

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

PETITIONER'S REQUEST FOR REHEARING BY THE DIRECTOR

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

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I. INTRODUCTION

In denying institution, the Board abused its discretion by: (1) finding a product-by-process limitation, “obtained by gel spinning,” was entitled to patentable weight without performing the requisite analysis; (2) erroneously rewriting Petitioner’s proposed combination; (3) insufficiently addressing obvious-to-try; and (4) erroneously applying its “reasonable expectation of success” analysis, which permeates each and every ground and led to the irreconcilable result here—that the POSITA would not have had a reasonable expectation of success in adding a known pigment used in polyethylene sutures to a known gel spinning process that already called for the addition of a colorant. For the reasons set forth herein, Petitioner respectfully requests Director review of the Board’s denial of institution of *inter partes* review (Paper 7) (the “Decision”).

II. BACKGROUND

As admitted in U.S. Patent No. 10,280,532 B2 (Ex. 1001, “the ’532 Patent”), there was a design need for colored sutures to improve visibility, especially colored sutures having high strength. Petition, 9-10, n. 3; Ex. 1001, 1:11-17, 1:22-27. It was also known that Ultra High Molecular Weight Polyethylene (“UHMWPE”) filaments were usable as sutures and that UHMWPE filaments had been colored using pigments. *Id.*, 10. As such, the ’532 Patent is nothing more than the result of market pressure to deliver colored sutures made of gel spun UHMWPE filaments.

Id., 9-12. Worse still, the '532 Patent is exceedingly light on details regarding the addition of pigment, leaving the reader with the inescapable conclusion that the inventors simply added known pigment to the known gel spinning process. *Id.*, 8-9, 15; Ex. 1001, 1:58-2:3, 3:43-60; Ex. 1003, ¶¶ 187-189. The '532 Patent does nothing more than to confirm that known pigments for use in polyethylene sutures would be successfully added to a known gel spinning process for forming filaments. *Id.*, 8, 15.

Petitioner relied on several grounds that taught what the '532 Patent purported to have “discovered”—that pigment could successfully be added during a gel spinning process. Indeed, Simmelink, Patent Owner’s own reference, is a gel spinning process that teaches that colorants may be used in the formation process and Nanri discloses incorporating pigments in a gel spinning process. *Id.*, 10, 30.

The Petition further provides that a POSITA would have turned to (and in fact did turn to) Section 73.1015. First, in addition to the clear teaching by Simmelink to add a colorant, a POSITA would be motivated to turn to the exempted color additive of Section 73.1015 to save not only time, but significant expense on FDA certification. *Id.*, 11. Indeed, the Petition specifically contemplated “mixing less than 2 wt.% of the inorganic chromium-cobalt-aluminum oxide pigment of Section 73.1015 into the gel spinning mixture of Simmelink” to obtain such benefits. *Id.*, 12.

If these motivations and the resultant combination itself was not enough on its own, which it was, Petitioner introduced undisputed evidence that Patent Owner did

in fact add the pigment of Section 73.1015 to obtain regulatory approval. *Id.*, 11-12. Patent Owner admitted that it chose chromium-cobalt-aluminum oxide to facilitate regulatory approval for its own suture. *Id.*, citing Ex. 1010, 55-56 (“To facilitate regulatory approval, blue fibers with Chromium-Cobalt-Aluminum Oxide were produced, as this pigment is listed on the FDA’s 21 CFR part 73 on *Color Additives Exempt from Certification* for coloring linear polyethylene surgical sutures for use in general surgery.”); Ex. 1003, n. 3. After receiving a Patent Owner Preliminary Response (“POPR”), the Board declined Institution on August 21, 2024.

III. LEGAL STANDARD

Director review of an institution decision is limited to decisions presenting (a) an abuse of discretion or (b) important issues of law or policy. 37 C.F.R. § 42.71(c),(d); *see Ericsson Inc. v. Intell. Ventures I LLC*, 901 F.3d 1374, 1379 (Fed. Cir. 2018) (stating that the Board abuses its discretion when its decision “is based on an erroneous conclusion of law” or “rests on clearly erroneous fact finding”).

