

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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AMNEAL PHARMACEUTICALS LLC AND  
AMNEAL PHARMACEUTICALS OF NEW YORK, LLC,  
Petitioner,

v.

ALLERGAN, INC.,  
Patent Owner.

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Case IPR2018-00608  
Patent 9,161,926 B2

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Before GRACE KARAFFA OBERMANN, SHERIDAN K. SNEDDEN,  
and CHRISTOPHER G. PAULRAJ, *Administrative Patent Judges*.

SNEDDEN, *Administrative Patent Judge*.

FINAL WRITTEN DECISION  
Claims 1–6 Not Shown to Be Unpatentable  
*35 U.S.C. § 318(a); 37 C.F.R. § 42.73*

ORDERS

Dismissing Petitioner’s Motion to Exclude (Paper 34)  
*37 C.F.R. § 42.64(c)*

Dismissing Patent Owner’s Motion to Exclude (Paper 36)  
*37 C.F.R. § 42.64(c)*

I. INTRODUCTION

This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. For the reasons that follow, we determine that Petitioner has failed to establish by a preponderance of the evidence that claims 1–6 of U.S. Patent No. 9,161,926 B2 (Ex. 1001, “the ’926 patent”) are unpatentable.

*A. Procedural History*

Amneal Pharmaceuticals LLC and Amneal Pharmaceuticals of New York, LLC (collectively, “Petitioner”), filed a Petition requesting an *inter partes* review of claims 1–6 of the ’926 patent. Paper 2 (“Pet.”). Biogen, Inc. (“Patent Owner”) filed a Preliminary Response. Paper 8 (“Prelim. Resp.”). Based on the information set forth in the Petition, we instituted trial on the following grounds of unpatentability asserted by Petitioner:

| Ground | Claims | Basis    | References                                           |
|--------|--------|----------|------------------------------------------------------|
| 1      | 1–6    | § 103(a) | Garrett <sup>1</sup> and Nadau-Fourcade <sup>2</sup> |
| 2      | 1–6    | § 103(a) | Garrett and Bonacucina <sup>3</sup>                  |

Decision to Institute (Paper 10, “DI”).

After institution of trial, Patent Owner filed a Patent Owner Response (Paper 23, “PO Resp.”), Petitioner filed a Reply (Paper 29; “Reply”), and Patent Owner filed a Sur-Reply (Paper 33; “Sur-Reply”).

Petitioner relies on the Declarations of Bozena B. Michniak-Kohn, Ph.D. (Exs. 1002, 1050) and Dr. Elaine Gilmore, M.D., Ph.D. (Exs. 1018, 1034) in support of the proposed grounds of unpatentability.

Patent Owner relies on the Declarations of Alexander M. Klivanov, Ph.D. (Ex. 2003) and Julie Harper, M.D. (Ex. 2022).

Oral argument was conducted on June 5, 2019. A transcript is entered as Paper 48 (“Tr.”).

*B. The '926 patent*

The '926 patent describes compositions containing the drug dapsone, which are useful for treating a variety of dermatological conditions.

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<sup>1</sup> Ex. 1004, International Patent Application Publication No. WO 2009/061298 (“Garrett”).

<sup>2</sup> Ex. 1015, Bonacucina, G., et al., *Characterization and Stability of Emulsion Gels Based on Acrylamide/Sodium Acryloyldimethyl Taurate Copolymer*, 10 AAPS PHARMASCI TECH 368–75 (2009) (“Bonacucina”).

<sup>3</sup> Ex. 1005, International Application Publication No. WO 2010/072958 A2, English Translation at pages 38–72 (“Nadau-Fourcade”).

Ex. 1001, Abst. The '926 patent discloses that “[u]se of the polymeric viscosity builder provides compositions with increased concentrations of diethylene glycol monoethyl ether relative to compositions without the polymeric viscosity builder.” *Id.* at Abst.

The '926 patent describes the invention as follows:

it has been found that use of a polymeric viscosity builder minimizes the intensity of yellowing of the composition caused by the increased solubility of dapsone in diethylene glycol monoethyl ether. In addition, the polymeric viscosity builder influences dapsone crystallization. This, in turn, results in compositions with improved aesthetics (i.e., reduction in particle size which minimizes “gritty” feeling upon application).

