. 07010217 ("the '217 Application"), filed May 23, 2007.

92. For purposes of this IPR proceeding, I have been asked to assume that the earliest possible priority date is May 23, 2007, the date of filing of the '217 Application.

VII. File History

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

93. U.S. Patent Application No. 15/338,085 ("the '085 Application") was filed on October 26, 2016, and resulted in U.S. Patent No. 10,280,532 ("the '532

Patent”). The ’085 Application was filed as a continuation of the ’168 Patent, which was the U.S. national phase filing of the ’135 Application, which in turn, claimed priority to the ’217 Application.

94. As stated above, the ’085 Application was filed on October 26, 2016, containing 9 claims, of which Claim 1 was independent. Ex. 1002, pages 3-13.

95. The first non-final Office Action was mailed on October 5, 2018. Ex. 1002, pages 44-48. In the Office Action, the Examiner rejected Claims 1-9 on the ground of nonstatutory double patenting as being unpatentable over Claims 1-12 of the ’168 Patent.

96. In response, the Patent Owner filed a Terminal Disclaimer over the ’168 Patent. Ex. 1002, pages 69-70. The Patent Owner also filed an amendment, amending the cross-reference paragraph of the specification to specifically identify the patent number of the ’168 Patent. Ex. 1002, pages 76-78.

97. A Notice of Allowance was mailed on December 21, 2018. Ex. 1002, pages 81-87. The Notice of Allowance indicated that “[w]ith regards to base claim 1, the prior art fails to disclose, in combination with other limitations of the claim, a colored multi-filament yarn comprising filaments that have been obtained by gel spinning, the filament consist of ultra-high molecular weight polyethylene (UHMwPE), between 0.1 and 0.7 [sic] wt. % of an inorganic chromium oxide-containing pigment. The prior art WO 2005/066401 A1 to Simmelink discloses

process for making high-performance polyethylene multifilament yarn, US 2008/0009903 to Schmieding et al. discloses suture with filaments formed of polyether-ketone variant and 2008/0027534 to Edwin et al. discloses self-sealing PTFE graft with kink resistance. Theses [sic] prior arts taken alone or in combination do not anticipate or make obvious applicants claimed invention.” Ex. 1002, page 86. Applicant thereafter paid the issue fee on March 21, 2019 (Ex. 1002, pages 107-109), and the ’532 Patent issued on April 17, 2019. Ex. 1001.

E. U.S. Patent No. 9,506,168

98. Claim 1 of the ’168 Patent is directed to a colored suture consisting of multi-filamentary yarn and at most 20 mass % of other components, wherein at least 50 mass % of the yarn consists of colored gel-spun filaments obtained by 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, wherein the colored filaments consists of UHMwPE, between about 0.1 and 7.0 wt. % of an inorganic chromium oxide-containing pigment, a residual amount of less than about 100 ppm of the spin solvent, and less than 1000 ppm of further constituents. Ex. 1029, Claim 1.

99. The ’168 Patent matured from U.S. Patent Application No. 12/599,869 (“the ’869 Application”), which was the U.S. national phase filing of

the '135 Application, which was filed on May 23, 2008. The '135 Application claimed priority to the '217 Application.

100. A copy of the '135 Application, along with a Preliminary Amendment, was first transmitted to the USPTO on November 12, 2009. The '135 Application as filed originally contained 10 claims, of which Claim 1 was independent. Ex. 1030, pages 10-20. The Preliminary Amendment amended the claims, along with other priority-related amendments, to eliminate various multiple dependent claims. Ex. 1030, pages 5-9. Claim 1 of the '869 Application, as filed, recited a suture containing filaments of ultra-high molecular weight polyethylene (UHMwPE), characterized in that the suture contains a multi-filament yarn that is obtained by a process comprising the steps of: a) providing a mixture containing UHMwPE, a spinning solvent and a pigment, and b) spinning a multi-filament yarn from the mixture by the gel spinning process.

101. The first non-final Office Action was mailed on July 16, 2012. Ex. 1030, pages 170-174. In the Office Action, the Examiner rejected Claims 1-10 under 35 U.S.C. § 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over, a DSM reference, U.S. Patent Publication No. 2008/0287990 A1 to Smit ("Smit"). Ex. 1030, pages 172-173. Citing MPEP 2113, the Examiner further noted that product by process claims are not limited to the manipulation of the recited steps, only the structure implied by the steps, and once

a product appearing to be substantially the same or similar is found, a prior art rejection may be made and burden is shifted to the applicant to show an unobvious difference. Ex. 1030, page 173.

102. In response, the Applicant amended Claims 1-9 “for the purpose of clarity”, including deleting embedded preferences from Claim 9 regarding residual amounts of spin solvent and instead appearing as new Claims 11-14. Ex. 1030, pages 181-187. The Applicant also canceled Claim 10 “to obviate any issue under 35 USC §101.” Ex. 1030, page 184.

103. The Applicant argued that the claims were patentable over Smit. In particular, the Applicant noted that “Smit discloses that a UHMWPE filament may contain customary additives. These additives may (if present) be one or more of a range of substances and as one of these substances, colorants are mentioned.” Ex. 1030, page 184. After indicating that “colorants cover a range of different types of substances...including Dyes, Pigments, Inks, Paints and Colored Chemicals”, the Applicant argued that “[s]electing one member of this group of different types of substances is [] not arbitrary” as they “interact physically and chemically with the material in which they are mixed in fundamentally different ways.” Ex. 1030, page 185. The Applicant further argued that Smit did not disclose or specify any list of colorants or utilize colorants in its examples. Ex. 1030, page 185. Instead, the Applicant argued that “the present applicants have discovered that using a *pigment*

had major advantages over other types of colorants in that leaching was diminished” and that “no leaching or cytotoxicity was observed” in the claimed particular pigments. Ex. 1030, page 185 (emphasis in original).

104. The Applicant further argued that “the structural implication to the suture” of the claimed process “is that the suture will have pigment incorporated into the filaments of the yarn”, with “[a]n unobvious difference” being a “resulting improvement in leaching behavior”. Ex. 1030, pages 185-186 (emphasis in original).

105. A final Office Action was mailed on May 30, 2013. Ex. 1030, pages 193-198. In the Office Action, the Examiner rejected Claims 1-9 and 11-14 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,060,007 to Hutton et al. (“Hutton”) in view of U.S. Patent Application Publication No. 2003/0050667 to Grafton et al. (“Grafton”). Ex. 1030, page 195. Citing Hutton (Col. 2, ll. 26-27 (“The colorant employed to dye the suture is preferably a free-flowing dye or pigment powder at room temperature”)), the Examiner asserted that Hutton taught a process for forming a dyed braided suture comprising a colorant to dye the suture, the colorant comprising pigment powder, and that it would have been obvious to employ the teaching in Grafton of using a suture containing UHMwPE filaments in order to strengthen the suture. Ex. 1030, pages 195-196.

106. In response, the Applicant filed a Notice of Appeal on December 2, 2013, followed by an Amendment and Request for Continued Examination on February 3, 2014. Ex. 1030, pages 205-220. The Applicant amended independent Claim 1 to recite a suture comprising a multi-filamentary yarn comprised of multiple gel-spun pigment-containing filaments of ultra-high molecular weight polyethylene (UHMwPE) that is obtained by a process comprising the steps of: a) providing a mixture comprised of UHMwPE having an intrinsic viscosity (IV) of at least 5 dl/g, a spinning solvent and a pigment; b) spinning multiple filaments from the mixture by a gel spinning process; and c) at least partly removing the spinning solvent from the multiple filaments to obtain a multi-filamentary yarn comprised of the multiple gel-spun pigment-containing UHMwPE filaments. Ex. 1030, page 212. The Applicant also canceled Claim 2, amended Claims 9 and 11-14, and added new Claims 15-24, including independent Claim 16 which recited a suture consisting of a multi-filamentary yarn, wherein at least 50 mass% of the yarn consists of gel-spun filaments consisting of ultra-high molecular weight polyethylene (UHMwPE) having an intrinsic viscosity (IV) of between about 8 and 40 dl/g, between about 0.1 and 7.0 wt.% of an inorganic pigment, a residual amount of less than about 800 ppm of a spin solvent, and less than 1000 ppm of further constituents. Ex. 1030, pages 212-215.

107. With respect to Hutton, the Applicant argued that “[n]o inorganic pigments are disclosed”, and that at least one of the disclosed pigments “is specifically not suitable for low density (LD) and high density (HD) polyethylene”. Ex. 1030, page 218 (emphasis in original). The Applicant further argued that “Hutton requires a dry mix of dye and thermoplastic resin”, as well as “melt spinning”, and there is “no disclosure in Hutton that the techniques therein would also apply outside the strict limitations regarding ‘melt spinning’ and ‘dry blend’.” Ex. 1030, page 218 (emphasis in original). The Applicant also argued that “the IV of the UHMwPE” as claimed “would be much too high to melt extrude” and Hutton was not “pertinent to high IV resins” since “high IV resins could not be melt-spun.” Ex. 1030, page 218.

108. With respect to Grafton, the Applicant argued that Grafton teaches pigment-free UHMwPE filaments braided with polyester strands and “if one wants to impart color to the suture, then filaments other than UHMwPE filaments are dyed.” Ex. 1030, page 219 (emphasis in original).

109. A non-final Office Action was mailed on August 20, 2014. Ex. 1030, pages 228-239. In the Office Action, the Examiner rejected Claim 1 under pre-AIA 35 U.S.C § 102(b) as being anticipated by Grafton.

110. The Examiner also rejected Claims 3-5 under 35 U.S.C. § 103(a) as being unpatentable over Grafton in view of U.S. Patent Application Publication

No. 2006/0045899 to Sarangapani et al. (“Sarangapani”). In particular, the Examiner asserted that Sarangapani taught an “[a]ntimicrobial composition for medical articles disclosing coloring pigments is approved by the FDA to be used is about 0.001 to about 0.25 wt.%” and “discovering the optimum or workable ranges [of the pigment] involves only routine skill in the art.” Ex. 1030, page 231.

111. The Examiner further rejected Claim 6 under 35 U.S.C. § 103(a) as being unpatentable over Grafton in view of U.S. Patent Application Publication No. 2005/0208096 to Shalaby (“Shalaby”). The Examiner asserted that Shalaby taught “Color-Fast radiation sterilized implants comprising surgical implants such as sutures comprising inorganic pigment” and it would have been obvious to substitute one known method of dyeing sutures for another. Ex. 1030, page 232.

112. The Examiner also rejected Claim 7 under 35 U.S.C. § 103(a) as being unpatentable over Grafton in view of Shalaby and further in view of U.S. Patent No. 3,565,652 to Burnet (“Burnet”). In particular, the Examiner asserted that Burnet taught a “[m]ethod of coloring viscose comprising filament that used pigments containing chromium oxide” and it would have been obvious to substitute one known method of dyeing for another. Ex. 1030, pages 232-233.

113. The Examiner also rejected Claim 8 under 35 U.S.C. § 103(a) as being unpatentable over Grafton in view of Shalaby and Burnet and further in view of U.S. Patent Application Publication No. 2006/0084745 to Kuhn (“Kuhn”). In

particular, the Examiner asserted that Kuhn taught a “[s]ilicone rubber composition comprising pigments containing aluminum-chromium-cobalt oxide” and it would have been obvious to substitute one known method of dying for another. Ex. 1030, page 233.

114. The Examiner also rejected Claim 15 under 35 U.S.C. § 103(a) as being unpatentable over Grafton in view of U.S. Patent Application Publication No. 2009/0012251 to Dirks et al. (“Dirks”), which was co-owned by DSM at the time. In particular, the Examiner asserted that Dirks taught “[a] process for making a monofilament-like product compris[ing] UHMWPE having an IV of more than 5 dl/g”. Ex. 1030, page 234.

115. The Examiner also rejected Claims 9, 11-14, and 21-24 as product-by-process claims, further asserting that U.S. Patent Application Publication No. 2004/0267313 to Amery et al. (“Amery”) “discloses the spinning solvent in UHMWPE suture should be below 100 ppm to prevent irritation in humans [] is old and well known in the art.” Ex. 1030, page 234.

116. The Examiner also rejected Claims 16-18 under 35 U.S.C. § 103(a) as being unpatentable over Grafton in view of Sarangapani, Shalaby, Amery, and further in view of Dirks. Ex. 1030, page 235. In particular, the Examiner asserted that it would have been obvious to: “employ[] the teaching of using pigments as taught by Sarangapani into Grafton for suture coloring since the FDA approved

coloring pigments are commonly used by the medical industry of about 0.001-0.25 wt. % of pigment”, “employ the process of dying sutures as taught by Shalaby into the suture of Grafton”, “modify the UHMWPE suture having a[n] IV of more than 5 dl/g as taught by Dirks in order to enhance solubility of the UHMWPE and processability of the solution used”, and “have an UHMWPE suture containing the residual amount of less than 1000 ppm since the more pure the material, UHMWPE, and the less of other constituent or other materials, the stronger the strength for the suture.” Ex. 1030, pages 236-237. The Examiner further asserted that the “residual amount of less than about 800 ppm of a spin solvent, and less than 1000 ppm of further constituents” limitation was being treated as a product by process limitation. Ex. 1030, page 235.

117. The Examiner also rejected Claim 19 under 35 U.S.C. § 103(a) as being unpatentable over Grafton in view of Sarangapani, Shalaby, and Dirks and Claim 20 as being unpatentable over Grafton in view of Sarangapani, Shalaby, Dirks, and Kuhn. Ex. 1030, pages 237-238.

118. In response, the Applicant filed an Amendment on November 20, 2014, canceling Claims 1-15 and 19. Ex. 1030, pages 254-270. The Applicant also amended independent Claim 16 to further require that the suture consist of multi-filamentary yarn and, at most, 20 mass% of other components and to further specify that the inorganic pigment is an inorganic chromium oxide-containing

pigment. Ex. 1030, page 255. The Applicant also added new dependent Claims 25-31 “so as to specify the content of the ‘further constituents’, the content of the filaments and the content of the ‘other components’”. Ex. 1030, pages 256-257.

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

120. The Applicant also argued that “Grafton discloses a colored braided suture, which suture comprises a mixture of non-colored UHMwPE multi-filamentary yarn and colored nylon or polyester multi-filamentary yarn, and typically comprises a coating”. Ex. 1030, page 259 (emphasis in original). The Applicant further argued that Grafton does not disclose “a suture containing colored UHMwPE yarn”. Ex. 1030, pages 259-260 (emphasis in original).

121. The Applicant also commented on the number of secondary references cited by the Examiner. Ex. 1030, page 260. In particular, the Applicant asserted that “[t]he mere fact [] that such numerous [secondary] references have been required to be cited for various isolated and disparate disclosures in order to establish the alleged obviousness of the claims [sic] invention in fact is evidence to the contrary”. Ex. 1030, page 260.

122. The Applicant argued that the problem solved by the claims is “to provide a suture containing colored UHMwPE filaments from which colorant does not leach and which filaments have mechanical properties, such as tensile strength, that do not deteriorate due to the presence of the colorant.” Ex. 1030, page 261.

123. The Applicant further argued that Grafton does not “suggest to use a colored UHMwPE yarn to make a suture and in fact teaches directly against the use of colored UHMwPE yarn..., namely the use [of] a colored fiber based on a polymer other than UHMwPE in order to make colored suture.” Ex. 1030, page 261 (emphases in original).

124. The Applicant further argued that Sarangapani, “which concerns an antimicrobial composition that can be used to form an antimicrobial coating on a surface, especially on a metal-based medical device”, is not pertinent prior art, that the rejection was “based impermissibly on hindsight”, and even if combined with Grafton, would, at best, result in employing relatively low amounts of copper-based pigments. Ex. 1030, pages 261-265.

125. Turning to the application of Shalaby, the Applicant asserted that “Shalaby [] relates to colored surgical implants that can be radiation-sterilized without compromising their color” and teaches mixing a polymer “with a lipophilic dispersed organic dye, specifically with the organic dye D&C Yellow 11”, which the Applicant further argued is “fundamentally different from a ‘pigment’.” Ex.

1030, page 265 (emphasis in original). The Applicant asserted that Shalaby's teaching of "an organic dye -- not an inorganic pigment -- [] would lead away from the [] claimed invention." Ex. 1030, page 266.

126. The Applicant admitted that Amery, which "relates to a braided suture made from UHMwPE filaments", "confirms that the level of residual spin solvent, especially decalin, in gel-spun UHMwPE should be low, and preferably below 100 ppm for biocompatibility reasons." Ex. 1030, page 266.

127. The Applicant asserted that the "obtained monofilament-like product" of Dirks "from multifilament UHMwPE yarn", which was "especially suited for use as fishing line", was not pertinent prior art and even if pertinent, did "not disclose or suggest the amount and/or type of pigment" in the pending claims. Ex. 1030, page 267.

128. The Applicant further asserted that Burnet, which concerned "a method of making colored yarn of viscose also called rayon or regenerated cellulose", was "entirely irrelevant." Ex. 1030, page 267. The Applicant asserted that even if Burnet were considered relevant, Burnet teaches using "silica-based mixed oxide glass frits as pigment particles in a spinning process (to make colored viscose) and not the metal oxide itself" because "pigments like chromium and cobalt oxides cannot be used as such in a viscose process without causing great

loss of strength of the yarn product”. Ex. 1030, pages 267-268 (emphases in original).

129. The Applicant argued that Kuhn, which “relates to curable silicone rubber compositions for high-voltage insulators”, was not pertinent and “merely confirms that aluminum-chromium-cobalt pigments were known materials”. Ex. 1030, pages 268-269. The Applicant further asserted that they “do not dispute that aluminum-chromium-cobalt pigments were *per se* known” and “the general knowledge in the art that aluminum-chromium-cobalt compounds may be employed as pigments generally would not have provided any suggestion at all that such pigment would be suitable for and offer specific advantages in making colored UHMwPE multifilament yarn for use in a suture”. Ex. 1030, page 269.

130. Finally, the Applicant argued that the Examiner’s assertion regarding “...the more pure the material, UHMwPE, and the less of other constituent or other materials, the stronger the strength for the suture” with respect to the “less than 1000 ppm of other constituents” limitation actually “strongly supports the conclusion that [the claimed pigment-colored suture] is indeed a very surprising and unexpected result” as the “ordinarily skilled person (as acknowledged by the Examiner) would seek to eliminate the presence of such pigment.” Ex. 1030, pages 269-270.

131. A final Office Action was mailed on April 15, 2015. Ex. 1030, pages 276-282. In the Office Action, the Examiner rejected Claims 16-18, 20, and 25-31 under pre-AIA 35 U.S.C. § 103(a) as being unpatentable over Dirks in view of Kuhn. In particular, the Examiner asserted that it would have been obvious to employ pigments containing aluminum-chromium-cobalt oxide as taught by Kuhn into the suture of Dirks as a substitution of one known method of dying for another and that discovering the optimum or workable percentage ranges of inorganic pigment involved only routine skill in the art. Ex. 1030, pages 278-279. The Examiner further asserted that the limitations regarding consisting of gel-spun filaments, residual spin solvent, and residual amounts of further constituents would have been obvious “since the more pure the material, UHMWPE, and the less of other constituent or other materials, the stronger the strength for the suture.” Ex. 1030, page 279.

132. The Examiner also rejected the remaining claims, Claims 21-24, under pre-AIA 35 U.S.C. § 103(a) as being unpatentable over Dirks in view of Kuhn and further in view of Amery. Ex. 1030, page 280.

133. Without amending the then-pending claims, the Applicant filed an After-Final Response on July 15, 2015 (Ex. 1030, pages 291-302), arguing that Dirks teaches “at least three different routes to making a colored suture comprising UHMWPE yarn”, “including using colored yarn, but also by adding a colored oil

or solvent or by applying a colored coating later in the process of making a fused product.” Ex. 1030, pages 294-295. The Applicant further argued that Dirks “is completely silent on choice of colorant (organic vs inorganic; dye vs pigment), effects of colorant on mechanical properties of the suture, as well as on leaching behaviour of a colorant.” Ex. 1030, page 295.

134. The Applicant further argued that Kuhn relates to the “disparately remote” technical field of “curable silicone rubber compositions for high-voltage insulators” such that Kuhn is not pertinent art. Ex. 1030, pages 295-296. The Applicant also argued that even if pertinent, “[t]here is no indication in Kuhn that the therein disclosed pigments would or could be employed in gel-spun UHMWPE filaments.” Ex. 1030, page 298 (emphasis in original).

135. Finally, the Applicant argued that the commonly-owned Dirks reference was disqualified as a prior art reference under 35 U.S.C. § 103, asserting that Dirks “qualifies as prior art *only* under 35 U.S.C. § 102(e)”. Ex. 1030, pages 300-301.

136. Thereafter, on October 15, 2015, the Applicant filed a Request for Continued Examination, requesting the Examiner to consider the reply previously filed on July 15, 2015. Ex. 1030, page 305.

137. A final Office Action was mailed on October 23, 2015. Ex. 1030, pages 310-315. In the Office Action, the Examiner indicated that the finality of the

rejection in the Office Action mailed April 15, 2015, was withdrawn, but that a new rejection was being issued. Ex. 1030, page 312. The Office Action rejected Claims 16-18 and 20-31 under pre-AIA 35 U.S.C. § 103(a) as being unpatentable over International Publication No. WO2005066401 to Simmelink et al. (“Simmelink”) in view of U.S. Patent Application Publication No. 2008/0027534 to Edwin et al. (“Edwin”). Ex. 1030, page 312. In particular, the Examiner asserted that Simmelink teaches a process for making high-performance polyethylene multi-filament yarn, at least 50 mass% of the yarn consisting of gel-spun filaments consisting of ultra-high molecular weight polyethylene, having an intrinsic viscosity (IV) of between about 8 and 40 dl/g, less than 3% of customary additives and a residual less than 50 ppm of solvents. Ex. 1030, pages 312-313. The Examiner further asserted that Simmelink failed to teach that the inorganic pigment is aluminum-chromium-cobalt oxide, but Edwin taught “[a] self-sealing PTFE graft with kink resistance comprising a coating of pigments or dyes of Chromium-cobalt-aluminum oxide” and it would have been obvious “to employ pigments containing chromium-cobalt-aluminum oxide as taught by Edwin into the multi yarn of Simmelink as a substitute [for] one known method of dying for another.” Ex. 1030, page 313. The Examiner further asserted it would have been obvious to discover the optimum or workable percentage ranges of the inorganic pigment used

and that “the more pure the material, UHMWPE, and the less of other constituent or other materials, the stronger the strength for the suture.” Ex. 1030, page 313.

138. On November 5, 2015, the Examiner mailed an Examiner-Initiated Interview Summary and a non-final Office Action, repeating the rejections as set forth in the final Office Action mailed October 23, 2015, “since the applicant did not provide []any arguments to the previous Final-Rejection mailed on 10/23/2015.” Ex. 1030, pages 365-371. The Interview Summary indicated that the Applicant’s representative “would like the examiner to send out a Non-Final Office Action even though it would have the exact rejections as the latest Final” since “he would like it to be clear on record since it is showing that the Final Rejection is the first action after the filing of the RCE.” Ex. 1030, page 371.

139. Thereafter, the Applicant filed an Amendment on April 5, 2016. Ex. 1030, pages 383-392. Therein, the Applicant amended independent Claim 16 to recite “[a] colored suture consisting of multi-filamentary yarn and at most 20 mass% of other components, wherein at least 50 mass% of the yarn consists of colored gel-spun filaments obtained by spinning a mixture containing ~~consisting of~~ 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, wherein the colored filaments consist of UHMwPE, between about 0.1 and 7.0 wt.% of an inorganic chromium oxide-containing pigment, a residual amount of less than

about 100 800-ppm of ~~[[a]]~~the spin solvent, and less than 1000 ppm of further constituents.” Ex. 1030, page 384 (emphases in original). The Applicant also canceled Claims 21-23 and amended the preamble of the remaining dependent claims in line with the colored suture of Claim 16. Ex. 1030, pages 384-386.

140. The Applicant argued that “what is claimed is not a material that is post-colored using a dye solution or other colored component” but instead “[t]he inorganic chromium oxide-containing pigment is physically part of the composition used to form the yarn via the gel spinning process and is thus incorporated into the filaments forming part of the yarn that (at least partly) constitutes the colored suture.” Ex. 1030, pages 388-389 (emphases in original).

141. The Applicant further asserted that Simmelink teaches that “the UHMwPE in the mixture used for spinning may further contain small amounts of customary additives, including colorants”, but that “Simmelink provides no further information on methods of making colored UHMwPE yarn or on type of suitable colorants, and also in the experiments no colorants like a dye – which is soluble in the polymer – or a pigment – which is present as solid particles in the polymer – were applied.” Ex. 1030, page 389. The Applicant further asserted that Simmelink “does not disclose a suture comprising UHMwPE filaments that contain an *inorganic aluminum-chromium-cobalt oxide pigment* in an amount of between 0.1 and 7.0 wt.%” nor does Simmelink “provide the skilled person with any guidance

on how to make such a product containing colored UHMWPE yarn.” Ex. 1030, page 389 (emphasis in original).

142. The Applicant further argued that “Edwin teaches that an ePTFE graft surface can be provided with an orientation line on the surface of the graft via printing with an ink” and “[i]n a list of suitable pigments and dyes for use in the ink, a chromium-cobalt-aluminum oxide is mentioned.” Ex. 1030, page 390. The Applicant asserted that “Edwin only discloses chromium-cobalt-aluminum oxide as a component of an ink that is used to print a line on the surface of an ePTFE graft” and such teaching is in contrast to “an inorganic chromium oxide-containing pigment is part of the mixture including UHMWPE and spin solvent that has been gel spun into the colored filaments of the multi-filament yarn itself.” Ex. 1030, page 390 (emphases in original). The Applicant further asserted that the combination of Simmelink and Edwin would result in “a suture comprising multi-filamentary yarn gel spun from a mixture comprising UHMWPE and having a colored orientation line printed on its surface.” Ex. 1030, page 391. The Applicant also asserted that “Edwin does not indicate or suggest to color the ePTFE graft material itself” and that there is “no indication in Edwin that the therein disclosed pigments would or could be employed in gel spun UHMwPE filaments, and which would invite the skilled person [sic] do experiments that go against the general

belief in the art that mechanical strength of UHMWPE filaments would be jeopardized by incorporating pigments.” Ex. 1030, pages 390-391.

143. In arguing that “[t]here are large differences in materials and processes” in Edwin and Simmelink, the Applicant admitted that “Simmelink describes gel spinning of a mixture comprising UHMwPE into multi-filamentary yarn”, and “mentions colorant could be added to a mixture comprising UHMwPE”. Ex. 1030, page 391.

144. A Notice of Allowance was mailed on July 19, 2016. Ex. 1030, pages 398-404. The Notice of Allowability, allowing Claims 16-18, 20, and 24-31, included an Examiner’s Statement of Reasons for Allowance indicating that “[w]ith regards to base claim 16, the prior art fails to disclose, in combination with other limitations of the claim, a colored suture consisting of multi-filament yarn, wherein the yarn consists of colored gel-spun filaments, wherein the colored filaments consist of ultra-high molecular weight polyethylene (UHMwPE), between 0.1 and 7.0 wt. % of an inorganic chromium oxide-containing pigment. The prior art WO 2005/066401 A1 to Simmelink discloses process for making high-performance polyethylene multifilament yarn, US 2008/0009903 to Schmieding et al. discloses suture with filaments formed of polyether-ketone variant and 2008/0027534 to Edwin et al. discloses self-sealing PTFE graft with kink resistance. These prior arts taken alone or in combination do not anticipate or

make obvious applicants claimed invention.” Ex. 1030, page 403. Applicant thereafter paid the issue fee on October 19, 2016 (Ex. 1030, pages 420-422), and the ’168 Patent issued on November 29, 2016. Ex. 1029.

VIII. Litigation related to the ’532 Patent

145. I understand that the ’532 Patent is currently the subject of litigation in the District of Delaware. *See DSM IP Assets, B.V. et al. v. Honeywell International Inc.*, C.A. No. 23-675-WCB, filed by Patent Owner on June 22, 2023. I understand that, to date, there have been no determinations related to claim construction, invalidity, or infringement.

IX. Claim Construction

146. My opinions concern what I believe a person of ordinary skill in the art would have understood the claim language of Claims 1-9 of the ’532 Patent as of the assumed priority date of May 23, 2007.

147. It is my opinion that no express constructions are necessary of the claim terms of Claims 1-9 of the ’532 Patent and the claim terms should be given their ordinary and customary meaning as understood by a person of ordinary skill in the art at the time of invention.

X. Summary of Opinions

148. I have been asked to provide my opinions as to the validity of Claims 1-9 of the ’532 Patent, the challenged claims at issue. As discussed in further detail

below, it is my opinion that Claims 1-9 of the '532 patent are invalid as obvious in view of at least the prior art discussed herein.

149. As discussed in further detail below, it is my opinion that Claims 1-9 of the '532 Patent are invalid as obvious over Simmelink in view of Section 73.1015.

150. It is my further opinion that Claims 1-9 of the '532 Patent are invalid as obvious over Section 73.1015 in view of Nanri, further in view of Ohta, and further in view of Kavesh.

151. It is my further opinion that Claims 1-9 of the '532 Patent are invalid as obvious over Section 73.1015 in view of Nanri and further in view of Simmelink.

152. The citations to these prior art references in my analysis below provide examples of why they render the claims invalid. I reserve the right to cite and rely on additional references or portions of the cited references in any future declarations, deposition, or testimony.

XI. GROUND 1: THE COMBINATION OF SIMMELINK AND SECTION 73.1015 RENDERS OBVIOUS CLAIMS 1-9

153. It is my opinion that the combination of Simmelink and Section 73.1015 teaches, suggests, or discloses all of the recitations of Claims 1-9 of the '532 Patent and renders the subject matter of each claim as a whole obvious and unpatentable.

A. Simmelink Overview

154. International Publication No. WO2005066401 to Simmelink et al, entitled “Process for Making High-Performance Polyethylene Multifilament Yarn”, filed by DSM IP Assets B.V., published on July 21, 2005. Ex. 1005. Thus, it is my understanding that Simmelink is prior art to the ‘532 Patent under 35 U.S.C. § 102(b).

155. During prosecution of the ’532 Patent, Simmelink was cited by Patent Owner in an Information Disclosure Statement (“IDS”) on October 28, 2016, and identified in the Examiner’s Statement of Reasons for Allowance. Ex. 1002, pages 26, 86.

156. During prosecution of the ’168 Patent, Simmelink was cited by Patent Owner in an Information Disclosure Statement (“IDS”) on November 12, 2009, cited by the Examiner in the Office Actions mailed October 23, 2015, and November 5, 2015, discussed by the Patent Owner in its Amendment filed April 5, 2016, and identified in the Examiner’s Statement of Reasons for Allowance. Ex. 1030, pages 22, 42-78, 122-126, 310-353, 365-371, 383-392, and 403.