IV. ARGUMENT

A. “Obtained by gel spinning” is not entitled to patentable weight

The Board appears to have understood the proper analysis of “obtained by gel spinning,” a product-by-process claim element, right up to its conclusion. In fact, the Board’s summary of the law is a guide to its own abuse of discretion—for an element to be limiting, any structural or functional differences must “*distinguish the claimed*

product from the prior art.” Decision, 9 (emphasis added). Patent Owner never met its burden to distinguish the claimed product (i.e., filament) and, indeed, never argued that any limitations were missing in its POPR. *Kamstrup A/S v. Axioma Metering UAB*, 43 F.4th 1374, 1383 (Fed. Cir. 2022) (“because [patent owner] fails to show that the process claimed imparts ‘structural and functional differences’ distinguished from the prior art, it is not entitled to patentable weight”). Worse still, the Board never analyzed the cited prior art and, thus, abused its discretion.

The Board rightfully finds that “obtained by gel spinning” “is a product-by-process claim element because it describes the filament being obtained in a particular way, i.e., by gel spinning.” Decision, 9. The rule is that a product-by-process element is *not* afforded patentable weight (*Kamstrup A/S*, 43 F.4th at 1381) and there is no dispute that *Amgen* carved out an *exception* providing that “if the process by which a product is made imparts ‘structural and functional differences’ *distinguishing the claimed product from the prior art*, then those differences ‘are relevant as evidence of no anticipation’ although they ‘are not explicitly part of the claim.’” *Greenliant Sys., Inc. v. Xicor LLC*, 692 F.3d 1261, 268 (Fed. Cir. 2012) (emphasis added) (citing *Amgen v. F. Hoffman-La Roche*, 580 F.3d 1340 (Fed. Cir. 2009)). With this case law in mind, the Board correctly found that “the gel spinning process recited in claim 1 imparts to the claimed multifilament yarn product a feature, i.e., high tensile strength, that *may* distinguish the claimed invention from the prior art.” Decision,

10 (emphasis added). But the Board also recognizes that for the “obtained by gel spinning” “element to *actually* be limiting, it must impart “structural and functional differences” *that distinguish the claimed product from the prior art. Id.*, 9 (citing *Amgen*, 580 F.3d at 1365-67)). Inexplicably, however, the Board does not follow its own analysis and, without analyzing any prior art, holds “[a]ccordingly, we consider the claim phrase “obtained by gel spinning” to limit claim 1.” *Id.* at 9-10.

The ’532 Patent did not invent gel spinning. The specification identifies more than eight prior art references that describe “[t]he preparation of filaments of ultra high molecular weight polyethylene (UHMWPE) filaments, prepared by a gel spinning process.” Ex. 1001, 2:24–42. Regardless, Petitioner cited Simmelink in Grounds 1 and 3, Nanri in Grounds 2 and 3, and Ohta and Kavesh in Ground 2, each of which teach gel-spinning. Petition, 16 (“Simmelink specifies a variety of parameters and process steps for making high-performance polyethylene multifilament yarn from a gel spinning process”), 41 (“Nanri specifically discloses manufacturing a colored high-strength polyethylene fiber including ‘solution spinning an [UHMWPE].’”), 42 (“Ohta likewise discloses the preparation of yarn via a gel spinning method using decalin and UHMWPE....”), 42 (“Kavesh likewise discloses...a gel spinning process), 55. The Decision confirms that the ’532 Patent did not invent gel spinning. Decision, 11 (Simmelink relies on spin solvent “decalin” in its process), 16 (“Simmelink’s gel spinning process” (citing POPR, 47)).

Neither Patent Owner nor the Board identified any structural differences between the filaments of the recited grounds and the claims, because any structure or feature identified in the Decision, i.e., high tensile strength, is generic to all gel-spun UHMWPE filaments. Ex. 1014, 62 (“Gel-spun polyethylene fibres are ultra-strong, high-modulus fibres that are based on the simple and flexible polyethylene molecule....The gel-spinning process uses physical processes to make available the high potential properties of the molecule.”); Ex. 1003, ¶ 52. Because the recited gel spinning process does not impart “structural and functional differences” *that distinguish the product over the prior art* gel spinning process, the gel spinning term should not be afforded patentable weight. *Amgen*, 580 F.3d at 1370.

B. The Board erroneously rewrote Petitioner’s proposed combination

Petitioner’s combination details how a POSITA would have solved the *admitted* design need by relying on the gel spinning process of Simmelink and its disclosure that colorants may be used in the fiber formation process, in combination with Section 73.1015 and its disclosure of chromium-cobalt-aluminum oxide pigment, which had been successfully used as a suitable colorant in coloring linear polyethylene surgical sutures. Petition, 9-12. Indeed, throughout the ground, Petitioner relies on the disclosure in Simmelink of a *colorant* in the gel spinning process as the POSITA’s motivation for turning to the pigment described in Section 73.1015. *Id.*, 12, 14-22.