*Id.* at 2:46–53.

According to one embodiment, the compositions include about 5% w/w to about 10% w/w dapsone, a first solubilizing agent (i.e., diethylene glycol monoethyl ether), optionally at least one second solubilizing agent, a polymeric viscosity builder, and water. *Id.* at 2:54–59.

Example 1 of the '926 patent “show[s] the impact of acrylamide/sodium acryloyldimethyltaurate copolymer based thickener on dapsone particle size.” *Id.* at 12:23–26. The results disclosed in that example show that larger crystals were observed in the sample with carbomer homopolymer type C, as compared to an acrylamide/sodium acryloyldimethyltaurate copolymer based thickener. *Id.* at 12:23–35.

### *C. Illustrative Claims*

Independent claims 1 and 5, reproduced below, are illustrative:

1. A topical pharmaceutical composition comprising:  
about 7.5% w/w dapsone;

about 30% w/w to about 40% w/w diethylene glycol monoethyl ether;

about 2% w/w to about 6% w/w of a polymeric viscosity builder consisting of acrylamide/sodium acryloyldimethyl taurate copolymer; and

water;

wherein the composition does not comprise adapalene.

5. A topical pharmaceutical composition comprising:

about 7.5% w/w dapsone;

about 30% w/w diethylene glycol monoethyl ether;

about 4% w/w of a polymeric viscosity builder consisting of acrylamide/sodium acryloyldimethyl taurate copolymer; and

water;

wherein the composition does not comprise adapalene.

Ex. 1001, 15:21–16:14–21.

## II. DISCUSSION

### *A. Person of Ordinary Skill in the Art*

Petitioner asserts that a person having ordinary skill in the art (“POSA”) “would have the knowledge of both a formulator of topical pharmaceutical compositions and [a] clinician with experience treating dermatological diseases.” Pet. 7. Petitioner asserts that a “formulator POSA”

would possess a Ph.D. or equivalent degree in pharmaceuticals, chemistry or a related discipline such as pharmacology, who also has practical experience (at least two years) of formulating topical drug delivery products, or the POSA could possess a

Bachelors or Masters degree in one of the preceding disciplines with a greater level (at least four years) of the same formulating experience. (AMN1002, ¶¶16-18).

Pet. 7. Petitioner defines a “clinical POSA” as a person who would possess an M.D. with a board certification in dermatology with at least two years of experience in dermatology, or otherwise treating skin conditions.” *Id.*

Patent Owner contends that “the claims of the ’926 patent are not directed to methods of treatment, but rather to compositions useful for treating dermatological conditions,” and thus “Petitioner’s requirement that a person of ordinary skill in the art have both the formulator and rigorous clinical qualifications is incorrect.” PO Resp. 29. Rather, Patent Owner contends that a POSA

would have either (i) a bachelor- or master-level degree in chemistry, polymer science, pharmaceuticals, or a related discipline, plus at least three years of experience in drug delivery, pharmaceutical formulations, or a related field; or (ii) a doctoral degree in chemistry, polymer science, pharmaceuticals, or a related discipline, plus some experience in drug delivery, pharmaceutical formulations, or a related field. Ex. 2003 ¶ 41. In addition, a person of ordinary skill in the art to which the ’926 patent pertains would have consulted with a person having clinical experience treating acne and other dermatological conditions. *Id.* ¶ 42; Ex. 2022 ¶¶ 33–34.

*Id.*

Having considered the parties positions and evidence of record, summarized above, we agree with Patent Owner that the claims are limited to compositions useful for treating dermatological conditions and also agree that the definition of a POSA should likewise be limited to those persons having the relevant education and/or expertise in formulating such

compositions. Accordingly, we adopt Patent Owner’s definition of a POSA for the purposes of this decision. That said, we discern no appreciable difference in the respective definitions of a POSA as that definition relates to the dispositive issues of this case, discussed below.

We further note that prior art may also demonstrate the level of skill in the art at the time of the invention. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (explaining that specific findings regarding ordinary skill level are not required “where the prior art itself reflects an appropriate level and a need for testimony is not shown”) (quoting *Litton Indus. Prods., Inc. v. Solid State Sys. Corp.*, 755 F.2d 158, 163 (Fed. Cir. 1985)).