157. Simmelink generally describes a variety of parameters and a series of process steps for preparing a multifilament yarn. *See e.g.*, Ex. 1005, Abstract. More specifically, the majority of Simmelink is dedicated to the disclosure of an alleged inventive continuous process for preparing high performance polyethylene (HPPE)

multifilament yarn. Ex. 1005, 1:7-8. Simmelink further discloses a high-performance polyethylene multifilament yarn obtainable by such process, and semi-finished or end-use products or articles containing such HPPE multifilament yarn. Ex. 1005, 1:18-20, 10:34-11:30, 12:24-30. Examples of such articles include “medical implants like suture and cables”. Ex. 1005, 12:28.

158. The process steps disclosed by Simmelink include “a) making a 3-25 mass% solution of ultra-high molar mass polyethylene having an intrinsic viscosity as measured on solutions in decalin at 135°C of between about 8 and 40 dl/g, in a solvent; b) spinning of the solution through a spinplate containing at least 5 spinholes into an air-gap to form fluid filaments, while applying a draw ratio DR_{fluid} ; c) cooling the fluid filaments to form solvent-containing gel filaments; d) removing at least partly the solvent from the filaments; and e) drawing the filaments in at least one step before, during and/or after said solvent removing, while applying a draw ratio DR_{solid} of at least 4.” Ex. 1005, 1:7-21 (stating that such a continuous process was already known from WO 01/73173 A1 to Honeywell).

159. Simmelink describes a high-performance polyethylene multifilament yarn as “a yarn containing at least 5 filaments made from ultra-high molar mass, or ultra-high molecular weight, polyethylene having an intrinsic viscosity (IV, as measured on solutions in decalin at 135°C) of at least about 4 dl/g (UHPE), the

yarn having a tensile strength of at least 3.0 GPa and a tensile modulus of at least 100 GPa.” Ex. 1005, 1:37-2:3. According to Simmelink, such multifilament yarns “have a properties profile that make them an interesting material for use” in a variety of products, including “medical applications”. Ex. 1005, 2:4-7.

160. Simmelink indicates that the UHPE is preferably “a linear polyethylene with less than one branch per 100 carbon atoms” and “can be a single polymer grade, but also a mixture of two or more different polyethylene grades.” Ex. 1005, 8:12-27, 8:31-33.

161. With respect to intrinsic viscosity, Simmelink further discloses that “[t]he ultra-high molar mass polyethylene applied in the process according to the invention has an intrinsic viscosity (IV, as measured on solution in decalin at 135°C) of between about 8 and 40 dl/g, preferably between 10 and 30, or 12 and 28, more preferably between 15 and 25 dl/g, to provide a balance between processability of the solution to be spun and mechanical properties of the obtained filaments.” Ex. 1005, 7:32-8:2.

162. With respect to spin solvent, Simmelink discloses that “any of the known solvents suitable for gel spinning of UHPE can be used as solvent for making the polyethylene solution, for example paraffin wax, paraffin oil or mineral oil, kerosenes, decalin, tetralin, or a mixture thereof.” Ex. 1005, 8:34-9:2. According to Simmelink, it is especially advantageous to use “relatively volatile

solvents, preferably solvents having a boiling point at atmospheric conditions of less than 275°C, more preferably less than 250 or 225°C”, such as “decalin, tetralin, and several kerosene grades.” Ex. 1005, 9:2-5.

163. Simmelink teaches that, “[i]n addition to its mechanical properties,” “the amount of other components or foreign materials in the yarn is very important” “[f]or medical applications.” Ex. 1005, 12:6-7. Specifically, Simmelink describes a HPPE multifilament yarn “containing less than 150 ppm of residual solvent, specifically of solvent having a boiling point at atmospheric conditions of less than 275°C, preferably containing less than 100, 75, or even less than 50 ppm of solvent, and to medical implants containing such yarn.” Ex. 1005, 12:8-12. Simmelink further teaches that “[s]olvent removal can be performed by known methods, for example, by evaporating a relatively volatile solvent, by using an extraction liquid, or by a combination of both methods.” Ex.1005, 9:31-33.

164. Simmelink also discloses the preparation of multiple multifilament yarn examples, including Examples 19, 29, and 30, which contained residual decalin solvent contents of 135 ppm, 16 ppm, and 18 ppm, respectively. Ex. 1005, 19:15-22, 20:13-30; *see also*, Ex. 1005, 18:8-13, 20:20-22 (describing preparation of a yarn with 390 filaments in Comparative Experiment E, containing a residual decalin solvent content of 400 ppm).

165. Simmelink discloses that the UHPE 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.” Ex. 1005, 8:28-31.

166. According to Simmelink, the high-performance polyethylene multifilament yarn contains “at least 5 filaments”, and preferably “at least 10, 50, 100, 150, 200, 300, 375 or even at least 450” filaments. Ex. 1005, 1:37-2:4, 4:21-22, 11:29-30. Simmelink further teaches that “[f]or practical reasons, handling during spinning and drawing becoming increasingly difficult, the number of filaments is preferably at most about 5000.” Ex. 1005, 4:22-24. Simmelink further elaborates that “[y]arn of relatively low titer, containing for example from 5 to 300 filaments, but of extremely high strength is a.o. very suited for making high-strength surgical sutures and cables, or other medical implants.” Ex. 1005, 12:3-6.

167. Simmelink further teaches that “[t]he number of spinholes [in a spinplate, also known as a spinneret,] determines the maximum number of filaments in an as-spun yarn.” Ex. 1005, 4:26-27. In a “special embodiment”, Simmelink discloses “a 3-15 mass% solution of linear UHPE of IV 15-25 dl/g is spun through a spinplate containing at least 10 spinholes”. Ex. 1005, 10:17-19. Simmelink sets forth numerous examples and comparative experiments outlining the preparation of high-performance polyethylene multifilament yarns produced

from spinplates having 24, 195, 390, 588, 780, and 1176 spinholes. Ex. 1005, 16:17-20:30 (describing Examples 1-20, 29, and 30 and Comparative Experiments A-J), Table 1 at page 24. Simmelink further acknowledges that “[a] yarn may also be made by assembling separately produced yarns containing less filaments” and that “as-produced yarn according to the invention can further be assembled into yarns, or ropes etc, of higher titer or linear density.” Ex. 1005, 11:31-35.

B. Section 73.1015 Overview

168. 21 C.F.R. §73.1015, entitled “Chromium-cobalt-aluminum oxide,” published on April 1, 2006. Ex. 1006, pages 1 and 18. Thus, it is my understanding that Section 73.1015 is prior art to the ’532 Patent under 35 U.S.C. § 102(b). Section 73.1015 was not cited during prosecution of the ’532 Patent.

169. Section 73.1015 identifies chromium-cobalt-aluminum oxide as a color additive exempt from certification for use in drugs. Ex. 1006, pages 16-18. Specifically, Section 73.1015 indicates that “the color additive chromium-cobalt-aluminum oxide is a blue-green pigment” that “may be safely used for coloring linear polyethylene surgical sutures, United States Pharmacopeia (U.S.P.), for use in general surgery”. Ex. 1006, page 18, (a), (c).

170. Section 73.1015 provides that the chromium-cobalt-aluminum oxide shall contain 34-37% chromium (calculated as Cr_2O_3), 29-34% cobalt (calculated as CoO), and 29-35% aluminum (calculated as Al_2O_3), with a total of the oxides of

aluminum, chromium, and cobalt to be “not less than 97[%].” Ex. 1006, page 18, (b).

171. With respect to the coloring procedure, Section 73.1015 indicates that “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”, after which “[t]he filaments are cooled, oriented by drawing, and set by annealing.” Ex. 1006, page 18, (c)(1).

172. Section 73.1015 also puts a limit on the maximum weight percent of the chromium-cobalt-aluminum oxide pigment, further indicating that “the quantity of the color additive does not exceed 2 percent by weight of the suture material.” Ex. 1006, page 18, (c)(2).

173. According to Section 73.1015, “there is no migration of the color additive [from the suture] to the surrounding tissue” “[w]hen the sutures are used for the purpose specified in their labeling.” Ex. 1006, page 18, (c)(4).

C. Rationale for Combining Simmelink and Section 73.1015

174. Each of Simmelink and Section 73.1015 was within the knowledge of a person of ordinary skill in the art and is directly relevant to multi-filament yarns and coloring of the same. Simmelink, for its part, is generally directed to “a continuous process for making high-performance polyethylene (HPPE) multifilament yarn”, “a high-performance polyethylene multifilament yarn, and to

semi-finished or end-use products containing said yarn.” Ex. 1005, 1:7-8, 18-20. Specifically, Simmelink confirms that such high-strength yarn is very useful for a variety of applications and that “yarn of relatively low titer, containing for example from 5 to 300 filaments, but of extremely high strength is a.o. very suited for making high-strength surgical sutures and cables, or other medical implants.” Ex. 1005, 12:3-6.²

175. A person of ordinary skill in the art at the time of the assumed priority date of the ’532 Patent was well aware of the design need for colored sutures, especially colored sutures having high strength. Even the Patent Owner admitted in the specification of the ’532 Patent such design need for colored sutures with high strength was known. *See* Ex. 1001, 1:11-17 (“The coloring of sutures is for example used to make the suture better contrast with the blood or tissue in the operating area. In complicated surgical operations, for example in arthroscopic surgery, when different suture ends are used in a small area, sutures of different color are used to assist surgeons in differing between the suture ends.”); 1:22-27

² As I discuss above with respect to the Technical Background/State of the Art at Section V.A., it was well known by the earliest alleged priority date of the ’532 Patent that UHMWPE filaments were usable as sutures and that UHMWPE filaments had been colored using pigments.

(the Patent Owner further admitted that “[n]ext to coloring”, it was already known in the art that “suture strength [was] an important consideration in selecting filaments for producing a suture” and, as recognized in the prior art, “filaments of ultra-high molecular weight polyethylene (UHMwPE) produced according to the gel spinning process”, were known as very strong filaments that were already available for the production of sutures.). Thus, as reflected by the Patent Owner’s admissions and consistent with the state of the art, there was a stated and well-known design need for colored sutures formed from the high-performance polyethylene multifilament yarns. *See* Ex. 1001, 1:11-27.

176. Understanding the importance of colored high-strength sutures, a person of ordinary skill in the art would have been motivated to color the high-performance polyethylene multifilament yarns of Simmelink to produce colored sutures. Simmelink discloses that “[t]he UHPE that is applied in the process according to the invention may further contain small amounts, **generally less than 5 mass%, preferably less than 3 mass% of customary additives**, such as anti-oxidants, thermal stabilizers, **colorants**, flow promoters, etc.” Ex. 1005, 8:28-31 (emphasis added). As admitted in the background of the ’532 Patent and as was well known in the art, there was a need to color sutures to improve visibility. *See* Ex. 1001, 1:11-17.

177. When coloring sutures, a person of ordinary skill would understand that sutures are implantable devices and thus are subject to specific requirements, including containing only colorants approved for use in sutures by the United States Food and Drug Administration (FDA). Specific colorants for use in sutures are listed in the Code of Federal Regulations (CFR) depending on the particular suture material and whether or not the color additive is exempt from batch certification requirements. Thus, to facilitate regulatory approval, a person of ordinary skill in the art would have turned to Section 73.1015 and its disclosure of the color additive chromium-cobalt-aluminum oxide as a pigment in coloring linear polyethylene surgical sutures.³

³ Indeed, DSM admitted this exact need – to facilitate regulatory approval – was the reason why its blue fibers were produced with Chromium-Cobalt-Aluminum Oxide. *See* H. Smelt, et al. “Advances in Medical-Grade UHMWPE Fiber Development: Additives for Visualization” (7th UHMWPE International Meeting Proceedings, 2015) (Ex. 1010 at pages 55-56) (“UHMWPE fiber’s chemical inertness and high crystallinity makes it a difficult material to dye. The very low percentage of amorphous or semicrystalline phase and the apolar nature of the aliphatic C₂H₂ backbone of the UHMWPE polymer does not provide sufficient compatibility with most available color dyes. In this respect, the addition

178. As of the priority date of the '532 Patent, Section 73.1015 identified chromium-cobalt-aluminum oxide as a color additive that was approved for linear polyethylene surgical sutures and exempt from batch certification requirements.

See generally, Ex. 1006, 18. The person of ordinary skill in the art would understand that using a color additive exempt from batch certification would save not only time but expense as compared to petitioning for use of a new, not already authorized, color additive or otherwise requiring certification of each batch.

Specifically, Section 73.1015 discloses, *inter alia*:

(a) *Identity*. The color additive chromium-cobalt-aluminum oxide is a blue-green pigment obtained by calcining a mixture of chromium oxide, cobalt carbonate, and aluminum oxide. It may contain small amounts (less than 1 percent each) of oxides of barium, boron, silicon, and nickel.

of the color as a pigment during the gel-spinning process would be a better alternative, as the pigment would be well dispersed in the solution of solvent and disentangled UHMWPE, facilitating a homogeneous physical incorporation. **To facilitate regulatory approval, blue fibers with Chromium-Cobalt-Aluminum Oxide were produced, as this pigment is listed on the FDA's 21 CFR part 73 on *Color Additives Exempt from Certification* for coloring linear polyethylene surgical sutures for use in general surgery."** (Emphasis added).

(b) *Specifications.* Chromium-cobalt-aluminum oxide shall conform to the following specifications:

Chromium, calculated as Cr_2O_3 , 34-37 percent.

Cobalt, calculated as CoO , 29-34 percent.

Aluminum, calculated as Al_2O_3 , 29-35 percent.

Lead (as Pb), not more than 30 parts per million.

Arsenic (as As), not more than 3 parts per million.

Total oxides of aluminum, chromium, and cobalt not less than 97 percent.

Lead and arsenic shall be determined in the solution obtained by boiling 10 grams of the chromium-cobalt-aluminum oxide for 15 minutes in 50 milliliters of 0.5 *N* hydrochloric acid.

(c) *Uses and restrictions.* The color additive chromium-cobalt-aluminum oxide may be safely used for coloring linear polyethylene surgical sutures, United States Pharmacopeia (U.S.P.), for use in general surgery, subject to the following restrictions:

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

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

(3) The dyed suture shall conform in all respects to the requirements of the U.S.P. XX (1980).

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

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

(d) *Labeling.* The label of the color additive shall conform to the requirements of §70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and batches thereof are exempt from the certification requirements of section 721(c) of the act.

Ex. 1006, page 18.

179. A person of ordinary skill in the art would have been motivated to utilize such chromium-cobalt-aluminum oxide as a pigment in UHMWPE multifilament yarn to produce a colored suture and would use such pigment in an amount that does not exceed 2 percent by weight of the suture material, as instructed by Section 73.1015, in order to facilitate regulatory approval, since such use was exempt from certification and already approved for linear polyethylene surgical sutures, which were the type of sutures taught by Simmelink.

180. Section 73.1015 discloses that, in its coloring procedure, the pigment is blended with the polyethylene resin to form a mixture that is then heated and extruded. *See* Ex. 1006, page 18, (c)(1). The person of ordinary skill in the art would have been similarly motivated to add the chromium-cobalt-aluminum oxide pigment to the gel spinning mixture of Simmelink, in accordance with the pigmentation process of 73.1015, thereby forming a gel spinning mixture of the polyethylene, a spin solvent, and the chromium-cobalt-aluminum oxide pigment.

181. Consequently, in light of these disclosures, a person of ordinary skill in the art would have been motivated to combine the teachings of the high strength polyethylene multi-filament yarn and process of making same as disclosed in Simmelink with the color additive chromium-cobalt-aluminum oxide as a pigment and the pigmentation process identified in Section 73.1015, thereby, obtaining improved colored multi-filament yarns for use in linear polyethylene surgical sutures so as to meet the well-known need for colored sutures, especially colored sutures having high strength that were exempt from further certification by the FDA. Accordingly, it would have been within the skill of the person of ordinary skill in the art to combine Section 73.1015 with Simmelink.

182. Additionally, a person of ordinary skill in the art would have been motivated to try the chromium-cobalt-aluminum oxide pigment that was disclosed in Section 73.1015 when developing the high-performance polyethylene multi-

filament yarn disclosed by Simmelink. The person of ordinary skill in the art would have understood that there was a need for a colored suture made from UHMWPE fiber, as I have explained throughout this document and as admitted in the background of the '532 Patent. *See* Ex. 1001, 1:11-17; *see also*, Section V.A. The person of ordinary skill in the art would have further understood that there were a limited number of ways to color a UHMWPE fiber, including the use of pigments and dyes. However, as confirmed by Section 73.1015 and as was known by the person of ordinary skill in the art, any colorant used for sutures would need to be added so that “there is no migration of the color additive to the surrounding tissue” (Ex. 1006, page 18, (c)(4)), thereby narrowing the potential choices of colorants. The options for colorant of UHMWPE fibers in medical applications would have been further reduced by governmental requirements, such as those espoused by the FDA in Section 73.1015. As a result, in view of Simmelink and the understanding of the person of skill in the art, it would have been obvious to try blending an FDA approved pigment, such as chromium-cobalt-aluminum oxide, with a linear polyethylene prior to extrusion when developing UHMWPE fibers for use in medical applications, including linear polyethylene surgical sutures.

183. It is also my opinion that the person of ordinary skill in the art would have a reasonable expectation of success in combining Simmelink and Section 73.1015 to achieve the predictable result of improved colored multi-filament yarns

for several reasons. First, as described by Simmelink itself and as was well known, colorants would have been added to UHMWPE fibers in the amounts of less than 5 mass%, preferably less than 3 mass%. Ex. 1005, Page 8, lines 28-31. Section 73.1015 discloses the addition of a pigment in an amount that does not exceed 2 percent by weight of the suture material (Ex. 1006, page 18, (a), (c)(2)), which is consistent with the express disclosures of Simmelink.

184. Second, Section 73.1015 discloses that the pigment “may be safely used for coloring linear polyethylene surgical sutures” and the person of ordinary skill in the art would have understood that the sutures prepared by the process disclosed in Simmelink were linear polyethylene surgical sutures. *See e.g.*, Ex. 1005, 8:12-17 (“Preferably, the UHPE is a linear polyethylene with less than one branch per 100 carbon atoms....”); Ex. 1006, 18, (c).

185. Third, Section 73.1015 discloses that in its coloring procedure, the pigment is blended with the polyethylene resin and is then heated to a temperature of 500°-550°F (Ex. 1006, page 18, (c)(1)), which is not inconsistent with the gel spinning process disclosed in Simmelink. To the extent that this process may be interpreted as being consistent with a melt process, the person of skill in the art would have understood that the addition of a pigment with polyethylene in a gel

spinning process would have likewise been successful.⁴ That is, the person of ordinary skill in the art would have understood that the gel spinning process and melt process were similar, especially with regard to the addition of an inert pigment, such as the pigment of Section 73.1015. Other than the addition of an inert solvent, which would not affect the inert pigment, the polyethylene polymer used in a gel spinning process is similar to that in a melt process (e.g., linear polyethylene). Moreover, any differences in temperature of the gel spinning and melt processes would not impact the pigment. Finally, the person of ordinary skill in the art would have also expected that the pigment would have worked with the crystalline structure of the fiber. *See e.g.*, Ex. 1007, Page 2, [0005].⁵

⁴ As described above in the Technical Background/State of the Art at Section V.A., the person of skill in the art understood that the pigment “infiltrates into the interior of the polyethylene and, as a result, the physical bonding between the polyethylene and the pigment and/or the dye becomes strong, causing substantially no color fading.” Ex. 1028, 10:35-41.

⁵ To be clear, this ground is obviousness in view of Simmelink and Section 73.1015. Nanri does not form part of the combination/modification. Rather, Nanri is provided to confirm the knowledge, motivations, and expectations of a person of ordinary skill in the art.

186. Fourth, Section 73.1015 explicitly teaches that “there is no migration of the color additive to the surrounding tissue.” Ex. 1006, page 18, (c)(4). In medical applications, the migration or leeching of color additive is disfavored. In light of these teachings, a person of ordinary skill in the art would have expected the addition of the chromium-cobalt-aluminum oxide pigment as a color additive to the gel spinning mixture of Simmelink to form a colored multi-filament yarn to be effective.

187. The person of ordinary skill in the art 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 person of ordinary skill would consider either selecting a pigment with a particle size much less than such diameter and/or 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. Such considerations and/or pre-treatment methods would be common and within the skill of the person of ordinary skill. Moreover, I reviewed the background of the '532 Patent as I noted above and specifically reviewed the assertion that “[i]n order to obtain a sufficient dispersion of the pigment [in a concentrated pre-mixture,] the wetting of the

pigment particles must be enhanced by the use of a low viscous carrier polymer and dispersants.” Ex. 1001, 1:58-63. The ’532 Patent further asserts that it is disadvised to use pigments in UHMwPE filaments because such a “low viscous carrier polymer has a negative influence on mechanical properties of the UHMwPE filaments” and UHMwPE “filaments have a very low diameter compared to the diameter of polypropylene filaments [such] that un-dispersed or re-agglomerated clumps of pigment particles will have a detrimental effect on the tensile strength of filaments.” Ex. 1001, 1:63-2:3 (asserting that it is therefore “disadvised in U.S. Patent No. 5,613,987 to use pigments in UHMwPE filaments”).

188. However, in my review of the ’532 Patent specification, I only identified disclosure relating to the types of pigment and the amount of pigment. For example, the ’532 Patent indicates:

Suitable pigments include organic and inorganic pigments. Examples of organic pigments include azo-pigments and phtalo-pigments. Good results are obtained with C.I. Vat brown I and C.I. Solvent Yellow 18. Examples of inorganic pigments include pigments containing titanium dioxide, iron oxides and chromium oxides. Good results are obtained with aluminum-chromium-cobalt oxide, since a suture with good mechanical properties and a low degree of leaching out is obtained.

The amount of pigment used may be between 0.1-7 wt. % of the final filament, as used for the production of the suture. Preferably the final filament contains at least 0.3 wt. %, more preferably at least 0.5 wt. % even more preferably at least 0.7 wt. % of pigment. Preferably the final filament contains at most 5.0 wt. %, more preferably at most 3 wt. % of pigment, even more preferably at least 2.5 wt. %, most preferably at most 2 wt. %. This is in view of obtaining a bright colour and good mechanical properties.

Ex. 1001, 3:43-60.

189. These disclosures (or lack of disclosure regarding the details of the pigment itself or the preparation thereof) confirm that there was no need for a special formulation or that further steps were required and/or needed to be disclosed in order for the person of ordinary skill in the art to add pigments to UHMWPE. That is, the inventors of the '532 Patent identified that pigments indeed work fine in UHMwPE fibers without any specified modification beyond the ordinary skill of the person of ordinary skill in the art. I see nothing in the claims or specification to suggest otherwise. Similarly, the person of ordinary skill in the art would have understood that the addition of a pigment from Section 73.1015 would have been successful in the process of Simmelink. Indeed, Section 73.1015 does not reference dispersants and indicates that the chromium-cobalt-

aluminum oxide pigment “is blended with the polyethylene resin”. Ex. 1006, page 18, (c)(1).

190. Accordingly, a person of ordinary skill in the art would have been motivated to combine and would have had a reasonable expectation of success in combining, Simmelink and Section 73.1015.

D. Analysis

i. Claim 1: [1.Pre] A colored multi-filament yarn comprising

191. Claim 1 of the ’532 Patent is directed to a product that is developed by way of a process, such as the process described with regard to limitation [1.A]. As such, I understand that the determination of patentability is based on the product (e.g., the yarn) itself and the “physical constituent of the fiber” that “is a quantifiable and hence physical attribute of the fiber.” Ex. 1030, page 258 (emphases in original). Regardless, as is described in at least limitation [1.A], the cited art of Ground 1 renders obvious a gel spinning process.

192. Moreover, and to the extent the preamble is limiting, it is disclosed by the combination of Simmelink and Section 73.1015 as is described throughout Ground 1. *See* [1.A-1.E].

193. With respect to limitation [1.Pre], Section 73.1015 expressly discloses “[a] colored multi-filament yarn”. That is, Section 73.1015 discloses wherein “the color additive [chromium-cobalt-aluminum oxide] is blended with the

polyethylene resin”, “[t]he mixture is heated to a temperature of 500°–550 °F. and extruded through a fixed orifice”, and “[t]he filaments are cooled, oriented by drawing, and set by annealing.” Ex. 1006, page 18.

194. Simmelink generally describes a variety of parameters and a series of process steps for preparing a multifilament yarn. *See e.g.*, Ex. 1005, Abstract. More specifically, the majority of Simmelink is dedicated to the disclosure of an alleged inventive continuous process for preparing high performance polyethylene (HPPE) multifilament yarn. Ex. 1005, 1:7-8. Simmelink further discloses a high-performance polyethylene multifilament yarn obtainable by such process, and semi-finished or end-use products or articles, including “medical implants like suture and cables”, containing such HPPE multifilament yarn. Ex. 1005, 1:18-20, 10:34-11:30, 12:24-30.

195. Simmelink further teaches that “[t]he UHPE that is applied in the process according to the invention may further contain small amounts, **generally less than 5 mass%, preferably less than 3 mass% of customary additives**, such as anti-oxidants, thermal stabilizers, **colorants**, flow promoters, etc.” Ex. 1005, 8:28-31 (emphasis added).

196. As discussed above, a person of ordinary skill in the art would have been motivated to combine the chromium-cobalt-aluminum oxide pigment and pigmentation process teachings of Section 73.1015 with the process for producing

high performance multifilament polyethylene yarns disclosed in Simmelink. In particular and as I described above in the motivation to combine at Section XI.C, a person of ordinary skill in the art at the time of the assumed priority date of the '532 Patent would have been well aware of the design need for colored high strength sutures and it would have been within the skill of the person of ordinary skill in the art to combine Section 73.1015 with Simmelink to produce colored multi-filament yarns to be used as such sutures. In doing so, the person of ordinary skill in the art would have had a reasonable expectation of success in achieving the predictable result of improved colored multi-filament yarns.

197. Accordingly, it is my opinion that the combination of Simmelink and Section 73.1015 renders obvious the recitation of limitation [1.Pre].

ii. Claim 1: [1.A] filaments that have been obtained by gel spinning a mixture containing ultra-high molecular weight polyethylene (UHMwPE) having an intrinsic viscosity (IV) of between about 8 and 40 dl/g, a spin solvent and a pigment, and

198. As I noted above with regard to limitation [1.Pre], it is my understanding that Claim 1 is directed to a product that is developed by way of a process, such as the process described with regard to limitation [1.A]. Moreover, in my review of the '532 Patent, I do not see a particular process outlined for gel

spinning. Even though I understand that no patentable weight should be given to limitation [1.A], the combination discloses it, nonetheless.⁶

199. Specifically, Simmelink discloses an alleged inventive continuous process for preparing high performance polyethylene (HPPE) multifilament yarn, a high-performance polyethylene multifilament yarn obtainable by such process, and semi-finished or end-use products or articles containing such HPPE multifilament yarn(s). Ex. 1005, 1:18-20, 10:34-11:30, 12:24-30. The person of ordinary skill would understand that the term ‘UHMWPE fiber’ or ‘drawn UHMWPE’ is often used interchangeably with high performance polyethylene (HPPE) fibers. *See e.g.*, International Publication No. WO 01/59397 to Steeghs et al. (Ex. 1014), Page 4, lines 11-15 (referring to “drawn ultra-high molecular weight polyethylene” as “HPPE”).⁷

⁶ As is described above and is admitted in the ’532 Patent, the gel spinning process for preparing UHMWPE filaments was well known in the prior art and was indeed conventional by the assumed priority date of the ’532 Patent. Ex. 1001, 2:24-31.

⁷ To be clear, this ground is obviousness in view of Simmelink and Section 73.1015. Steeghs does not form part of the combination/modification. Rather, Steeghs is provided to confirm the knowledge of a person of ordinary skill in the art.

200. The process steps disclosed by Simmelink include “a) making a 3-25 mass% **solution of ultra-high molar mass polyethylene having an intrinsic viscosity as measured on solutions in decalin at 135°C of between about 8 and 40 dl/g, in a solvent**; b) **spinning of the solution through a spinplate containing at least 5 spinholes into an air-gap to form fluid filaments**, while applying a draw ratio DR_{fluid} ; c) cooling the fluid filaments **to form solvent-containing gel filaments**; d) removing at least partly the solvent from the filaments; and e) drawing the filaments in at least one step before, during and/or after said solvent removing, while applying a draw ratio DR_{solid} of at least 4.” Ex. 1005, 1:7-17 (emphasis added). A person of ordinary skill in the art would understand this disclosure to be a gel spinning process using decalin as a spin solvent such that the filaments produced by such process are “filaments that have been obtained by gel spinning a mixture containing ultra-high molecular weight polyethylene (UHMwPE) having an intrinsic viscosity (IV) of between about 8 and 40 dl/g [and] a spin solvent”. To the extent [1.A] is interpreted as requiring multiple filaments, Simmelink discloses it. That is, with regard to limitation [1.A], Simmelink discloses “filaments”. As discussed above with respect to claim limitation [1.A], Simmelink discloses “spinning of the solution through a spinplate containing at least 5 spinholes into an air-gap to form fluid filaments”, cooling the fluid filaments to form solvent-containing gel filaments, removing at least partly the

solvent from the filaments, and drawing the filaments. Ex. 1005, 1:7-17. Moreover, Simmelink discloses the number of filaments in the multi-filament yarn is preferably “at least 10, 50, 100, 150, 200, 300, 375 or even at least 450.” Ex. 1005, 5:21-24.

201. Moreover, with respect to intrinsic viscosity, Simmelink further discloses that “[t]he ultra-high molar mass polyethylene applied in the process according to the invention has an intrinsic viscosity (IV, as measured on solution in decalin at 135°C) of between about 8 and 40 dl/g, preferably between 10 and 30, or 12 and 28, more preferably between 15 and 25 dl/g, to provide a balance between processability of the solution to be spun and mechanical properties of the obtained filaments.” Ex. 1005, 7:32-8:2. I understand that a specific example or disclosure in the prior art which is within a claimed range, such as Simmelink’s disclosure of “an intrinsic viscosity (IV, as measured on solution in decalin at 135°C) of between about 8 and 40 dl/g”, anticipates the claimed range.

202. With respect to spin solvent, Simmelink further discloses that “any of the known solvents suitable for gel spinning of UHPE can be used as solvent for making the polyethylene solution, for example paraffin wax, paraffin oil or mineral oil, kerosenes, decalin, tetralin, or a mixture thereof.” Ex. 1005, 8:34-9:2. According to Simmelink, it is especially advantageous to use “relatively volatile solvents, preferably solvents having a boiling point at atmospheric conditions of

less than 275°C, more preferably less than 250 or 225°C”, such as “decalin, tetralin, and several kerosene grades.” Ex. 1005, 9:2-5.