In addition, the Petition specifically asserts that “sutures are implantable devices...subject to specific regulatory requirements, including containing only colorants approved for use in sutures by the [FDA]” and “a POSITA would have turned to Section 73.1015 and its disclosure of the exempted color additive chromium-cobalt-aluminum oxide as a pigment in an amount that does not exceed 2 percent by weight of the suture material in coloring linear polyethylene surgical sutures.” *Id.*, 10-11. Moreover, a POSITA would be motivated to turn to Section 73.1015 in an attempt to use a **color additive** previously exempted from batch certification with respect to polyethylene sutures to save not only time, but expense, a motivation that neither Patent Owner nor the Board disputes. *Id.*, 11.

Overlooking the motivation to combine as laid out, and apparently requiring FDA certification, the Board erroneously rendered its decision **solely** based on the “coloring **process** described in [Section 73.1015] for a certification exemption”, seemingly rewriting Petitioner’s proposed combination to instead require the process of Section 73.1015 alone. Decision, 20-22. This was not Petitioner’s proposed combination. Petitioner’s combination relied on the color additive of Section 73.1015, not the details of certification exemption of Section 73.1015 because FDA certification, while beneficial, is not a requirement of the claims of the ’532 Patent.

In reaching its erroneous conclusion, the Board seems to have interpreted the claims as requiring FDA certification and/or Section 73.1015 in a way that is

inconsistent with the proposed ground, the teachings in Simmelink regarding a colorant, the sole expert testimony in this case, and the admissions by Patent Owner. Decision, 20-23. Petitioner, through the testimony of Dr. Grubb, demonstrated that a POSITA would understand that the use of the Section 73.1015 pigment enabled an additional advantage—a filament would be “exempt from batch certification requirements.” Ex. 1003, ¶ 177. In addition, Patent Owner’s own actions support Dr. Grubb’s interpretation and contradict the Board’s interpretation of Section 73.1015 at least inasmuch as Patent Owner has since admitted that it relies on the Section 73.1015 pigment in a gel spinning process to avoid batch certification.¹ Petition, 11-12, 15, 19, 20; Ex. 1010, 55-56. Accordingly, the Board’s fundamental misreading of Section 73.1015 led the Board to find that “Petitioner has not shown that its proposed combination provides a multifilament yarn “obtained by gel-spinning,” as required by claim 1.” Decision at 21 *compare* Petition at 17-19 (“Simmelink specifies a variety of parameters and process steps for making high-performance polyethylene multifilament yarn from a gel spinning process”), 55-56; *see also*,

¹ Patent Owner’s admissions regarding how Section 73.1015 was interpreted in 2015 equally evidences POSITA’s interpretation as of the earliest priority date. *Yeda Rsch. & Dev. Co. v. Mylan Pharms., Inc.*, 906 F.3d 1031, 1041 (Fed. Cir. 2018).

Decision at 11. Remand is thus necessary to address these abuses.

C. The Board did not evaluate the obvious to try analysis

The Petition outlined (1) a design need for a colored suture made from UHMWPE and (2) a finite number of solutions to color a UHMWPE fiber. Petition, 13 (citing Ex. 1001, 1:11-17; Ex. 1003, ¶ 182). Guided by Simmelink’s colorant disclosure, Petitioner asserted that any colorant would need to be added so that “there is no migration of the color additive to the surrounding tissue” (Ex. 1006, 18, (c)(4)), thereby further reducing the choices of colorants to *a finite set*. Petition, 13. Finally, Petitioner asserted that the “*finite number of options for colorant* of UHMWPE fibers in medical applications would have been further reduced by governmental requirements, such as those...in Section 73.1015.” *Id* (emphasis added).

In response, the Board failed to provide the requisite analysis of the record evidence, simply holding that that “Petitioner’s obvious to try rationale” is deficient as “rely[ing] on an erroneous reading of Section 73.1015 and unsupported testimony of Dr. Grubb.” Decision, 19. The Board fails to provide any analysis on what the so-called “erroneous reading” entails when Section 73.1015 provides (1) the exact pigment type and (2) the amount of pigment claimed—(1) the color additive “chromium-cobalt-aluminum oxide” and (2) less than “2 percent by weight of the suture material.” Petition, 20 (citing Ex. 1006, 18; Ex. 1003, ¶¶ 211-212). Regardless, the Board also overlooked evidence presented in the Petition regarding

the design need, known solutions, and lack of disclosure in the '532 Patent itself.

In *KSR*, the Supreme Court stated:

When there is a ***design need or market pressure to solve a problem*** and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to ***pursue the known options within his or her technical grasp***. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense.

KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 421 (2007). Here, the Board ***never considered*** the admitted “design need or market pressure to solve a problem.” Petition, 9-10 (citing Ex. 1001, 1:11-17, 1:22-27; Ex. 1003, ¶ 175). The Board ***did not address*** the testimony evidencing that “there were a limited number of ways to color a UHMWPE fiber, including the use of pigments and dyes” and the “options for colorant of UHMWPE fibers in medical applications would have been further reduced by governmental requirements.” *Id.*, 13; Ex. 1003, ¶ 182. Worse still, the Board ignored that using “chromium-cobalt-aluminum oxide” and “[t]he quantity of the color additive does not exceed 2 percent by weight of the suture material” from Section 73.1015 was in fact a ***known solution for polyethylene sutures***. *Id.*, 20. Finally, the Board ignored that the '532 Patent itself lacks any detail regarding its solution, other than implying that pigment was added. This lack of detail confirms that trying known pigments in known amounts, especially those that had been used

for polyethylene sutures, was within the technical grasp of the POSITA. *See In re Epstein*, 32 F.3d 1559, 1568 (Fed. Cir. 1994) (“[T]he Board’s observation that appellant did not provide the type of detail in his specification that he now argues is necessary in prior art references supports the Board’s finding that one skilled in the art would have known how to implement the features of the references.”).

D. The Board erroneously applied its “reasonable expectation of success” analysis

Instead of conducting a reasonable expectation of success analysis, the Board, without support from the claims or the patent and overlooking record evidence, undertook an analysis as to whether the proposed combination would result in certification. This was an abuse of discretion. The correct test is whether the POSITA would have had a reasonable expectation of success in adding the pigment in Section 73.1015, which already disclosed a pigment in a polyethylene suture, to Simmelink, which already disclosed adding colorants to a gel-spinning process.

Petitioner enumerated at least five rationales to support a finding of reasonable expectation of success, the majority of which were not addressed in the Decision. First, Simmelink teaches the addition of a colorant to a gel spinning process. Petition, 13-14 (citing Ex. 1005, 8:28-31; Ex. 1006, 18, (a), (c)(2); Ex. 1003, ¶ 183). Second, Section 73.1015 discloses its pigment may be safely used for coloring linear polyethylene surgical sutures. *Id.*, 14 (citing Ex. 1005, 8:12-17; Ex. 1006; Ex. 1003, ¶ 184). Third, the pigment of Section 73.1015 is disclosed as being usable in a

process that is not inconsistent with Simmelink's process such that a POSITA would have understood the addition of an inert pigment with polyethylene in Simmelink's gel spinning process would have likewise been successful and would have worked with the crystalline structure of the fiber. Ex. 1007, 2, [0005]; Ex. 1003, ¶ 185. To support its third rationale, Petitioner cited Ex. 1028 to corroborate that a pigment infiltrates and bonds with the polyethylene resulting in no color fading, which the Board overlooked. Petition, n. 4. Fourth, the leeching of a color additive is disfavored in medical applications. *Id.*, 14; Ex. 1006; Ex. 1003, ¶ 186. Fifth, Patent Owner admitted that it relied on the pigment of Section 73.1015 in its own gel spinning process, which Patent Owner does not dispute is similar to what is disclosed in its own Simmelink reference. *Id.*, 14-15; Ex. 1010, 55-56; Ex. 1003, n.3.

Despite these rationales, the Board was focused solely on its own unsupported interpretation of Section 73.1015. Specifically, the Board held that “critically, Petitioner and Dr. Grubb have not persuasively supported their position that a skilled artisan would have had a reasonable expectation of successfully combining the gel spinning mixture of Simmelink with the color additive in Section 73.1015, *according to the coloring process described in the latter for a certification exemption.*” Decision, 21 (emphasis added). The Board seemingly requires that a showing of a reasonable expectation of success *must demonstrate* that the POSITA would not only be absolutely successful in the proposed combination, but also that

the proposed combination would, in fact, be certified. *See also, id.*, at 30 (“if the motivation for selecting the Section 73.1015 color is to facilitate regulatory approval, the uses and restrictions in that provision must be satisfied”). Again, there is no requirement in the claims that a suture be certified, only that it be colored.

The Board clearly erred by applying a higher standard than is required for showing the likelihood of success. That is, “the Board’s decision puts too high a burden on Petitioner to establish not only an expectation of success, but absolute success,” and, in this case, success in something that is irrelevant to the inquiry—whether the POSITA would have had a reasonable expectation in FDA certification. *Prime Time Toys, LLC v. Spin Master, Inc.*, No. IPR2023-01339, Paper 12 at 3, 7, 13 (Jul. 9, 2024), citing *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1364 (Fed. Cir. 2007) (“the expectation of success need only be reasonable, not absolute”).