#### *B. Claim Construction*

For petitions filed before November 13, 2018, such as the case here,<sup>4</sup> we interpret the claims of an unexpired patent that will not expire before issuance of a final written decision using the broadest reasonable interpretation in light of the specification. *See* 37 C.F.R. § 42.100(b) (2018); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016). Under the broadest reasonable construction standard, claim terms are presumed to have their ordinary and customary meaning, as would be understood by one

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<sup>4</sup> The Petition was filed on February 12, 2018. The Final Rule changing the claim construction standard does not apply here, as the Petition was filed before the effective date of the Final Rule, November 13, 2018. *See* Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board, 83 Fed. Reg. 51,340, 51,340, 51,344 (Oct. 11, 2018).

of ordinary skill in the art in the context of the entire disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). Any special definitions for claim terms must be set forth with reasonable clarity, deliberateness, and precision. *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

Only terms that are in controversy need to be construed, and then only to the extent necessary to resolve the controversy. *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999); *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (applying *Vivid Techs.* in the context of an *inter partes* review).

1. “*consisting of acrylamide/sodium acryloyldimethyl taurate copolymer*”

Independent claim 1 is directed to a topical pharmaceutical composition comprising, *inter alia*, “about 2% w/w to about 6% w/w of a polymeric viscosity builder *consisting of* acrylamide/sodium acryloyldimethyl taurate copolymer.” Ex. 1001, 16:1–3 (emphasis added). Although not presented as a claim construction issue, Patent Owner contends that this element is properly interpreted to mean that the claims of the '926 patent require a polymeric viscosity builder (“PVB”) that contains only acrylamide/sodium acryloyldimethyl taurate copolymer (“A/SA copolymer”). PO Resp. 53–54 (citing *Multilayer Stretch Cling Film Holdings, Inc. v. Berry Plastics Corp.*, 831 F.3d 1350, 1359 (Fed. Cir. 2016) (explaining that “a claim term set off with ‘consisting of’ is closed to unrecited elements”)). Petitioner does not dispute that the “consisting of” language limits “polymeric viscosity builders” to only A/SA copolymers.

Reply 10. Petitioner, however, contends that because the recitation of the “comprising” transitional phrase in the claims’ preamble allows for additional unrecited ingredients, “the ‘consisting of’ language only limits the universe of ‘polymeric viscosity builders’ to A/SA copolymers, but does not, as a matter of law, foreclose any unrecited features that are *not* PVBs.” *Id.* (emphasis added). As such, the real dispute between the parties is whether certain additional ingredients included in prior art compositions may properly fall within the broader open-ended “comprising” language of the claims, or whether those additional ingredients should be considered part of the PVBs in the prior art composition and thus excluded from the claim scope based on the closed “consisting of” language. *See id.* (arguing that isohexadecane (a solvent) and polysorbate 80 (a surfactant), found in the commercial product Sepineo that contains A/SA copolymers, are not PVBs). We address that dispute hereinbelow as part of our analysis of Petitioner’s grounds.

Nonetheless, to the extent the phrase needs to be construed, we do not perceive any reason or evidence that compels deviation from Patent Owner’s interpretation of the phrase “consisting of acrylamide/sodium acryloyldimethyl taurate copolymer,” which is consistent with the “exceptionally strong presumption that a claim term set off with ‘consisting of’ is closed to unrecited elements.” *Multilayer Stretch Cling Film Holdings, Inc.*, 831 F.3d at 1359. We conclude that the plain language of the claim indicates that the composition must contain A/SA as the only PVB present in the formulation, and A/SA must be present in an amount the falls within the claimed range of between about 2% and 6% w/w. Accordingly,

we adopt Patent Owner's interpretation of that phrase to require a PVB that contains *only* A/SA copolymers within the recited weight percentages.

## 2. *Other Claim Terms*

We determine that no explicit construction of any other claim term is necessary to resolve the dispute between the parties. *See Nidec*, 868 F.3d at 1017 (“[W]e need only construe terms ‘that are in controversy, and only to the extent necessary to resolve the controversy.’” (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999))).