203. Simmelink teaches that “[t]he UHPE that is applied in the process according to the invention may further contain small amounts, **generally less than 5 mass%, preferably less than 3 mass% of customary additives**, such as anti-oxidants, thermal stabilizers, **colorants**, flow promoters, etc.” Ex. 1005, Page 8, lines 28-31 (emphasis added).

204. Section 73.1015 specifically discloses the use of a chromium-cobalt-aluminum oxide pigment in polyethylene, including blending such pigment with the polyethylene, heating the mixture, and extruding the mixture. *See generally*, Ex. 1006, page 18.

205. As I discussed above in the motivation to combine section set forth in Section XI.C., a person of ordinary skill in the art would have been motivated to combine the chromium-cobalt-aluminum oxide pigment and pigmentation process teachings of Section 73.1015 with the process for producing high performance multifilament polyethylene yarns disclosed in Simmelink to produce a colored multifilament yarn for a colored suture. That is, a person of ordinary skill in the art would have been motivated to blend the chromium-cobalt-aluminum oxide pigment with the gel spinning mixture of Simmelink such that the filaments of the colored multifilament yarn would be obtained from such gel spinning mixture

containing UHMWPE having an intrinsic viscosity of between about 8 and 40 dl/g, a spin solvent (e.g., decalin), and the chromium-cobalt-aluminum oxide pigment. In doing so, the person of ordinary skill in the art would have had a reasonable expectation of success in achieving the predictable result of improved colored multi-filament yarns.

206. Accordingly, it is my opinion that the combination of Simmelink and Section 73.1015 renders obvious the recitation of limitation [1.A].

iii. Claim 1: [1.B] wherein the filaments consist of UHMwPE,

207. To the extent [1.B] is interpreted as requiring multiple filaments, Simmelink discloses it. That is, with regard to limitation 1.B, Simmelink discloses “filaments consist[ing] of UHMwPE”. As discussed above with respect to claim limitation [1.A], Simmelink specifies a variety of parameters and process steps for making high-performance polyethylene multifilament yarn from a gel spinning process. Ex. 1005, Page 1, lines 7-17 (describing making a solution of UHMwPE in a solvent, “**spinning of the solution through a spinplate containing at least 5 spinholes into an air-gap to form fluid filaments**”, cooling the fluid filaments to form solvent-containing gel filaments, removing at least partly the solvent from the filaments, and drawing the filaments) (emphasis added). Simmelink further specifies certain parameters for the UHMwPE applied in the process “to provide a balance between processability of the solution to be spun and mechanical

properties of the obtained filaments.” Ex. 1005, Page 7, line 32-Page 8, line 2. A person of ordinary skill would understand the resulting filaments of Simmelink to contain UHMWPE.

208. Moreover, 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.” Ex. 1005, Page 12, lines 6-7. Simmelink teaches keeping the amount of other components or foreign materials low, elaborating such teachings with respect to HPPE multifilament yarns containing less than 150 ppm, preferably less than 100, 75, or even less than 50 ppm, of solvent, for medical implants containing such yarn. Ex. 1005, Page 12, lines 8-12.

209. Accordingly, it is my opinion that the combination of Simmelink and Section 73.1015 renders obvious the recitation of limitation [1.B].

iv. Claim 1: [1.C] between 0.1 and 7.0 wt. % of an inorganic chromium oxide-containing pigment,

210. With regard to limitation [1.C], Simmelink discloses that the UHPE 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.” Ex. 1005, Page 8, lines 28-31.

211. Section 73.1015 discloses the color additive “chromium-cobalt-aluminum oxide”, which is an inorganic “blue-green pigment obtained by calcining a mixture of chromium oxide, cobalt carbonate, and aluminum oxide”, “may be

safely used for coloring linear polyethylene surgical sutures”. *See generally*, Ex. 1006, page 18.

212. Section 73.1015 further recites that the “[t]he quantity of the color additive does not exceed 2 percent by weight of the suture material.” Ex. 1006, page 18, (c)(2). The person of ordinary skill in the art would understand that the disclosed range was of particular importance given the fact that a suture formed from polyethylene filaments having less than 2 percent by weight of the exempted pigment would not have to go through an additional FDA certification process.

213. Such disclosures from Section 73.1015 are consistent with the recitation of limitation [1.C] of “between 0.1 and 7.0 wt. % of an inorganic chromium oxide-containing pigment”. Moreover, I understand from counsel that if a range taught by a prior art reference overlaps a range claimed in the ’532 Patent, then the range taught by the prior art reference would render the claimed range obvious.

214. Accordingly, it is my opinion that the combination of Simmelink and Section 73.1015 renders obvious the recitation of limitation [1.C].

v. Claim 1: [1.D] a residual amount of spin solvent of less than about 500 ppm, and

215. With regard to limitation [1.D], Simmelink discloses filaments consisting of “a residual amount of spin solvent of less than about 500 ppm.” Simmelink confirms that “[f]or medical applications[,] the amount of other

components or foreign materials in the yarn is very important, in addition to its mechanical properties.” Ex. 1005, Page 12, lines 6-7. Specifically, Simmelink discloses that “a HPPE multifilament yarn according to the invention containing less than 150 ppm of residual solvent, specifically of solvent having a boiling point at atmospheric conditions of less than 275°C, preferably containing less than 100, 75, or even less than 50 ppm of solvent, and to medical implants containing such yarn.” Ex. 1005, Page 12, lines 8-12.

216. Simmelink further discloses “removing at least partly the solvent from the filaments” and teaches that “[s]olvent removal can be performed by known methods, for example by evaporating a relatively volatile solvent, by using an extraction liquid, or by a combination of both methods.” Ex. 1005, Page 1, line 15; Page 9, lines 31-33. Simmelink further admits that it is well known to a POSITA to “remov[e] the solvent from the filaments by extraction with trichlorofluorethane” with reference to WO 01/73173 A1. Ex. 1005, Page 1, lines 21-36.

217. Simmelink also discloses the preparation of multiple multi-filament yarn examples, including Examples 19, 29, and 30, which contained residual decalin solvent contents of 135 ppm, 16 ppm, and 18 ppm, respectively. Ex. 1005, Page 19, lines 15-22; Page 20, lines 13-30.

218. Simmelink further discloses Comparative Experiment E, which was a multi-filament yarn having a residual decalin content of 400 ppm, wherein the

multi-filament yarn was prepared from a solution of UHPE polymer having an IV of 19.8 dl/g in decalin by extruding the solution through a spinplate having 390 spinholes and quenching and drawing the filaments. Ex. 1005, Page 17, lines 17-30; Page 18, lines 8-13; Page 20, lines 20-24.

219. Such disclosures are consistent with limitation [1.D]’s recitation of “a residual amount of spin solvent of less than about 500 ppm”. Moreover, I understand from counsel that a specific example or disclosure in the prior art which is within a claimed range, such as Simmelink’s disclosures of 132 ppm, 16 ppm, and 18 ppm in Examples 19, 29 and 30, respectively, anticipates the claimed range.

220. Moreover, in the case of decalin as the spin solvent, a person of ordinary skill in the art would have been motivated to obtain as low of a level of residual spin solvent in the UHMWPE filaments as possible in order to prevent irritation when used as a suture in the body, which the Applicant admitted was well known in the art during prosecution of the ’168 Patent, the parent application of the ’532 Patent. Ex. 1030, page 266. (“Amery confirms that the level of residual spin solvent, especially decalin, in gel-spun UHMwPE should be low, and preferably below 100 ppm for biocompatibility reasons.”).

221. Accordingly, it is my opinion that the combination of Simmelink and Section 73.1015 renders obvious the recitation of limitation [1.D].

vi. Claim 1: [1.E] less than 1000 ppm of further constituents.

222. The '532 Patent discloses:

The UHMwPE filaments in the suture according to the invention consist preferably of UHMwPE, the pigment and less than 1000 ppm of further constituents, preferably less than 500 ppm of further constituents, more preferably less than 200 ppm of further constituents, most preferably less than 100 ppm of further constituents, such as less than 80 ppm, or less than 60 ppm.

Ex. 1001, Col. 3, lines 61-67.

223. Other than the disclosure that suggests that the further constituents are substances other than the UHMWPE and the pigment, the '532 Patent is silent as to what the further constituents entail or why further constituents should be limited. Having reviewed the disclosure of the '532 Patent, I found no disclosure indicating how further constituents are limited. The claims are likewise silent. As a result, a person of ordinary skill in the art would understand that "further constituents" could include spin solvent as well as other additives. Regardless, the references cited render obvious limitation [1.E], whether or not "further constituents" is construed to include spin solvent or not.

224. Regardless of the construction, Simmelink renders limitation [1.E] obvious. Simmelink discloses that the UHMWPE 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.” Ex. 1005, Page 8, lines 28-31. The person of ordinary skill in the art would understand that Simmelink discloses that any additives, including colorants, are preferably less than 3 mass% or 30,000 ppm.

225. In its listing of additives, Simmelink includes colorants, such as pigments, whereas the claims of the '532 Patent recite the pigment separately from the “further constituents.” *Compare e.g.*, Ex. 1005, 8:28-31 to Ex. 1001, Claim 1. Accordingly, a person of ordinary skill in the art would understand that, as a colorant is added to Simmelink as is disclosed by the combination of Simmelink and Section 73.1015, such amount of colorant will necessarily lower the amount (i.e., lower the upper bound of 3 mass% or 30,000 ppm) of any other customary additives that Simmelink discloses may be added. As the combination of Simmelink and Section 73.1015 discloses that “[t]he quantity of the color additive does not exceed 2 percent by weight of the suture material” (Ex.1006), the amount, in mass% or ppm, of additives could go down to as low as 1 mass% or 10,000 ppm in view of the upper bound of the pigment. Such disclosures from Simmelink and Section 73.1015 are consistent with the recitation of limitation [1.E] of “less than 1000 ppm of further constituents.” Moreover, I understand from counsel that if a range taught by a prior art reference overlaps a range claimed in the '532 Patent,

then the range taught by the prior art reference would render the claimed range obvious.

226. Indeed, a person of ordinary skill would want to have even lower amounts of such customary additives in medical applications, and possibly less than 1 mass% or 10,000 ppm. That is, the person of ordinary skill in the art would have understood that any additives or other components should be minimized and, thus, be as close to non-existent as possible for use in medical applications. Indeed, a person of ordinary skill in the art would have understood that a high additive count would reduce the strength of the fiber and may introduce dangerous foreign substances in the body.⁸ For example, Simmelink discloses that “[f]or medical

⁸ The Examiner further asserted that at least the limitation regarding residual amounts of further constituents would have been obvious “since the more pure the material, UHMWPE, and the less of other constituent or other materials, the stronger the strength for the suture.” Ex. 1030, pages 236-237. In response, I understand that the Applicant never addressed the Examiner’s finding with respect to “other constituents” or whether such constituents would be a result effective variable, instead arguing that that the “ordinarily skilled person (as acknowledged by the Examiner) would seek to eliminate the presence of such pigment.” Ex. 1030, pages 269-270. Moreover, as discussed above in the Technical

applications[,] the amount of other components or foreign materials in the yarn is very important, in addition to its mechanical properties.” Ex. 1005, Page 12, lines 6-7. Simmelink teaches keeping the amount of other components or foreign materials low, elaborating such teachings with respect to HPPE multifilament yarns containing less than 150 ppm, preferably less than 100, 75, or even less than 50 ppm, of solvent, for medical implants containing such yarn. Ex. 1005, Page 12, lines 8-12. Accordingly, as preparation of a colored multi-filament yarn for a colored suture would necessarily require the addition of a pigment and a spin solvent, a person of ordinary skill in the art would know to keep any other components or additives as low as possible. *See, e.g.*, Ex. 1030, page 266 (The Applicant admitting that it was known that “the level of residual spin solvent, especially decalin, in gel-spun UHMwPE should be low, and preferably below 100 ppm for biocompatibility reasons.”).

227. Further, the examples of Simmelink further confirm the lack of further constituents. For example, Simmelink discloses the preparation of multiple multi-

Background/State of the Art at Section V.A, Applicant had already admitted there was a need in the art for colored sutures, which, in my opinion, indicates that the person of ordinary skill in the art would minimize or eliminate constituents other than the desired pigment.

filament yarn examples. *See e.g.*, Ex. 1005, Page 16, line 17-Page 20, line 30. In each example, the multi-filament yarn was prepared from a solution of UHPE polymer in decalin. *Id.* The examples of Simmelink do not describe any other components or material being added during preparation of the multi-filament yarn examples such that a person of ordinary skill in the art would not expect the resulting multi-filament yarn to have “further constituents”.

228. Moreover, to the effect “further constituents” is interpreted to include residual spin solvent, at least Examples 19, 29, and 30 of Simmelink, which indicate residual decalin solvent contents of 135 ppm, 16 ppm, and 18 ppm, respectively (*see e.g.*, Ex. 1005, 19:15-22; 20:13-30), disclose filaments containing “less than 1000 ppm of further constituents.”

229. Simmelink further disclosed at least Comparative Experiment E, which was a multi-filament yarn having a residual decalin content of 400 ppm, wherein the multi-filament yarn was prepared from a solution of UHPE polymer having an IV of 19.8 dl/g in decalin by extruding the solution through a spinplate having 390 spinholes and quenching and drawing the filaments. Ex. 1005, 17:17-30; 18:8-13; 20:20-24. Accordingly, to the effect “further constituents” is interpreted to include residual spin solvent, at least Comparative Experiment E of Simmelink also discloses filaments containing “less than 1000 ppm of further constituents.”

230. Accordingly, it is my opinion that Simmelink renders obvious less than 1000 ppm of further constituents.

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

231. With regard to Claim 2, Simmelink discloses that the UHPE 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.” Ex. 1005, Page 8, lines 28-31.

232. Section 73.1015 similarly recites that the color additive “chromium-cobalt-aluminum oxide”, an inorganic “blue-green pigment obtained by calcining a mixture of chromium oxide, cobalt carbonate, and aluminum oxide”, “may be safely used for coloring linear polyethylene surgical sutures” and requires that the “[t]he quantity of the color additive does not exceed 2 percent by weight of the suture material.” Ex. 1006, page 18.

233. Such disclosures are consistent with Claim 2’s recitation of “wherein the amount of the inorganic pigment present in the filaments is between 0.3 and 5.0 wt. %” Moreover, I understand from counsel that if a range taught by a prior art reference overlaps a range claimed in the ’532 Patent, then the range taught by the prior art reference would render the claimed range obvious.

234. Accordingly, it is my opinion that the combination of Simmelink and Section 73.1015 discloses each and every element of, and renders obvious, Claim 2.

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

235. With regard to Claim 3, Simmelink discloses that the UHPE 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.” Ex. 1005, Page 8, lines 28-31. I understand from counsel that if a range taught by a prior art reference overlaps a range claimed in the ’532 Patent, then the range taught by the prior art reference would render the claimed range obvious.

236. Section 73.1015 similarly discloses that “[t]he quantity of the color additive [the inorganic pigment, chromium-cobalt-aluminum oxide,] does not exceed 2 percent by weight of the suture material.” Ex. 1006, page 18, (c)(2). Such disclosure is consistent with Claim 3’s recitation of “wherein the amount of the inorganic pigment present in the filaments is lower than 2.0 wt. %.” Moreover, I understand that a specific example or disclosure in the prior art which is within a claimed range, anticipates the claimed range.

237. Accordingly, it is my opinion that the combination of Simmelink and Section 73.1015 discloses each and every element of, and renders obvious, Claim 3.

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

238. With regard to Claim 4, Section 73.1015 discloses the color additive “chromium-cobalt-aluminum oxide”, which “is a blue-green pigment obtained by calcining a mixture of chromium oxide, cobalt carbonate, and aluminum oxide.” Ex. 1006, page 18, (a). Section 73.1015 further provides that “[c]hromium-cobalt-aluminum oxide shall conform to the following specifications: Chromium, calculated as Cr_2O_3 , 34-37 percent. Cobalt, calculated as CoO , 29-34 percent. Aluminum, calculated as Al_2O_3 , 29-35 percent. Lead (as Pb), not more than 30 parts per million. Arsenic (as As), not more than 3 parts per million. Total oxides of aluminum, chromium, and cobalt not less than 97 percent.” Ex. 1006, page 18, (b).

239. A person of ordinary skill in the art would have understood that “chromium-cobalt-aluminum oxide” as disclosed by Section 73.1015 is the same as “aluminum-chromium-cobalt oxide”. Even if it were to be argued that chromium-cobalt-aluminum oxide is not the same as aluminum-chromium-cobalt oxide, which would be incorrect, aluminum-chromium-cobalt oxide would

nonetheless be obvious. Accordingly, such disclosure is consistent with Claim 4's recitation of "wherein the inorganic pigment is aluminum-chromium-cobalt oxide."

240. Accordingly, it is my opinion that the combination of Simmelink and Section 73.1015 discloses each and every element of, and renders obvious, Claim 4.

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

241. With regard to Claim 5, Simmelink discloses "[f]or medical applications the amount of other components or foreign materials in the yarn is very important, in addition to its mechanical properties." Ex. 1005, Page 12, lines 6-7. Specifically, Simmelink discloses "a HPPE multifilament yarn according to the invention containing less than 150 ppm of residual solvent, specifically of solvent having a boiling point at atmospheric conditions of less than 275°C, preferably containing less than 100, 75, or even less than 50 ppm of solvent, and to medical implants containing such yarn." Ex. 1005, Page 12, lines 8-12.

242. Simmelink also discloses the preparation of multiple multifilament yarn examples, including Examples 19, 29, and 30, which contained residual decalin solvent contents of 135 ppm, 16 ppm, and 18 ppm, respectively. Ex. 1005, Page 19, lines 15-22; Page 20, lines 13-30. Moreover, I understand from counsel that a specific example or disclosure in the prior art which is within a claimed

range, such as Simmelink's disclosure of residual decalin solvent contents of 135 ppm, 16 ppm, and 18 ppm, anticipates the claimed range.

243. Such disclosures are consistent with Claim 6's recitation of "wherein the residual amount of spin solvent is less than 250 ppm."

244. Accordingly, it is my opinion that the combination of Simmelink and Section 73.1015 discloses each and every element of, and renders obvious, Claim 5.

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

245. With regard to Claim 6, Simmelink discloses "[f]or medical applications the amount of other components or foreign materials in the yarn is very important, in addition to its mechanical properties." Ex. 1005, Page 12, lines 6-7. Specifically, Simmelink discloses "a HPPE multifilament yarn according to the invention containing less than 150 ppm of residual solvent, specifically of solvent having a boiling point at atmospheric conditions of less than 275°C, preferably containing less than 100, 75, or even less than 50 ppm of solvent, and to medical implants containing such yarn." Ex. 1005, Page 12, lines 8-12.

246. Simmelink also discloses the preparation of multiple multifilament yarn examples, including Examples 29 and 30, which contained residual decalin solvent contents of 16 ppm and 18 ppm, respectively. Ex. 1005, Page 20, lines 13-

30. Moreover, I understand from counsel that a specific example or disclosure in the prior art which is within a claimed range, such as Simmelink's disclosure of residual decalin solvent contents of 16 ppm and 18 ppm, anticipates the claimed range.

247. Such disclosures are consistent with Claim 6's recitation of "wherein the residual amount of spin solvent is less than 100 ppm."

248. Accordingly, it is my opinion that the combination of Simmelink and Section 73.1015 discloses each and every element of, and renders obvious, Claim 6.

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

249. With regard to Claim 7, Simmelink discloses "[f]or medical applications the amount of other components or foreign materials in the yarn is very important, in addition to its mechanical properties." Ex. 1005, Page 12, lines 6-7. Specifically, Simmelink discloses "a HPPE multifilament yarn according to the invention containing less than 150 ppm of residual solvent, specifically of solvent having a boiling point at atmospheric conditions of less than 275°C, preferably containing less than 100, 75, or even less than 50 ppm of solvent, and to medical implants containing such yarn." Ex. 1005, Page 12, lines 8-12.

250. Simmelink also discloses the preparation of multiple multifilament yarn examples, including Examples 29 and 30, which contained residual decalin solvent contents of 16 ppm and 18 ppm, respectively. Ex. 1005, Page 20, lines 13-30. Moreover, I understand from counsel that a specific example or disclosure in the prior art which is within a claimed range, such as Simmelink's disclosure of residual decalin solvent contents of 16 ppm and 18 ppm, anticipates the claimed range.

251. Such disclosures are consistent with Claim 7's recitation of "wherein the residual amount of spin solvent is less than 60 ppm."

252. Accordingly, it is my opinion that the combination of Simmelink and Section 73.1015 discloses each and every element of, and renders obvious, Claim 7.

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

253. Simmelink renders Claim 8 obvious. As discussed previously with respect to limitation [1.E], Simmelink discloses that the UHMwPE 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." Ex. 1005, Page 8, lines 28-31. The person of ordinary skill in the

art would understand that Simmelink discloses that any additives, including colorants, are preferably less than 3 mass% or 30,000 ppm.

254. In its listing of additives, Simmelink includes colorants, such as pigments, whereas the claims of the '532 Patent recite the pigment separately from the "further constituents." *Compare e.g.*, Ex. 1005, 8:28-31 to Ex. 1001, Claim 1. Accordingly, a person of ordinary skill in the art would understand that, as a colorant is added to Simmelink as is disclosed by the combination of Simmelink and 73.1015, such amount of colorant will necessarily lower the amount (i.e., lower the upper bound of 3 mass% or 30,0000 ppm) of any other customary additives that Simmelink discloses may be added. As the combination of Simmelink and Section 73.1015 discloses that "[t]he quantity of the color additive does not exceed 2 percent by weight of the suture material" (Ex.1006), the amount, in mass% or ppm, of additives could go down to as low as 1 mass% or 10,000 ppm in view of the upper bound of the pigment.

255. Indeed, a person of ordinary skill would want to have even lower amounts of such customary additives in medical applications, and possibly less than 1 mass% or 10,000 ppm. That is, the person of ordinary skill in the art would have understood that any additives or other components should be minimized and, thus, be as close to non-existent as possible for use in medical applications. Indeed, a person of ordinary skill in the art would have understood that a high additive

count would reduce the strength of the fiber and may introduce dangerous foreign substances in the body.⁹ For example, 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.” Ex. 1005, Page 12, lines 6-7. Simmelink teaches keeping the amount of other components or foreign materials low, elaborating such teachings with respect to HPPE multifilament

⁹ The Examiner further asserted that at least the limitation regarding residual amounts of further constituents would have been obvious “since the more pure the material, UHMWPE, and the less of other constituent or other materials, the stronger the strength for the suture.” Ex. 1030, pages 236-237. In response, I understand that the Applicant never addressed the Examiner’s finding with respect to “other constituents” or whether such constituents would be a result effective variable, instead arguing that that the “ordinarily skilled person (as acknowledged by the Examiner) would seek to eliminate the presence of such pigment.” Ex. 1030, pages 269-270. Moreover, as discussed above in the Technical Background/State of the Art at Section V.A, Applicant had already admitted there was a need in the art for colored sutures, which, in my opinion undercuts Applicant’s argument that the person of ordinary skill in the art would eliminate a pigment.

yarns containing less than 150 ppm, preferably less than 100, 75, or even less than 50 ppm, of solvent, for medical implants containing such yarn. Ex. 1005, Page 12, lines 8-12. Accordingly, as preparation of a colored multi-filament yarn for a colored suture would necessarily require the addition of a pigment and a spin solvent, a person of ordinary skill in the art would know to keep any other components or additives as low as possible. *See, e.g.*, Ex. 1030, page 266 (The Applicant admitting that it was known that “the level of residual spin solvent, especially decalin, in gel-spun UHMwPE should be low, and preferably below 100 ppm for biocompatibility reasons.”).

256. Further, the examples of Simmelink further confirm the lack of further constituents. For example, Simmelink discloses the preparation of multiple multi-filament yarn examples. *See e.g.*, Ex. 1005, Page 16, line 17-Page 20, line 30. In each example, the multi-filament yarn was prepared from a solution of UHPE polymer in decalin. *Id.* The examples of Simmelink do not describe any other components or material being added during preparation of the multi-filament yarn examples such that a person of ordinary skill in the art would not expect the resulting multi-filament yarn to have “further constituents”.

257. Moreover, to the effect “further constituents” is interpreted to include residual spin solvent, at least Examples 19, 29, and 30 of Simmelink, which indicate residual decalin solvent contents of 135 ppm, 16 ppm, and 18 ppm,

respectively (*see e.g.*, Ex. 1005, 19:15-22; 20:13-30), disclose filaments containing “less than 500 ppm of further constituents.”

258. Simmelink further disclosed at least Comparative Experiment E, which was a multi-filament yarn having a residual decalin content of 400 ppm, wherein the multi-filament yarn was prepared from a solution of UHPE polymer having an IV of 19.8 dl/g in decalin by extruding the solution through a spinplate having 390 spinholes and quenching and drawing the filaments. Ex. 1005, 17:17-30; 18:8-13; 20:20-24. Accordingly, to the effect “further constituents” is interpreted to include residual spin solvent, at least Comparative Experiment E of Simmelink also discloses filaments containing “less than 500 ppm of further constituents.”

259. Accordingly, it is my opinion that the combination of Simmelink and Section 73.1015 discloses each and every element of, and renders obvious, Claim 8.

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

260. With regard to Claim 9, Simmelink discloses the number of filaments in the multi-filament yarn is preferably “at least 10, 50, 100, 150, 200, 300, 375 or even at least 450. For practical reasons, handling during spinning and drawing becoming increasingly difficult, the number of filaments is preferably at most about 5000.” Ex. 1005, Page 4, lines 21-24. Simmelink further specifies that

“[y]arn of relatively low titer, containing for example from 5 to 300 filaments, but of extremely high strength is a.o. very suited for making high-strength surgical sutures and cables, or other medical implants.” Ex. 1005, Page 12, lines 3-6.

261. Such disclosure is consistent with Claim 9’s recitation of “wherein the number of filaments is between 10 and 1000.” Moreover, I understand from counsel that if a range taught by a prior art reference overlaps a range claimed in the ’532 Patent, then the range taught by the prior art reference would render the claimed range obvious.

262. Accordingly, it is my opinion that the combination of Simmelink and Section 73.1015 discloses each and every element of, and renders obvious, Claim 9.

XII. GROUND 2: THE COMBINATION OF SECTION 73.1015, NANRI, OHTA, AND KAVESH RENDERS OBVIOUS CLAIMS 1-9

263. It is my opinion that the combination of Section 73.1015, Nanri, Ohta, and Kavesh teaches, suggests, or discloses all of the recitations of Claims 1-9 of the ’532 Patent and renders the subject matter of each claim as a whole obvious and unpatentable.

A. Section 73.1015 Overview

264. 21 C.F.R. §73.1015, entitled “Chromium-cobalt-aluminum oxide,” published on April 1, 2006. Ex. 1006, pages 1 and 18. Thus, it is my understanding

that Section 73.1015 is prior art to the '532 Patent under 35 U.S.C. § 102(b).

Section 73.1015 was not cited during prosecution of the '532 Patent.

265. Section 73.1015 identifies chromium-cobalt-aluminum oxide as a color additive exempt from certification for use in drugs. Ex. 1006, pages 16-18. Specifically, Section 73.1015 indicates that “the color additive chromium-cobalt-aluminum oxide is a blue-green pigment” that “may be safely used for coloring linear polyethylene surgical sutures, United States Pharmacopeia (U.S.P.), for use in general surgery”. Ex. 1006, page 18, (a), (c).

266. Section 73.1015 provides that the chromium-cobalt-aluminum oxide shall contain 34-37% chromium (calculated as Cr_2O_3), 29-34% cobalt (calculated as CoO), and 29-35% aluminum (calculated as Al_2O_3), with a total of the oxides of aluminum, chromium, and cobalt to be “not less than 97[%].” Ex. 1006, page 18, (b).

267. With respect to the coloring procedure, Section 73.1015 indicates that “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”, after which “[t]he filaments are cooled, oriented by drawing, and set by annealing.” Ex. 1006, page 18, (c)(1).

268. Section 73.1015 also puts a limit on the maximum weight percent of the chromium-cobalt-aluminum oxide pigment, further indicating that “the quantity

of the color additive does not exceed 2 percent by weight of the suture material.”

Ex. 1006, page 18, (c)(2).

269. According to Section 73.1015, “there is no migration of the color additive [from the suture] to the surrounding tissue” “[w]hen the sutures are used for the purpose specified in their labeling.” Ex. 1006, page 18, (c)(4).

B. Nanri Overview

270. Japanese Unexamined Patent Application Publication No. H11-21721 to Nanri et al, entitled “Colored High-Strength Polyethylene Fiber”, filed by Toyobo Co., Ltd., published on January 26, 1999. Ex. 1007. Thus, it is my understanding that Nanri is prior art to the ‘532 Patent under 35 U.S.C. § 102(b). Nanri was not cited during prosecution of the ’532 Patent.

271. Nanri generally relates to a colored high-strength polyethylene fiber. Ex. 1007, 2, [0001].

272. Nanri describes past attempts to color a high-strength polyethylene fiber, including “a so-called ‘spin-dyeing method’ of producing by mixing various dyes, pigments, or inorganic compounds such as carbon black and titanium oxide with a raw material polymer, or a method for obtaining a colored fiber by various dyeing techniques generally performed after forming the fiber.” Ex. 1007, 2, [0002]. However, Nanri discloses issues with such attempts. For example, “[i]n the spin-dyeing method, because an inorganic compound or the like is added in the

manufacturing process, the additive acts as a defect in the crystal formation process and the like for expressing high strength, and is a factor in strength reduction, and therefore becomes difficult to add at a high concentration.” Ex. 1007, 2, [0002]. In addition, “when a technique for dyeing fibers after formation is applied to high-strength polyethylene fibers, it has been difficult to obtain dyed goods or colored goods having sufficient fastness from a polyethylene having a very high degree of crystallinity and a simple structure.” Ex. 1007, 2, [0002].

273. To overcome such issues, Nanri explains that “particle diameter, agglomeration state, and content of pigments that do not act as defects in the crystal formation process and the like for expressing high strength” were researched resulting in “a high-strength polyethylene fiber containing a pigment composed of a particle aggregate having an average particle diameter of 10 to 100 nm, having a strength of 2.0 GPa or more, and an initial modulus of elasticity of 70 GPa or more.” Ex. 1007, 2, [0003], [0004]. In particular, Nanri discloses “a strong polyethylene fiber described above wherein the particle aggregate is composed of 10 or fewer particles and the strong polyethylene fiber described above wherein a pigment content is 0.01 to 2.50 wt%.” Ex. 1007, 2, [0004].

274. According to Nanri, “it is essential that the colorant contained in the fiber is composed of a pigment such as an organic pigment, inorganic pigment, and carbon black” to obtain high-strength polyethylene fibers that are colored while

maintaining a sufficiently high strength. Ex. 1007, 2, [0005]. “This is because the pigment particles in the fiber are incorporated into the polyethylene crystal, and therefore migration to outside the fiber is suppressed, therefore it is thought that the pigment particles will be held stably.” Ex. 1007, 2, [0005].