There is a reasonable expectation of success for the proposed combination of the pigment of Section 73.1015 with the gel spinning process of Simmelink because the pigment did in fact work in the process espoused in Section 73.1015. *See* Section IV.B., *supra*. The Petition also makes clear that the POSITA would have a reasonable expectation of success of incorporating *the pigment* of Section 73.1015 into the gel spinning process of Simmelink, despite the fact that Section 73.1015 may be interpreted as suggesting the use of the pigment in a melt process. Petition, 14 (citing Ex. 1003, ¶ 185). That is, despite the fact that the pigment was

undisputably successful in a melt process, Petitioner demonstrated that the pigment would also have a reasonable expectation of success in a gel spinning process. *Id.*

Because the Petition proposed adding *the pigment* of Section 73.1015 into the gel spinning process of Simmelink, the Petition explained that the processes disclosed by Simmelink and Section 73.1015 are not inconsistent with each other such that a POSITA would not be deterred from incorporating the pigment of Section 73.1015 into the gel spinning process of Simmelink. Petition, 13-15. Both processes use similar polyethylene polymers, are directed to preparing linear polyethylene sutures, and disclose overlapping ranges of colorant/pigments. The inert pigment of Section 73.1015, when added to the gel spinning process of Simmelink, would not be affected by the presence of the spin solvent or any temperature differences in the gel spinning process. *Id.*; Ex. 1003, ¶ 185. Moreover, the POSITA would have understood that the addition of the inert pigment of Section 73.1015 in the gel spinning process as disclosed in Simmelink would have been successful and would have worked with the crystalline structure of the UHMWPE fiber. *Id.*

Finally, the lack of disclosure regarding the addition of a pigment in a gel spinning process in the '532 Patent confirms that either there was no need for a “specially designed” formulation or that further steps beyond the ordinary skill of the POSITA were not required to be disclosed in order to successfully add pigments to UHMWPE. This further undercuts any arguments regarding reasonable

expectation of success. Indeed, the POPR admitted that the “commercially available pigment was already properly sized to be much smaller than the diameter of an individual gel-spun UHMWPE filament.” POPR, 53-55 (“C.I. Pigment Blue 36[—*the chromium-cobalt-aluminum oxide pigment disclosed in Section 73.1015*—] commercially available from Ferro Corporation (*i.e., the original manufacturer of the Section 73.1015 pigment*) has an average particle size of 0.70 microns or 700 nm” and “is also much smaller than the diameter of a typical UHMWPE filament and can fit within its confines”) (emphases added). Neither the Board nor Patent Owner can require a showing of a “specialized” teaching to support reasonable expectation of success when the patent itself admittedly does nothing more than rely on the pigment in the prior art in known amounts for its known purpose. *Smith & Nephew, Inc. v. Rea*, 721 F.3d 1371, 1381 (Fed. Cir. 2013).

E. The Board’s abuse of discretion permeates each and every ground

The clear errors in the Board’s findings with respect to at least its erroneous application of its “reasonable expectation of success” analysis is also present in Ground 2 (Decision, 29-34) and Ground 3 (Decision, 34) and, thus, the Board’s abuse of discretion permeates these Grounds as well.

V. CONCLUSION

Petitioner requests that the Director overturn the Board’s decision.

Date: September 18, 2024

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

CERTIFICATE OF SERVICE

The undersigned certifies that Petitioner served a copy of the foregoing PETITIONER'S REQUEST FOR REHEARING BY THE DIRECTOR by filing this document through the PTAB's P-TACTS Filing System as well as sending a copy via electronic service (as agreed by counsel for Patent Owners) on the following:

Lead Counsel	Back-Up Counsel
Erick J. Palmer Registration No. 64,456 Mayer Brown LLP 71 South Wacker Drive Chicago, IL 60606 Telephone: 312-701-8352 Facsimile: 312-701-8352 ejpalmer@mayerbrown.com	Joseph A. Maloney Registration No. 38,956 Cecilia Rambarat Registration No. 79,775 Mayer Brown LLP 300 South Tryon Street Suite 1800 Charlotte, NC 28202 Telephone: 704-444-3654 Facsimile: 704-377-2033 jmahoney@mayerbrown.com crambarat@mayerbrown.com

Date: September 18, 2024

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

Attorney for Petitioner