### C. *Petitioner's Ground 1: Obviousness over the Combination of Garrett and Nadau-Fourcade*

#### 1. *Garrett*

Garrett discloses a topical pharmaceutical composition containing dapson e useful for treating glucose-6-phosphate dehydrogenase-deficient patients. Ex. 1004, 3:9–10, 11:14–16. In particular, Garrett discloses “a pharmaceutical carrier system comprising a dermatological composition that is a semi-solid aqueous gel, wherein dapson e is dissolved in the gel such that the dapson e has the capacity to cross the stratum corneum layer of the epidermis, and wherein the composition also contains dapson e in a microparticulate state that does not readily cross the stratum corneum of the epidermis.” *Id.* at Abst. That is, “the composition may include dissolved dapson e and microparticulate dapson e.” *Id.* at 3.

With regard to the concentrations of dapson e, diethylene glycol monoethyl ether, and water in the disclosed compositions, Garrett discloses the following:

In one preferred embodiment, the composition includes about 0.5% to 4.0% carbomer; **about 53.8% to 84.2% water; about 10% to 30% ethoxydiglycol**; about 0.2% methylparaben; **about 5% to 10% dapsone** in a microparticulate and dissolved state; and about 0.1% to 2% sodium hydroxide solution.

*Id.* at 4:2–5 (emphasis added); *see also* Ex. 1018 ¶ 23 (indicating that the chemical names “ethoxydiglycol” and “diethylene glycol monoethyl ether” refer to the same compound).

Garrett further discloses the use of polymer thickeners in its compositions. In particular, Garrett discloses:

Thickening agents include polymer thickeners. Polymer thickeners that may be used include those known to one skilled in the art, such as hydrophilic and hydroalcoholic gelling agents frequently used in the cosmetic and pharmaceutical industries . . . . Preferably, the gelling agent comprises between **about 0.2% to about 4% by weight** of the composition.

*Id.* at 13:3–11 (emphasis added).

Garrett discloses the role of the solvent system for the dapsone microparticulate compositions in the following manner:

The solvent or mixed solvent system is important to the formation of the microparticulate to dissolved dapsone ratio. The formation of the microparticulate, however, should not interfere with the ability of the polymer thickener or preservative systems to perform their functions.

*Id.* at 14:15–19. Garrett also discloses that “[t]he relative percentages for each of the reagents used in the present invention may vary depending upon . . . the desired ratio of microparticulate to dissolved dapsone.” *Id.* at 18:17–20.

Garrett does not disclose specifically the use of acrylamide/sodium acryloyldimethyl as a polymeric thickener or gelling agent.

### 2. *Nadau-Fourcade*

Nadau-Fourcade discloses “a topical pharmaceutical composition containing, as an active pharmaceutical ingredient, a water-sensitive compound in a dissolved form in a physiologically acceptable medium, . . . the method of preparing it, and . . . its use in dermatology.” Ex. 1005, 38:4–6. Nadau-Fourcade discloses the use of hydrophilic-phase gelling agents in its compositions and expressly identifies polyacrylamides as preferred gelling agents. *Id.* at 47:11–12, 48:5–6 (“Preferred gelling agents include . . . polyacrylamides, for instance Sepineo P 600® or Simulgel 600 PHA®.”). Nadau-Fourcade further discloses that “[t]he gelling agent . . . may be used at preferential concentrations ranging from 0.001% to 15% and more preferentially ranging from 0.01% to 5%.” *Id.* at 48:8–9.

### 3. *Petitioner’s Contentions*

Petitioner asserts that claims 1–6 are unpatentable under § 103 as obvious in view of the combination of Garrett and Nadau-Fourcade. Pet. 21–40. In support of its assertion that the combination of Garrett and Nadau-Fourcade renders claims 1–6 obvious, Petitioner sets forth the foregoing teachings of Garrett and Nadau-Fourcade and provides a detailed claim chart explaining how each claim limitation is disclosed in the combination of references. *Id.* Specifically, Petitioner contends that Garrett discloses a “topical pharmaceutical composition” of “about 7.5% w/w

dapsone,” “water,” and “about 30% w/w to about 40% w/w ethoxydiglycol.” *Id.* at 24–30 (citing Ex. 1004, 3:33–4:15; Ex. 1002 ¶¶ 50–54).