275. Nanri discloses an “average particle diameter of the pigment, which is a particle aggregate dispersed in the cross-section of the fiber, [that] is preferably in the range of 10 nm to 100 nm.” Ex. 1007, 2, [0006]. “This is because the particles of the pigment are of a diameter that does not act as a defect during orientated crystallization that occurs during the fiber formation process of the polyethylene and is thus incorporated into the crystal.” Ex. 1007, 2, [0006].

276. According to Nanri, “the content of the pigment—which is a colorant contained in the fiber—is 0.01 to 2.50 wt%, preferably 0.10 to 2.00 wt%” for sufficient coloring effect while maintaining favorable strength and initial modulus of elasticity. Ex. 1007, 2, [0008].

277. Nanri discloses “a method for stretching gel filaments obtained by solution spinning an ultra-high molecular weight polyethylene solution” in order to manufacture the high-strength polyethylene fiber.” Ex. 1007, 3, [0013], citing JP S55-107506 A and JP S56-154508 A.

278. Nanri sets forth three examples, including Example 1 which describes “[a] mixture of 10 wt% of ultra-high molecular weight polyethylene having a

viscosity average molecular weight of 3,200,000 and 90 wt% of decahydronaphthalene [also known as decalin] was kneaded and dissolved using a screw extruder set to a temperature of 180°C to 220°C, extruded from an orifice of a 0.5 mm diameter and drawn at a drawing speed of 75 m/min., and then stretched four-fold in an oven under heated air (100°C). In this case, carbon black obtained by subjecting carbon black REGAL 330R (average diameter of agglomerates: 1.41 mm, Max 9.29 mm, Min 0.22 mm) manufactured by Cabot to fine pulverization processing was added as a colorant to the mixture of polyethylene and decahydronaphthalene at 0.05 wt% relative to decahydronaphthalene. By further stretching the obtained intermediate stretched product to 4.3 fold, a colored high-strength polyethylene fiber having a strength of 3.62 GPa and an initial modulus of elasticity of 129 GPa was obtained. Furthermore, the particle diameter of the carbon black dispersed in the fiber cross-section was in the range of 10 nm to 50 nm, and the number of aggregated particles was 1 to 6. Furthermore, the evaluation results for the weather resistance of this fiber were excellent at grade 4 to 5, and the strength retention rate was 90%.” Ex. 1007, 3, [0015].

279. Examples 2 and 3 of Nanri similarly disclose adding 0.20 wt% and 0.25 wt%, respectively, of carbon black pigment subjected to fine pulverization processing and relative to decahydronaphthalene. The obtained colored high-strength polyethylene fiber had strengths of 2.5 GPa and 1.9 GPa, respectively, and

initial modulus of elasticity of 90 GPa and 67 GPa, respectively. Ex. 1007, 3, [0016], [0017].

280. Claim 1 of Nanri recites “[a] high-strength polyethylene fiber containing a pigment composed of a particle aggregate having an average particle diameter of 10 to 100 nm, having a strength of 2.0 GPa or more, and an initial modulus of elasticity of 70 GPa or more.” Ex. 1007, 2.

281. Claim 3 of Nanri recites “[t]he strong polyethylene fiber according to claim 1, wherein the pigment content is 0.01 to 2.50 wt%.” Ex. 1007, 2.

C. Ohta Overview

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

283. Ohta generally relates to high strength polyethylene fiber, and particularly, to a high strength polyethylene fiber having extremely superior creep resistance. Ex. 1008, 1.

284. Ohta confirms that UHMWPE fibers are well known. Specifically, Ohta confirms that “[a]ttempts to obtain a polyethylene fiber having high strength and high modulus of elasticity by using so-called super high molecular weight

polyethylene having a viscosity average molecular weight of several hundred thousand to several million as a raw material have been actively conducted in recent years, and polyethylene fibers having very high strength and modulus of elasticity have been developed (for example, see JP S56-15408 A and JP S55-107506 A).” Ex. 1008, 1.

285. Ohta discloses that the polymer, mainly composed of polyethylene, “must have a viscosity average molecular weight of 500,000 or more, preferably 1,000,000 or more, and more preferably 1,500,000 or more.” Ex. 1008, 2.

According to Ohta, “[t]his ultra high molecular weight is an essential requirement for the production of high strength polyethylene fibers, and this has an effect of reducing defects derived from molecular terminals by decreasing the number of molecular terminals via molecular weight increase.” Ex. 1008, 2.

286. Ohta also makes clear that the gel spinning process to manufacture such a high strength polyethylene fiber is also well known. According to Ohta, “one example of an appropriate method for this is a method that is normally known as a ‘gel spinning method’ using a solvent as disclosed in, for example, JP S55-107506 A and the like. According to this gel spinning method, to a certain extent, a polyethylene fiber having a strength of 25 g/d or more and a modulus of elasticity of 800 g/d or more can be obtained.” Ex. 1008, 2.

287. With respect to solvents, Ohta discloses “it is essential to use a volatile solvent so that the ratio of the residual components, that is, the solvent component and additives, in the fiber that is ultimately formed is 1000 ppm or less, and it is favorable to use a solvent having a melting point lower than the melting point of the polymer component and a boiling point higher than the melting point of the polymer component by 15°C or more, and insofar as possible no greater than 15°C higher.” Ex. 1008, 3. Ohta identifies example solvents including “decalin, tetralin, dichlorobenzene, naphthalene, mixtures thereof, and the like.” Ex. 1008, 3.

288. Ohta discloses that “[u]pon conducting a detailed investigation of the relationship between g value, other defects in the crystal and impurities other than polyethylene, and creep characteristics, the present inventors discovered that the greater the amount of disorder in the crystals or the greater the amount of impurities such as residual solvent and additives, the worse the creep resistance. Although the cause is not clear, it is presumed that disorder in the crystal causes weaker intermolecular force, promoting slip between molecular chains, or that displacement that causes this defect to move along with creep is the dominant cause.” Ex. 1008, 2. With respect to “g values”, Ohta provides that “molecular chain folding, molecular ends, and the like are present as amorphous portions, but when incorporated into a crystal, these become defects within the crystal. In recent years, a model in which the structure of a high strength polyethylene drawn

product is a single layer system in which amorphous portions (defects) are localized in the crystal has become popular, and g values from Hosemann plots (Hosemann Plot) are used as a method for quantitatively describing disorder of such crystals.” Ex. 1008, 2.

289. According to Ohta, “[a] high strength polyethylene fiber having excellent creep resistance can be obtained by keeping the residual components, particularly the solvent and additives, in fibers made from a polymer mainly composed of ultra high molecular polyethylene at 1000 ppm or less and by reducing the disorder of the crystal structure.” Ex. 1008, 3.

290. Ohta further elaborates that “defects and impurities [that] are present in the crystal of the fibers” have “a drawback [in a polyethylene fiber] that creep resistance is poor.” Ex. 1008, 2-3. That is, “the greater the amount of impurities such as residual solvent and additives, the worse the creep resistance” and “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.” Ex. 1008, 3. According to Ohta, “[w]hen the residual components exceed 1000 ppm, the creep resistance deteriorates significantly.” Ex. 1008, 3. Thus, Ohta teaches that “[a] high strength

polyethylene fiber having excellent creep resistance can be obtained by keeping the residual components, particularly the solvent and additives, in fibers made from a polymer mainly composed of ultra high molecular polyethylene at 1000 ppm or less and by reducing the disorder of the crystal structure.” Ex. 1008, 3. Ohta further elaborates that “[t]he polyethylene fiber of the present invention must have a structure having very little disorder in the crystal structure in the fiber in addition to having few residues.” Ex. 1008, 3.

291. Ohta further explained that “gel spinning method is suited as the method for producing the polyethylene fiber according to the present invention, and thus a large amount of a solvent is inevitably used as described below. Therefore, the used solvent is the main residual component. When additives other than solvents are also used, the residual components must be 1000 ppm or less, including these.” Ex. 1008, 3. Accordingly, Ohta teaches that an antioxidant additive, which may be “added in order to prevent molecular weight reduction during the fiber manufacturing process”, “is preferably not used” and that “other normal additives be used as little as possible.” Ex. 1008, 3.

292. Ohta further discloses Example 1 wherein “[f]ive parts by weight of ultra high molecular weight polyethylene having a viscosity average molecular weight of 1,900,000 and 95 parts by weight of decalin were kneaded and dissolved using a screw extruder at a temperature of 210°C and 300 rpm, and extruded from

an orifice having a diameter of 0.5. At this time, pressure from the mixing tank of the ultra high molecular weight polyethylene solution to the extruder was substantially maintained at 150 mmHg. The extruded filament was cooled by air flow, drawn at a draw rate of 30 m/minute, and drawn to 6x in an air oven adjusted to 100°C. In this case, the average residence time of the filament in the oven was 0.95 minutes.” Ex. 1008, 4. Ohta further describes “[t]his yarn was continuously drawn to 5x in a heated atmosphere at a temperature of 100°C. The final winding rate was 100 m/minute. The strength of the obtained drawn yarn was 37 g/d, and the modulus of elasticity was excellent at 1580 g/d. Furthermore, as a result of analyzing the extract from the drawn yarn by a method such as gas chromatography, the remaining residual materials other than polyethylene were 55 ppm.” Ex. 1008, 4.

293. Examples 2, 3, and 4 of Ohta summarize the preparation of yarns by the same manufacturing method as Example 1, except that the number of screw revolutions and the melting temperature (screw temperature) of the melting were changed in Examples 2 and 3 and the ratio of UHMWPE to decalin was changed to 10:90 in Example 4. *See, e.g.*, Ex. 1008, 4. According to Ohta, “[i]n order to create such a structure having little disorder, the most important factor is the melting condition in the screw, and it is necessary to select a screw rotation speed and temperature that sufficiently homogeneously mix so that the g value is 0.035 or

less.” Ex. 1008, 3. Ohta further teaches that the measured values of the Examples and Comparative Examples set forth in Table 2 of Ohta indicate that “when the g value exceeds 0.03, the residual components exceed 1000 ppm, or when the dissolution and mixing are insufficient and the mixture does not form a uniform mixture, and the selected conditions are not favorable, the creep rate increases to an extreme degree.” Ex. 1008, 5.

294. Claim 1 of Ohta recites, *inter alia*, “[a] creep-resistant high strength polyethylene fiber, comprising of a polymer mainly composed of an ultra high molecular polyethylene having a viscosity average molecular weight of 500,000 or higher substantially”. Ex. 1008, 1.

295. Claim 2 of Ohta recites “The polyethylene fiber according to claim 1, wherein a weight fraction of additives and residual solvent other than the polymer mainly composed of polyethylene is 1000 ppm or less.” Ex. 1008, 1.

D. Kavesh Overview

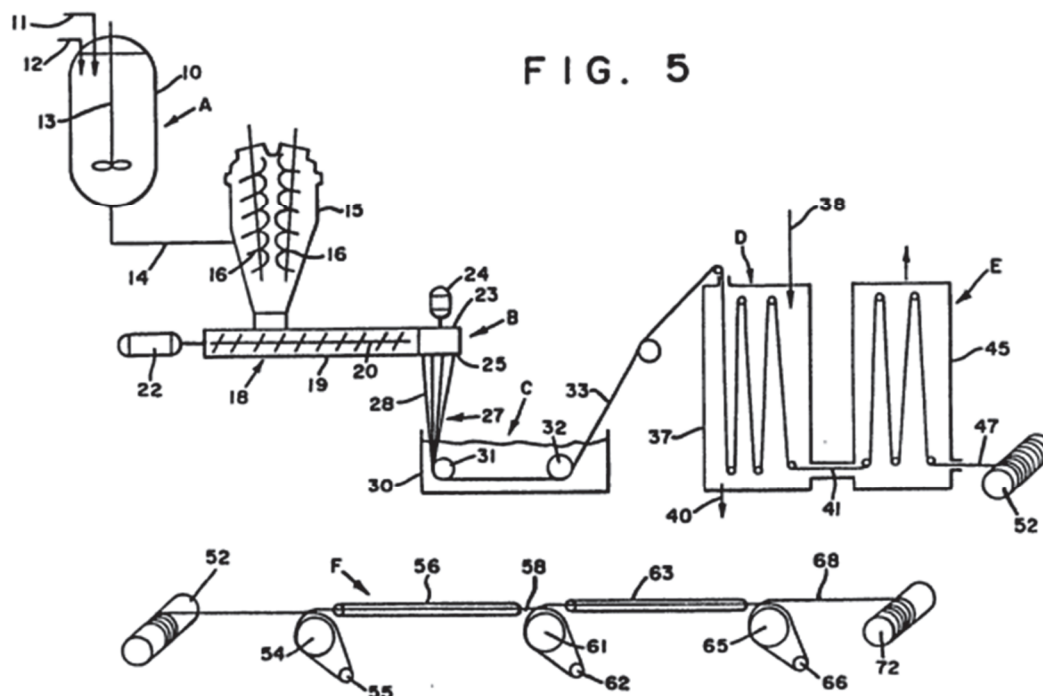
296. Japanese Unexamined Patent Application Publication No. S58-5228 to Kavesh et al., entitled “Production Method of High Strength, High Modulus Crystalline Thermoplastic Article, and Fiber as New Product”, filed by Allied Corporation, published on January 12, 1983. Ex. 1009. Thus, it is my understanding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

297. Kavesh generally relates to crystalline thermoplastic articles, such as fibers or films, having high tenacity, high elastic modulus, and high toughness values, and a process for their production which includes a gel intermediate. Ex. 1009, page 3. In particular, Kavesh is related to a continuous process for producing such high strength, high modulus fibers or films. *See e.g.*, Ex. 1009, page 3, Claim 1 at page 1.

298. According to Kavesh, “[t]here is a wide variety of applications requiring highly load resistant elements with high tenacity, high modulus, high toughness, high dimensional stability and hydrolysis resistance, and high creep resistance under long-term loads” and “[t]he fiber and film of the present invention have high tenacity, an outstandingly high modulus, and excellent toughness, have dimensional stability and hydrolytic stability and have abundant creep resistance under long-term loads.” Ex. 1009, page 4.

299. Kavesh describes the polymer intrinsic viscosity values and weight average molecular weights of the UHMWPE used therein. Ex. 1009, page 5 (“The weight average molecular weight of polyethylene used is at least 500,000 (6 IV), preferably at least 1,000,000 (10 IV), and more preferably 2,000,000 (16 IV) to 8,000,000 (42 IV)....The IV numbers represent intrinsic viscosity of the polymer in decalin at 135°C.”).

300. With reference to FIG. 5 (reproduced below):



which depicts a schematic view of the gel spinning process disclosed in Kavesh, Kavesh describes:

a first mixing vessel 10 is illustrated, the vessel being fed an ultrahigh molecular weight polymer 11 such as polyethylene of weight average molecular weight at least 500,000 and preferably at least 1,000,000 and a relatively non-volatile solvent 12 such as paraffin oil. The first mixing vessel 10 is equipped with an agitator 13. The residence time of the polymer and first solvent in first mixing vessel 10 is a time sufficient to form a slurry containing some dissolved polymer and some relatively finely divided polymer particles, which slurry is removed in a pipe 14

to an intensive mixing vessel 15. The intensive mixing vessel 15 is equipped with helical agitator blades 16. The residence time and agitator speed in intensive mixing vessel 15 are sufficient to convert the slurry into a solution. The temperature in the intensive mixing vessel 15, either because of external heating, heating of the slurry 14, heat generated by the intensive mixing, or a combination of the above, is sufficiently high that the polymer is completely dissolved in the solvent at the desired concentration (generally 6 to 10%). The solution from the intensive mixing vessel 15 is fed to an extrusion device 18. The extrusion device 18 has a barrel 19, and within the barrel is a screw 20 operated by a motor 22 to deliver the polymer solution at a reasonably high pressure to a gear pump and housing 23 at a controlled flow rate. A motor 24 is provided to drive a gear pump 23 and **extrude the polymer solution, still hot, through a spinneret 25. The spinneret 25 contains many apertures, which may be circular, X-shaped, or, oval-shaped, or in any of a variety of shapes having a relatively small major axis in the plane of the spinneret when it is desired to form fibers, and having a rectangular or other shape with an extended major axis in the plane of the spinneret when it is desired to form films.** The temperatures of the solution in the mixing vessel 15, in the

extrusion device 18, and at the spinneret 25 must all equal or exceed a first temperature (for example, 200°C) chosen to exceed the gelation temperature (approximately 100 to 130°C for polyethylene in paraffin oil). The temperature may vary (for example, 220°C, 210°C, and 200°C) or may be constant (for example, 220°C) from the mixing vessel 15 to extrusion device 18 to the spinneret 25. However, at all points, the concentration of polymer in the solution must be substantially the same. **The number of apertures, and thus the number of fibers formed, is not critical, but convenient numbers of apertures are 16, 120, or 240.**

Ex. 1009, FIG. 5, page 8 (emphases added).

301. In addition to examples using a single-hole spinneret, Kavesh discloses numerous examples of multi-filament spinning using a spinning die or spinneret having multiple holes. *See e.g.*, Ex. 1009, pages 24-32 (setting forth Examples 487-551 prepared from UHMWPE and using spinning dies having 16 apertures, including several examples wherein multiple 16-filament yarn ends were combined and stretched together).

E. Rationale for Combining Section 73.1015, Nanri, Ohta, and Kavesh

302. Each of Section 73.1015, Nanri, Ohta, and Kavesh was within the knowledge of a person of ordinary skill in the art and is directly relevant to colored multi-filament yarn that is usable as a suture.

303. A person of ordinary skill in the art at the time of the assumed priority date of the '532 Patent was well aware of the design need for colored sutures, especially colored sutures having high strength. Even the Patent Owner admitted in the specification of the '532 Patent such design need for colored sutures with high strength was known. *See* Ex. 1001, 1:11-17 (“The coloring of sutures is for example used to make the suture better contrast with the blood or tissue in the operating area. In complicated surgical operations, for example in arthroscopic surgery, when different suture ends are used in a small area, sutures of different color are used to assist surgeons in differing between the suture ends.”); 1:22-27 (the Patent Owner further admitted that “[n]ext to coloring”, it was already known in the art that “suture strength [was] an important consideration in selecting filaments for producing a suture” and, as recognized in the prior art, “filaments of ultra-high molecular weight polyethylene (UHMwPE) produced according to the gel spinning process”, were known as very strong filaments that were already available for the production of sutures.). Thus, as reflected by the Patent Owner’s admissions and consistent with the state of the art, there was a stated and well-

known design need for colored sutures formed from high-strength polyethylene fibers.¹⁰ *See* Ex. 1001, 1:11-27.

304. A person of ordinary skill would further understand that sutures are implantable devices and thus are subject to specific requirements, including containing only colorants approved for use in sutures by the United States Food and Drug Administration (FDA). Specific colorants for use in sutures are listed in the Code of Federal Regulations (CFR) depending on the particular suture material and whether or not the color additive is exempt from batch certification requirements. Thus, to facilitate regulatory approval, a person of ordinary skill in the art would have started with Section 73.1015 and its disclosure of chromium-cobalt-aluminum oxide pigment as a color additive in coloring linear polyethylene surgical sutures.

305. As of the priority date of the '532 Patent, Section 73.1015 identified chromium-cobalt-aluminum oxide as a pigment that was approved for linear polyethylene surgical sutures and exempt from batch certification requirements.

¹⁰ As I discuss above with respect to the Technical Background/State of the Art at Section V.A., it was well known by the earliest alleged priority date of the '532 Patent that UHMWPE filaments were usable as sutures and that UHMWPE filaments had been colored using pigments.

See generally, Ex. 1006, 18. The person of ordinary skill in the art would understand that using a color additive exempt from batch certification would save not only time but expense as compared to petitioning for use of a new, not already authorized or exempted, color additive or otherwise requiring certification of each batch. Specifically, Section 73.1015 discloses, *inter alia*:

(a) *Identity*. The color additive chromium-cobalt-aluminum oxide is a blue-green pigment obtained by calcining a mixture of chromium oxide, cobalt carbonate, and aluminum oxide. It may contain small amounts (less than 1 percent each) of oxides of barium, boron, silicon, and nickel.

(b) *Specifications*. Chromium-cobalt-aluminum oxide shall conform to the following specifications:

Chromium, calculated as Cr_2O_3 , 34-37 percent.

Cobalt, calculated as CoO , 29-34 percent.

Aluminum, calculated as Al_2O_3 , 29-35 percent.

Lead (as Pb), not more than 30 parts per million.

Arsenic (as As), not more than 3 parts per million.

Total oxides of aluminum, chromium, and cobalt not less than 97 percent.

Lead and arsenic shall be determined in the solution obtained by boiling 10 grams of the chromium-cobalt-aluminum oxide for 15 minutes in 50 milliliters of 0.5 *N* hydrochloric acid.

(c) *Uses and restrictions.* The color additive chromium-cobalt-aluminum oxide may be safely used for coloring linear polyethylene surgical sutures, United States Pharmacopeia (U.S.P.), for use in general surgery, subject to the following restrictions:

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

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

(3) The dyed suture shall conform in all respects to the requirements of the U.S.P. XX (1980).

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

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

(d) *Labeling.* The label of the color additive shall conform to the requirements of §70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and batches thereof are exempt from the certification requirements of section 721(c) of the act.

Ex. 1006, page 18.

306. A person of ordinary skill in the art developing a colored suture would have been motivated to choose such chromium-cobalt-aluminum oxide as a pigment in coloring high strength polyethylene fibers to produce such a colored suture and would use such pigment in an amount that does not exceed 2 percent by weight of the suture material in order to facilitate regulatory approval, since such use was exempt from certification and already approved for colored linear polyethylene surgical sutures.

307. In view of the disclosure of colored linear polyethylene surgical sutures in Section 73.1015 and understanding the well-known importance of “suture strength” in “selecting filaments for producing a suture”,¹¹ the person of

¹¹ As admitted by the '532 Patent, the person of ordinary skill in the art was well aware of the design need for colored sutures having high strength. *See* Ex. 1001, 1:22-27 (the Patent Owner further admitted that “[n]ext to coloring”, it was already known in the art that “suture strength [was] an important consideration in selecting

ordinary skill in the art would have understood the need for selecting high strength polyethylene filaments for use in the colored linear polyethylene surgical suture. *See* Ex. 1001, 1:22-27; Ex. 1006, page 18.¹² As a result, the person of ordinary skill in the art would have turned to Nanri to implement a colored linear polyethylene surgical suture that had high strength, high modulus, and that was colored so as make the suture better contrast with the blood or tissue in the operating area.¹³

filaments for producing a suture” and, as recognized in the prior art, UHMwPE filaments, “produced according to the gel spinning process”, were known as very strong filaments that were already available for the production of sutures.).

¹² As I discuss above with respect to the Technical Background/State of the Art at Section V.A., it was well known by the earliest alleged priority date of the ’532 Patent that UHMWPE filaments were usable as sutures and that UHMWPE filaments had been colored using pigments.

¹³ As admitted by the ’532 Patent, the person of ordinary skill in the art was well aware of the design need for colored sutures. *See* Ex. 1001, 1:11-17 (“The coloring of sutures is for example used to make the suture better contrast with the blood or tissue in the operating area. In complicated surgical operations, for example in

308. Nanri teaches a colored high-strength polyethylene fiber prepared from gel spinning UHMWPE that, *inter alia*, maintains high strength and high modulus. Ex. 1007, Page 1. Specifically, Nanri teaches incorporating pigments in a gel spinning process so as to “not act as defects in the crystal formation process and the like for expressing high strength”, the pigment particles being stably held by incorporating pigment particles into the polyethylene crystal such that “migration to [the] outside of the fiber is suppressed.” Ex. 1007, Page 2, [0005].

Nanri further elaborates:

[0006] In colored high-strength polyethylene fiber, the average particle diameter of the pigment, which is a particle aggregate dispersed in the cross-section of the fiber, is preferably in the range of 10 nm to 100 nm. This is because the particles of the pigment are of a diameter that does not act as a defect during orientated crystallization that occurs during the fiber formation process of the polyethylene and is thus incorporated into the crystal. That is, 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. On the other hand, migration occurs when the average particle diameter is less than 10 nm, which is not preferable.

arthroscopic surgery, when different suture ends are used in a small area, sutures of different color are used to assist surgeons in differing between the suture ends.”).

[0007] The particle aggregate is preferably constituted of 10 or fewer particles. When more than 10 are used, the colored high-strength polyethylene fiber is hindered from expressing strength and stretchability and as a result, the colored high-strength polyethylene fiber has a low strength and stretchability. Between 1 and 8 particles are preferred.

[0008] In the high-strength polyethylene fiber colored while maintaining sufficiently high strength, the content of the pigment—which is a colorant contained in the fiber—is 0.01 to 2.50 wt%, preferably 0.10 to 2.00 wt%, a coloring effect cannot be demonstrated at less than 0.01 wt%, and when the content of the pigment exceeds 2.50 wt%, weather resistance of the high-strength polyethylene fiber is favorable but strength and initial modulus of elasticity are reduced.

Ex. 1007, Page 2, Paras. [0006]-[0008].

309. Indeed, Nanri discloses the following examples:

[0015] [Examples] (Example 1) **A mixture of 10 wt% of ultra-high molecular weight polyethylene having a viscosity average molecular weight of 3,200,000 and 90 wt% of decahydronaphthalene was kneaded and dissolved using a screw extruder set to a temperature of 180°C to 220°C, extruded from an orifice of a 0.5 mm diameter and drawn at a drawing speed of 75**

m/min., and then stretched four-fold in an oven under heated air (100°C). In this case, carbon black obtained by subjecting carbon black REGAL 330R (average diameter of agglomerates: 1.41 mm, Max 9.29 mm, Min 0.22 mm) manufactured by Cabot to fine pulverization processing was added as a colorant to the mixture of polyethylene and decahydronaphthalene at 0.05 wt% relative to decahydronaphthalene. By further stretching the obtained intermediate stretched product to 4.3 fold, a colored high-strength polyethylene fiber having a strength of 3.62 GPa and an initial modulus of elasticity of 129 GPa was obtained. Furthermore, the particle diameter of the carbon black dispersed in the fiber cross-section was in the range of 10 nm to 50 nm, and the number of aggregated particles was 1 to 6. Furthermore, the evaluation results for the weather resistance of this fiber were excellent at grade 4 to 5, and the strength retention rate was 90%.

[0016] (Example 2) A high-strength polyethylene fiber was produced by the same method as in example 1, except that carbon black subjected to fine pulverization processing was added at 0.20 wt% relative to decahydronaphthalene. The obtained colored high-strength polyethylene fiber had a strength of 2.5 GPa and an initial

modulus of elasticity of 90 GPa, and the evaluation results for the weather resistance of the fiber were grade 4 to 5.

[0017] (Example 3) A **high-strength polyethylene fiber was produced by the same method as in example 1, except that carbon black subjected to fine pulverization processing was added at 0.25 wt% relative to decahydronaphthalene.** The obtained colored high-strength polyethylene fiber had a strength of 1.9 GPa and an initial modulus of elasticity of 67 GPa. The evaluation results of the weather resistance were grade 4 to 5.

Ex. 1007, page 3, paras. [0015]-[0017]. (Emphases added).

310. A person of ordinary skill in the art would understand Nanri as disclosing the addition of the finely pulverized pigment to the gel spinning mixture, so that the pigment particles do not migrate or “act as a defect during orientated crystallization that occurs during the fiber formation process of the polyethylene and [are] thus incorporated into the crystal”. *See* Ex. 1007, page 2, para. [0006] and page 3, para. [0015] (“A **mixture** of 10 wt% of ultra-high molecular weight polyethylene having a viscosity average molecular weight of 3,200,000 and 90 wt% of decahydronaphthalene” and pigment subjected to “fine pulverization processing was **added as a colorant to the mixture** of polyethylene

and decahydronaphthalene at 0.05 wt% relative to decahydronaphthalene.”)

(Emphases added).

311. In light of these disclosures in Nanri, a person of ordinary skill in the art would have been motivated to improve the properties and benefits of the colored linear polyethylene surgical sutures of Section 73.1015 that was already exempted from certification by the FDA by including the teachings of the colored high strength polyethylene fiber and pigmentation process for making same of Nanri to increase the strength of the resultant colored linear polyethylene surgical sutures while continuing to suppress migration of the colorant to the outside of the fiber and otherwise facilitate regulatory approval (i.e., maintain exemption of the resultant colored linear polyethylene surgical sutures from certification). Indeed, the person of ordinary skill in the art would have understood that the chromium-cobalt-aluminum oxide of Section 73.1015 would have been readily used in the process of Nanri to achieve both the exemption from certification benefits of the chromium-cobalt-aluminum oxide¹⁴ as well as the above properties and benefits of the fiber resulting from the Nanri gel-spinning process.

¹⁴ Indeed, DSM admitted this exact need – to facilitate regulatory approval – was the reason why its blue fibers were produced with Chromium-Cobalt-Aluminum Oxide. *See* H. Smelt, et al. “Advances in Medical-Grade UHMWPE

312. Being aware of the polymer properties of UHMWPE and known issues with leaching when attempting to use dyes and other colorants with UHMWPE (as admitted by the Patentee in the '532 Patent), as well as the limited colors exempted from batch certification for linear polyethylene suture materials, a person of ordinary skill in the art would be motivated to combine the chromium-cobalt-aluminum oxide pigment of Section 73.1015 into the gel spinning slurry

Fiber Development: Additives for Visualization” (7th UHMWPE International Meeting Proceedings, 2015) (Ex. 1010 at page 55-56) (“UHMWPE fiber’s chemical inertness and high crystallinity makes it a difficult material to dye. The very low percentage of amorphous or semicrystalline phase and the apolar nature of the aliphatic C₂H₂ backbone of the UHMWPE polymer does not provide sufficient compatibility with most available color dyes. In this respect, the addition of the color as a pigment during the gel-spinning process would be a better alternative, as the pigment would be well dispersed in the solution of solvent and disentangled UHMWPE, facilitating a homogeneous physical incorporation. **To facilitate regulatory approval, blue fibers with Chromium-Cobalt-Aluminum Oxide were produced, as this pigment is listed on the FDA’s 21 CFR part 73 on Color Additives Exempt from Certification for coloring linear polyethylene surgical sutures for use in general surgery.**”) (Emphasis added).

mixture as taught by Nanri such that “migration to outside the fiber is suppressed” and “there is no migration of the color additive to the surrounding tissue.” Ex. 1007, page 2, [0005]; Ex. 1006, page 18, (c)(4).