With regard to the specific thickening agent required by the claims, Petitioner contends that “[i]t would have been obvious to a [person of ordinary skill in the art] to substitute the claimed acrylamide copolymer for the thickening agent disclosed in Garrett because such thickening agents were known in the art to be predictable and interchangeable.” Pet. 31 (citing Ex. 1002 ¶¶ 56–57). In this regard, Petitioner contends that both Garrett and Nadau-Fourcade “relate to topical pharmaceutical compositions of drugs that are insoluble in water and are within the pertinent art to the claims of the ’926 patent.” *Id.* Petitioner also notes that Garrett discloses dapsone compositions containing polymeric thickeners, and specifically teaches that “polymeric thickeners that may be used include those known to one skilled in the art, such as hydrophilic and hydroalcohol gelling agents frequently used in the cosmetic and pharmaceutical industries.” *Id.* at 31 (quoting Ex. 1004, 13:2–25). By comparison, Petitioner notes that Nadau-Fourcade discloses polyacrylamides (i.e., Sepineo® P 600 or Simulgel® 600 PHA)<sup>5</sup> as “preferred” gelling agents for use in the hydrophilic-phase of topical pharmaceutical compositions of water-insoluble drugs. Pet. 31–32 (citing Ex. 1002 ¶ 56; Ex. 1005, 47:12–32, 48:1–7).

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<sup>5</sup> Petitioner contends that “Nadau-Fourcade shows that Sepineo® P 600 or Simulgel® 600 PHA are commercial grade acrylamide/sodium acryloyldimethyl taurate copolymers.” Pet. 32, n.5 (citing Ex. 1005, 48:5–7).

Based on the disclosures of the cited prior art, summarized above, Petitioner contends that it would have been obvious to substitute the thickening agents disclosed in Garrett for the polyacrylamide thickening agents of Nadau-Fourcade because, “[w]here two known alternatives are interchangeable for a desired function, an express suggestion to substitute one for the other is not needed to render a substitution obvious.” *Id.* at 32 (quoting *Conopco, Inc. v. Procter & Gamble Co.*, Case IPR2013-00505, slip op. at 21–23 (PTAB Feb. 10, 2015) (Paper 69)); *see also KSR International Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007) (holding that a claim is obvious if it is no “more than the predictable use of prior art elements according to their established functions,” even without an express suggestion to combine).

With regard to the amount of thickening agent in the composition, Petitioner further contends as follows:

modification of the amount of copolymer was known in the art. Dr. Michniak-Kohn explains that modifying the amount of a thickening agent is well-known and routine in the development of topical compositions, and would have had a known impact on the viscosity of the composition. (AMN1002, ¶58). Consistent with this understanding, Garrett teaches that “the relative percentages for [the thickening agent] may vary depending on ... gel viscosity,” which a [person of ordinary skill in the art] would have understood to mean that modifications to the amount of thickening agent are routine, well-understood, and predictable. (AMN1004, 18:17-22). Thus, a [person of ordinary skill in the art] in 2012 would have had a reason to use between about 2% w/w to about 6% w/w of the claimed acrylamide copolymer in Garrett’s composition, with a reasonable expectation of success, thus rendering the claimed invention obvious.

Pet. 33–34.

With regard to the negative limitation expressly excluding adapalene from the recited composition, Petitioner contends that “none of Garrett’s compositions include adapalene.” *Id.* at 30 (citing Ex. 1002 ¶ 54, Ex. 1004, Abst., 3:33–4:15, 14:20–15:18; *Sud-Chemie, Inc. v. Multisorb Techs., Inc.*, 554 F.3d 1001, 1004–05 (Fed. Cir. 2009) (finding prior art reference that did not require adhesive coatings on films to teach “uncoated” films, even though the reference “fail[ed] to specifically refer to the films as uncoated”)).