313. As noted above, Section 73.1015 discloses that in its coloring procedure, the pigment is blended with the polyethylene resin and is then heated to a temperature of 500°-550°F (Ex. 1006, page 18, (c)(1)), which is not inconsistent with the gel spinning process. To the extent that this process may be interpreted as being consistent with a melt process, the person of skill in the art would have understood that the addition of a pigment with polyethylene in a gel spinning process, such as Nanri, would have likewise been successful.¹⁵ That is, the person of ordinary skill in the art would have understood that the gel spinning process and melt process were similar, especially with regard to the addition of an inert pigment, such as the pigment of Section 73.1015. Other than the addition of an inert solvent, which would not affect the inert pigment, the polyethylene polymer

¹⁵ As described above in the Technical Background/State of the Art at Section V.A., the person of skill in the art understood that the pigment “infiltrates into the interior of the polyethylene and, as a result, the physical bonding between the polyethylene and the pigment and/or the dye becomes strong, causing substantially no color fading.” Ex. 1028, 10:35-41.

used in a gel spinning process is similar to that in a melt process (e.g., linear polyethylene). Moreover, any differences in temperature of the gel spinning and melt processes would not impact the pigment. Finally, the person of ordinary skill in the art would have also expected that the pigment would have worked with the crystalline structure of the fiber. *See e.g.*, Ex. 1007, Page 2, [0005].

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

315. In addition to suture strength, a person of ordinary skill in the art would also understand creep resistance to be an important consideration for the production of sutures. As described above in the Technical Background/State of the Art above at Section V.C., creep is the long term, longitudinal deformation of a material over time when subjected to a continuing load. The UHMWPE fibers in medical applications often experience or encounter such static tensions, which may cause the fibers to elongate and, in some instances, fail, with time. Such failure would result in injury to the patient and/or ineffectiveness of the suture.

316. Ohta, for its part, is generally directed to “a high strength polyethylene fiber having extremely superior creep resistance.” Ex. 1008, 1. Specifically, Ohta teaches that a high strength polyethylene fiber having excellent creep resistance can be obtained by keeping the residual components, particularly

the solvent and additives, in fibers made from a polymer mainly composed of UHMWPE, at 1000 ppm or less and by reducing the disorder of the crystal structure. Ex. 1008, 3. According to Ohta, “[w]hen the residual components exceed 1000 ppm, the creep resistance deteriorates significantly.” Ex. 1008, 3. Ohta explains that “a large amount of solvent is inevitably used” in the gel spinning method for producing the polyethylene fiber such that “the used solvent is the main residual component” and “[w]hen additives other than solvents are also used, the residual components must be 1000 ppm or less, including these.” Ex. 1008, 3.

317. Ohta also discloses the preparation of example yarns in Examples 1-4. Ex. 1008, page 4. The yarn of Example 1 was prepared by kneading and dissolving UHMWPE and decalin using a screw extruder at a temperature of 210°C and a screw rotation rate of 300 rpm, and initially drawing an extruded filament to 6x in an air oven adjusted to 100°C, and then continuously drawing the filament to 5x in a heated atmosphere at a temperature of 100°C. *Id.* The yarn of Examples 2 and 3 were prepared by the same manufacturing method as Example 1, except that the melting temperature (screw temperature) of the melting in Example 2 was changed to 190°C and the screw rotation rate was changed to 100 rpm in Example 3. *Id.* The yarn of Example 4 was also prepared by the same manufacturing method as Example 1, except the ratio of UHMWPE to decalin was changed from 5:95 to 10:90. *Id.*

318. According to Ohta, “[i]n order to create such a structure having little disorder, the most important factor is the melting condition in the screw, and it is necessary to select a screw rotation speed and temperature that sufficiently homogeneously mix so that the g value is 0.035 or less.” Ex. 1008, 3. Ohta further teaches that the measured values of the Examples and Comparative Examples set forth in Table 2 of Ohta indicate that “when the g value exceeds 0.03, the residual components exceed 1000 ppm, or when the dissolution and mixing are insufficient and the mixture does not form a uniform mixture, and the selected conditions are not favorable, the creep rate increases to an extreme degree.” Ex. 1008, pg. 5.

319. In light of these disclosures in Ohta, a person of ordinary skill in the art would have been motivated to improve the properties and benefits of the colored linear polyethylene surgical sutures of Section 73.1015 and Nanri by including the teachings of the high strength polyethylene fiber with excellent creep resistance and process for making same of Ohta to improve the creep resistance of the resultant colored linear polyethylene surgical sutures. That is, the person of ordinary skill in the art would have been motivated to combine the teachings of the high strength polyethylene fiber with excellent creep resistance and process for making same as disclosed in Ohta with the colored high strength polyethylene fiber and pigmentation process for making same as disclosed in Nanri and further with the chromium-cobalt-aluminum oxide pigment and pigmentation process identified

in Section 73.1015, thereby, obtaining improved colored multi-filament yarns for use in linear polyethylene surgical sutures so as to meet the well-known need for colored sutures, especially colored sutures having high strength that were exempt from further certification by the FDA. Accordingly, it would have been within the skill of the person of ordinary skill in the art to combine Section 73.1015 with Nanri and Ohta.

320. That is, the person of ordinary skill in the art would be motivated to apply the teachings of Ohta – reducing the disorder of the crystal structure by obtaining a “g value” below 0.35, keeping the residual components to 1000 ppm or less, and sufficiently dissolving and mixing the mixture by optimizing the number of screw revolutions and the melting temperature (screw temperature) of the melting to form a uniform mixture – to thereby obtain a colored fiber having extremely superior creep resistance.

321. Although Ohta teaches that “it is preferable to use a mixture composed of only the ultra high molecular weight polymer component and solvent described above as the spinning solution” (Ex. 1008, 3), the disclosure is not limited thereto. That is, a person of ordinary skill in the art at the time of the assumed priority date of the ’532 Patent would not be deterred by such statement in Ohta because the person of ordinary skill in the art would be well aware of the

design need for colored sutures, especially colored sutures having high strength (as admitted by the Patent Owner in the '532 Patent, *see* Ex. 1001, 1:11-17).

322. Nor would the person of ordinary skill in the art interpret the teaching in Ohta to keep residual components below 1000 ppm as being inclusive of the pigment added to the fiber formation process, as taught by Section 73.1015 and Nanri. That is, a person of ordinary skill in the art developing a colored suture would know that a sufficient amount of pigment would be required in order to provide the benefit of the color to the fiber (i.e., to improve visibility).¹⁶ Indeed, Nanri teaches that “a coloring effect cannot be demonstrated at less than 0.01 wt%” and Nanri further teaches that preferably, at least 0.10 wt% is used, which corresponds to 1000 ppm of the pigment with respect to the fiber. Ex. 1007, 2, para. [0008]. A person of ordinary skill in the art would understand that a sufficient amount of the pigment would be required to be able to perceive the color in the colored suture. The person of ordinary skill would also understand that removal of, or an insufficient amount of, pigment would be undesirable because the benefit of the color would be lost. A person of ordinary skill in the art would thus not omit the pigment in developing a colored suture.

¹⁶ As admitted in the background of the '532 Patent and as was well known in the art, there was a need to color sutures to improve visibility. *See* Ex. 1001, 1:11-17.

323. Moreover, Ohta teaches that the “remaining residual materials other than polyethylene” were determined “as a result of analyzing the extract from the drawn yarn by a method such as gas chromatography”. *See* Ex. 1008, 4. At least in much as Nanri teaches adding pigment that has been subjected to a fine pulverization process “to the mixture of polyethylene and decahydronaphthalene at [a specified] wt% relative to decahydronaphthalene” (Ex. 1007, 3, paras. [0015]-[0017]) and that “the pigment particles in the fiber are incorporated into the polyethylene crystal, and therefore migration to outside the fiber is suppressed, therefore it is thought that the pigment particles will be held stably” (Ex. 1007, 2, para. [0005]), a person of ordinary skill in the art would understand that such pigment would not leach or migrate from the fiber such that the pigment would not be present as a residual material in such an analyzed extract. That is, Nanri teaches that the finely pulverized pigment particles are “thus incorporated into the crystal.” Ex. 1007, 2, para. [0006].

324. Moreover, a person of ordinary skill in the art would understand that the pigment and pigmentation process taught by Nanri “do not act as a defect during orientated crystallization that occurs during the fiber formation process of the polyethylene” such that the addition of the pigment would also not affect the *g* value, which quantitatively describes structural disorder of the crystals, as taught by Ohta. That is, the person of ordinary skill in the art would understand that a colored

fiber obtained using the pigmentation teachings of Nanri would not act as defects to adversely affect the g value, which is thought to be one of the causes of low creeping.

325. Accordingly, it would have been within the skill of the person of ordinary skill in the art to combine Section 73.1015 with Nanri and Ohta.

326. A person of ordinary skill in the art would also know that multi-filament yarns are common and are indeed preferred for UHMWPE sutures as described above in the Technical Background/State of the Art above at Section V.A. Indeed, Ohta explicitly cites to Kavesh, which discloses that it is common knowledge to have spinnerets or spinning dies with various numbers of spinholes. *See* Ex. 1008 at 3 (“Note that removing the solvent when manufacturing polyethylene fiber using a mixture of a solvent and a polymer mainly composed of ultra high molecular weight polyethylene is disclosed, for example, in [Kavesh].”). Given the explicit teaching in Ohta to look to Kavesh, the person of ordinary skill in the art would have combined Kavesh when producing fibers.

327. A person of ordinary skill in the art would also know that the number of holes in the spinneret or spinning die forms a corresponding number of filaments, including between 10 and 1000 filaments. *See, e.g.,* Ex. 1009, page 8 (“**The number of apertures, and thus the number of fibers formed,** is not critical, but convenient **numbers of apertures are 16, 120, or 240.**”) (Emphases

added). That is, when the solution is passed through the spinneret, it can be extruded into any suitable number of filaments depending on the number of spinholes or orifices defined in the spinneret. As such, a person of ordinary skill in the art would understand that using a spinneret with multiple spinholes or orifices would result in a yarn of multiple individual filaments, i.e., a multi-filament yarn.

328. A person of ordinary skill in the art would also know that multi-filament yarns can also be prepared by combining the products of multiple spinnerets depending on the filament count (i.e., number of fibers) that is desired for the multifilament yarn, including between 10 and 1000 filaments. *See* Ex. 1009, page 27 (describing preparation of nine rolls of 16-filament yarns using spinning dies having 16 apertures), page 28 (“In the first stage three of the rolls of 16 filament gel yarns described in Example 502 were combined and stretched together to prepare a 48 filament stretched gel yarn.”), page 31 (setting forth yarn properties of various multi-filament yarns in a table, including several yarns prepared by combining multiple 16-filament yarns resulting in 48-filament and 64- filament multi-filament yarns).

329. It is also my opinion that the person of ordinary skill in the art would have a reasonable expectation of success in combining Section 73.1015 with Nanri, Ohta, and Kavesh to achieve the predictable result of improved colored multi-filament yarns. First, Section 73.1015 discloses the addition of a pigment in an

amount that does not exceed 2 percent by weight of the suture material (Ex. 1006, page 18, (c)(2)). As described by Nanri itself and as was well known, pigments, including an inorganic pigment, would have been added to UHMWPE fibers in a pigment content of 0.01 to 2.50 wt%, preferably 0.1 to 2.00 wt% (Ex. 1007, Page 2, Claim 3), which is consistent with the express disclosures of Nanri. Second, each of Section 73.1015, Nanri, Ohta, and Kavesh disclose use of linear polyethylene. Moreover, at least Nanri, Ohta, and Kavesh disclose the same or similar gel-spinning processes, UHMWPE, intrinsic viscosity values, and same or similar spin solvents, to prepare their respective UHMWPE fibers. Additionally, Nanri, Ohta, and Kavesh are all directed to retaining or improving mechanical properties of the resulting UHMWPE fibers. Moreover, at least Nanri and Ohta teach the same or similar screw extruder temperatures for mixing the gel spinning slurry mixture. *See e.g.*, Ex. 1007, 3, para. [0015] (“kneaded and dissolved using a screw extruder set to a temperature of 180°C to 220°C”) and Ex. 1008, 4 (disclosing a screw temperature of 210°C for Examples 1, 3, and 4 and 190°C for Example 2).

330. Third, Kavesh explicitly discloses “[t]he **number of apertures, and thus the number of fibers formed**, is not critical, but convenient numbers of **apertures are 16, 120, or 240**” (Ex. 1009, page 8), and as such, the person of ordinary skill in the art would have understood that any configuration was common

and was usable in the process of Ohta. Indeed, it would be a design choice by the user based on the thickness and required strength of the resultant yarn.

331. Fourth, Nanri is clear that a pigment, such as the one disclosed in Section 73.1015, would be incorporated in UHMWPE fibers prepared by a gel spinning process. For example, Nanri discloses that the color agent includes pigments “such as an organic pigment, inorganic pigment, and carbon black”. Ex. 1007, Page 2, [0005]. Moreover, 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.” Ex. 1007, Page 2, [0006]. As such, the person of ordinary skill 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.¹⁷

332. In light of these teachings, a person of ordinary skill in the art would have expected the addition of the pigment particles of the color additive disclosed in Section 73.1015 and sized according to the gel-spinning disclosure of Nanri with

¹⁷ The '532 Patent is silent with regard to any requirements as to the sizing of pigment particles.

the with the creep resistance modifications for the fiber production process of Ohta using the multi-aperture spinplate of Kavesh to be effective.

333. Moreover, Nanri explicitly teaches that “the pigment particles in the fiber are incorporated into the polyethylene crystal, and therefore migration to outside the fiber is suppressed” and Section 73.1015 teaches that “there is no migration of the color additive to the surrounding tissue.” Ex. 1006, page 18, (c)(4); Ex. 1007, 2, [0005]. In light of these teachings, a person of ordinary skill in the art would have expected the combination of Section 73.1015, Nanri, Ohta, and Kavesh to be effective.

334. Accordingly, a person of ordinary skill in the art would have been motivated to combine and would have had a reasonable expectation of success in combining Section 73.1015, Nanri, Ohta, and Kavesh.

F. Analysis

i. Claim 1: [1.Pre] A colored multi-filament yarn comprising

335. Claim 1 of the '532 Patent is directed to a product that is developed by way of a process, such as the process described with regard to limitation [1.A]. As such, I understand that the determination of patentability is based on the product (e.g., the yarn) itself and the “physical constituent of the fiber” that “is a quantifiable and hence physical attribute of the fiber.” Ex. 1030, page 258

(emphases in original). Regardless, as is described in at least limitation [1.A], the cited art of Ground 2 renders obvious a gel spinning process.

336. Moreover, and to the extent the preamble is limiting, it is disclosed by the combination of Section 73.1015, Nanri, Ohta, and Kavesh as is described throughout Ground 1. *See* [1.A-1.E].

337. Section 73.1015 discloses limitation [1.Pre] for the same reasons discussed above with respect to Ground 1. That is, Section 73.1015 expressly discloses “the color additive [chromium-cobalt-aluminum oxide] is blended with the polyethylene resin”, “[t]he mixture is heated to a temperature of 500°–550 °F. and extruded through a fixed orifice”, and “[t]he **filaments** are cooled, oriented by drawing, and set by annealing.” Ex. 1006, page 18, (c)(1) (emphasis added).

338. Nanri discloses Examples 1-3, which detail the preparation of a colored high strength polyethylene fiber via a gel spinning method and extruding the UHMWPE/pigment/solvent mixture “from an orifice of a 0.5 mm diameter”. Ex. 1007, 3, [0015].

339. Similarly, Ohta discloses extruding a gel spinning mixture “from a spinning nozzle”. Ex. 1008, 4. Ohta further describes Examples 1-4, which detail the preparation of yarn via a gel spinning method and extruding the UHMWPE/solvent mixture “from an orifice having a diameter of 0.5.” Ex. 1008, 4.

340. Kavesh discloses a spinneret having a plurality of apertures, with convenient numbers of apertures being 16, 120, or 240. Ex. 1009, page 8.

341. Kavesh further discloses preparing multi-filament yarns using such spinnerets, including as-spun multi-filament yarns and multi-filament yarns prepared by combining the products of multiple spinnerets. *See, e.g.*, Ex. 1009, page 27 (describing preparation of nine rolls of 16-filament yarns using spinning dies having 16 apertures), page 28 (“In the first stage three of the rolls of 16 filament gel yarns described in Example 502 above were combined and stretched together to prepare a 48 filament stretched gel yarn.”), page 31 (setting forth yarn properties of various multi-filament yarns in a table, including several yarns prepared by combining multiple 16-filament yarns resulting in 48-filament and 64-filament multi-filament yarns).

342. Accordingly, it is my opinion that the combination of Section 73.1015, Nanri, Ohta, and Kavesh discloses each and every element of, and renders obvious, the recitation of limitation [1.Pre].

ii. Claim 1: [1.A] filaments that have been obtained by gel spinning a mixture containing ultra-high molecular weight polyethylene (UHMwPE) having an intrinsic viscosity (IV) of between about 8 and 40 dl/g, a spin solvent and a pigment, and

343. As I noted above with regard to limitation [1.Pre], it is my understanding that Claim 1 is directed to a product that is developed by way of a

process, such as the process described with regard to limitation [1.A]. Moreover, in my review of the '532 Patent, I do not see a particular process outlined for gel spinning. Even though I understand that no patentable weight should be given to limitation [1.A], the combination discloses it, nonetheless.¹⁸

344. Specifically, with regard to limitation [1.A], Nanri identifies “a method for stretching gel filaments obtained by solution spinning an ultra-high molecular weight polyethylene solution” in order to manufacture the colored high-strength polyethylene fiber. Ex. 1007, 3, [0013], citing JP S55-107506 A and JP S56-154508 A.

345. Nanri sets forth three examples, including Example 1 which describes “[a] mixture of 10 wt% of ultra-high molecular weight polyethylene having a viscosity average molecular weight of 3,200,000 and 90 wt% of decahydronaphthalene [also known as decalin] was kneaded and dissolved using a screw extruder set to a temperature of 180°C to 220°C, extruded from an orifice of a 0.5 mm diameter and drawn at a drawing speed of 75 m/min., and then stretched

¹⁸ As is described above and is admitted in the '532 Patent, the gel spinning process for preparing UHMWPE filaments was well known in the prior art and was indeed conventional by the assumed priority date of the '532 Patent. Ex. 1001, 2:24-31.

four-fold in an oven under heated air (100°C). In this case, carbon black obtained by subjecting carbon black REGAL 330R (average diameter of agglomerates: 1.41 mm, Max 9.29 mm, Min 0.22 mm) manufactured by Cabot to fine pulverization processing was added as a colorant to the mixture of polyethylene and decahydronaphthalene at 0.05 wt% relative to decahydronaphthalene. By further stretching the obtained intermediate stretched product to 4.3 fold, a colored high-strength polyethylene fiber having a strength of 3.62 GPa and an initial modulus of elasticity of 129 GPa was obtained. Furthermore, the particle diameter of the carbon black dispersed in the fiber cross-section was in the range of 10 nm to 50 nm, and the number of aggregated particles was 1 to 6. Furthermore, the evaluation results for the weather resistance of this fiber were excellent at grade 4 to 5, and the strength retention rate was 90%.” Ex. 1007, 3. Examples 2 and 3 of Nanri similarly disclose adding 0.20 wt% and 0.25 wt%, respectively, of carbon black pigment subjected to fine pulverization processing and relative to decahydronaphthalene. The obtained colored high-strength polyethylene fiber had strengths of 2.5 GPa and 1.9 GPa, respectively, and initial modulus of elasticity of 90 GPa and 67 GPa, respectively. Ex. 1007, 3, paras. [0015]-[0017].

346. As discussed above in the Technical Background/State of the Art section of this declaration at Section V.C., and as confirmed by the ’532 Patent (Ex. 1001, 2:53-60), Nominal Viscosity Molecular Weight = $5.37 \times 10^4 [\eta]^{1.37}$, where

[η] is the intrinsic viscosity. Accordingly, Nanri's disclosure of a viscosity average molecular weight of 3,200,000 corresponds to an intrinsic viscosity value of 19.79 dl/g.

347. Such disclosure is consistent with the recitation of limitation [1.A] of "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". Moreover, I understand from counsel that a specific example or disclosure in the prior art which is within a claimed range, such as Nanri's disclosure of an intrinsic viscosity value of 19.79 dl/g, anticipates the claimed range.

348. With respect to spin solvent, Nanri discloses decahydronaphthalene in its Examples, which is also known as decalin. Ex. 1007, 3, paras. [0015]-[0017]. Such disclosure is consistent with the recitation of limitation [1.A] of "filaments that have been obtained by gel spinning a mixture containing...a spin solvent".

349. Nanri further discloses a pigment providing that "it is essential that the colorant contained in the fiber is composed of a pigment such as an organic pigment, inorganic pigment, and carbon black" to obtain high-strength polyethylene fibers that are colored while maintaining a sufficiently high strength. Ex. 1007, 2, para. [0005]. "This is because the pigment particles in the fiber are incorporated into the polyethylene crystal, and therefore migration to outside the

fiber is suppressed, therefore it is thought that the pigment particles will be held stably.” Ex. 1007, 2, para. [0005]. Nanri discloses carbon black in its Examples. Ex. 1007, 3, paras. [0015]-[0017].

350. A person of ordinary skill in the art would further understand that Nanri discloses the addition of the finely pulverized pigment to the gel spinning mixture. *See* Ex. 1007, page 2, para. [0006] (“the particles of the pigment are of a diameter that does not act as a defect during orientated crystallization that occurs during the fiber formation process of the polyethylene and [are] thus incorporated into the crystal”), and page 3, para. [0015] (“A **mixture** of 10 wt% of ultra-high molecular weight polyethylene having a viscosity average molecular weight of 3,200,000 and 90 wt% of decahydronaphthalene” and pigment subjected to “fine pulverization processing was **added as a colorant to the mixture** of polyethylene and decahydronaphthalene at 0.05 wt% relative to decahydronaphthalene.”) (Emphases added). Such disclosure is consistent with the recitation of limitation [1.A] of “filaments that have been obtained by gel spinning a mixture containing...a pigment”.

351. Accordingly, Nanri discloses a fiber that has “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”.

352. Ohta identifies a “gel spinning method” as a generally known and appropriate method for “manufacturing a high strength polyethylene fiber using a polymer mainly composed of ultra high molecular weight polyethylene”, since doing so with a normal melt spinning method is difficult. Ex. 1008, 2. Ohta further explains that “[a] gel spinning method is suited as the method for producing the polyethylene fiber according to the present invention”. Ex. 1008, 3.

353. According to Ohta, “a polymer mainly composed of polyethylene having a viscosity average molecular weight of 500,000 or more is used for spinning by a gel spinning method, and thus a mixture of the foregoing polymer components and solvent is used as a mixture of raw materials for spinning”, such mixture “is fed to a screw extruder under reduced pressure of 150 mmHg or less, and mixed and dissolved so as to become sufficiently uniform, extruded from a spinning nozzle, the obtained gel-like undrawn yarn is heated to remove the solvent, and the undrawn yarn is drawn simultaneously with or subsequently to the heating.” Ex. 1008, 3.

354. With respect to viscosity average molecular weight, Ohta further elaborates:

As described above, the polymer mainly composed of polyethylene used in the present invention must have a viscosity average molecular weight of 500,000 or more, preferably 1,000,000 or more, and more preferably 1,500,000 or more. This ultra high molecular weight is an

essential requirement for the production of high strength polyethylene fibers, and this has an effect of reducing defects derived from molecular terminals by decreasing the number of molecular terminals via molecular weight increase.

Ex. 1008, 2.

355. Based on Nominal Viscosity Molecular Weight = $5.37 \times 10^4 [\eta]^{1.37}$, where $[\eta]$ is the intrinsic viscosity, Ohta's disclosure of preferable viscosity average molecular weights of 1,000,000 or more and 1,500,000 or more correspond to intrinsic viscosity values of 8.47 dl/g or more and 11.38 dl/g or more, respectively.

356. Moreover, Ohta further describes Examples 1-4, each of which detail the preparation of yarn via a gel spinning method using UHMWPE having a viscosity average molecular weight of 1,900,000, which corresponds to an intrinsic viscosity value of 13.53 dl/g. Ex. 1008, 4.

357. Such disclosures are consistent with the recitation of limitation [1.A] of "ultra-high molecular weight polyethylene (UHMwPE) having an intrinsic viscosity (IV) of between about 8 and 40 dl/g". Moreover, I understand from counsel that if a range taught by a prior art reference overlaps a range claimed in the '532 Patent, then the range taught by the prior art reference would render the claimed range obvious. I further understand from counsel that a specific example or disclosure in the prior art which is within a claimed range, such as Ohta's

disclosures of an intrinsic viscosity value of 13.53 dl/g, anticipates the claimed range.

358. With respect to spin solvent, Ohta discloses “it is essential to use a volatile solvent” and “it is favorable to use a solvent having a melting point lower than the melting point of the polymer component and a boiling point higher than the melting point of the polymer component by 15°C or more, and insofar as possible no greater than 15°C higher.” Ex. 1008, 3. Ohta indicates that “[s]olvents that can be used change based on the molecular weight of the raw material polyethylene, but examples include decalin, tetralin, dichlorobenzene, naphthalene, mixtures thereof, and the like.” Ex. 1008, 3. Moreover, Ohta further describes Examples 1-4, each of which detail the preparation of yarn via a gel spinning method using decalin. Ex. 1008, 4.

359. Accordingly, Ohta discloses a fiber that has “been obtained by gel spinning a mixture containing ultra-high molecular weight polyethylene (UHMwPE) having an intrinsic viscosity (IV) of between about 8 and 40 dl/g [and] a spin solvent”.

360. With regard to limitation [1.A], Kavesh describes “(a) forming a solution by dissolving a thermoplastic crystalline polymer selected from the group consisting of polyethylene, polypropylene, polyoxymethylene, polybutene-1, poly(vinylidene fluoride), and poly-4-methylpentene-1 in a first non-volatile

solvent at a first concentration”, “(b) extruding the solution through an aperture”, “(c) cooling the solution...at which a rubbery gel is formed to form a gel of a substantially unfixed length containing the first solvent”, “(d) using a second volatile solvent to extract the gel containing the first solvent for sufficient contact time to form a gel containing the second solvent, containing substantially none of the first solvent and being of a substantially unfixed length”, “(e) drying the gel containing the second solvent to form a xerogel (xerogel) of substantially unfixed length that does not contain the first or second solvent”, and “(f) stretching at least one of (i) the gel containing the first solvent, (ii) the gel containing the second solvent and, (iii) the xerogel at a total stretch ratio that is (i) in the case of polyethylene sufficient to achieve a tenacity (tenacity) of at least 20 g/denier and an elastic modulus of at least 180 g/denier”. Ex. 1009, page 3.

361. According to Kavesh, “[t]he weight average molecular weight of polyethylene used is at least 500,000 (6 IV), preferably at least 1,000,000 (10 IV), and more preferably 2,000,000 (16 IV) to 8,000,000 (42 IV)....The IV numbers represent intrinsic viscosity of the polymer in decalin at 135°C.” Ex. 1009, page 5. Kavesh also discloses that “[i]n the case of polyethylene, a favorable molecular weight (due to intrinsic viscosity) is 1 million to 10 million [as such] molecular weight corresponds to a weight average chain length of 3.6×10^4 to 3.6×10^5 monomer units or 7×10^4 to 7.1×10^5 carbons.” Ex. 1009, page 5. Kavesh further

discloses Claim 13, which is directed to a polyethylene fiber “having a weight average molecular weight of 2,000,000 to 8,000,000”. Ex. 1009, page 2.

362. With respect to FIG. 5, Kavesh also provides the first mixing vessel 10 “being fed an ultrahigh molecular weight polymer 11 such as polyethylene of a weight average molecular weight of at least 500,000 and preferably at least 1,000,000 and a relatively non-volatile solvent 12 such as paraffin oil.” Ex. 1009, page 8.

363. Moreover, Kavesh further describes Example 2, which details the preparation of yarn via a gel spinning method using paraffin oil and “linear polyethylene (Hercules UHMW 1900, 17 IV, approximately 2.5×10^6 molecular weight)” as well as at least the preparation of multi-filament yarns in Examples 487-551, the yarns prepared from polyethylene (UHMWPE) having intrinsic viscosity values of 17.5 or 22.6. Ex. 1009, pages 12 and 24-32.

364. Such disclosures are consistent with the recitation of limitation [1.A] of “ultra-high molecular weight polyethylene (UHMwPE) having an intrinsic viscosity (IV) of between about 8 and 40 dl/g”. I understand from counsel that if a range taught by a prior art reference overlaps a range claimed in the '532 Patent, then the range taught by the prior art reference would render the claimed range obvious. Moreover, I understand from counsel that a specific example or disclosure

in the prior art which is within a claimed range, such as Kavesh's disclosure of intrinsic viscosity values of 17.5 and 22.6, anticipates the claimed range.

365. With respect to spin solvent, Kavesh discloses “[t]he first solvent must be non-volatile under the processing conditions. This is necessary in order to maintain the concentration of solvent upstream fiber and through the aperture (die) substantially constant and to prevent non-uniformity in liquid content of the gel fiber or film containing the first solvent.” Ex. 1009, page 5. According to Kavesh, “[p]referred first solvents for hydrocarbon polymers are aliphatic and aromatic hydrocarbons of the desired non-volatility and solubility in the polymer.” Ex. 1009, page 5; *see also*, page 7 (“When the polymer is a polyolefin such as ultrahigh molecular weight polyethylene, the first solvent is preferably a hydrocarbon.”).

366. Kavesh further provides that “[e]xtraction using the second solvent is conducted such that the first solvent in the gel is replaced with the second solvent without significantly changing the gel structure. Some swelling or shrinkage of the gel may occur, but preferably the polymer does not substantially dissolve, coagulate, or precipitate.” Ex. 1009, page 6. When the first solvent is a hydrocarbon, Kavesh discloses “suitable second solvents include hydrocarbons, chlorinated hydrocarbons, chlorofluorinated hydrocarbons, and others, for example, pentane, hexane, heptane, toluene, methylene chloride, carbon

tetrachloride, trichlorotrifluoroethane (TCTFE), diethyl ether, dioxane, and the like”, with “[t]he most suitable second solvents [being] methylene chloride (boiling point of 39.8°C) and TCFE (boiling point of 47.5°C).” Ex. 1009, page 6. Kavesh further provides that “[f]avorable second solvents are non-flammable volatile solvents having an atmospheric boiling point of 80°C or lower, more preferably 70°C or lower, and most preferably 50°C or lower.” Ex. 1009, page 6. Moreover, Kavesh further describes Example 2, which details the preparation of yarn via a gel spinning method using “paraffin oil” and “trichlorotrifluoroethane (fluorocarbon 113 or ‘TCTFE’)” as well as at least the preparation of multi-filament yarns in Examples 487-551, the yarns prepared using paraffin oil and TCTFE. Ex. 1009, pages 12 and 24-32.

367. Accordingly, Kavesh likewise discloses “filaments that have been obtained by gel spinning a mixture containing ultra-high molecular weight polyethylene (UHMwPE) having an intrinsic viscosity (IV) of between about 8 and 40 dl/g [and] a spin solvent”.

368. As discussed with respect to Ground 1, Section 73.1015 specifically discloses the use of a chromium-cobalt-aluminum oxide pigment in polyethylene, including blending such pigment with the polyethylene, heating the mixture, and extruding the mixture. *See generally*, Ex. 1006, page 18. Accordingly, Section 73.1015 likewise discloses “filaments...containing... a pigment”.

369. Accordingly, it is my opinion that the combination of Section 73.1015, Nanri, Ohta, and Kavesh renders obvious the recitation of limitation [1.A].

iii. Claim 1: [1.B] wherein the filaments consist of UHMwPE,

370. With regard to limitation [1.B], Nanri discloses “a method for stretching gel filaments obtained by solution spinning an ultra-high molecular weight polyethylene solution” in order to manufacture the colored high-strength polyethylene fiber, such that the colored high strength polyethylene fiber of Nanri contains UHMwPE. Ex. 1007, 3, [0013], citing JP S55-107506 A and JP S56-154508 A.

371. Likewise, Ohta discloses a filament consisting of “UHMwPE.” Ohta identifies a “gel spinning method” as a generally known and appropriate method for “manufacturing a high strength polyethylene fiber using a polymer mainly composed of ultra high molecular weight polyethylene”, since doing so with a normal melt spinning method is difficult. Ex. 1008, 2. Ohta further explains that “[a] gel spinning method is suited as the method for producing the polyethylene fiber according to the present invention”. Ex. 1008, 3.

372. According to Ohta, “a polymer mainly composed of polyethylene having a viscosity average molecular weight of 500,000 or more is used for spinning by a gel spinning method, and thus a mixture of the foregoing polymer

components and solvent is used as a mixture of raw materials for spinning”, such mixture “is fed to a screw extruder under reduced pressure of 150 mmHg or less, and mixed and dissolved so as to become sufficiently uniform, extruded from a spinning nozzle, the obtained gel-like undrawn yarn is heated to remove the solvent, and the undrawn yarn is drawn simultaneously with or subsequently to the heating.” Ex. 1008, 3.

373. Moreover, Ohta discloses that “a method was discovered for producing ultra high molecular weight polyethylene fibers that have more complete crystals than considered until now and that do not contain impurities, and a high strength polyethylene fiber having creep resistance that could not be obtained conventionally was successfully obtained. What is emphasized here is that the ultra high molecular weight polyethylene fiber according to the present invention not only has improved creep resistance, but also maintains the high strength and high modulus of elasticity inherent to ultra high molecular weight polyethylene fiber and is superior.” Ex. 1008, 2. Accordingly, a person of ordinary skill would understand the resulting filaments of Ohta to contain UHMWPE.

374. Ohta also discloses that “in order to obtain the polyethylene fiber having superior creep resistance...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.” Ex. 1008, 3. Ohta elaborates that “creep resistance is more favorable the more scarce impurities other than polyethylene are” and “[w]hen the residual components exceed 1000 ppm, the creep resistance deteriorates significantly.” Ex. 1008, 2 (“the greater the amount of disorder in the crystals or the greater the amount of impurities such as residual solvent and additives, the worse the creep resistance.”), 3.

375. To the extent [1.B] is interpreted as requiring multiple filaments, Kavesh discloses it. That is, Kavesh discloses the preparation of multi-filament yarns by extruding a polymer solution including “an ultrahigh molecular weight polymer 11 such as polyethylene of a weight average molecular weight of at least 500,000 and preferably at least 1,000,000”, further indicating that “[t]he weight average molecular weight of polyethylene used is at least 500,000 (6 IV), preferably at least 1,000,000 (10 IV), and more preferably 2,000,000 (16 IV) to 8,000,000 (42 IV)”, through a spinneret, the spinneret containing many apertures, “[t]he number of apertures, and thus the number of fibers formed, is not critical, but convenient numbers of apertures are 16, 120, or 240.” Ex. 1009, pages 5 and 8. Accordingly, the obtained filaments of Kavesh contain “UHMwPE”.

376. Accordingly, it is my opinion that the combination of Section 73.1015, Nanri, Ohta, and Kavesh renders obvious the recitation of limitation [1.B].

iv. Claim 1: [1.C] between 0.1 and 7.0 wt. % of an inorganic chromium oxide-containing pigment,

377. Section 73.1015 discloses limitation [1.C] for the same reasons discussed above with respect to Ground 1. That is, Section 73.1015 discloses the color additive “chromium-cobalt-aluminum oxide”, which is an inorganic “blue-green pigment obtained by calcining a mixture of chromium oxide, cobalt carbonate, and aluminum oxide”, “may be safely used for coloring linear polyethylene surgical sutures”. *See generally*, Ex. 1006.

378. Section 73.1015 further recites that the “[t]he quantity of the color additive does not exceed 2 percent by weight of the suture material.” Ex. 1006, page 18, (c)(2). The person of ordinary skill in the art would understand that the disclosed range was of particular importance given the fact that a suture formed from polyethylene filaments having less than 2 percent by weight of the exempted pigment would not have to go through an additional FDA certification process.

379. Nanri similarly teaches that it is essential that the colorant contained in the fiber is composed of a “pigment”, identifying an inorganic pigment as one such example. Ex. 1007, 2, [0005] (“With respect to a high-strength polyethylene fiber colored while maintaining a sufficiently high strength, it is essential that the colorant contained in the fiber is composed of a pigment such as an organic pigment, inorganic pigment, and carbon black.”). Nanri explains a pigment is essential “because the pigment particles in the fiber are incorporated into the

polyethylene crystal, and therefore migration to outside the fiber is suppressed, therefore it is thought that the pigment particles will be held stably.” Ex. 1007, 2, [0005].

380. Nanri further describes a “strong polyethylene fiber...wherein a pigment content is 0.01 to 2.50 wt%.” Ex. 1007, 2, [0004]; *see also*, Claim 3 (“The strong polyethylene fiber according to claim 1, wherein the pigment content is 0.01 to 2.50 wt%.”). Nanri further discloses that “[i]n the high-strength polyethylene fiber colored while maintaining sufficiently high strength, the content of the pigment—which is a colorant contained in the fiber—is 0.01 to 2.50 wt%, preferably 0.10 to 2.00 wt%, a coloring effect cannot be demonstrated at less than 0.01 wt%, and when the content of the pigment exceeds 2.50 wt%, weather resistance of the high-strength polyethylene fiber is favorable but strength and initial modulus of elasticity are reduced.” Ex. 1007, 2, [0008].

381. Such disclosures are consistent with the recitation of limitation [1.C] requiring the filaments to include “between 0.1 and 7.0 wt. % of an inorganic chromium oxide-containing pigment”. Moreover, I understand from counsel that if a range taught by a prior art reference overlaps a range claimed in the ’532 Patent, then the range taught by the prior art reference would render the claimed range obvious.

382. Accordingly, it is my opinion that the combination of Section 73.1015, Nanri, Ohta, and Kavesh renders obvious the recitation of limitation [1.C].

v. *Claim 1: [1.D] a residual amount of spin solvent of less than about 500 ppm, and*

383. Ohta discloses “a residual amount of spin solvent of less than about 500 ppm”. With regard to limitation [1.D], Ohta discloses that “in order to obtain the polyethylene fiber having superior creep resistance...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.” Ex. 1008, 3. Ohta elaborates that “creep resistance is more favorable the more scarce impurities other than polyethylene are” and “[w]hen the residual components exceed 1000 ppm, the creep resistance deteriorates significantly.” Ex. 1008, 2 (“the greater the amount of disorder in the crystals or the greater the amount of impurities such as residual solvent and additives, the worse the creep resistance.”), 3.

384. Ohta elaborates that “[a] gel spinning method is suited as the method for producing the polyethylene fiber according to the present invention, and thus a large amount of a solvent is inevitably used as described below. Therefore, the used solvent is the main residual component.” Ex. 1008, 3. Ohta further provides

the “gel-like undrawn yarn” obtained after extruding the mixture from the spinning nozzle “is heated to remove the solvent.” Ex. 1008, 3.

385. Ohta further describes the preparation of Examples 1-4 and Comparative Examples 1-5, each of which have remaining residual components other than polyethylene of 60 ppm or less, as measured “as a result of analyzing the extract from the drawn yarn by a method such as gas chromatography”, including solvent residual fraction, as set forth in Table 2 of Ohta:

Table 2

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

Ex. 1008, 4-5. Moreover, I understand from counsel that a specific example or disclosure in the prior art which is within a claimed range, such as Ohta’s disclosure of residual fractions other than polyethylene, including solvent residual

fraction, of 35 ppm, 37 ppm, 45 ppm, 55 ppm, and 60 ppm, anticipates the claimed range.

386. Accordingly, it is my opinion that the combination of Section 73.1015, Nanri, Ohta, and Kavesh renders obvious the recitation of limitation [1.D].

vi. Claim 1: [1.E] less than 1000 ppm of further constituents.

387. Ohta discloses “less than 1000 ppm of further constituents”. With regard to limitation 1.E, Ohta provides “in order to obtain the polyethylene fiber having superior creep resistance...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.” Ex. 1008, 3. Ohta elaborates that “creep resistance is more favorable the more scarce impurities other than polyethylene are” and “[w]hen the residual components exceed 1000 ppm, the creep resistance deteriorates significantly.” Ex. 1008, 2 (“the greater the amount of disorder in the crystals or the greater the amount of impurities such as residual solvent and additives, the worse the creep resistance.”), 3.

388. According to Ohta, “[w]hen additives other than solvents are also used, the residual components must be 1000 ppm or less, including these.” Ex. 1008, 2. For example, Ohta indicates that “[s]uch additives other than solvents

include antioxidants that are added in order to prevent molecular weight reduction during the fiber manufacturing process.” Ex. 1008, 2. However, Ohta teaches that “an antioxidant is preferably not used” because “equivalent effects can be obtained without using antioxidants by reducing the heating atmosphere to a substantially oxygen-free state, specifically to a reduced pressure of 150 mmHg or less, in a screw extruder.” Ex. 1008, 2. Ohta further provides that “it is preferable that other normal additives be used as little as possible.” Ex. 1008, 2. The polyethylene fibers of Ohta have “few residues.” Ex. 1008, 3.

389. Ohta further describes the preparation of Examples 1-4 and Comparative Examples 1-5, each of which have remaining residual components other than polyethylene of 60 ppm or less, as measured “as a result of analyzing the extract from the drawn yarn by a method such as gas chromatography”, including solvent residual fraction, as set forth in Table 2 of Ohta:

Table 2

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

Ex. 1008, 4-5. Moreover, I understand from counsel that a specific example or disclosure in the prior art which is within a claimed range, such as Ohta's disclosure of residual fractions other than polyethylene, including solvent residual fraction, of 35 ppm, 37 ppm, 45 ppm, 55 ppm, and 60 ppm, anticipates the claimed range.

390. The examples of Nanri similarly confirm the lack of further constituents. For example, Nanri discloses the preparation of multiple colored high-strength polyethylene fiber examples. *See e.g.*, Ex. 1007, page 3, paras. [0015]-[0017]. In each example, the colored high-strength polyethylene fiber was prepared from a solution of UHMWPE and finely pulverized carbon black pigment

in decahydronaphthalene (i.e., decalin). *Id.* The examples of Nanri do not describe any other components or material being added during preparation of the colored high-strength polyethylene fiber examples such that a person of ordinary skill in the art would not expect the resulting colored high-strength polyethylene fiber to have “further constituents”.

391. Accordingly, it is my opinion that the combination of Section 73.1015, Nanri, Ohta, and Kavesh renders obvious the recitation of limitation [1.E].

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

392. Section 73.1015 discloses Claim 2 for the same reasons discussed above with respect to Ground 1. That is, Section 73.1015 discloses the color additive “chromium-cobalt-aluminum oxide”, which is an inorganic “blue-green pigment obtained by calcining a mixture of chromium oxide, cobalt carbonate, and aluminum oxide”, “may be safely used for coloring linear polyethylene surgical sutures”. *See generally*, Ex. 1006.

393. Section 73.1015 further recites that the “[t]he quantity of the color additive does not exceed 2 percent by weight of the suture material.” Ex. 1006, page 18, (c)(2).

394. Nanri similarly discloses a “strong polyethylene fiber...wherein a pigment content is 0.01 to 2.50 wt%.” Ex. 1007, 2, [0004]; *see also*, Claim 3 (“The strong polyethylene fiber according to claim 1, wherein the pigment content is 0.01 to 2.50 wt%.”). Nanri further discloses that “[i]n the high-strength polyethylene fiber colored while maintaining sufficiently high strength, the content of the pigment—which is a colorant contained in the fiber—is 0.01 to 2.50 wt%, preferably 0.10 to 2.00 wt%, a coloring effect cannot be demonstrated at less than 0.01 wt%, and when the content of the pigment exceeds 2.50 wt%, weather resistance of the high-strength polyethylene fiber is favorable but strength and initial modulus of elasticity are reduced.” Ex. 1007, 2, [0008].

395. Nanri similarly teaches that it is essential that the colorant contained in the fiber is composed of a “pigment”, identifying an inorganic pigment as one such example. Ex. 1007, 2, [0005].

396. Such disclosures are consistent with Claim 2’s recitation of “wherein the amount of the inorganic pigment present in the filaments is between 0.3 and 5.0 wt. %” Moreover, I understand from counsel that if a range taught by a prior art reference overlaps a range claimed in the ’532 Patent, then the range taught by the prior art reference would render the claimed range obvious.

397. Accordingly, it is my opinion that the combination of Section 73.1015, Nanri, Ohta, and Kavesh discloses each and every element of, and renders obvious, Claim 2.

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

398. Section 73.1015 discloses Claim 3 for the same reasons discussed above with respect to Ground 1. That is, Section 73.1015 discloses the color additive “chromium-cobalt-aluminum oxide”, which is an inorganic “blue-green pigment obtained by calcining a mixture of chromium oxide, cobalt carbonate, and aluminum oxide”, “may be safely used for coloring linear polyethylene surgical sutures”. *See generally*, Ex. 1006.

399. Section 73.1015 further recites that the “[t]he quantity of the color additive does not exceed 2 percent by weight of the suture material.” Ex. 1006, page 18, (c)(2). Moreover, I understand that a specific example or disclosure in the prior art which is within a claimed range, anticipates the claimed range.

400. As discussed with respect to Claim 2, Nanri discloses a “strong polyethylene fiber...wherein a pigment content is 0.01 to 2.50 wt%.” Ex. 1007, 2, [0004]; *see also*, Ex. 1007, Claim 3 (“The strong polyethylene fiber according to claim 1, wherein the pigment content is 0.01 to 2.50 wt%.”). Nanri further discloses that “[i]n the high-strength polyethylene fiber colored while maintaining

sufficiently high strength, the content of the pigment—which is a colorant contained in the fiber—is 0.01 to 2.50 wt%, preferably 0.10 to 2.00 wt%, a coloring effect cannot be demonstrated at less than 0.01 wt%, and when the content of the pigment exceeds 2.50 wt%, weather resistance of the high-strength polyethylene fiber is favorable but strength and initial modulus of elasticity are reduced.” Ex. 1007, 2, [0008].

401. Nanri similarly teaches that it is essential that the colorant contained in the fiber is composed of a “pigment”, identifying an inorganic pigment as one such example. Ex. 1007, 2, [0005].

402. Such disclosures are consistent with Claim 3’s recitation of “wherein the amount of the inorganic pigment present in the filaments is lower than 2.0 wt. %.” Moreover, I understand from counsel that if a range taught by a prior art reference overlaps a range claimed in the ’532 Patent, then the range taught by the prior art reference would render the claimed range obvious.

403. Accordingly, it is my opinion that the combination of Section 73.1015, Nanri, Ohta, and Kavesh discloses each and every element of, and renders obvious, Claim 3.

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

404. Section 73.1015 discloses the limitation of Claim 4 for the reasons discussed above with respect to Ground 1. That is, Section 73.1015 discloses the color additive “chromium-cobalt-aluminum oxide”, which “is a blue-green pigment obtained by calcining a mixture of chromium oxide, cobalt carbonate, and aluminum oxide.” Ex. 1006, page 18, (a). Section 73.1015 further provides that “[c]hromium-cobalt-aluminum oxide shall conform to the following specifications: Chromium, calculated as Cr_2O_3 , 34-37 percent. Cobalt, calculated as CoO , 29-34 percent. Aluminum, calculated as Al_2O_3 , 29-35 percent. Lead (as Pb), not more than 30 parts per million. Arsenic (as As), not more than 3 parts per million. Total oxides of aluminum, chromium, and cobalt not less than 97 percent.” Ex. 1006, page 18, (b).

405. A person of ordinary skill in the art would have understood that “chromium-cobalt-aluminum oxide” is the same as “aluminum-chromium-cobalt oxide”. Even if it were to be argued that chromium-cobalt-aluminum oxide is not the same as aluminum-chromium-cobalt oxide, which would be incorrect, aluminum-chromium-cobalt oxide would nonetheless be obvious. Accordingly, such disclosure is consistent with Claim 4’s recitation of “wherein the inorganic pigment is aluminum-chromium-cobalt oxide.”

406. As discussed with respect to limitation [1.C], Nanri also teaches that it is essential that the colorant contained in the fiber is composed of a “pigment”, identifying an inorganic pigment as one such example. Ex. 1007, 2, [0005] (“With respect to a high-strength polyethylene fiber colored while maintaining a sufficiently high strength, it is essential that the colorant contained in the fiber is composed of a pigment such as an organic pigment, inorganic pigment, and carbon black.”). Nanri explains a pigment is essential “because the pigment particles in the fiber are incorporated into the polyethylene crystal, and therefore migration to outside the fiber is suppressed, therefore it is thought that the pigment particles will be held stably.” Ex. 1007, 2, [0005].

407. Accordingly, it is my opinion that the combination of Section 73.1015, Nanri, Ohta, and Kavesh discloses each and every element of, and renders obvious, Claim 4.

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

408. As discussed above with respect to limitation [1.D], Ohta describes the preparation of Examples 1-4 and Comparative Examples 1-5, each of which have remaining residual components other than polyethylene of 60 ppm or less, as measured “as a result of analyzing the extract from the drawn yarn by a method

such as gas chromatography”, including solvent residual fraction, as set forth in

Table 2 of Ohta:

Table 2

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

Ex. 1008, 4-5. Moreover, I understand from counsel that a specific example or disclosure in the prior art which is within a claimed range, such as Ohta’s disclosure of residual fractions other than polyethylene, including solvent residual fraction, of 35 ppm, 37 ppm, 45 ppm, 55 ppm, and 60 ppm, anticipates the claimed range.

409. Accordingly, it is my opinion that the combination of Section 73.1015, Nanri, Ohta, and Kavesh discloses each and every element of, and renders obvious, Claim 5.

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

410. As discussed above with respect to limitation [1.D], Ohta describes the preparation of Examples 1-4 and Comparative Examples 1-5, each of which have remaining residual components other than polyethylene of 60 ppm or less, as measured “as a result of analyzing the extract from the drawn yarn by a method such as gas chromatography”, including solvent residual fraction, as set forth in Table 2 of Ohta:

Table 2

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

Ex. 1008, 4-5. Moreover, I understand from counsel that a specific example or disclosure in the prior art which is within a claimed range, such as Ohta’s disclosure of residual fractions other than polyethylene, including solvent residual

fraction, of 35 ppm, 37 ppm, 45 ppm, 55 ppm, and 60 ppm, anticipates the claimed range.

411. Accordingly, it is my opinion that the combination of Section 73.1015, Nanri, Ohta, and Kavesh discloses each and every element of, and renders obvious, Claim 6.

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

412. As discussed above with respect to limitation [1.D], Ohta describes the preparation of Examples 1-4 and Comparative Examples 1-5, each of which have remaining residual components other than polyethylene of 60 ppm or less, as measured “as a result of analyzing the extract from the drawn yarn by a method such as gas chromatography”, including solvent residual fraction, as set forth in Table 2 of Ohta:

Table 2

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

Ex. 1008, 4-5. Moreover, I understand from counsel that a specific example or disclosure in the prior art which is within a claimed range, such as Ohta's disclosure of residual fractions other than polyethylene, including solvent residual fraction, of 35 ppm, 37 ppm, 45 ppm, and 55 ppm, anticipates the claimed range.

413. Accordingly, it is my opinion that the combination of Section 73.1015, Nanri, Ohta, and Kavesh discloses each and every element of, and renders obvious, Claim 7.

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

414. As discussed above with respect to limitation [1.E], Ohta describes the preparation of Examples 1-4 and Comparative Examples 1-5, each of which have

remaining residual components other than polyethylene of 60 ppm or less, as measured “as a result of analyzing the extract from the drawn yarn by a method such as gas chromatography”, including solvent residual fraction, as set forth in Table 2 of Ohta:

Table 2

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

Ex. 1008, 4-5. Moreover, I understand from counsel that a specific example or disclosure in the prior art which is within a claimed range, such as Ohta’s disclosure of residual fractions other than polyethylene, including solvent residual fraction, of 35 ppm, 37 ppm, 45 ppm, 55 ppm, and 60 ppm, anticipates the claimed range.

415. Nanri similarly confirms the lack of further constituents for the same reasons listed above with respect to limitation [1.E]. That is, Nanri discloses the preparation of multiple colored high-strength polyethylene fiber examples. *See*

e.g., Ex. 1007, page 3, paras. [0015]-[0017]. In each example, the colored high-strength polyethylene fiber was prepared from a solution of UHMWPE and finely pulverized carbon black pigment in decahydronaphthalene (i.e., decalin). *Id.* The examples of Nanri do not describe any other components or material being added during preparation of the colored high-strength polyethylene fiber examples such that a person of ordinary skill in the art would not expect the resulting colored high-strength polyethylene fiber to have “further constituents”.

416. Accordingly, it is my opinion that the combination of Section 73.1015, Nanri, Ohta, and Kavesh discloses each and every element of, and renders obvious, Claim 8.

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

417. As discussed above with respect to limitation [1.Pre], Section 73.1015 expressly discloses “[t]he **filaments** are cooled, oriented by drawing, and set by annealing.” Ex. 1006, page 18, (c)(1) (emphasis added).

418. Nanri and Ohta each disclose extruding the UHMWPE mixture “from an orifice of 0.5 mm diameter” and “from an orifice having a diameter of 0.5”, respectively. *See* Ex. 1007, 3, [0015]; Ex. 1008, 4.

419. Kavesh explicitly discloses a spinneret having a plurality of apertures, with convenient numbers of apertures being 16, 120, or 240. Ex. 1009, page 8.

420. Kavesh further discloses preparing multi-filament yarns using such spinnerets, including as-spun multi-filament yarns and multi-filament yarns prepared by combining the products of multiple spinnerets. *See, e.g.*, Ex. 1009, page 27 (describing preparation of nine rolls of 16-filament yarns using spinning dies having 16 apertures), page 28 (“In the first stage three of the rolls of 16 filament gel yarns described in Example 502 above were combined and stretched together to prepare a 48 filament stretched gel yarn.”), page 31 (setting forth yarn properties of various multi-filament yarns in a table, including several yarns prepared by combining multiple 16-filament yarns resulting in 48-filament and 64-filament multi-filament yarns).

421. Accordingly, it is my opinion that the combination of Section 73.1015, Nanri, Ohta, and Kavesh discloses each and every element of, and renders obvious, Claim 9.

XIII. GROUND 3: THE COMBINATION OF SECTION 73.1015, NANRI, AND SIMMELINK RENDERS OBVIOUS CLAIMS 1-9

422. It is my opinion that the combination of Section 73.1015, Nanri, and Simmelink teaches, suggests, or discloses all of the recitations of Claims 1-9 of the ’532 Patent and renders the subject matter of each claim as a whole obvious and unpatentable.

A. Rationale for Combining Section 73.1015, Nanri, and Simmelink

423. Each of Section 73.1015, Nanri, and Simmelink was within the knowledge of a person of ordinary skill in the art and is directly relevant to colored multi-filament yarn that is usable as a suture.

424. A person of ordinary skill in the art at the time of the assumed priority date of the '532 Patent was well aware of the design need for colored sutures, especially colored sutures having high strength. Even the Patent Owner admitted in the specification of the '532 Patent such design need for colored sutures with high strength was known. *See* Ex. 1001, 1:11-17 (“The coloring of sutures is for example used to make the suture better contrast with the blood or tissue in the operating area. In complicated surgical operations, for example in arthroscopic surgery, when different suture ends are used in a small area, sutures of different color are used to assist surgeons in differing between the suture ends.”); 1:22-27 (the Patent Owner further admitted that “[n]ext to coloring”, it was already known in the art that “suture strength [was] an important consideration in selecting filaments for producing a suture” and, as recognized in the prior art, “filaments of ultra-high molecular weight polyethylene (UHMwPE) produced according to the gel spinning process”, were known as very strong filaments that were already available for the production of sutures.). Thus, as reflected by the Patent Owner’s admissions and consistent with the state of the art, there was a stated and well-

known design need for colored sutures formed from high-strength polyethylene fibers.¹⁹ *See* Ex. 1001, 1:11-27.

425. A person of ordinary skill would further understand that sutures are implantable devices and thus are subject to specific requirements, including containing only colorants approved for use in sutures by the United States Food and Drug Administration (FDA). Specific colorants for use in sutures are listed in the Code of Federal Regulations (CFR) depending on the particular suture material and whether or not the color additive is exempt from batch certification requirements. Thus, to facilitate regulatory approval, a person of ordinary skill in the art would have started with Section 73.1015 and its disclosure of chromium-cobalt-aluminum oxide pigment as a color additive in coloring linear polyethylene surgical sutures.

426. As of the priority date of the '532 Patent, Section 73.1015 identified chromium-cobalt-aluminum oxide as a pigment that was approved for linear polyethylene surgical sutures and exempt from batch certification requirements.

¹⁹ As I discuss above with respect to the Technical Background/State of the Art at Section V.A., it was well known by the earliest alleged priority date of the '532 Patent that UHMWPE filaments were usable as sutures and that UHMWPE filaments had been colored using pigments.

See generally, Ex. 1006. The person of ordinary skill in the art would understand that using a color additive exempted from batch certification would save not only time but expense as compared to petitioning for use of a new, not already authorized or exempted, color additive or otherwise requiring certification of each batch. Specifically, Section 73.1015 discloses, *inter alia*:

(a) *Identity*. The color additive chromium-cobalt-aluminum oxide is a blue-green pigment obtained by calcining a mixture of chromium oxide, cobalt carbonate, and aluminum oxide. It may contain small amounts (less than 1 percent each) of oxides of barium, boron, silicon, and nickel.

(b) *Specifications*. Chromium-cobalt-aluminum oxide shall conform to the following specifications:

Chromium, calculated as Cr_2O_3 , 34-37 percent.

Cobalt, calculated as CoO , 29-34 percent.

Aluminum, calculated as Al_2O_3 , 29-35 percent.

Lead (as Pb), not more than 30 parts per million.

Arsenic (as As), not more than 3 parts per million.

Total oxides of aluminum, chromium, and cobalt not less than 97 percent.

Lead and arsenic shall be determined in the solution obtained by boiling 10 grams of the chromium-cobalt-aluminum oxide for 15 minutes in 50 milliliters of 0.5 *N* hydrochloric acid.

(c) *Uses and restrictions.* The color additive chromium-cobalt-aluminum oxide may be safely used for coloring linear polyethylene surgical sutures, United States Pharmacopeia (U.S.P.), for use in general surgery, subject to the following restrictions:

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

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

(3) The dyed suture shall conform in all respects to the requirements of the U.S.P. XX (1980).

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

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

(d) *Labeling.* The label of the color additive shall conform to the requirements of §70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and batches thereof are exempt from the certification requirements of section 721(c) of the act.

Ex. 1006, page 18.

427. A person of ordinary skill in the art developing a colored suture would have been motivated to choose such chromium-cobalt-aluminum oxide as a pigment in coloring high strength polyethylene fibers to produce such a colored suture and would use such pigment in an amount that does not exceed 2 percent by weight of the suture material in order to facilitate regulatory approval, since such use was exempt from certification and already approved for colored linear polyethylene surgical sutures.

428. In view of the disclosure of colored linear polyethylene surgical sutures in Section 73.1015 and understanding the well-known importance of “suture strength” in “selecting filaments for producing a suture”,²⁰ the person of

²⁰ As admitted by the '532 Patent, the person of ordinary skill in the art was well aware of the design need for colored sutures having high strength. *See* Ex. 1001, 1:22-27 (the Patent Owner further admitted that “[n]ext to coloring”, it was already known in the art that “suture strength [was] an important consideration in selecting

ordinary skill in the art would have understood the need for selecting high strength polyethylene filaments for use in the colored linear polyethylene surgical suture. *See* Ex. 1001, 1:22-27; Ex. 1006, page 18.²¹ As a result, the person of ordinary skill in the art would have turned to Nanri to implement a colored linear polyethylene surgical suture that had high strength, high modulus, and that was colored so as make the suture better contrast with the blood or tissue in the operating area.²²

filaments for producing a suture” and, as recognized in the prior art, UHMwPE filaments, “produced according to the gel spinning process”, were known as very strong filaments that were already available for the production of sutures.).

²¹ As I discuss above with respect to the Technical Background/State of the Art at Section V.A., it was well known by the earliest alleged priority date of the ’532 Patent that UHMWPE filaments were usable as sutures and that UHMWPE filaments had been colored using pigments.

²² As admitted by the ’532 Patent, the person of ordinary skill in the art was well aware of the design need for colored sutures. *See* Ex. 1001, 1:11-17 (“The coloring of sutures is for example used to make the suture better contrast with the blood or tissue in the operating area. In complicated surgical operations, for example in

429. Nanri teaches a colored high-strength polyethylene fiber prepared from gel spinning UHMWPE that, *inter alia*, maintains high strength and high modulus. Ex. 1007, Page 1. Specifically, Nanri teaches incorporating pigments in a gel spinning process so as to “not act as defects in the crystal formation process and the like for expressing high strength”, the pigment particles being stably held by incorporating pigment particles into the polyethylene crystal such that “migration to [the] outside of the fiber is suppressed.” Ex. 1007, Page 2, [0005].

Nanri further elaborates:

[0006] In colored high-strength polyethylene fiber, the average particle diameter of the pigment, which is a particle aggregate dispersed in the cross-section of the fiber, is preferably in the range of 10 nm to 100 nm. This is because the particles of the pigment are of a diameter that does not act as a defect during orientated crystallization that occurs during the fiber formation process of the polyethylene and is thus incorporated into the crystal. That is, 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. On the other hand, migration occurs when the average particle diameter is less than 10 nm, which is not preferable.

arthroscopic surgery, when different suture ends are used in a small area, sutures of different color are used to assist surgeons in differing between the suture ends.”).

[0007] The particle aggregate is preferably constituted of 10 or fewer particles. When more than 10 are used, the colored high-strength polyethylene fiber is hindered from expressing strength and stretchability and as a result, the colored high-strength polyethylene fiber has a low strength and stretchability. Between 1 and 8 particles are preferred.