*D. Petitioner’s Ground 2: Obviousness over the Combination of Garrett and Bonacucina*

*1. Bonacucina*

Bonacucina discloses that “Sepineo P 600 is a prime candidate for use in the formulation of gels and emulsion gels with rheological properties suitable for topical administration.” Ex. 1015, 7. In particular, Bonacucina discloses that

Sepineo P 600, a concentrated dispersion of acrylamide/sodium acryloyldimethyl taurate copolymer in isohexadecane, has self-gelling and thickening properties and the ability to emulsify oily phases, which make it easy to use in the formulation of gels and o/w emulsion gels. In this paper, gels were prepared using a Sepineo P 600 concentration between the 0.5% and 5% (w/w) . . . . [T]he elastic properties of the gel-like structure even at elevated polymer concentrations were not strongly long-lasting, as demonstrated by the increase of the viscous contribution in the low frequency range during acoustic spectroscopy analysis. This fact could indicate that the gel structure is characterized by weak polymer–polymer interactions, an advantageous characteristic for topical administration, as the sample is thus easier to rub into the skin. . . . Thus, Sepineo P 600 gel and emulsion gel are very

effective systems for use in topical and other types of applications.

*Id.* at Abst.

Bonacucina further discloses that

Sepineo® P 600 thickens and gels well, a property that depends strongly on polymer concentration. Concentration increases from 0.5% (w/w) to 5% (w/w) modified the viscoelastic properties of the Sepineo® samples, changing the typical behavior of a concentrated non-entangled solution to that of a ‘gel-like’ sample.”

*Id.* at 7.

## 2. *Petitioner’s Contentions*

For substantially similar reasons, Petitioner contends that claims 1–6 are unpatentable under § 103 as obvious in view of the combination of Garrett and Bonacucina. Pet. 52–54. For this ground, Petitioner substitutes Nadau-Fourcade for Bonacucina for, *inter alia*, its disclosure of the recited acrylamide copolymer in topical compositions. Pet. 47 (citing Ex. 1015, 1; Ex. 1002 ¶ 84). In particular, Petitioner contends that Bonacucina discloses the product Sepineo P 600 as “a concentrated dispersion of acrylamide/sodium acryloyldimethyl taurate copolymer in isohexadecane” that “has self-gelling and thickening properties . . . which make[s] it easy to use in the formulation of gels and [oil-in-water] emulsion gels.” *Id.* at 48 (citing Ex. 1015, Abst.). Petitioner contends that Bonacucina also discloses that the acrylamide copolymer has weak polymer-polymer interactions resulting in compositions that are “easier to rub into the skin”—an “advantageous characteristic for topical administration.” *Id.* (citing Ex. 1015, Abst.).

Petitioner further contends that Bonacucina discloses acrylamide/sodium acryloyldimethyl taurate copolymer concentrations up to 5% w/w were useful for topical applications, which encompasses the claimed range of “about 4% w/w.” *Id.* at 50 (citing Ex. 1015, 7 (“Concentration increases from 0.5% (w/w) to 5% (w/w) modified the viscoelastic properties of the Sepineo® samples, changing the typical behavior of a concentrated non-entangled solution to that of a ‘gel-like’ sample.”); *see also* Ex. 1002 ¶¶ 83, 88, and 89.

In combining the references, Petitioner contends as follows:

Because [the recited] components are used in the claims for the same purpose as they had been successfully used in the prior art . . . , a [person of ordinary skill in the art] would have reasonably expected those components to be acceptable and suitable for the claimed composition.”).

*Id.* at 52.

*E. Petitioner Has Not Shown That the Prior Art Teaches a Composition Comprising about 2% w/w to about 6% w/w of a PVB Consisting of A/SA copolymer*

Initially, we note that Petitioner does not point to—and we do not find—any express disclosure in an asserted prior art reference disclosing a composition comprising about 2% w/w to about 6% w/w of a PVB consisting of A/SA copolymer as required by the claims. In each of Petitioner’s Grounds, Petitioner contends that commercial PVB compositions disclosed in Nadau-Fourcade and Bonacucina meet this element of the claims. For example, in Ground 1, Petitioner relies on Nadau-Fourcade for its disclosure of the commercial PVB compositions Sepineo P 600 or Simulgel 600 PHA and contends that “[i]t would have