[0008] In the high-strength polyethylene fiber colored while maintaining sufficiently high strength, the content of the pigment—which is a colorant contained in the fiber—is 0.01 to 2.50 wt%, preferably 0.10 to 2.00 wt%, a coloring effect cannot be demonstrated at less than 0.01 wt%, and when the content of the pigment exceeds 2.50 wt%, weather resistance of the high-strength polyethylene fiber is favorable but strength and initial modulus of elasticity are reduced.

Ex. 1007, Page 2, Paras. [0006]-[0008].

430. Indeed, Nanri discloses the following examples:

[0015] [Examples] (Example 1) **A mixture of 10 wt% of ultra-high molecular weight polyethylene having a viscosity average molecular weight of 3,200,000 and 90 wt% of decahydronaphthalene was kneaded and dissolved using a screw extruder set to a temperature of 180°C to 220°C, extruded from an orifice of a 0.5 mm diameter and drawn at a drawing speed of 75**

m/min., and then stretched four-fold in an oven under heated air (100°C). In this case, carbon black obtained by subjecting carbon black REGAL 330R (average diameter of agglomerates: 1.41 mm, Max 9.29 mm, Min 0.22 mm) manufactured by Cabot to fine pulverization processing was added as a colorant to the mixture of polyethylene and decahydronaphthalene at 0.05 wt% relative to decahydronaphthalene. By further stretching the obtained intermediate stretched product to 4.3 fold, a colored high-strength polyethylene fiber having a strength of 3.62 GPa and an initial modulus of elasticity of 129 GPa was obtained. Furthermore, the particle diameter of the carbon black dispersed in the fiber cross-section was in the range of 10 nm to 50 nm, and the number of aggregated particles was 1 to 6. Furthermore, the evaluation results for the weather resistance of this fiber were excellent at grade 4 to 5, and the strength retention rate was 90%.

[0016] (Example 2) A high-strength polyethylene fiber was produced by the same method as in example 1, except that carbon black subjected to fine pulverization processing was added at 0.20 wt% relative to decahydronaphthalene. The obtained colored high-strength polyethylene fiber had a strength of 2.5 GPa and an initial

modulus of elasticity of 90 GPa, and the evaluation results for the weather resistance of the fiber were grade 4 to 5.

[0017] (Example 3) A **high-strength polyethylene fiber was produced by the same method as in example 1, except that carbon black subjected to fine pulverization processing was added at 0.25 wt% relative to decahydronaphthalene.** The obtained colored high-strength polyethylene fiber had a strength of 1.9 GPa and an initial modulus of elasticity of 67 GPa. The evaluation results of the weather resistance were grade 4 to 5.

Ex. 1007, page 3, paras. [0015]-[0017]. (Emphases added).

431. A person of ordinary skill in the art would understand Nanri as disclosing the addition of the finely pulverized pigment to the gel spinning mixture, so that the pigment particles do not migrate or “act as a defect during orientated crystallization that occurs during the fiber formation process of the polyethylene and [are] thus incorporated into the crystal”. *See* Ex. 1007, page 2, para. [0006] and page 3, para. [0015] (“A **mixture** of 10 wt% of ultra-high molecular weight polyethylene having a viscosity average molecular weight of 3,200,000 and 90 wt% of decahydronaphthalene” and pigment subjected to “fine pulverization processing was **added as a colorant to the mixture** of polyethylene

and decahydronaphthalene at 0.05 wt% relative to decahydronaphthalene.”)
(Emphases added).

432. In light of these disclosures in Nanri, a person of ordinary skill in the art would have been motivated to improve the properties and benefits of the colored linear polyethylene surgical sutures of Section 73.1015 that was already exempted from certification by the FDA by including the teachings of the colored high strength polyethylene fiber and pigmentation process of Nanri to increase the strength of the resultant colored linear polyethylene surgical sutures while continuing to suppress migration of the colorant to the outside of the fiber and otherwise facilitate regulatory approval (i.e., maintain exemption of the resultant colored linear polyethylene surgical sutures from certification). Indeed, the person of ordinary skill in the art would have understood that the chromium-cobalt-aluminum oxide of Section 73.1015 would have been readily used in the process of Nanri to achieve both the exemption from certification benefits of the chromium-cobalt-aluminum oxide²³ as well as the above properties and benefits of the fiber resulting from the Nanri gel-spinning process.

²³ Indeed, DSM admitted this exact need – to facilitate regulatory approval – was the reason why its blue fibers were produced with Chromium-Cobalt-Aluminum Oxide. *See* H. Smelt, et al. “Advances in Medical-Grade UHMWPE

433. Being aware of the polymer properties of UHMWPE and known issues with leaching when attempting to use dyes and other colorants with UHMWPE (as admitted by the Patentee in the '532 Patent), as well as the limited colors exempted from batch certification for linear polyethylene suture materials, a person of ordinary skill in the art would be motivated to combine the chromium-cobalt-aluminum oxide pigment of Section 73.1015 into the gel spinning slurry

Fiber Development: Additives for Visualization” (7th UHMWPE International Meeting Proceedings, 2015) (Ex. 1010 at page 55-56) (“UHMWPE fiber’s chemical inertness and high crystallinity makes it a difficult material to dye. The very low percentage of amorphous or semicrystalline phase and the apolar nature of the aliphatic C₂H₂ backbone of the UHMWPE polymer does not provide sufficient compatibility with most available color dyes. In this respect, the addition of the color as a pigment during the gel-spinning process would be a better alternative, as the pigment would be well dispersed in the solution of solvent and disentangled UHMWPE, facilitating a homogeneous physical incorporation. **To facilitate regulatory approval, blue fibers with Chromium-Cobalt-Aluminum Oxide were produced, as this pigment is listed on the FDA’s 21 CFR part 73 on Color Additives Exempt from Certification for coloring linear polyethylene surgical sutures for use in general surgery.**”) (Emphasis added).

mixture as taught by Nanri such that “migration to outside the fiber is suppressed” and “there is no migration of the color additive to the surrounding tissue.” Ex. 1007, page 2, [0005]; Ex. 1006, page 18, (c)(4).

434. As noted above, Section 73.1015 discloses that in its coloring procedure, the pigment is blended with the polyethylene resin and is then heated to a temperature of 500°-550°F (Ex. 1006, page 18, (c)(1)), which is not inconsistent with the gel spinning process. To the extent that this process may be interpreted as being consistent with a melt process, the person of skill in the art would have understood that the addition of a pigment with polyethylene in a gel spinning process, such as Nanri, would have likewise been successful.²⁴ That is, the person of ordinary skill in the art would have understood that the gel spinning process and melt process were similar, especially with regard to the addition of an inert pigment, such as the pigment of Section 73.1015. Other than the addition of an inert solvent, which would not affect the inert pigment, the polyethylene polymer

²⁴ As described above in the Technical Background/State of the Art at Section V.A., the person of skill in the art understood that the pigment “infiltrates into the interior of the polyethylene and, as a result, the physical bonding between the polyethylene and the pigment and/or the dye becomes strong, causing substantially no color fading.” Ex. 1028, 10:35-41.

used in a gel spinning process is similar to that in a melt process (e.g., linear polyethylene). Moreover, any differences in temperature of the gel spinning and melt processes would not impact the pigment. Finally, the person of ordinary skill in the art would have also expected that the pigment would have worked with the crystalline structure of the fiber. *See e.g.*, Ex. 1007, Page 2, [0005].

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

436. In view of the end use application as a colored suture in the human body that is disclosed in Section 73.1015, the person of ordinary skill in the art would have also understood the need for additional production considerations of the colored UHMWPE fiber produced by the combination of Section 73.1015 and Nanri so as to optimize the end product for medical use. That is, as disclosed in Simmelink, in addition to its mechanical properties, “the amount of other components or foreign materials in the yarn is very important” for medical applications, such as the production of sutures. Ex. 1005, 12:6-7. Specifically, Simmelink describes a HPPE multifilament yarn “containing less than 150 ppm of residual solvent, specifically of solvent having a boiling point at atmospheric conditions of less than 275°C, preferably containing less than 100, 75, or even less than 50 ppm of solvent, and to medical implants containing such yarn.” Ex. 1005,

12:9-12. Simmelink further teaches that “[s]olvent removal can be performed by known methods, for example, by evaporating a relatively volatile solvent, by using an extraction liquid, or by a combination of both methods.” Ex.1005, 9:31-33. By incorporating Simmelink’s disclosure of minimal residual solvent, the person of ordinary skill in the art would have understood that the resultant fiber would be more biocompatible. *See, e.g.*, Ex. 1030, page 266 (The Applicant admitting that it was known that “the level of residual spin solvent, especially decalin, in gel-spun UHMwPE should be low, and preferably below 100 ppm for biocompatibility reasons.”).

437. Simmelink further teaches that “[y]arn of relatively low titer, containing for example from 5 to 300 filaments, but of extremely high strength is a.o. very suited for making high-strength surgical sutures and cables, or other medical implants.” Ex. 1005, 12:3-6. Indeed, the person of ordinary skill in the art would have understood that multi-filament yarns are common and are indeed preferred for UHMWPE sutures as described above in the Technical Background/State of the Art above at Section V.B.

438. In light of these disclosures in Simmelink, a person of ordinary skill in the art would have been motivated to improve the fiber production process of the colored linear polyethylene surgical sutures of Section 73.1015 and Nanri by including the teachings of minimizing the amount of other components or foreign

materials in the yarn²⁵ and the filament count and relatively low titer (i.e., a yarn with multiple fine filaments) teachings for multi-filament surgical sutures as taught by Simmelink to improve the resultant colored linear polyethylene surgical sutures for use in the human body. That is, the person of ordinary skill in the art would have been motivated to combine the fiber production process considerations with respect to medical applications as disclosed in Simmelink with the colored high strength polyethylene fiber and pigmentation process as disclosed in Nanri and further with the chromium-cobalt-aluminum oxide pigment and pigmentation process identified in Section 73.1015, thereby, obtaining improved colored multi-filament yarns for use in linear polyethylene surgical sutures so as to meet the well-known need for colored sutures, especially colored sutures having high strength that were exempt from further certification by the FDA. Indeed, such a modification specifically improves the combination of Section 73.1015 and Nanri as it relates to sutures because of the increased biocompatibility that results from

²⁵ As admitted by the Applicant during prosecution of the parent to the '532 Patent, it was well known in the art "that the level of residual spin solvent, especially decalin, in gel-spun UHMwPE should be low, and preferably below 100 ppm for biocompatibility reasons." Ex. 1030, page 266.

the minimization of solvent. Accordingly, it would have been within the skill of the person of ordinary skill in the art to combine Simmelink with Section 73.1015 and Nanri.

439. It is also my opinion that the person of ordinary skill in the art would have a reasonable expectation of success in combining Section 73.1015 with Nanri and Simmelink to achieve the predictable result of improved colored multi-filament yarns. Each of Section 73.1015, Nanri, and Simmelink disclose use of linear polyethylene. *See e.g.*, Ex. 1005, 8:12-17; Ex. 1006, 18, (c); Ex. 1007, 3, [0013], [0015]-[0017]. Section 73.1015 and Nanri each expressly discloses the addition of a pigment, and Simmelink expressly discloses a colorant, in consistent amounts. Ex. 1005, 8:28-31; Ex. 1006, 18, (a), (c)(2); Ex. 1007, 2, [0008], Claim 3; Moreover, at least Nanri and Simmelink disclose the same or similar gel-spinning processes, UHMWPE, intrinsic viscosity values, and same or similar spin solvents, to prepare their respective UHMWPE fibers. Additionally, Nanri and Simmelink are both directed to retaining or improving mechanical properties of the resulting UHMWPE fibers. Moreover, the person of ordinary skill in the art would have had a reasonable expectation of success in the incorporation of Simmelink as Simmelink reduces the amount of solvent and other additives, which Simmelink itself confirms is well within the skill of the POSITA. *See generally*, Ex. 1005.

440. In addition, as described by Simmelink itself and as was well known, colorants would have been added to UHMWPE fibers in the amounts of less than 5 mass%, preferably less than 3 mass% (Ex. 1005, Page 8, lines 28-31), which is consistent with the express disclosures of Section 73.1015, which discloses the addition of a pigment in an amount that does not exceed 2 percent by weight of the suture material (Ex. 1006, page 18, (c)(2)), and Nanri, which discloses the addition of a pigment to a UHMWPE fiber in a pigment content of 0.01 to 2.50 wt%, preferably 0.1 to 2.00 wt% (Ex. 1007, Page 2, Claim 3). In addition, Nanri is clear that a pigment, such as the one disclosed in Section 73.1015, would be incorporated in UHMWPE fibers prepared by a gel spinning process. For example, Nanri discloses that the color agent includes pigments “such as an organic pigment, inorganic pigment, and carbon black”. Ex. 1007, Page 2, [0005]. Moreover, 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.” Ex. 1007, Page 2, [0006]. As such, the person of ordinary skill 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.²⁶

441. In light of these teachings, a person of ordinary skill in the art would have expected the addition of the pigment particles of the color additive disclosed in Section 73.1015 and sized according to the gel-spinning disclosure of Nanri with the medication application considerations for the fiber production process of Simmelink to be effective.

442. Moreover, Nanri explicitly teaches that “the pigment particles in the fiber are incorporated into the polyethylene crystal, and therefore migration to outside the fiber is suppressed” and Section 73.1015 teaches that “there is no migration of the color additive to the surrounding tissue.” Ex. 1006, page 18, (c)(4); Ex. 1007, 2, [0005]. In light of these teachings, a person of ordinary skill in the art would have expected the combination of Section 73.1015, Nanri, and Simmelink to be effective.

443. Accordingly, a person of ordinary skill in the art would have been motivated to combine and would have had a reasonable expectation of success in combining Section 73.1015, Nanri, and Simmelink.

²⁶ The '532 Patent is silent with regard to any requirements as to the sizing of pigment particles.

B. Analysis

i. Claim 1: [1.Pre] A colored multi-filament yarn comprising

444. Claim 1 of the '532 Patent is directed to a product that is developed by way of a process, such as the process described with regard to limitation [1.A]. As such, I understand that the determination of patentability is based on the product (e.g., the yarn) itself and the “physical constituent of the fiber” that “is a quantifiable and hence physical attribute of the fiber.” Ex. 1030, page 258 (emphases in original). Regardless, as is described in at least limitation [1.A], the cited art of Ground 3 renders obvious a gel spinning process.

445. Moreover, and to the extent the preamble is limiting, it is disclosed by the combination of Section 73.1015, Nanri, and Simmelink, as is described throughout Ground 3. *See* [1.A-1.E].

446. Section 73.1015 discloses limitation [1.Pre] for the same reasons listed above with respect to limitation [1.Pre] in Grounds 1 and 2. That is, Section 73.1015 expressly discloses “the color additive [chromium-cobalt-aluminum oxide] is blended with the polyethylene resin”, “[t]he mixture is heated to a temperature of 500°–550 °F. and extruded through a fixed orifice”, and “[t]he **filaments** are cooled, oriented by drawing, and set by annealing.” Ex. 1006, page 18, (c)(1) (emphasis added).

447. For the same reasons listed above with respect to limitation [1.Pre] in Ground 2, Nanri discloses Examples 1-3, which detail the preparation of colored high strength polyethylene fiber via a gel spinning method and extruding the UHMWPE/pigment/solvent mixture “from an orifice of a 0.5 mm diameter”. Ex. 1007, 3.

448. Likewise, and for the reasons listed above with respect to limitation [1.Pre] in Ground 1, Simmelink generally describes a variety of parameters and a series of process steps for preparing a multifilament yarn. *See e.g.*, Ex. 1005, Abstract. More specifically, Simmelink is dedicated to the disclosure of an alleged inventive continuous process for preparing high performance polyethylene (HPPE) multifilament yarn. Ex. 1005, 1:7-8. Simmelink further discloses a high-performance polyethylene multifilament yarn obtainable by such process, and semi-finished or end-use products or articles, including “medical implants like suture and cables”, containing such HPPE multifilament yarn. Ex. 1005, 1:18-20, 10:34-11:30, 12:24-30.

449. Simmelink further teaches that “[t]he UHPE that is applied in the process according to the invention may further contain small amounts, **generally less than 5 mass%, preferably less than 3 mass% of customary additives**, such as anti-oxidants, thermal stabilizers, **colorants**, flow promoters, etc.” Ex. 1005, 8:28-31 (emphasis added).

450. Accordingly, it is my opinion that the combination of Section 73.1015, Nanri, and Simmelink discloses each and every element of, and renders obvious, the recitation of limitation [1.Pre].

ii. Claim 1: [1.A] filaments that have been obtained by gel spinning a mixture containing ultra-high molecular weight polyethylene (UHMwPE) having an intrinsic viscosity (IV) of between about 8 and 40 dl/g, a spin solvent and a pigment, and

451. As I noted above with regard to limitation [1.Pre], it is my understanding that Claim 1 is directed to a product that is developed by way of a process, such as the process described with regard to limitation [1.A]. Moreover, in my review of the '532 Patent, I do not see a particular process outlined for gel spinning. Even though I understand that no patentable weight should be given to limitation [1.A], the combination discloses it, nonetheless.²⁷

452. Nanri discloses limitation [1.A] for the same reasons listed above with respect to limitation [1.A] in Ground 2. That is, Nanri identifies “a method for stretching gel filaments obtained by solution spinning an ultra-high molecular

²⁷ As is described above and is admitted in the '532 Patent, the gel spinning process for preparing UHMWPE filaments was well known in the prior art and was indeed conventional by the assumed priority date of the '532 Patent. Ex. 1001, 2:24-31.

weight polyethylene solution” in order to manufacture the high-strength polyethylene fiber. Ex. 1007, 3, [0013], citing JP S55-107506 A and JP S56-154508 A.

453. Nanri sets forth three examples, including Example 1 which describes “[a] mixture of 10 wt% of ultra-high molecular weight polyethylene having a viscosity average molecular weight of 3,200,000 and 90 wt% of decahydronaphthalene [also known as decalin] was kneaded and dissolved using a screw extruder set to a temperature of 180°C to 220°C, extruded from an orifice of a 0.5 mm diameter and drawn at a drawing speed of 75 m/min., and then stretched four-fold in an oven under heated air (100°C). In this case, carbon black obtained by subjecting carbon black REGAL 330R (average diameter of agglomerates: 1.41 mm, Max 9.29 mm, Min 0.22 mm) manufactured by Cabot to fine pulverization processing was added as a colorant to the mixture of polyethylene and decahydronaphthalene at 0.05 wt% relative to decahydronaphthalene. By further stretching the obtained intermediate stretched product to 4.3 fold, a colored high-strength polyethylene fiber having a strength of 3.62 GPa and an initial modulus of elasticity of 129 GPa was obtained. Furthermore, the particle diameter of the carbon black dispersed in the fiber cross-section was in the range of 10 nm to 50 nm, and the number of aggregated particles was 1 to 6. Furthermore, the evaluation results for the weather resistance of this fiber were excellent at grade 4 to 5, and

the strength retention rate was 90%.” Ex. 1007, 3. Examples 2 and 3 of Nanri similarly disclose adding 0.20 wt% and 0.25 wt%, respectively, of carbon black pigment subjected to fine pulverization processing and relative to decahydronaphthalene. The obtained colored high-strength polyethylene fiber had strengths of 2.5 GPa and 1.9 GPa, respectively, and initial modulus of elasticity of 90 GPa and 67 GPa, respectively. Ex. 1007, 3, paras. [0015]-[0017].

454. As discussed above in the Technical Background/State of the Art section of this declaration at Section V.C., and as confirmed by the ’532 Patent (Ex. 1001, 2:53-60), Nominal Viscosity Molecular Weight = $5.37 \times 10^4 [\eta]^{1.37}$, where $[\eta]$ is the intrinsic viscosity. Accordingly, Nanri’s disclosure of a viscosity average molecular weight of 3,200,000 corresponds to an intrinsic viscosity value of 19.79 dl/g.

455. Such disclosure is consistent with the recitation of limitation [1.A] of “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”. Moreover, I understand from counsel that a specific example or disclosure in the prior art which is within a claimed range, such as Nanri’s disclosure of an intrinsic viscosity value of 19.79 dl/g, anticipates the claimed range.

456. With respect to spin solvent, Nanri discloses decahydronaphthalene in its Examples, which is also known as decalin. Ex. 1007, 3, paras. [0015]-[0017]. Such disclosure is consistent with the recitation of limitation [1.A] of “filaments that have been obtained by gel spinning a mixture containing...a spin solvent”.

457. Nanri further discloses a pigment providing that “it is essential that the colorant contained in the fiber is composed of a pigment such as an organic pigment, inorganic pigment, and carbon black” to obtain high-strength polyethylene fibers that are colored while maintaining a sufficiently high strength. Ex. 1007, 2, para. [0005]. “This is because the pigment particles in the fiber are incorporated into the polyethylene crystal, and therefore migration to outside the fiber is suppressed, therefore it is thought that the pigment particles will be held stably.” Ex. 1007, 2, para. [0006]. Nanri discloses carbon black in its Examples. Ex. 1007, 3, paras. [0015]-[0017].

458. A person of ordinary skill in the art would further understand that Nanri discloses the addition of the finely pulverized pigment to the gel spinning mixture. *See* Ex. 1007, page 2, para. [0006] (“the particles of the pigment are of a diameter that does not act as a defect during orientated crystallization that occurs during the fiber formation process of the polyethylene and [are] thus incorporated into the crystal”), and page 3, para. [0015] (“A **mixture** of 10 wt% of ultra-high molecular weight polyethylene having a viscosity average molecular weight of

3,200,000 and 90 wt% of decahydronaphthalene” and pigment subjected to “fine pulverization processing was **added as a colorant to the mixture** of polyethylene and decahydronaphthalene at 0.05 wt% relative to decahydronaphthalene.”) (Emphases added). Such disclosure is consistent with the recitation of limitation [1.A] of “filaments that have been obtained by gel spinning a mixture containing...a pigment”.

459. Accordingly, Nanri discloses a fiber that has “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”.

460. Further underscoring the combination, Simmelink discloses a similar process to that of Nanri. Indeed, similar to Nanri, Simmelink likewise discloses limitation [1.A] for the same reasons listed above with respect to limitation [1.A] in Ground 1. That is, Simmelink discloses an alleged inventive continuous process for preparing high performance polyethylene (HPPE) multifilament yarn, a high-performance polyethylene multifilament yarn obtainable by such process, and semi-finished or end-use products or articles containing such HPPE multifilament yarn(s). Ex. 1005,1:18-20, 10:34-11:30, 12:24-30. The person of ordinary skill would understand that the term ‘UHMWPE fiber’ or ‘drawn UHMWPE’ is often used interchangeably with high performance polyethylene (HPPE) fibers. *See e.g.,*

International Publication No. WO 01/59397 to Steeghs et al. (Ex. 1014), Page 4, lines 11-15 (referring to “drawn ultra-high molecular weight polyethylene” as “HPPE”).²⁸

461. The process steps disclosed by Simmelink include “a) making a 3-25 mass% **solution of ultra-high molar mass polyethylene having an intrinsic viscosity as measured on solutions in decalin at 135°C of between about 8 and 40 dl/g, in a solvent**; b) **spinning of the solution through a spinplate containing at least 5 spinholes into an air-gap to form fluid filaments**, while applying a draw ratio DR_{fluid} ; c) **cooling the fluid filaments to form solvent-containing gel filaments**; d) removing at least partly the solvent from the filaments; and e) drawing the filaments in at least one step before, during and/or after said solvent removing, while applying a draw ratio DR_{solid} of at least 4.” Ex. 1005, 1:7-17 (emphasis added). A person of ordinary skill in the art would understand this disclosure to be a gel spinning process such that the filaments produced by such process are “filaments that have been obtained by gel spinning a mixture

²⁸ To be clear, this ground is obviousness in view of Section 73.1015, Nanri, and Simmelink. Steeghs does not form part of the combination/modification. Rather, Steeghs is provided to confirm the knowledge of a person of ordinary skill in the art.

containing ultra-high molecular weight polyethylene (UHMwPE) having an intrinsic viscosity (IV) of between about 8 and 40 dl/g [and] a spin solvent”. To the extent [1.A] is interpreted as requiring multiple filaments, Simmelink discloses it. That is, with regard to limitation [1.A], Simmelink discloses “filaments”. As discussed above with respect to claim limitation [1.A], Simmelink discloses “spinning of the solution through a spinplate containing at least 5 spinholes into an air-gap to form fluid filaments”, cooling the fluid filaments to form solvent-containing gel filaments, removing at least partly the solvent from the filaments, and drawing the filaments. Ex. 1005, 1:7-17. Moreover, Simmelink discloses the number of filaments in the multi-filament yarn is preferably “at least 10, 50, 100, 150, 200, 300, 375 or even at least 450.” Ex. 1005, 5:21-24.

462. Moreover, with respect to intrinsic viscosity, Simmelink further discloses that “[t]he ultra-high molar mass polyethylene applied in the process according to the invention has an intrinsic viscosity (IV, as measured on solution in decalin at 135°C) of between about 8 and 40 dl/g, preferably between 10 and 30, or 12 and 28, more preferably between 15 and 25 dl/g, to provide a balance between processability of the solution to be spun and mechanical properties of the obtained filaments.” Ex. 1005, 7:32-8:2.

463. With respect to spin solvent, Simmelink further discloses that “any of the known solvents suitable for gel spinning of UHPE can be used as solvent for

making the polyethylene solution, for example paraffin wax, paraffin oil or mineral oil, kerosenes, decalin, tetralin, or a mixture thereof.” Ex. 1005, 8:34-9:2.

According to Simmelink, it is especially advantageous to use “relatively volatile solvents, preferably solvents having a boiling point at atmospheric conditions of less than 275°C, more preferably less than 250 or 225°C”, such as “decalin, tetralin, and several kerosene grades.” Ex. 1005, 9:2-5.

464. Simmelink, like Nanri, discloses adding such colorant to its high performance polyethylene fiber. Simmelink teaches “[t]he UHPE that is applied in the process according to the invention may further contain small amounts, **generally less than 5 mass%, preferably less than 3 mass% of customary additives**, such as anti-oxidants, thermal stabilizers, **colorants**, flow promoters, etc.” Ex. 1005, Page 8, lines 28-31 (emphasis added). Such disclosure is consistent with that of Nanri.

465. As discussed with respect to Ground 1, Section 73.1015 specifically discloses the use of a chromium-cobalt-aluminum oxide pigment in polyethylene, including blending such pigment with the polyethylene, heating the mixture, and extruding the mixture. *See generally*, Ex. 1006, page 18.

466. Accordingly, Section 73.1015 likewise discloses “filaments...containing... a pigment”. Accordingly, it is my opinion that the

combination of Section 73.1015, Nanri, and Simmelink renders obvious the recitation of limitation [1.A].

iii. Claim 1: [1.B] wherein the filaments consist of UHMwPE,

467. Nanri discloses limitation [1.B] for the same reasons listed above with respect to limitation [1.B] in Ground 2. That is, Nanri discloses “a method for stretching gel filaments obtained by solution spinning an ultra-high molecular weight polyethylene solution” in order to manufacture the colored high-strength polyethylene fiber, such that the colored high strength polyethylene fiber of Nanri contains UHMwPE. Ex. 1007, 3, [0013], citing JP S55-107506 A and JP S56-154508 A.

468. To the extent [1.B] is interpreted as requiring multiple filaments Simmelink discloses it. Simmelink discloses “filaments consist[ing] of UHMwPE” for the same reasons listed above with respect to limitation [1.B] in Ground 1. That is, Simmelink specifies a variety of parameters and process steps for making high-performance polyethylene multifilament yarn from a gel spinning process. Ex. 1005, Page 1, lines 7-17 (describing making a solution of UHMwPE in a solvent, spinning of the solution “**through a spinplate containing at least 5 spinholes into an air-gap to form fluid filaments**”, cooling the fluid filaments to form solvent-containing gel filaments, removing at least partly the solvent from the filaments, and drawing the filaments) (emphasis added). Simmelink further specifies certain

parameters for the UHMwPE applied in the process “to provide a balance between processability of the solution to be spun and mechanical properties of the obtained filaments.” Ex. 1005, Page 7, line 32-Page 8, line 2. A person of ordinary skill would understand the resulting filaments of Simmelink to contain UHMWPE.

469. Moreover, 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.” Ex. 1005, Page 12, lines 6-7. Simmelink teaches keeping the amount of other components or foreign materials low, elaborating such teachings with respect to HPPE multifilament yarns containing less than 150 ppm, preferably less than 100, 75, or even less than 50 ppm, of solvent, for medical implants containing such yarn. Ex. 1005, Page 12, lines 8-12.

470. Accordingly, it is my opinion that the combination of Section 73.1015, Nanri, and Simmelink renders obvious the recitation of limitation [1.B].

iv. Claim 1: [1.C] between 0.1 and 7.0 wt. % of an inorganic chromium oxide-containing pigment,

471. Section 73.1015 discloses limitation [1.C] for the same reasons listed above with respect to limitation [1.C] in Grounds 1 and 2. That is, Section 73.1015 discloses the color additive “chromium-cobalt-aluminum oxide”, which is an inorganic “blue-green pigment obtained by calcining a mixture of chromium oxide, cobalt carbonate, and aluminum oxide”, “may be safely used for coloring linear polyethylene surgical sutures”. *See generally*, Ex. 1006.

472. Section 73.1015 further recites that the “[t]he quantity of the color additive does not exceed 2 percent by weight of the suture material.” Ex. 1006, page 18, (c)(2). The person of ordinary skill in the art would understand that the disclosed range was of particular importance given the fact that a suture formed from polyethylene filaments having less than 2 percent by weight of the exempted pigment would not have to go through an additional FDA certification process.

473. Nanri discloses limitation [1.C] for the same reasons listed above with respect to limitation [1.C] in Ground 2. That is, Nanri teaches that it is essential that the colorant contained in the fiber is composed of a “pigment”, identifying an inorganic pigment as one such example. Ex. 1007, 2, [0005] (“With respect to a high-strength polyethylene fiber colored while maintaining a sufficiently high strength, it is essential that the colorant contained in the fiber is composed of a pigment such as an organic pigment, inorganic pigment, and carbon black.”). Nanri explains a pigment is essential “because the pigment particles in the fiber are incorporated into the polyethylene crystal, and therefore migration to outside the fiber is suppressed, therefore it is thought that the pigment particles will be held stably.” Ex. 1007, 2, [0005].