been obvious to a POSA to substitute the claimed acrylamide copolymer for the thickening agent disclosed in Garrett because such thickening agents were known in the art to be predictable and interchangeable.” Pet. 31 (citing Ex. 1002 ¶¶ 56–57). In Ground 2, Petitioner relies on Bonacucina for its disclosure of the commercial PVB composition Sepineo P 600 and similarly contends that “it would have been obvious to a POSA to combine the claimed acrylamide copolymer as taught in Bonacucina with Garrett’s topical dapsone composition.” Pet 46 (citing Ex. 1002 ¶¶ 80–85). However, even assuming that a person of ordinary skill in the art would have been motivated to substitute the thickening agents disclosed by Garret with the Sepineo products disclosed by Nadau-Fourcade and Bonacucina, the evidence of record fails to support the conclusion that any of the disclosed Sepineo compositions contains about 2% w/w to about 6% w/w of a PVB consisting of A/SA copolymer. Nor does Petitioner explain how or why an ordinarily skilled artisan, having made the proposed substitution, would have further manipulated the composition to attain, through routine optimization, a composition containing PVB consisting of A/SA copolymer in the required w/w concentration. *See* Pet. 33–34.

Rather, as noted by Patent Owner, although the Sepineo compositions appear to contain A/SA copolymer and at least isohexadecane and polysorbate 80, Petitioner provides insufficient evidence of the relative concentrations of the various components of the Sepineo products. PO Resp. 53–54, 58–59 (citing Ex. 1005, 48:5–7; Ex. 1015, 2; Ex. 1026, 2; Ex. 2053, 196:19–197:2). That is, Petitioner has not identified the percentages (w/w) of A/SA copolymer in any of the disclosed Sepineo compositions.

Thus, we are unable to find, based on the evidence of record, that the Sepineo products disclosed by the asserted prior art are, in fact, compositions having about 2% w/w to about 6% w/w of a PVB consisting of A/SA copolymer as required by the challenged claims. Accordingly, we determine that the combination of references fails to disclose all elements of the challenged claims, namely, a composition comprising about 2% w/w to about 6% w/w of a PVB consisting of A/SA copolymer as required by the claims.

Petitioner also argues that a person of ordinary skill in the art would have understood that Sepineo P 600 falls within the scope of the challenged claims because the FDA's Orange Book lists the '926 patent with reference to the ACZONE® gel, 7.5% commercial product, and that product allegedly contains a Sepineo product. Reply 7, 12. During oral argument, Patent Owner argued that the composition of the commercially available Sepineo products are not disclosed anywhere in the record developed during trial and, therefore, it is not known on this record whether Sepineo contains the required about 2% w/w to about 6% w/w of a PVB consisting of A/SA copolymer. Tr. 54. Patent Owner conceded that its ACZONE® gel product contains Sepineo and, because of that very reason, Patent Owner has requested that the FDA remove the '926 patent from the FDA Orange Book as a patent that covers their ACZONE® gel product.<sup>6</sup> Tr. 45, 17–23; Ex. 3001.

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<sup>6</sup> Petitioner, in its Reply, also recognizes that Patent Owner has requested that the FDA delist the '926 patent from the Orange Book. Reply, 12 n.5.

Petitioner also argues that “the patent specification expressly contemplates Sepineo®’s use with the claimed compositions by prominently stating that the viscosity builder ‘further includes isohexadecane, . . . and polysorbate 80’” and that, during prosecution, “co-inventor Dr. Warner submitted a declaration . . . showing alleged ‘unexpected results’ for what he called ‘dapsones/Sepineo compositions,’ which standing alone negates any presumption that ‘consisting of’ excludes Sepineo®.” Reply 11 (citing Ex. 1001, 5:35-38; Ex. 1050 ¶ 62; Ex. 1017, 349–355, 504–506; Ex. 1031, 29–30). We are not persuaded that either of those arguments is sufficient to overcome the “strong presumption” that the use of the phrase “consisting of” is closed and therefore “exclude[s] any elements, steps, or ingredients not specified in the claim.” *Shire Dev., LLC v. Watson Pharm., Inc.*, 848 F.3d 981, 984 (Fed. Cir. 2017). “Overcoming that presumption requires the specification and prosecution history to unmistakably manifest an alternative meaning, such as when the patentee acts as its own lexicographer.” *Id.* at 1359 (internal citation omitted). As discussed in Section II.A.1. above, we interpret the phrase “consisting of acrylamide/sodium acryloyldimethyl taurate copolymer” to require a PVB that contains *only* A/SA copolymers within the recited weight percentages.