474. Nanri further describes a “strong polyethylene fiber...wherein a pigment content is 0.01 to 2.50 wt%.” Ex. 1007, 2, [0004]; *see also*, Claim 3 (“The strong polyethylene fiber according to claim 1, wherein the pigment content is 0.01

to 2.50 wt%.”). Nanri further discloses that “[i]n the high-strength polyethylene fiber colored while maintaining sufficiently high strength, the content of the pigment—which is a colorant contained in the fiber—is 0.01 to 2.50 wt%, preferably 0.10 to 2.00 wt%, a coloring effect cannot be demonstrated at less than 0.01 wt%, and when the content of the pigment exceeds 2.50 wt%, weather resistance of the high-strength polyethylene fiber is favorable but strength and initial modulus of elasticity are reduced.” Ex. 1007, 2, [0008].

475. Simmelink likewise discloses limitation [1.C] for the same reasons listed above with respect to limitation [1.C] in Ground 1. That is, Simmelink discloses that the UHPE 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.” Ex. 1005, Page 8, lines 28-31.

476. The person of ordinary skill in the art would have understood that the ranges disclosed by Nanri and Simmelink are consistent with those disclosed by Section 73.1015. Such disclosures are consistent with the recitation of limitation [1.C] requiring the filaments to include “between 0.1 and 7.0 wt. % of an inorganic chromium oxide-containing pigment”. Moreover, I understand from counsel that if a range taught by a prior art reference overlaps a range claimed in the ’532 Patent,

then the range taught by the prior art reference would render the claimed range obvious.

477. Accordingly, it is my opinion that the combination of Section 73.1015, Nanri, and Simmelink renders obvious the recitation of limitation [1.C].

v. *Claim 1: [1.D] a residual amount of spin solvent of less than about 500 ppm, and*

478. Simmelink discloses limitation [1.D] for the same reasons listed above with respect to limitation [1.D] in Ground 1. That is, Simmelink discloses filaments consisting of “a residual amount of spin solvent of less than about 500 ppm.” Simmelink confirms that “[f]or medical applications[,] the amount of other components or foreign materials in the yarn is very important, in addition to its mechanical properties.” Ex. 1005, Page 12, lines 6-7. Specifically, Simmelink discloses that “a HPPE multifilament yarn according to the invention containing less than 150 ppm of residual solvent, specifically of solvent having a boiling point at atmospheric conditions of less than 275°C, preferably containing less than 100, 75, or even less than 50 ppm of solvent, and to medical implants containing such yarn.” Ex. 1005, Page 12, lines 8-12.

479. Simmelink further discloses “removing at least partly the solvent from the filaments” and teaches that “[s]olvent removal can be performed by known methods, for example by evaporating a relatively volatile solvent, by using an

extraction liquid, or by a combination of both methods.” Ex. 1005, Page 1, line 15; Page 9, lines 31-33.

480. Simmelink also discloses the preparation of multiple multi-filament yarn examples, including Examples 19, 29, and 30, which contained residual decalin solvent contents of 135 ppm, 16 ppm, and 18 ppm, respectively. Ex. 1005, Page 19, lines 15-22; Page 20, lines 13-30.

481. Simmelink further discloses Comparative Experiment E, which was a multi-filament yarn having a residual decalin content of 400 ppm, wherein the multi-filament yarn was prepared from a solution of UHPE polymer having an IV of 19.8 dl/g in decalin by extruding the solution through a spinplate having 390 spinholes and quenching and drawing the filaments. Ex. 1005, Page 17, lines 17-30; Page 18, lines 8-13; Page 20, lines 20-24.

482. Such disclosures are consistent with limitation [1.D]’s recitation of “a residual amount of spin solvent of less than about 500 ppm”. Moreover, I understand from counsel that a specific example or disclosure in the prior art which is within a claimed range, such as Simmelink’s disclosures of 132 ppm, 16 ppm, and 18 ppm in Examples 19, 29 and 30, respectively, anticipates the claimed range.

483. Moreover, in the case of decalin as the spin solvent, a person of ordinary skill in the art would have been motivated to obtain as low of a level of residual spin solvent in the UHMWPE filaments as possible in order to prevent

irritation when used as a suture in the body, which the Applicant admitted was well known in the art during prosecution of the '168 Patent, the parent application of the '532 Patent. Ex. 1030, page 266. (“Amery confirms that the level of residual spin solvent, especially decalin, in gel-spun UHMwPE should be low, and preferably below 100 ppm for biocompatibility reasons.”).

484. Accordingly, it is my opinion that the combination of Section 73.1015, Nanri, and Simmelink renders obvious the recitation of limitation [1.D].

vi. Claim 1: [1.E] less than 1000 ppm of further constituents.

485. The '532 Patent discloses:

The UHMwPE filaments in the suture according to the invention consist preferably of UHMwPE, the pigment and less than 1000 ppm of further constituents, preferably less than 500 ppm of further constituents, more preferably less than 200 ppm of further constituents, most preferably less than 100 ppm of further constituents, such as less than 80 ppm, or less than 60 ppm.

Ex. 1001, Col. 3, lines 61-67.

486. Other than the disclosure that suggests that the further constituents are substances other than the UHMWPE and the pigment, the '532 Patent is silent as to what the further constituents entail or why further constituents should be limited. Having reviewed the disclosure of the '532 Patent, I found no disclosure indicating

how further constituents are limited. The claims are likewise silent. As a result, a person of ordinary skill in the art would understand that “further constituents” could include spin solvent as well as other additives. Regardless, the references cited render obvious limitation [1.E], whether or not “further constituents” is construed to include spin solvent or not.

487. Regardless of the construction, Simmelink renders limitation [1.E] obvious for the same reasons listed above with respect to limitation [1.E] in Ground 1. That is, Simmelink discloses that the UHMwPE 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.” Ex. 1005, Page 8, lines 28-31. The person of ordinary skill in the art would understand that Simmelink discloses that any additives, including colorants, are preferably less than 3 mass% or 30,000 ppm.

488. In its listing of additives, Simmelink includes colorants, such as pigments, whereas the claims of the ’532 Patent recite the pigment separately from the “further constituents.” *Compare e.g.*, Ex. 1005, 8:28-31 to Ex. 1001, Claim 1. Accordingly, a person of ordinary skill in the art would understand that, as a colorant is added to Simmelink as is disclosed by the combination of Section 73.1015, Nanri, and Simmelink, such amount of colorant will necessarily lower the amount (i.e., lower the upper bound of 3 mass% or 30,000 ppm) of any other

customary additives that Simmelink discloses may be added. As the combination of Section 73.1015, Nanri, and Simmelink discloses that “[t]he quantity of the color additive does not exceed 2 percent by weight of the suture material” (Ex.1006), the amount, in mass% or ppm, of additives could go down to as low as 1 mass% or 10,000 ppm in view of the upper bound of the pigment. Such disclosures from Section 73.1015, Nanri, and Simmelink, are consistent with the recitation of limitation [1.E] of “less than 1000 ppm of further constituents.” Moreover, I understand from counsel that if a range taught by a prior art reference overlaps a range claimed in the ’532 Patent, then the range taught by the prior art reference would render the claimed range obvious.

489. Indeed, a person of ordinary skill would want to have even lower amounts of such customary additives in medical applications, and possibly less than 1 mass% or 10,000 ppm. That is, the person of ordinary skill in the art would have understood that any additives or other components should be minimized and, thus, be as close to non-existent as possible for use in medical applications. Indeed, a person of ordinary skill in the art would have understood that a high additive count would reduce the strength of the fiber and may introduce dangerous foreign

substances in the body.²⁹ For example, 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.” Ex. 1005, Page 12, lines 6-7. Simmelink teaches keeping the amount of other components or foreign materials low, elaborating such teachings with respect to HPPE multifilament yarns containing less than 150 ppm, preferably less than 100, 75, or even less than

²⁹ The Examiner further asserted that at least the limitation regarding residual amounts of further constituents would have been obvious “since the more pure the material, UHMWPE, and the less of other constituent or other materials, the stronger the strength for the suture.” Ex. 1030, pages 236-237. In response, I understand that the Applicant never addressed the Examiner’s finding with respect to “other constituents” or whether such constituents would be a result effective variable, instead arguing that that the “ordinarily skilled person (as acknowledged by the Examiner) would seek to eliminate the presence of such pigment.” Ex. 1030, pages 269-270. Moreover, as discussed above in the Technical Background/State of the Art at Section V.A, Applicant had already admitted there was a need in the art for colored sutures, which, in my opinion, indicates that the person of ordinary skill in the art would minimize or eliminate constituents other than the desired pigment.

50 ppm, of solvent, for medical implants containing such yarn. Ex. 1005, Page 12, lines 8-12. Accordingly, as preparation of a colored multi-filament yarn for a colored suture would necessarily require the addition of a pigment and a spin solvent, a person of ordinary skill in the art would know to keep any other components or additives as low as possible. *See, e.g.*, Ex. 1030, page 266 (The Applicant admitting that it was known that “the level of residual spin solvent, especially decalin, in gel-spun UHMwPE should be low, and preferably below 100 ppm for biocompatibility reasons.”).

490. Further, the examples of Simmelink further confirm the lack of further constituents. For example, Simmelink discloses the preparation of multiple multi-filament yarn examples. *See e.g.*, Ex. 1005, Page 16, line 17-Page 20, line 30. In each example, the multi-filament yarn was prepared from a solution of UHPE polymer in decalin. *Id.* The examples of Simmelink do not describe any other components or material being added during preparation of the multi-filament yarn examples such that a person of ordinary skill in the art would not expect the resulting multi-filament yarn to have “further constituents”.

491. Moreover, to the effect “further constituents” is interpreted to include residual spin solvent, at least Examples 19, 29, and 30 of Simmelink, which indicate residual decalin solvent contents of 135 ppm, 16 ppm, and 18 ppm,

respectively (*see e.g.*, Ex. 1005, 19:15-22; 20:13-30), disclose filaments containing “less than 1000 ppm of further constituents.”

492. Simmelink further disclosed at least Comparative Experiment E, which was a multi-filament yarn having a residual decalin content of 400 ppm, wherein the multi-filament yarn was prepared from a solution of UHPE polymer having an IV of 19.8 dl/g in decalin by extruding the solution through a spinplate having 390 spinholes and quenching and drawing the filaments. Ex. 1005, 17:17-30; 18:8-13; 20:20-24. Accordingly, to the effect “further constituents” is interpreted to include residual spin solvent, at least Comparative Experiment E of Simmelink also discloses filaments containing “less than 1000 ppm of further constituents.”

493. Nanri similarly confirms the lack of further constituents for the same reasons listed above with respect to limitation [1.E] in Ground 2. That is, Nanri discloses the preparation of multiple colored high-strength polyethylene fiber examples. *See e.g.*, Ex. 1007, page 3, paras. [0015]-[0017]. In each example, the colored high-strength polyethylene fiber was prepared from a solution of UHMWPE and finely pulverized carbon black pigment in decahydronaphthalene (i.e., decalin). *Id.* The examples of Nanri do not describe any other components or material being added during preparation of the colored high-strength polyethylene

fiber examples such that a person of ordinary skill in the art would not expect the resulting colored high-strength polyethylene fiber to have “further constituents”.

494. Accordingly, it is my opinion that at least Simmelink renders obvious “less than 1000 ppm of further constituents” such that the combination of Section 73.1015, Nanri, and Simmelink renders obvious the recitation of limitation [1.E].

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

495. Section 73.1015 discloses the amount of the inorganic pigment present in the filaments is between 0.3 and 5.0 wt. % for the same reasons listed above with respect to Claim 2 in Grounds 1 and 2. That is, Section 73.1015 discloses the color additive “chromium-cobalt-aluminum oxide”, which is an inorganic “blue-green pigment obtained by calcining a mixture of chromium oxide, cobalt carbonate, and aluminum oxide”, “may be safely used for coloring linear polyethylene surgical sutures”. *See generally*, Ex. 1006.

496. Section 73.1015 further recites that the “[t]he quantity of the color additive does not exceed 2 percent by weight of the suture material.” Ex. 1006, page 18, (c)(2).

497. Nanri discloses the amount of the inorganic pigment present in the filaments is between 0.3 and 5.0 wt. % for the same reasons listed above with respect to Claim 2 in Ground 2. That is, Nanri discloses a “strong polyethylene

fiber...wherein a pigment content is 0.01 to 2.50 wt%.” Ex. 1007, 2, [0004]; *see also*, Claim 3 (“The strong polyethylene fiber according to claim 1, wherein the pigment content is 0.01 to 2.50 wt%.”). Nanri further discloses that “[i]n the high-strength polyethylene fiber colored while maintaining sufficiently high strength, the content of the pigment—which is a colorant contained in the fiber—is 0.01 to 2.50 wt%, preferably 0.10 to 2.00 wt%, a coloring effect cannot be demonstrated at less than 0.01 wt%, and when the content of the pigment exceeds 2.50 wt%, weather resistance of the high-strength polyethylene fiber is favorable but strength and initial modulus of elasticity are reduced.” Ex. 1007, 2, [0008].

498. Nanri similarly teaches that it is essential that the colorant contained in the fiber is composed of a “pigment”, identifying an inorganic pigment as one such example. Ex. 1007, 2, [0005].

499. Simmelink similarly discloses the amount of the inorganic pigment present in the filaments is between 0.3 and 5.0 wt. % for the same reasons listed above with respect to Claim 2 in Ground 1. That is, Simmelink similarly discloses that the UHPE 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.” Ex. 1005, Page 8, lines 28-31.

500. The person of ordinary skill in the art would have understood that the ranges disclosed by Nanri and Simmelink are consistent with those disclosed by

Section 73.1015. Such disclosures are consistent with Claim 2's recitation of "wherein the amount of the inorganic pigment present in the filaments is between 0.3 and 5.0 wt. %" Moreover, I understand from counsel that if a range taught by a prior art reference overlaps a range claimed in the '532 Patent, then the range taught by the prior art reference would render the claimed range obvious.

501. Accordingly, it is my opinion that the combination of Section 73.1015, Nanri, and Simmelink discloses each and every element of, and renders obvious, Claim 2.

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

502. Section 73.1015 similarly discloses the amount of the inorganic pigment present in the filaments is lower than 2.0 wt. % for the same reasons listed above with respect to Claim 3 in Grounds 1 and 2. That is, Section 73.1015 discloses the color additive "chromium-cobalt-aluminum oxide", which is an inorganic "blue-green pigment obtained by calcining a mixture of chromium oxide, cobalt carbonate, and aluminum oxide", "may be safely used for coloring linear polyethylene surgical sutures". *See generally*, Ex. 1006.

503. Section 73.1015 further recites that the "[t]he quantity of the color additive does not exceed 2 percent by weight of the suture material." Ex. 1006,

page 18, (c)(2). Moreover, I understand that a specific example or disclosure in the prior art which is within a claimed range, anticipates the claimed range.

504. Nanri similarly discloses the amount of the inorganic pigment present in the filaments is lower than 2.0 wt. % for the same reasons listed above with respect to Claim 3 in Ground 2. That is, Nanri discloses a “strong polyethylene fiber...wherein a pigment content is 0.01 to 2.50 wt%.” Ex. 1007, 2, [0004]; *see also*, Ex. 1007, Claim 3 (“The strong polyethylene fiber according to claim 1, wherein the pigment content is 0.01 to 2.50 wt%.”). Nanri further discloses that “[i]n the high-strength polyethylene fiber colored while maintaining sufficiently high strength, the content of the pigment—which is a colorant contained in the fiber—is 0.01 to 2.50 wt%, preferably 0.10 to 2.00 wt%, a coloring effect cannot be demonstrated at less than 0.01 wt%, and when the content of the pigment exceeds 2.50 wt%, weather resistance of the high-strength polyethylene fiber is favorable but strength and initial modulus of elasticity are reduced.” Ex. 1007, 2, [0008].

505. Nanri similarly teaches that it is essential that the colorant contained in the fiber is composed of a “pigment”, identifying an inorganic pigment as one such example. Ex. 1007, 2, [0005].

506. Simmelink similarly discloses the amount of the inorganic pigment present in the filaments is lower than 2.0 wt. % for the same reasons listed above

with respect to Claim 3 in Ground 1. That is, Simmelink similarly discloses that the UHPE 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.” Ex. 1005, Page 8, lines 28-31.

507. Such disclosures are consistent with Claim 3’s recitation of “wherein the amount of the inorganic pigment present in the filaments is lower than 2.0 wt. %.” Moreover, I understand from counsel that if a range taught by a prior art reference overlaps a range claimed in the ’532 Patent, then the range taught by the prior art reference would render the claimed range obvious.

508. Accordingly, it is my opinion that the combination of Section 73.1015, Nanri, and Simmelink discloses each and every element of, and renders obvious, Claim 3.

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

509. Section 73.1015 similarly discloses the inorganic pigment is aluminum-chromium-cobalt oxide for the same reasons listed above with respect to Claim 4 in Grounds 1 and 2. That is, Section 73.1015 discloses the color additive “chromium-cobalt-aluminum oxide”, which “is a blue-green pigment obtained by calcining a mixture of chromium oxide, cobalt carbonate, and aluminum oxide.” Ex. 1006, page 18, (a). Section 73.1015 further provides that “[c]hromium-cobalt-

aluminum oxide shall conform to the following specifications: Chromium, calculated as Cr_2O_3 , 34-37 percent. Cobalt, calculated as CoO , 29-34 percent. Aluminum, calculated as Al_2O_3 , 29-35 percent. Lead (as Pb), not more than 30 parts per million. Arsenic (as As), not more than 3 parts per million. Total oxides of aluminum, chromium, and cobalt not less than 97 percent.” Ex. 1006, page 18, (b).

510. A person of ordinary skill in the art would have understood that “chromium-cobalt-aluminum oxide” is the same as “aluminum-chromium-cobalt oxide”. Even if it were to be argued that chromium-cobalt-aluminum oxide is not the same as aluminum-chromium-cobalt oxide, which would be incorrect, aluminum-chromium-cobalt oxide would nonetheless be obvious. Accordingly, such disclosure is consistent with Claim 4’s recitation of “wherein the inorganic pigment is aluminum-chromium-cobalt oxide.”

511. As discussed with respect to Claim 4 in Ground 2, Nanri also teaches that it is essential that the colorant contained in the fiber is composed of a “pigment”, identifying an inorganic pigment as one such example. Ex. 1007, 2, [0005] (“With respect to a high-strength polyethylene fiber colored while maintaining a sufficiently high strength, it is essential that the colorant contained in the fiber is composed of a pigment such as an organic pigment, inorganic pigment, and carbon black.”). Nanri explains a pigment is essential “because the pigment

particles in the fiber are incorporated into the polyethylene crystal, and therefore migration to outside the fiber is suppressed, therefore it is thought that the pigment particles will be held stably.” Ex. 1007, 2, [0005].

512. Accordingly, it is my opinion that the combination of Section 73.1015, Nanri, and Simmelink discloses each and every element of, and renders obvious, Claim 4.

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

513. Simmelink similarly discloses the residual amount of spin solvent is less than 250 ppm for the same reasons listed above with respect to Claim 5 in Ground 1. That is, Simmelink discloses “[f]or medical applications the amount of other components or foreign materials in the yarn is very important, in addition to its mechanical properties.” Ex. 1005, Page 12, lines 6-7. Specifically, Simmelink discloses “a HPPE multifilament yarn according to the invention containing less than 150 ppm of residual solvent, specifically of solvent having a boiling point at atmospheric conditions of less than 275°C, preferably containing less than 100, 75, or even less than 50 ppm of solvent, and to medical implants containing such yarn.” Ex. 1005, Page 12, lines 8-12.

514. Simmelink also discloses the preparation of multiple multifilament yarn examples, including Examples 19, 29, and 30, which contained residual

decalin solvent contents of 135 ppm, 16 ppm, and 18 ppm, respectively. Ex. 1005, Page 19, lines 15-22; Page 20, lines 13-30.

515. Such disclosures are consistent with Claim 6's recitation of "wherein the residual amount of spin solvent is less than 250 ppm." Moreover, I understand from counsel that a specific example or disclosure in the prior art which is within a claimed range, such as Simmelink's disclosures of 132 ppm, 16 ppm and 18 ppm in Examples 19, 29, and 30, respectively, anticipates the claimed range.

516. Accordingly, it is my opinion that the combination of Section 73.1015, Nanri, and Simmelink discloses each and every element of, and renders obvious, Claim 5.

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

517. Simmelink similarly discloses that the residual amount of spin solvent is less than 100 ppm for the same reasons listed above with respect to Claim 6 in Ground 1. That is, Simmelink discloses "[f]or medical applications the amount of other components or foreign materials in the yarn is very important, in addition to its mechanical properties." Ex. 1005, Page 12, lines 6-7. Specifically, Simmelink discloses "a HPPE multifilament yarn according to the invention containing less than 150 ppm of residual solvent, specifically of solvent having a boiling point at atmospheric conditions of less than 275°C, preferably containing less than 100, 75,

or even less than 50 ppm of solvent, and to medical implants containing such yarn.” Ex. 1005, Page 12, lines 8-12.

518. Simmelink also discloses the preparation of multiple multifilament yarn examples, including Examples 29 and 30, which contained residual decalin solvent contents of 16 ppm and 18 ppm, respectively. Ex. 1005, Page 20, lines 13-30.

519. Such disclosures are consistent with Claim 6’s recitation of “wherein the residual amount of spin solvent is less than 100 ppm.” Moreover, I understand from counsel that a specific example or disclosure in the prior art which is within a claimed range, such as Simmelink’s disclosures of 16 ppm and 18 ppm in Examples 29 and 30, respectively, anticipates the claimed range.

520. Accordingly, it is my opinion that the combination of Section 73.1015, Nanri, and Simmelink discloses each and every element of, and renders obvious, Claim 6.

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

521. Simmelink similarly discloses that the residual amount of spin solvent is less than 60 ppm for the same reasons listed above with respect to Claim 7 in Ground 1. That is, Simmelink discloses “[f]or medical applications the amount of other components or foreign materials in the yarn is very important, in addition to

its mechanical properties.” Ex. 1005, Page 12, lines 6-7. Specifically, Simmelink discloses “a HPPE multifilament yarn according to the invention containing less than 150 ppm of residual solvent, specifically of solvent having a boiling point at atmospheric conditions of less than 275°C, preferably containing less than 100, 75, or even less than 50 ppm of solvent, and to medical implants containing such yarn.” Ex. 1005, Page 12, lines 8-12.

522. Simmelink also discloses the preparation of multiple multifilament yarn examples, including Examples 29 and 30, which contained residual decalin solvent contents of 16 ppm and 18 ppm, respectively. Ex. 1005, Page 20, lines 13-30.

523. Such disclosures are consistent with Claim 7’s recitation of “wherein the residual amount of spin solvent is less than 60 ppm.” Moreover, I understand from counsel that a specific example or disclosure in the prior art which is within a claimed range, such as Simmelink’s disclosures of 16 ppm and 18 ppm in Examples 29 and 30, respectively, anticipates the claimed range.

524. Accordingly, it is my opinion that the combination of Section 73.1015, Nanri, and Simmelink discloses each and every element of, and renders obvious, Claim 7.

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

525. Simmelink similarly discloses that the filaments contain less than 500 ppm of further constituents for the same reasons listed above with respect to Claim 8 in Ground 1. That is, Simmelink discloses that the UHMwPE 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.” Ex. 1005, Page 8, lines 28-31. The person of ordinary skill in the art would understand that Simmelink discloses that any additives, including colorants, are preferably less than 3 mass% or 30,000 ppm.

526. In its listing of additives, Simmelink includes colorants, such as pigments, whereas the claims of the '532 Patent recite the pigment separately from the “further constituents.” *Compare e.g.*, Ex. 1005, 8:28-31 to Ex. 1001, Claim 1. Accordingly, a person of ordinary skill in the art would understand that, as a colorant is added to Simmelink as is disclosed by the combination of Simmelink, Nanri, and Section 73.1015, such amount of colorant will necessarily lower the amount (i.e., lower the upper bound of 3 mass% or 30,000 ppm) of any other customary additives that Simmelink discloses may be added. As the combination of Simmelink, Nanri, and Section 73.1015 discloses that “[t]he quantity of the color additive does not exceed 2 percent by weight of the suture material”

(Ex.1006), the amount, in mass% or ppm, of additives could go down to as low as 1 mass% or 10,000 ppm in view of the upper bound of the pigment. Such disclosures from Section 73.1015, Nanri, and Simmelink are consistent with the recitation of Claim 8 of “less than 500 ppm of further constituents.” Moreover, I understand from counsel that if a range taught by a prior art reference overlaps a range claimed in the ’532 Patent, then the range taught by the prior art reference would render the claimed range obvious.

527. Indeed, a person of ordinary skill in the art would want to have even lower amounts of such customary additives in medical applications, and possibly less than 1 mass% or 10,000 ppm. That is, the person of ordinary skill in the art would have understood that any additives or other components should be minimized and, thus, be as close to non-existent as possible for use in medical applications. Indeed, a person of ordinary skill in the art would have understood that a high additive count would reduce the strength of the fiber and may introduce dangerous foreign substances in the body.³⁰ For example, Simmelink discloses that

³⁰ The Examiner further asserted that at least the limitation regarding residual amounts of further constituents would have been obvious “since the more pure the material, UHMWPE, and the less of other constituent or other materials, the stronger the strength for the suture.” Ex. 1030, pages 236-237. In response, I

“[f]or medical applications[,] the amount of other components or foreign materials in the yarn is very important, in addition to its mechanical properties.” Ex. 1005, Page 12, lines 6-7. Simmelink teaches keeping the amount of other components or foreign materials low, elaborating such teachings with respect to HPPE multifilament yarns containing less than 150 ppm, preferably less than 100, 75, or even less than 50 ppm, of solvent, for medical implants containing such yarn. Ex. 1005, Page 12, lines 8-12. Accordingly, as preparation of a colored multi-filament yarn for a colored suture would necessarily require the addition of a pigment and a spin solvent, a person of ordinary skill in the art would know to keep any other components or additives as low as possible. *See, e.g.*, Ex. 1030, page 266 (The

understand that the Applicant never addressed the Examiner’s finding with respect to “other constituents” or whether such constituents would be a result effective variable, instead arguing that that the “ordinarily skilled person (as acknowledged by the Examiner) would seek to eliminate the presence of such pigment.” Ex. 1030, pages 269-270. Moreover, as discussed above in the Technical Background/State of the Art at Section V.A, Applicant had already admitted there was a need in the art for colored sutures, which, in my opinion undercuts Applicant’s argument that the person of ordinary skill in the art would eliminate a pigment.

Applicant admitting that it was known that “the level of residual spin solvent, especially decalin, in gel-spun UHMwPE should be low, and preferably below 100 ppm for biocompatibility reasons.”).

528. Further, the examples of Simmelink further confirm the lack of further constituents. For example, Simmelink discloses the preparation of multiple multi-filament yarn examples. *See e.g.*, Ex. 1005, Page 16, line 17-Page 20, line 30. In each example, the multi-filament yarn was prepared from a solution of UHPE polymer in decalin. *Id.* The examples of Simmelink do not describe any other components or material being added during preparation of the multi-filament yarn examples such that a person of ordinary skill in the art would not expect the resulting multi-filament yarn to have “further constituents”.

529. Moreover, to the effect “further constituents” is interpreted to include residual spin solvent, at least Examples 19, 29, and 30 of Simmelink, which indicate residual decalin solvent contents of 135 ppm, 16 ppm, and 18 ppm, respectively (*see e.g.*, Ex. 1005, 19:15-22; 20:13-30), disclose filaments containing “less than 500 ppm of further constituents.”

530. Simmelink further discloses at least Comparative Experiment E, which was a multi-filament yarn having a residual decalin content of 400 ppm, wherein the multi-filament yarn was prepared from a solution of UHPE polymer having an IV of 19.8 dl/g in decalin by extruding the solution through a spinplate

having 390 spinholes and quenching and drawing the filaments. Ex. 1005, 17:17-30; 18:8-13; 20:20-24. Accordingly, to the effect “further constituents” is interpreted to include residual spin solvent, at least Comparative Experiment E of Simmelink also discloses filaments containing “less than 500 ppm of further constituents.”

531. Nanri similarly confirms the lack of further constituents for the same reasons listed above with respect to Claim 8 in Ground 2. That is, Nanri discloses the preparation of multiple colored high-strength polyethylene fiber examples. *See e.g.*, Ex. 1007, page 3, paras. [0015]-[0017]. In each example, the colored high-strength polyethylene fiber was prepared from a solution of UHMWPE and finely pulverized carbon black pigment in decahydronaphthalene (i.e., decalin). *Id.* The examples of Nanri do not describe any other components or material being added during preparation of the colored high-strength polyethylene fiber examples such that a person of ordinary skill in the art would not expect the resulting colored high-strength polyethylene fiber to have “further constituents”.

532. Accordingly, it is my opinion that the combination of Section 73.1015, Nanri, and Simmelink discloses each and every element of, and renders obvious, Claim 8.

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

533. Simmelink similarly discloses the number of filaments is between 10 and 1000 for the same reasons listed above with respect to Claim 9 in Ground 1. That is, Simmelink discloses the number of filaments in the multi-filament yarn is preferably “at least 10, 50, 100, 150, 200, 300, 375 or even at least 450. For practical reasons, handling during spinning and drawing becoming increasingly difficult, the number of filaments is preferably at most about 5000.” Ex. 1005, Page 5, lines 21-24. Simmelink further specifies that “[y]arn of relatively low titer, containing for example from 5 to 300 filaments, but of extremely high strength is a.o. very suited for making high-strength surgical sutures and cables, or other medical implants.” Ex. 1005, Page 12, lines 3-6.

534. As discussed with respect to Claim 9 in Grounds 1 and 2, Section 73.1015 expressly discloses “[t]he **filaments** are cooled, oriented by drawing, and set by annealing.” Ex. 1006, page 18, (c)(1) (emphasis added).

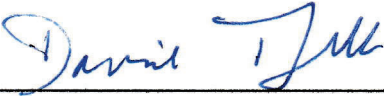
535. Such disclosures are consistent with Claim 9’s recitation of “wherein the number of filaments is between 10 and 1000.” Moreover, I understand from counsel that if a range taught by a prior art reference overlaps a range claimed in the ’532 Patent, then the range taught by the prior art reference would render the claimed range obvious.

536. Accordingly, it is my opinion that the combination of Section 73.1015, Nanri, and Simmelink discloses each and every element of, and renders obvious, Claim 9.

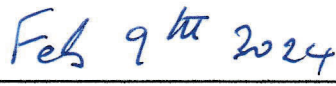
XIV. REVISION OR SUPPLEMENTATION

537. In this report, I have presented my opinions regarding the invalidity of Claims 1-9 of the '532 Patent based on the information available to me. My analysis of the materials produced in this case is ongoing. As new material is presented to me, I will continue my review of such material. Therefore, this report represents only those opinions I have formed to date. My opinions are subject to change in view of opinions provided by the Patent Owner or its expert, or any additional information that I may receive. I reserve the right to revise, supplement, and/or amend my opinions accordingly.

I hereby declare that all statements made herein of my own knowledge are true, that all opinions expressed herein are my own, and all statements made herein on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.



Dr. David T. Grubb



Date