We do not find that either the patent specification or the prosecution history clearly equates any Sepineo composition with the claimed PVB. While the patent does state that isohexadecane and polysorbate 80 may be included, among other ingredients, as part of the PVB in some embodiments, it does not mention Sepineo at all, let alone suggest that Sepineo compositions necessarily satisfy the claim requirements. *See* Ex. 1001,

5:35–38. Moreover, we recognize that, during prosecution, the inventor submitted a declaration referencing Sepineo and applicant made arguments relying upon that declaration to overcome the pending obviousness rejection. Ex. 1017, 349–359. But we find nothing in those prosecution history statements to suggest that the applicant or the Examiner intended to disregard the “consisting of” language, and allow for inclusion of additional ingredients contained in Sepineo as part of the claimed composition. Nor do we find the prosecution history statements to constitute an admission that the Sepineo composition necessarily contains A/SA copolymers within the recited weight percentages. We, therefore, determine that Petitioner has not persuasively demonstrated that the prosecution history “unmistakably manifest[s] an alternative meaning.” *Shire Dev., LLC*, 848 F.3d at 984.

Having considered the parties’ positions and evidence of record, summarized above, we conclude that Petitioner has failed to establish 1) obviousness of claims 1–6 over the combination of Garrett and Nadau-Fourcade, and 2) obviousness of claims 1–6 over the combination of Garrett and Bonacucina.

### III. MOTIONS TO EXCLUDE

#### *a. Petitioner’s Motion to Exclude*

Petitioner filed a motion to exclude evidence. Paper 34. Patent Owner opposed (Paper 39) and Petitioner submitted a reply in support of its motion (Paper 43). Petitioner moves to exclude Exhibits 2004, 2015, 2019, 2023, 2027, 2028, 2030–2035, 2038, 2040, 2041, and 2043–2047; paragraphs 1–40, 43, 61, 62, 64, 66–68, 71–80, 88–90, 92–98, 100, 104–

112, 116–122, 125–143, 146–148, 152–158, 161–171, 173, 175–181, 183–192, 194–196, 200, and 202–218 of Exhibit 2003; and paragraphs 1–32, 35–39, 65, 78–80, 85–94, 96–112, 115, 132, 150, 163, and 173–200 of Exhibit 2022. Because we do not rely on any of the above listed information to reach the final decision, we dismiss the Petitioner’s motion to exclude as moot.

*b. Patent Owner’s Motion to Exclude*

Patent Owner filed a motion to exclude evidence. Paper 36. Petitioner opposed (Paper 38) and Patent Owner submitted a reply in support of its motion (Paper 44). Patent Owner moves to exclude Exhibits 1041, 1042, 1043, 1044, 1045, 1046, 1047, and 1048. Because we do not rely on any of the above listed information to reach the final decision, we dismiss the Petitioner’s motion to exclude as moot.

IV. CONCLUSION

Having considered all the evidence, Petitioner has not demonstrated by a preponderance of the evidence the unpatentability of claims 1–6 of the ’926 patent. The parties’ motions to exclude evidence are addressed in the following Order.

V. ORDER

For the reasons given, it is  
ORDERED that claims 1–6 of the ’926 patent have not been shown to be unpatentable.

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FURTHER ORDERED that Petitioner's motion to exclude (Paper 34) is dismissed as moot.

FURTHER ORDERED that Patent Owner's motion to exclude (Paper 36) is dismissed as moot.

FURTHER ORDERED that, because this is a final written decision, parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

PETITIONER:

Dennies Varughese  
Adam C. LaRock  
STERNE KESSLER GOLDSTEIN & FOX P.L.L.C.  
dvarughe-ptab@sternekessler.com  
alarock-ptab@sternekessler.com

PATENT OWNER:

James Trainor  
Ewa Davison  
Elizabeth Hagan  
FENWICK & WEST LLP  
jtrainor@fenwick.com  
edavison@fenwick.com  
ehagan@fenwick.com